In February 2013, GlaxoSmithKline (GSK) announced a commitment to further clinical transparency through the public disclosure of GSK Clinical Study Reports (CSRs) on the GSK Clinical Study Register.

The following guiding principles have been applied to the disclosure:

- *Information will be excluded in order to protect the privacy of patients and all named persons associated with the study*
- *Patient data listings will be completely removed* to protect patient privacy. Anonymized data from each patient may be made available subject to an approved research proposal. For further information please see the Patient Level Data section of the* ***GSK Clinical Study Register****.*
- *Aggregate data will be included; with any direct reference to individual patients excluded*

**Complete removal of patient data listings may mean that page numbers are no longer consecutively numbered*

This study includes documents that were originally reported in a language other than English. All documents that are available in English have been made available via the GSK Clinical Study Register.

GlaxoSmithKline Biologicals, SA

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age.

Clinical Study Report for Study 115648 (MMR-160)

This report provides immunogenicity results at Day 42 and safety results obtained from Dose 1 (Day 0) up to Month 6.

Development Phase: IIIa

IND Number: BB-IND 7229

EUDRACT Number: 2011-004891-12

Name of Investigational Product: GlaxoSmithKline (GSK) Biologicals' live attenuated measles, mumps, rubella vaccine (MMR, vaccine number 209762)

Indication Studied: Combined measles, mumps and rubella vaccine is indicated for active immunization against measles, mumps and rubella diseases

Study initiation date:	09-November-2012
Study completion date:	16-April-2015
Data lock point (Date of database freeze) for measles, mumps and rubella immunogenicity data and solicited safety data:	18-January-2018
Date of report:	Final: 09-April-2018

Sponsor Signatory:	Dominique Descamps Vice President GlaxoSmithKline Biologicals, SA

This study was performed according to the principles of GCP including the archiving of essential documents.

Based on GSK Biologicals' Study Report INS-BIO-CLIN-1010 v05

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SYNOPSIS

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Study No.: 115648 (MMR-160)

Title of the study:

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Investigators and study centers:

This was a multicenter study conducted in 5 countries: Estonia (6 sites), Finland (11 sites), Mexico (2 sites), Spain (9 sites) and the United States of America (USA) (63 sites), including Puerto Rico (1 site).

Principal investigator: Dr. PPD PPD Mexico, PPD

Publication (reference): None at the time of this report

Study period: **Study initiation date:** 09-November-2012 **Study completion date:** 16-April-2015 **Data lock point (Date of database freeze):** 18-January-2018	**Phase:** IIIA

Indication: Combined measles, mumps and rubella vaccine is indicated for active immunization against measles, mumps and rubella diseases.

Objectives: There were 5 co-primary objectives for the study; a hierarchical procedure was used to analyze the primary and secondary objectives, i.e., each objective could only be reached if all the associated criteria were met and all previous objectives were reached.

Co-primary objectives: The 5 co-primary objectives were assessed in a hierarchical manner according to the order listed below:

1. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
   Criterion:
   For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for antibodies to measles, mumps, and rubella viruses.
2. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.
   Criterion:
   For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses.
3. To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
   Criterion:
   The lower limit of the two-sided 95% CI on the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses.
4. To demonstrate non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

viruses at Day 42.
Criterion:
The lower limit of the two-sided 95% CI on GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.

5. To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
Criterion:
The lower limit of the two-sided 95% CI for the seroresponse rate for the pooled Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.

Secondary objectives: According to the hierarchical analysis plan, the secondary objectives to evaluate non-inferiority of the immune response to the co-administered vaccines were only assessed when all co-primary objectives were met. No hierarchy between secondary objectives was made.

1. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of seroresponse rate and GMC for antibodies to varicella zoster virus (VZV) at Day 42 (in a subset of children enrolled in the US).
Criteria:
The lower limit of the two-sided 95% CI for the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rates for antibodies to VZV is ≥-10%.
The lower limit of the two-sided 95% CI on the GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to VZV.
2. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of GMC for antibodies to hepatitis A virus (HAV) at Day 42 (in a subset of children enrolled in the US).
Criterion:
The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to HAV (post-dose 1) is ≥0.5.
3. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of antibodies to *S. pneumoniae* (PS) (13 serotypes), at Day 42 (in a subset of children administered *Prevnar 13* in the US).
Criterion:
The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.
4. To assess the immunogenicity of *Havrix* with respect to the seroresponse rates for antibodies to HAV in the pooled Inv_MMR groups in contrast to the pooled Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).
5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with *Varivax*, *Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US).

Methodology:

Design: This was a phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with 5 parallel groups, designed to evaluate the consistency of the immune response to three different lots of GSK Biologicals' trivalent combined MMR vaccine (*Priorix*, referred to as Inv_MMR throughout this document) manufactured to target potencies. The study was designed to evaluate immunogenicity of Inv_MMR vaccine compared to the US standard of care (*M-M-R II/M-M-R VaxPro* vaccine, referred to as Com_MMR throughout this document) when both MMR vaccines were used as a first (primary) dose. Subjects 12 to 15 months of age were enrolled and randomized to the 5 study groups below:

- Group Inv_MMR_L1 received a single dose of Lot 1 of Inv_MMR vaccine;

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- Group Inv_MMR_L2 received a single dose of Lot 2 of Inv_MMR vaccine;
- Group Inv_MMR_L3 received a single dose of Lot 3 of Inv_MMR vaccine;
- Group Com_MMR_L1 received a single dose of Lot 1 of Com_MMR vaccine;
- Group Com_MMR_L2 received a single dose of Lot 2 of Com_MMR vaccine.

Throughout the study, Com_MMR_L1 and Com_MMR_L2 were analyzed as pooled lots.

Co-administered vaccines: All subjects also received appropriate co-administered vaccinations. *Varivax* (VV) and *Havrix* (HAV) were administered to all subjects while *Prevnar 13* (PCV-13) was administered only to subjects enrolled in the US.

Vaccination schedule: A single vaccination with either one of three lots of Inv_MMR or one of two Com_MMR active control lots was administered at Visit 1 (12 to 15 months of age), along with the appropriate co-administered vaccines.

Treatment allocation: 5,000 healthy subjects 12 to 15 months of age were planned to be enrolled and randomized in a 2:2:2:1:1 ratio to receive either one dose of Inv_MMR_L1 (1,250 subjects), one dose of Inv_MMR_L2 (1,250 subjects), one dose of Inv_MMR_L3 (1,250 subjects), or one dose of either Com_MMR_L1 (625 subjects) or Com_MMR_L2 (625 subjects). Overall, the randomization was 3:1 (Inv_MMR: Com_MMR).

Visits: Subjects from each treatment group participated in 3 study visits: Day 0, Day 42 and Day 180.

Sampling: Two blood samples were collected from each subject; one at Visit 1/Day 0 prior to vaccination and one at Visit 2/Day 42 post-vaccination.

Immunogenicity and safety assessments:

The antibody response to MMR was measured by enzyme-linked immunosorbent assay (ELISA). For evaluation of immune response in Inv_MMR and Com_MMR groups, blood samples were collected from each subject at Visit 1 (Day 0) prior to vaccination and at Visit 2 (Day 42) post-vaccination. Antibody response to measles and rubella was measured by GSK; antibody response to mumps was measured by Pharmaceutical Product Inc. (PPD) ELISA. The antibody response to the co-administered vaccines against VZV and hepatitis A virus was also measured by ELISA. The antibody response to the co-administered vaccines against PCV was measured by electrochemiluminescence (ECL).

Occurrences of solicited local symptoms (injection site redness, pain and swelling) were recorded from Day 0 to Day 3 following vaccination. Some solicited general symptoms (drowsiness, loss of appetite and irritability) were recorded from Day 0 to Day 14, while certain other solicited general symptoms (fever [temperature ≥38.0°C / 100.4°F], rash, parotid/salivary gland swelling, any sign of meningism including febrile convulsions) as well as unsolicited adverse events (AEs) were recorded from Day 0 to Day 42 after vaccination. Serious adverse events (SAEs) and AEs of specific interest (new onset chronic disease [NOCD] and AEs prompting emergency room [ER] visits) occurring at any time during the whole study period were recorded.

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Study vaccine, dose, mode of administration, lot no.:

Synopsis Table 1: Vaccination schedule/site

Type of contact and time point	Dose	Treatment Group	Vaccine/Product	Route[1]	Site	Side
Visit 1 (Day 0)	1	Inv_MMR_L1	Inv_MMR_L1	SC	Triceps region	Left
	1	Inv_MMR_L2	Inv_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L3	Inv_MMR_L3	SC	Triceps region	Left
	1	Com_MMR_L1	Com_MMR_L1	SC	Triceps region	Left
	1	Com_MMR_L2	Com_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Varivax*	SC	Triceps region	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Havrix*	IM	Anterolateral thigh	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Prevnar 13**	IM	Anterolateral thigh	Left

[1] Intramuscular (IM)/ Subcutaneous (SC); * For US children only

Synopsis Table 2: Vaccine composition, dose and lot number

Treatment name	Vaccine/product name	Formulation	Lot Numbers	Volume	Number of doses
Inv_MMR_L1	Inv_MMR_L1	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	AMJRC455A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	DD12A002A	0.5 mL	1
Inv_MMR_L2	Inv_MMR_L2	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	AMJRC456A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	DD12A003A	0.5 mL	1

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Treatment name	Vaccine/product name	Formulation	Lot Numbers	Volume	Number of doses
Inv_MMR_L3	Inv_MMR_L3	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	AMJRC457A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	DD12A004B	0.5 mL	1
Com_MMR_L1	Com_MMR_L1	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	H004594 J006933 H017980 J006564 0682AE H015824 J015488	0.5 mL†	1
	Com_MMR_L1 Diluent‡	water for injection	G004842 J003177 J015955	0.5 mL	1
Com_MMR_L2	Com_MMR_L2	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	G019547 J006564 H021002 H020866 J006933 0498AE H016132 J015222	0.5 mL†	1
	Com_MMR_L2 Diluent‡	water for injection	0184AE J002990 J015955	0.5 mL	1

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Treatment name	Vaccine/product name	Formulation	Lot Numbers	Volume	Number of doses
Varivax	*Varivax*	A minimum of 1350 pfu of Oka/Merck varicella virus; sucrose approximately 25 mg; hydrolyzed gelatin 12.5 mg, sodium chloride 3.2 mg; monosodium L-glutamate 0.5 mg; sodium phosphate dibasic 0.45 mg; potassium phosphate monobasic 0.08 mg; potassium chloride 0.08 mg; residual components of MRC-5 cells including DNA and protein; and trace quantities of sodium phosphate monobasic; EDTA; neomycin; and fetal bovine serum	H004550; H019070 H012704 J004098 0603AE 0604AE	0.5 mL†	2§
	Varivax Diluent	water for injection	H007994 H003763	0.5 mL	2§
Havrix	*Havrix*	720 EU of hepatitis A virus antigen; 0.25 mg aluminum (as hydroxide); amino acid supplement (0.3% w/v); in a phosphate-buffered saline solution and polysorbate 20 (0.05 mg/mL)	AHAVB666C AHAVB668A AHAVB573C AHAVB646BA AHAVVB738B	0.5 mL	2§
Prevnar 13	*Prevnar 13*	2.2 µg of the purified saccharides 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F; 4.4 mcg of the purified saccharide 6B; approximately 34 µg CRM_{197} carrier protein; 100 µg polysorbate 80; 295 µg succinate buffer; 125 µg aluminum as aluminum phosphate adjuvant	F94001 H17427	0.5 mL	1¥

L= Lot; CCID = Cell Culture Infectious Dose; TCID = Tissue Culture Infectious Dose; EU = ELISA Unit
ppm = Parts Per Million; pfu = Plaque Forming Unit; mL = Milliliter; mg = Milligram; mcg = Microgram; µg = Microgram
MRC = Medical Research Council; DNA = Deoxyribonucleic Acid; EDTA = Ethylenediamine-Tetraacetic Acid
CRM_{197} = Cross-Reactive Material (mutant diphtheria toxin)
† Volume after reconstitution
‡ The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
§ At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. Not applicable for subjects

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

enrolled in US. The second dose of HAV and varicella vaccine was not part of the study procedures.
¥ PCV-13 was administered to US children with a history of 3-doses of PCV-13 at least 60 days prior to study entry.

Study Population: Male or female children aged 12 to 15 months of age whose parent(s)/legally acceptable representative(s) could and would comply with protocol requirements and for whom a written informed consent was provided. For US sites only: a child who had received all routine vaccinations as per Advisory Committee on Immunization Practices (ACIP) recommendations prior to study entry.

Duration of treatment:
The duration of the study was approximately 6 months for each subject.

Criteria for evaluations:
Primary endpoint:

- Immunogenicity of the MMR vaccines at Day 42**.**
  - Seroresponse to measles, mumps and rubella viruses.
  - Measles, mumps and rubella virus antibody concentrations.

Secondary endpoints:

- Immunogenicity of the *Varivax, Havrix* and *Prevnar 13* vaccines in a subset of children at Day 42.
  - Seroresponse to VZV.
  - VZV antibody concentrations.
  - HAV antibody concentrations.
  - Seroresponse to HAV.
  - Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.
- Complementary read-out for immunogenicity of the MMR vaccines at Day 42.
  - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
  - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms.
  - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
  - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
  - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest.
  - Occurrence of new onset chronic disease (NOCD) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting emergency room (ER) visits from Day 0 through the end of study.
- Serious adverse events.
  - Occurrence of SAEs from Day 0 through the end of study**.**

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	Name of finished product: Priorix®	Name of active substance: Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Statistical methods:

Analysis of immunogenicity: The analysis of immunogenicity was based on the According-to-Protocol (ATP) cohort for immunogenicity. If, for any vaccine group, the percentage of enrolled children with serological results excluded from this ATP cohort was higher than 5%, a second analysis based on the Total Vaccinated cohort (TVC) would be required to complement the ATP analysis.

Except for antibody to *S.pneumoniae* (anti-PS), and unless otherwise stated, the analysis of post-vaccination samples tested by an assay described below was based on children seronegative for the assay at pre-vaccination.

Apart from the endpoints related to clinical consistency, the 3 Inv_MMR lots were pooled for analysis (referred to as Inv_MMR throughout the CSR). The 2 Com_MMR lots used in this study were pooled in all analyses (referred to as Com_MMR throughout the CSR).

Within groups assessment

The following descriptive analyses were performed for each Inv_MMR group, for the Inv_MMR groups, and for the Com_MMR groups at each blood sampling time point for which a serological result was available:

- Percentage of children above each specific cut-off and their exact 95% CIs were tabulated. The specific cut-offs were 150 and 200 mIU/mL for measles, 5 and 10 EU/mL for mumps by PPD ELISA and 4 and 10 IU/mL for rubella, respectively. For the co-administered vaccines, the specific cut-offs were 25 and 75 mIU/mL for varicella zoster, 15 mIU/mL for hepatitis A and in the range of 0.061 – 0.199 µg/mL for each of the 13 serotypes of PS.
- Antibody concentrations were summarized by GMCs with their 95% CIs after vaccination.
- Antibody concentration distributions were displayed as reverse cumulative curves for each antigen and each treatment group after vaccination.

Between Inv_MMR lots analysis (consistency)

At the Day 42 post-vaccination blood sampling, for measles, mumps and rubella:

- The 95% CI for the GMC ratio of each pair of Inv_MMR lots was computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations. The ANOVA model included the three Inv_MMR lot groups and the country as fixed effects. Only the three Inv_MMR lot groups were included in the model.
- The asymptomatic standardized 95% CIs for the pair-wise differences in seroresponse across the three Inv_MMR lots were computed.

Between Inv_MMR and Com_MMR group analysis (non-inferiority)

At the Day 42 post-vaccination blood sampling, for each antibody for which results were available:

- The asymptotic standardized 95% CIs for the difference in seroresponse rate and percentage of children with concentration/titer above each specific cut-off between groups [Inv_MMR lot group minus the Com_MMR lot group] were computed.
- The 95% CI for eachGMC/T group ratio [Inv_MMR lot group over the Com_MMR lot group] was computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model included the vaccine group and the country (only for measles, mumps & rubella) as fixed effects and, for pneumococcal immunogenicity, the pre-vaccination log-transformed concentration as the regressor. The vaccine groups were the Inv_MMR lot group and the Com_MMR lot group.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	Name of finished product: Priorix®	Name of active substance: Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Subgroup analysis of immunogenicity

All descriptive analyses for anti-measles, anti-mumps, and anti-rubella antibodies were repeated for the following subgroups:

- By country, provided that the country had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By gender, provided that each gender had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By geographic ancestry (race) category, provided that the category had at least 50 subjects per treatment group (Inv_MMR or Com_MMR). Subjects from the 'other' category were split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

Analysis of safety: The analysis of safety was based on the TVC. If more than 5% of the vaccinated subjects were excluded from the ATP cohort for the analysis of safety, a second analysis based on the ATP cohort would be required to complement the TVC analysis. All safety analyses were repeated by country.

Synopsis Table 3: Study population (Total vaccinated cohort)

Number of subjects	INV_MMR_1	INV_MMR_1	INV_MMR_1	COM_MMR	Total
Planned, N	1250	1250	1250	1250	5000
Randomized, N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Completed, n (%)	1175 (94.8)	1162 (94.3)	1190 (95.7)	1232 (95.6)	4759 (95.1)
Demographics	**INV_MMR_1**	**INV_MMR_2**	**INV_MMR_3**	**COM_MMR**	**Total**
N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Females : Males	607:632	594:638	615:628	618:671	2434:2569
Mean Age, months (SD)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)
Median Age, months (minimum, maximum)	12 (12, 16)	12 (12, 15)	12 (12, 16)	12 (11, 15)	12 (11, 16)
White - Caucasian / European Heritage, n (%)	932 (75.2)	938 (76.1)	944 (75.9)	970 (75.3)	3784 (75.6)
Other, n (%)	170 (13.7)	155 (12.6)	162 (13.0)	163 (12.6)	650 (13.0)
African Heritage / African American, n (%)	60 (4.8)	52 (4.2)	57 (4.6)	70 (5.4)	239 (4.8)

INV_MMR_1 = GSK MMR Lot 1; INV_MMR_2 = GSK MMR Lot 2; INV_MMR_3 = GSK MMR Lot 3
COM_MMR = Merck MMR

Summary:

Immunogenicity results:

Pair-wise comparison analyses of the antibodies to measles virus (anti-measles), mumps virus (anti-mumps) and rubella virus (anti-rubella) at Day 42 showed that the co-primary objectives to demonstrate consistency of the three manufacturing lots of Inv_MMR were met (Synopsis Table 4 and Synopsis Table 5).

For the comparison of three manufacturing lots of Inv_MMR:

- For each pair-wise comparison, the two sided 95% CI for the lot difference in seroresponse rates between lots was within the [-5%; 5%] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 1.

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- For each pair-wise comparison, the two sided 95% CI for the adjusted GMC ratio was within the [0.67; 1.5] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 2.

Synopsis table 4: Consistency of INV_MMR lots in terms of seroresponse rate for measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

					Difference (First group minus Second group)		
	First group		Second group			95% CI	
Antibody	**INV_MMR Lot**	**SR rate**	**INV_MMR Lot**	**SR rate**	**%**	**LL**	**UL**
anti-Measles antibody	1	98.1	2	98.6	-0.54	-1.69	0.58
	1	98.1	3	97.8	0.25	-0.98	1.50
	2	98.6	3	97.8	0.79	-0.35	1.98
anti-Mumps (PPD) antibody	1	98.6	2	98.6	0.02	-1.05	1.09
	1	98.6	3	98.0	0.63	-0.50	1.81
	2	98.6	3	98.0	0.61	-0.53	1.79
anti-Rubella antibody	1	97.2	2	97.1	0.14	-1.30	1.58
	1	97.2	3	97.7	-0.49	-1.86	0.86
	2	97.1	3	97.7	-0.62	-2.02	0.74

INV_MMR_1 = GSK MMR LOT 1; INV_MMR_2 = GSK MMR LOT 2; INV_MMR_3 = GSK MMR LOT 3
SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay -
seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively)
PPD = Pharmaceutical Product Development Inc.
95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Synopsis table 5: Consistency of INV_MMR lots in terms of adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

					Adjusted GMC ratio (First group over Second group)		
	First group		Second group			95% CI	
Antibody	**Lot**	**Adjusted GMC**	**Lot**	**Adjusted GMC**	**Value**	**LL**	**UL**
anti-Measles antibody (mIU/mL)	INV_MMR_1	3128.5	INV_MMR_2	3174.4	0.99	0.91	1.06
	INV_MMR_1	3128.5	INV_MMR_3	3217.7	0.97	0.90	1.05
	INV_MMR_2	3174.4	INV_MMR_3	3217.7	0.99	0.91	1.06
anti-Mumps (PPD) antibody (EU/mL)	INV_MMR_1	75.2	INV_MMR_2	80.5	0.93	0.87	1.00
	INV_MMR_1	75.2	INV_MMR_3	72.3	1.04	0.97	1.11
	INV_MMR_2	80.5	INV_MMR_3	72.3	1.11	1.04	1.19
anti-Rubella antibody (IU/mL)	INV_MMR_1	54.5	INV_MMR_2	50.5	1.08	1.01	1.15
	INV_MMR_1	54.5	INV_MMR_3	54.3	1.00	0.94	1.07
	INV_MMR_2	50.5	INV_MMR_3	54.3	0.93	0.87	0.99

INV_MMR_1 = GSK MMR LOT 1; INV_MMR_2 = GSK MMR LOT 2; INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for Country
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country - pooled variance with more than 2 groups), LL = lower limit, UL = upper limit

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Between group analyses of the anti-measles, anti-mumps and anti-rubella antibodies at Day 42 showed that the co-primary objectives to demonstrate non-inferiority of Inv_MMR compared to Com_MMR were met (Synopsis Table 6 and Synopsis Table 7).

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 3.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 4.

Synopsis table 6: NI of INV_MMR vs COM_MMR in terms of seroresponse rate to measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

			Difference (INV_MMR minus COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	**SR rate**	**SR rate**	**%**	**LL**	**UL**
anti-Measles antibody	98.2	98.0	0.18	-0.68	1.25
anti-Mumps (PPD) antibody	98.4	97.6	0.81	-0.10	1.96
anti-Rubella antibody	97.3	98.5	-1.15	-2.00	-0.15

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR; SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay - seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively); 95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Synopsis table 7: NI of INV_MMR vs COM_MMR in terms of post-vaccination adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only
(ATP cohort for immunogenicity)

			Adjusted GMC ratio (INV_MMR over COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	**Adjusted GMC**	**Adjusted GMC**	**Value**	**LL**	**UL**
anti-Measles antibody (mIU/mL)	3165.2	3215.4	0.98	0.93	1.05
anti-Mumps (PPD) antibody (EU/mL)	76.4	73.0	1.05	0.99	1.11
anti-Rubella antibody (IU/mL)	52.5	60.0	0.87	0.83	0.92

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR;
Adjusted GMC = geometric mean antibody concentration adjusted for Country;
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country - pooled variance), LL = lower limit, UL = upper limit

Analyses of anti-measles, anti-mumps and anti-rubella antibodies at Day 42 in Inv_MMR group showed that the co-primary objective of acceptable immune response for Inv_MMR in terms of seroresponse rates was met (Synopsis Table 8 to Synopsis Table 10).

- The lower limit of the two sided 95% CI for the seroresponse rate for Inv_MMR lots was ≥90% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 5.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Synopsis table 8: Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 mIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3196	98.4	97.9	98.8	3188	98.2	97.6	98.6	3017.4	2923.9	3113.8
	COM_MMR	PI(D42)	1137	1115	98.1	97.1	98.8	1114	98.0	97.0	98.7	3074.4	2911.0	3246.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Synopsis table 9: Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3187	3168	99.4	99.1	99.6	3135	98.4	97.9	98.8	72.4	70.4	74.5
	COM_MMR	PI(D42)	1107	1099	99.3	98.6	99.7	1080	97.6	96.5	98.4	69.1	65.7	72.7

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Synopsis table 10: Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3245	3229	99.5	99.2	99.7	3159	97.3	96.7	97.9	55.7	54.2	57.3
	COM_MMR	PI(D42)	1135	1130	99.6	99.0	99.9	1118	98.5	97.6	99.1	64.0	61.1	67.0

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Between group analyses of the anti-varicella zoster virus (anti-VZV) antibodies at Day 42 showed that secondary objective 1 to demonstrate non-inferiority of Inv_MMR compared to Com_MMR in terms of seroresponse rates and GMC ratio of anti-VZV antibodies was met (Synopsis Table 11 and Synopsis Table 12).

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies
- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies, thus meeting secondary objective 1.

Synopsis table 11: Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an VZV antibody concentration equal to or above 75 mIU/ML - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	**Type**	**N**	**n**	**%**	**N**	**n**	**%**	**%**	**LL**	**UL**
anti-VZV antibody	75 mIU/mL	1492	1376	92.2	540	491	90.9	1.30	-1.31	4.29

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Synopsis table 12: Ratios of Anti-VZV antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	**GMC**	**N**	**GMC**	**Value**	**LL**	**UL**
1492	169.6	540	167.2	1.01	0.95	1.08

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

Between groups analyses of the antibodies to HAV at Day 42 showed that secondary objective 2 to demonstrate non-inferiority of Inv_MMR compared to Com_MMR in terms of the GMC ratio of antibodies to HAV was met (Synopsis Table 13).

- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV, thus meeting secondary objective 2.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	Name of finished product: Priorix®	Name of active substance: Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Synopsis table 13: Ratios of Antibodies to HAV GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	GMC	N	GMC	Value	LL	UL
748	41.8	271	42.8	0.98	0.86	1.11

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

Between group analyses of the anti-*S.pneumoniae* (anti-PS) (13 serotypes) antibodies at Day 42 showed that secondary objective 3 to demonstrate non-inferiority of Inv_MMR compared to Com_MMR in terms of the adjusted GMC ratio of anti-PS antibodies was met (Synopsis Table 14).

- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for each of the thirteen *S. pneumoniae* serotypes, thus meeting secondary objective 3.

Synopsis table 14: Adjusted Ratios of Anti-S.Pneu GMCs at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

					Adjusted GMC ratio (INV_MMR / COM_MMR)		
	INV_MMR		COM_MMR			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PnPS 1 antibody (ECL) (µg/mL)	740	2.258	256	2.392	0.94	0.85	1.05
anti-PnPS 3 antibody (ECL) (µg/mL)	739	0.499	255	0.503	0.99	0.91	1.08
anti-PnPS 4 antibody (ECL) (µg/mL)	732	1.620	255	1.844	0.88	0.79	0.98
anti-PnPS 5 antibody (ECL) (µg/mL)	738	2.092	256	2.280	0.92	0.83	1.01
anti-PnPS 6A antibody (ECL) (µg/mL)	740	5.815	256	5.761	1.01	0.92	1.11
anti-PnPS 6B antibody (ECL) (µg/mL)	739	5.812	256	5.924	0.98	0.89	1.09
anti-PnPS 7F antibody (ECL) (µg/mL)	739	3.658	256	3.887	0.94	0.86	1.03
anti-PnPS 9V antibody (ECL) (µg/mL)	740	2.295	256	2.324	0.99	0.90	1.08
anti-PnPS 14 antibody (ECL) (µg/mL)	738	6.512	256	7.151	0.91	0.81	1.02
anti-PnPS 18C antibody (ECL) (µg/mL)	740	2.082	255	2.255	0.92	0.84	1.02
anti-PnPS 19A antibody (ECL) (µg/mL)	739	4.708	255	4.876	0.97	0.87	1.07
anti-PnPS 19F antibody (ECL) (µg/mL)	740	4.186	256	4.367	0.96	0.87	1.06
anti-PnPS 23F antibody (ECL) (µg/mL)	701	2.178	240	2.301	0.95	0.85	1.06

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for baseline concentration
N = Number of subjects with both pre- and post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Ancova model: adjustment for baseline concentration - pooled variance); LL = lower limit, UL = upper limit

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Safety results:

- Overall, during the 43-day post-vaccination period, at least one solicited or unsolicited symptom was reported by 84.1% of subjects in the Inv_MMR group and by 85.3% in the Com_MMR group. General symptoms were reported by 80.5% and 82.3% of subjects in Inv_MMR and Com_MMR groups, respectively. Local symptoms were reported by 40.2% and 41.9% of subjects in the Inv_MMR and Com_MMR groups, respectively.
- Within the 4-day post-vaccination period, the most frequently reported solicited local symptoms in the Inv_MMR and Com_MMR groups were pain (25.9% and 28.1%) and redness (24.5% and 25.2%), respectively. Solicited local symptoms of grade 3 were reported in up to 1.0% of subjects in any group.
- Within the 15-day post-vaccination period, the most commonly reported general symptom in the Inv_MMR group and Com_MMR groups was irritability or fussiness reported in 63.3% and 65.9% of subjects respectively. This was followed by drowsiness (44.9% and 47.1%) and loss of appetite (45.1% and 44.1%). Solicited general AEs of grade 3 were reported in a maximum of 4.9% of subjects in the Inv_MMR and Com_MMR groups.
- Within the 43-day post-vaccination period, the following solicited general symptoms were reported in both the Inv_MMR and Com_MMR groups, respectively: fever ≥38.0°C/100.4°F (34.7% and 33.1%), rash (29.2% and 30.4%) and febrile convulsions (10 subjects [0.3%] and 3 subjects [0.2%]; 4 of these 10 events in the Inv_MMR group and 2 of the 3 events in the Com_MMR group were considered related to vaccination). No subject reported parotid gland swelling in any of the groups.
- Within the 43-day post-vaccination period, 50.0% of subjects in the Inv_MMR group and 47.9% in the Com_MMR group reported at least one unsolicited AE. The most common AE by MedDRA preferred term was upper respiratory tract infection, reported in 9.5% of subjects of both the Inv_MMR and Com_MMR groups.
- During the entire study period, 102 subjects reported one or more SAEs in this study. A total of 98 SAEs were reported in 77 subjects (2.1%) in the Inv_MMR group and 40 were reported in 25 subjects (1.9%) in the Com_MMR group. Two of these SAEs in the Inv_MMR group were considered by the investigator to be related to the study vaccination. One subject in the Inv_MMR_2 group had gastroenteritis, and another subject in the Inv_MMR_3 group had febrile convulsion. There were no fatal SAEs in the study. Safety results were consistent between the 3 lots of Inv_MMR used in this study.
- The most frequently occurring SAE during the study period was bronchitis reported by 8 subjects (0.2%) in the Inv_MMR group and by 2 subjects (0.2%) in the Com_MMR group.
- Two subjects were withdrawn from the study due to an AE.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Conclusion:

All co-primary study objectives were met:

- The lot-to-lot consistency of the immune response to each of the three vaccine components after one dose of *Priorix*, out of three consistency lots, was demonstrated:

All 95% CIs for the pair-wise lot differences in seroresponse rates were between -5% and +5% for anti-measles, anti-mumps, and anti-rubella antibodies.

All 95% CIs for the pair-wise adjusted GMC ratios were between 0.67 and 1.50 for anti-measles, anti-mumps, and anti-rubella antibodies.

- Non-inferiority of the immune responses of the Inv_MMR lots versus *M-M-R-II* was demonstrated:

The lower limit of the 95% CI for the group difference in seroresponse rates (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps, and anti-rubella antibodies.

The lower limit of the 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps, and anti-rubella antibodies.

- The acceptability of the immune response of the Inv_MMR lots was demonstrated:

The lower limit of the 95% CI for the seroresponse rate in the Inv_MMR group was ≥90% for anti-measles, anti-mumps, and anti-rubella antibodies.

All secondary study objectives related to immunogenicity were met.

- Non-inferiority of the immune response of the Inv_MMR lots versus the Com_MMR lots in terms of co-administered vaccines was demonstrated:

The lower limit of the two-sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies.

The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies.

The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV.

The lower limit of the two-sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to each of the thirteen *S. pneumoniae* serotypes.

An acceptable safety profile was observed for the Inv_MMR groups when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US), which was similar to that observed with *M-M-R-II*.

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LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
ANOVA	Analysis of Variance
Anti-HAV	Antibody to Hepatitis A Virus
Anti-measles	Antibody to Measles Virus
Anti-mumps	Antibody to Mumps Virus
Anti-PS	Antibody to *S.pneumoniae* serotypes
Anti-rubella	Antibody to Rubella Virus
Anti-VZV	Antibody to Varicella Zoster Virus
ATP	According-To-Protocol
CBER	Center for Biologics Evaluation and Research
CDC	Center for Disease Control
Com_MMR_L1	Comparator MMR vaccine Lot 1
Com_MMR_L2	Comparator MMR vaccine Lot 2
CRO	Contract Research Organization
CSR	Clinical Study Report
CI	Confidence Interval
ECL	Electrochemiluminescence
eCRF	electronic Case Report Form
ELISA	Enzyme-linked Immunosorbent Assay
ER	Emergency Room
EU	European Union
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GMC	Geometric mean concentration
GSK	GlaxoSmithKline
HAV	Hepatitis A vaccine (*Havrix*)
Hib	*Haemophilus influenzae* type b
ICF	Informed Consent Form
IEC	Independent Ethics Committee
IM	Intramuscular
IND	Investigational New Drug

Inv_MMR	Investigational MMR Vaccine
Inv_MMR_L1	Investigational MMR Vaccine Lot 1
Inv_MMR_L2	Investigational MMR Vaccine Lot 2
Inv_MMR_L3	Investigational MMR Vaccine Lot 3
IRB	Institutional Review Board
LAR(s)	Legally Acceptable Representative(s)
LOD	Limit of Detection
LOQ	Limit of Quantitation
mcg / μg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
mIU	Milli International Unit
MMR	Measles, Mumps and Rubella
NOCD	New Onset Chronic Disease
PASS	Power Analysis and Sample Size (Software)
PCV-13	Pneumococcal Conjugate Vaccine (*Prevnar 13)*
PFU	Plaque Forming Units
PPD	Pharmaceutical Product Development, Inc.
RDE	Remote Data Entry
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis Software
SBIR	Central Randomization System on the Internet
SC	Subcutaneous
SD	Standard Deviation
SOP	Standard Operating Procedures
SP/MSD	Sanofi Pasteur/Merck Sharp and Dohme
SPM	Study Procedures Manual
TVC	Total Vaccinated Cohort
USA	United States (US) of America
VV	Varicella Vaccine (*Varivax*)
VZV	Varicella Zoster Virus
WHO	World Health Organization

GLOSSARY OF TERMS

Adverse event: Any untoward medical occurrence in a patient or clinical investigation child, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also includes failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse.

Blinding: A procedure in which one or more parties to the trial are kept unaware of the treatment assignment in order to reduce the risk of biased study outcomes. The level of blinding is maintained throughout the conduct of the trial, and only when the data are cleaned to an acceptable level of quality will appropriate personnel be unblinded or when required in case of a serious adverse event. In an observer-blind study, the subject/parent(s)/Legally Acceptable Representative(s) (LAR(s)) and the site and sponsor personnel involved in the clinical evaluation of the subjects are blinded while other study personnel may be aware of the treatment assignment. In a double blind study, the subject/parent(s)/LAR(s), the investigator and sponsor staff who are involved in the treatment or clinical evaluation of the subjects and the review or analysis of data are all unaware of the treatment assignments. Partially-blind is to be used for study designs with different blinding levels between different groups, e.g., double-blinded consistency lots which are open with respect to the control group.

Child in care: A child who has been placed under the control or protection of an agency, organization, institution or entity by the courts, the government or a government body, acting in accordance with powers conferred on them by law or regulation. The definition of a child in care can include a child cared for by foster parents or living in a care home or institution, provided that the arrangement falls within the definition above. The definition of a child in care does not include a child who is adopted or has an appointed LAR/s.

Eligible: Qualified for enrollment into the study based upon strict adherence to inclusion/exclusion criteria.

Epoch:	An epoch is a well-defined part of a protocol that covers a set of consecutive time points. Generally, an epoch is self-contained and allows performance of data analysis to address some of the trial objectives (e.g., primary, booster, yearly follow-ups).
eTrack:	GSK's tracking tool for clinical trials.
Evaluable:	Meeting all eligibility criteria, complying with the procedures defined in the protocol, and, therefore, included in the according-to-protocol (ATP) analysis.
Medically Attended Adverse Event:	An event for which the subject received medical attention defined as hospitalization, an emergency room visit or a visit to or from medical personnel (e.g., nurse practitioner or physician assistant or medical doctor) for any reason.
Randomization:	Process of random attribution of treatment to subjects in order to reduce bias of selection.
SBIR:	A central Internet randomization system.
Site Monitor:	An individual assigned by the sponsor who is responsible for assuring proper conduct of clinical studies at one or more investigational sites.
Solicited adverse event:	Adverse events (AEs) to be recorded as endpoints in the clinical study. The presence/occurrence/intensity of these events is actively solicited from the subject or an observer during a specified post-vaccination follow-up period.
Subject	Term used throughout the protocol to denote an individual who has been enrolled to participate or participates in the clinical study, either as a recipient of the investigational product(s) or as a control.
Subset:	A group of subjects who have the same study procedures at a given time point, but the biological assays performed on that sample will be different, relative to the other subsets.
Treatment:	Term used throughout the clinical study to denote a set of investigational product(s) or marketed product(s) or placebo intended to be administered to a subject, identified by a unique number, according to the study randomization or treatment allocation.

Unsolicited adverse event:	Any adverse event (AE) reported in addition to those solicited during the clinical study. Also any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms will be reported as an unsolicited adverse event.

TRADEMARKS

The following trademarks are used in the present report.

Note: In the body of the Study Report, the names of the vaccines/products and/or medications are written without the superscript symbol ™ or ® and in *italics*.

Trademarks of the GSK group of companies	Generic description
Priorix®*	Measles, mumps and rubella vaccine live
Havrix®	Hepatitis A vaccine (HAV)

* *Priorix* is not licensed in the US.

Trademarks not owned by the GSK group of companies	Generic description
M-M-R®II (Merck & Co., Inc.) also called M-M-R Vax Pro® (distributed by Sanofi Pasteur/Merck Sharp and Dohme [SPMSD] in certain countries)*	Measles, mumps, and rubella virus vaccine live
Varivax® (Merck & Co., Inc.)	Varicella virus vaccine live (VV)
Prevnar 13® (Pfizer Inc.)	Pneumococcal 13-valent conjugate vaccine (diphtheria CRM_{197} protein) (PCV-13)

* The Merck & Co., Inc.'s combined measles-mumps-rubella virus vaccine live is referred to as Com_MMR (Com_MMR_L1 and Com_MMR_L2, for lots 1 and 2 respectively) for the comparator vaccine throughout the study report.

1. ETHICS

1.1. Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The study protocol, any amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational center IEC or IRB.

1.2. Ethical conduct of the study

This study was conducted in accordance with ethical principles that have their origins in the Declaration of Helsinki, the principles of "good clinical practice" (GCP) and all applicable regulatory requirements.

During the course of the study, whenever potential issues with regard to the conduct of the study were identified, either via site monitoring activities or brought to GlaxoSmithKline (GSK) Biologicals' attention by other oversight mechanisms, these issues were investigated and appropriate corrective and / preventive actions where possible were taken.

Deviations that occurred during the study are described in Section 5.11 and Section 6.3.

1.3. Subject information and consent

Written informed consent was to be obtained from each subject's parent(s) / legally acceptable representative (LAR) prior to the performance of any study-specific procedures.

2. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This multicenter study, sponsored by GSK Biologicals, was conducted in Estonia (6 sites), Finland (11 sites), Mexico (2 sites), Spain (9 sites), the United States of America (USA) (63 sites) including Puerto Rico (1 site).

Principal investigator:

- Dr. PPD
PPD Mexico, PPD

The contract research organizations (CROs) involved in this study are given in Table 1. Study sites in Estonia and Mexico did not employ a CRO.

Table 1 Contract research organizations involved in the study

Country	Contract research organization	Scope
Finland	Smerud Medical Research Finland AB/Oy Jorvas High-tech Center, Hirsalantie 11 02420 Jorvas, Finland	Sample management, site monitoring and vaccine distribution
Canada	NÉOMED-LABS Inc. 525 Cartier Blvd. West, Laval, Quebec, Canada - H7V 3S8	Sample management
USA	PPD, Inc., 466 Devon Park Drive, Wayne, PA 19087-1816, USA	Sample management
USA	PPD, Inc., 929 North Front Street, Wilmington, NC 28401, USA	Site monitoring (Puerto Rico)
USA	BARC USA Inc. 5 Delaware Drive, Lake Success, NY 11042-1114, USA	Sample handling/processing

3. INTRODUCTION

Measles, mumps and rubella (MMR) are common viral illnesses of childhood. These highly infectious diseases and their complications are responsible for considerable morbidity and mortality throughout the world [WHO, 2007; WHO, 2009; WHO, 2011]. Measles can cause pneumonia and encephalitis. Mumps is associated with complications including aseptic meningitis, deafness and orchitis. Rubella symptoms in subjects include fever, swollen lymph nodes and rash; while rubella infection in pregnant women can cause congenital rubella syndrome. When immunization against these diseases is routinely practiced, significant reduction in disease incidence and associated complications has been reported [MMWR, 2013]. GSK Biologicals has developed a trivalent MMR vaccine that is licensed outside the USA under the trade name of *Priorix* in over 100 countries, including Canada, Australia, and all countries in the European Union (EU).

This study was intended to support licensure of GSK Biologicals' trivalent combined measles, mumps and rubella vaccine (*Priorix,* referred to as Inv_MMR vaccine in this document) in the USA by generating safety and immunogenicity data in subjects 12 to 15 months of age. The US Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommends routine 2-dose vaccination with MMR vaccine at 12 to 15 months and at 4 to 6 years of age [MMWR, 2013].

This study evaluated the consistency of the immune response to three different lots of Inv_MMR vaccine manufactured to target potencies. In addition, the study also evaluated the immunogenicity of Inv_MMR vaccine in contrast to the US standard of care (*M-M-R-II* / *M-M-R Vax Pro*, referred to as Com_MMR vaccine throughout this document) when both were used as a first (primary) dose. In order to obtain more representative data on the comparator vaccine, the Com_MMR used in this study consisted of two lots

designated Com_MMR_L1 and Com_MMR_L2. Throughout the study Com_MMR_L1 and Com_MMR_L2 were analyzed as pooled lots.

In the US, the primary dose of measles, mumps and rubella-containing vaccine is routinely co-administered with *Varivax* (VV), *Havrix* (HAV) and *Prevnar 13* (PCV-13) at 12 to 15 months of age. Hence, in the US, the study also evaluated the safety and immunogenicity of both Inv_MMR and Com_MMR vaccines when both were co-administered with these three vaccines. In other countries the study evaluated the safety and immunogenicity of Inv_MMR and Com_MMR vaccines when co-administered with *Varivax* and *Havrix*. Note: Given the heterogeneity in the use of pediatric pneumococcal vaccines globally, and administration of these vaccines generally begins in infancy, *Prevnar 13* was administered only to children enrolled in the US.

At the end of the study or shortly after the study, depending on vaccine availability, GSK provided a second dose of *Havrix* and/or varicella vaccine to participants enrolled in non-US countries where local health departments did not provide hepatitis A and varicella vaccinations.

4. STUDY OBJECTIVES

4.1. Primary objectives

The co-primary objectives were assessed in a hierarchical manner according to the order presented below. A co-primary objective can only be met if the statistical criteria for that objective were met as well as the statistical criteria for all previous co-primary objectives (see Section 5.10.3.1 for details).

All primary and secondary immunogenicity endpoints were tested with an ELISA.

Note: all criteria were assessed for each assay separately. With the exception of the anti-pneumococcal antibodies, the criteria were specific to children seronegative for the assay at pre-vaccination.

- To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

  Criterion*: For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for antibodies to measles, mumps, and rubella viruses.*

- To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.

  Criterion*: For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses*.

- To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

  Criterion*: The lower limit of the two-sided 95% CI on the group difference (Inv_MMR minus Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses*.

- To demonstrate non-inferiority of Inv_MMR (for the three lots) compared to Com_MMR (for the two lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.

  Criterion*: The lower limit of the two-sided 95% CI on GMC ratio (Inv_MMR over Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.*

- To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

  Criterion: *The lower limit of the two-sided 95% CI for the seroresponse rate for the Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.*

Refer to Section 5.10.1 for the definition of the primary endpoint.

4.2. Secondary objectives

1. To demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of seroresponse rate and GMC for antibodies to varicella zoster virus (VZV) at Day 42 (in a subset of children enrolled in the US).

   Criteria*: The lower limit of the two-sided 95% CI for the group difference (Inv_MMR minus Com_MMR) in seroresponse rates for antibodies to VZV is ≥-10%.*

   The lower limit of the two-sided 95% CI on the GMC ratio (Inv_MMR over Com_MMR) is ≥0.67 for antibodies to VZV.

2. To demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of GMC for antibodies to hepatitis A virus (HAV) at Day 42 (in a subset of children enrolled in the US).

   Criterion*: The lower limit of the two-sided 95% CI for the group GMC ratio (Inv_MMR over Com_MMR) for antibodies to HAV (post-dose 1) is ≥0.5.*

3. To demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of GMCs for antibodies to *S. pneumoniae* (PS) (13 serotypes), at Day 42 (in a subset of children administered *Prevnar 13* in the US).

   Criterion*: The lower limit of the two-sided 95% CI for the group GMC ratio (Inv_MMR over Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.*

4. To assess the immunogenicity of *Havrix* with respect to the seroresponse rates for antibodies to HAV in the Inv_MMR group in contrast to the Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).

5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US).

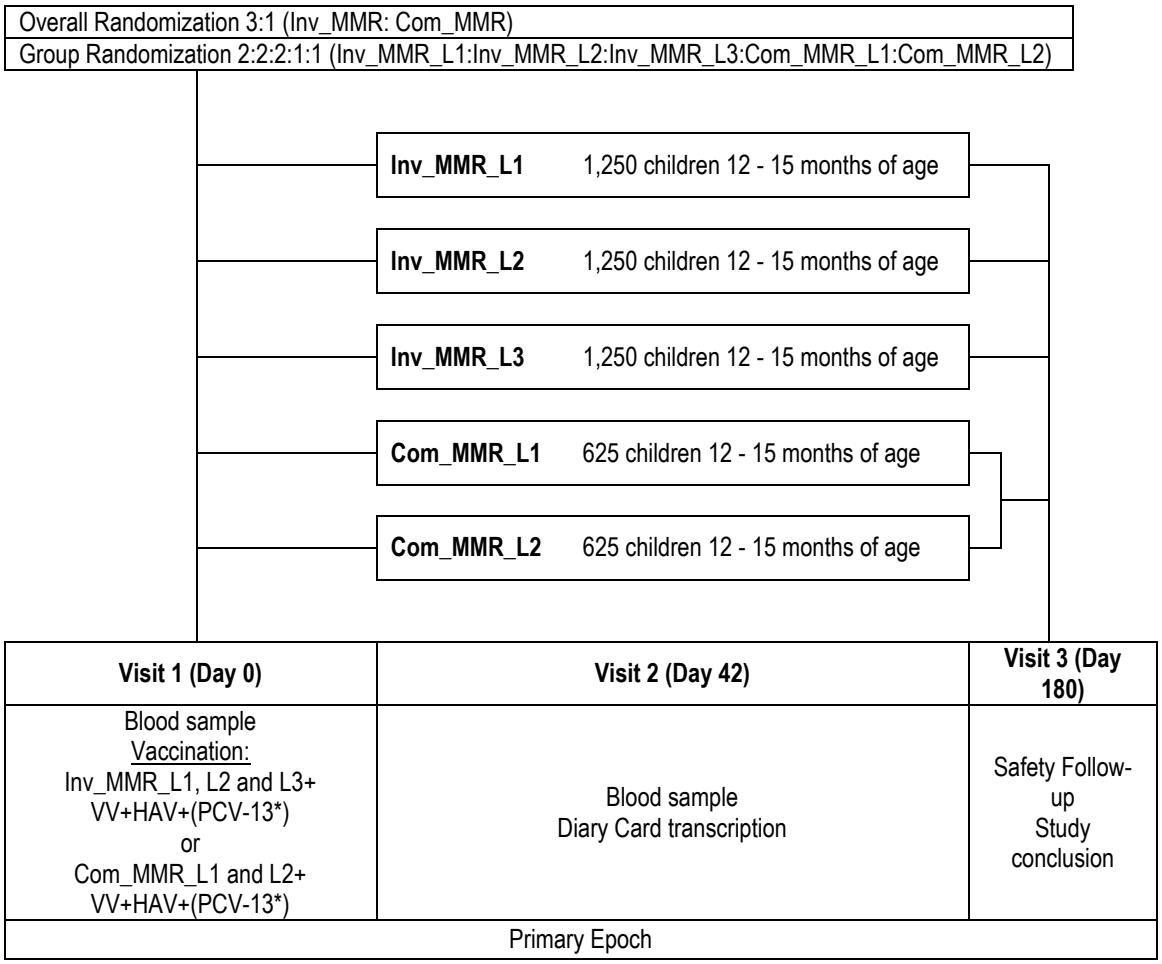
Refer to Section 5.10.2 for the definition of the secondary endpoints.

5. INVESTIGATIONAL PLAN

5.1. Study design

5.1.1. Overall study design – Description

Figure 1 Study design



L= Lot; VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* PCV-13 was only administered to children in the US

- **Experimental design**: Phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with 5 parallel groups.
- **Duration of the study**: The study period was approximately 6 months for each subject, starting at Visit 1 (Day 0) and ending with Visit 3 (Day 180).

Table 2 Study groups

Study groups	Number of subjects	Age (Min/Max)
Inv_MMR_L1	1,250	12 – 15 months
Inv_MMR_L2	1,250	12 – 15 months
Inv_MMR_L3	1,250	12 – 15 months
Com_MMR_L1	625	12 – 15 months
Com_MMR_L2	625	12 – 15 months

L = Lot

- **Control:** active control: Com_MMR_L1 and Com_MMR_L2 vaccines.
- **Co-administered vaccines:** All subjects received *Varivax* (VV) and *Havrix* (HAV) vaccines, concomitantly with MMR vaccine at 12 to 15 months of age. *Prevnar 13* (PCV-13) was co-administered only to US subjects. At the end of the study, GSK provided a second dose of HAV and/or VV vaccine to subjects enrolled in selected non-US countries if local health departments did not routinely provide hepatitis A and varicella vaccinations. The second dose of HAV and VV was not part of the study procedures.
- **Vaccination schedule:** A single vaccination, with either 1 of three lots of Inv_MMR or one of 2 Com_MMR active control lots was administered at Visit 1 (12-15 months of age), along with the appropriate co-administered vaccines. The VV and HAV vaccines were administered to all subjects while PCV-13 was administered only to subjects enrolled in the US.

Table 3 Treatment groups

Treatment name	Vaccine / Product name	Treatment Groups				
		Inv_MMR_L1 (active)	Inv_MMR_L2 (active)	Inv_MMR_L3 (active)	Com_MMR_L1 (control)	Com_MMR_L2 (control)
Inv_MMR_L1	Inv_MMR_L1	X				
	Inv_MMR Diluent	X				
Inv_MMR_L2	Inv_MMR_L2		X			
	Inv_MMR Diluent		X			
Inv_MMR_L3	Inv_MMR_L3			X		
	Inv_MMR Diluent			X		
Com_MMR_L1	Com_MMR_L1				X	
	Com_MMR_L1 Diluent†				X	
Com_MMR_L2	Com_MMR_L2					X
	Com_MMR_L2 Diluent†					X
Varivax	*Varivax*	X	X	X	X	X
	Varivax Diluent	X	X	X	X	X
Havrix	*Havrix*	X	X	X	X	X
*Prevnar 13**	*Prevnar 13*	X	X	X	X	X

L= Lot
† The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
* *Prevnar-13* was only given to children enrolled in the US

- **Treatment allocation:** 5,000 healthy children 12 to 15 months of age were planned to be enrolled and randomized in a 2:2:2:1:1 ratio to receive either one dose of Inv_MMR_L1 (1,250 subjects), one dose of Inv_MMR_L2 (1,250 subjects), one dose of Inv_MMR_L3 (1,250 subjects), or one dose of either Com_MMR_L1 (625 subjects) or Com_MMR_L2 (625 subjects). The vaccines *Havrix*, *Varivax* and *Prevnar 13* were co-administered according to the protocol) with Inv_MMR vaccine or Com_MMR vaccine. The treatment allocation at the investigator site was performed using a central randomization system on the Internet (SBIR). Overall, the randomization was 3:1 (Inv_MMR: Com_MMR).
- **Blinding:** observer-blind.
  - The study was conducted in a double-blind fashion with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots, and in an observer-blind fashion for the comparison of the Inv_MMR vaccine versus the Com_MMR vaccine.
- **Visits:** Children from each treatment group participated in three study visits (Day 0, Day 42 and Day 180).
- **Sampling:** Blood samples were to be collected from each child; one at Day 0 and one at Day 42.
- **Type of study:** self-contained.
- **Data collection:** Electronic Case Report Form (eCRF) encoded using remote data entry (RDE).

5.1.2. Discussion of study design

The MMR-160 study was designed to evaluate the consistency of the immune response to three different lots of Inv_MMR vaccine manufactured to target potencies. In addition, the study was designed to evaluate the immunogenicity of Inv_MMR vaccine in contrast to the US standard of care (*M-M-R II/ M-M-R VaxPro* vaccine) when both are used as a first (primary) dose. In order to obtain more representative data on the comparator vaccine, the Com_MMR used in this study consisted of two lots designated Com_MMR_L1 and Com_MMR_L2. Throughout the study Com_MMR_L1 and Com_MMR_L2 were analyzed as pooled lots.

In the US, the primary dose of measles, mumps and rubella-containing vaccine is routinely co-administered with VV, HAV and PCV-13 vaccines at 12 to 15 months of age. Hence, in the US, the study also evaluated the safety and immunogenicity of both Inv_MMR and Com_MMR vaccines when both are co-administered with these 3 vaccines. In other countries the study evaluated safety and immunogenicity of Inv_MMR and Com_MMR vaccines when co-administered only with VV and HAV. Given the heterogeneity in the use of pediatric pneumococcal vaccines globally, and administration of these vaccines generally begins in infancy, PCV-13 was to be administered only to subjects enrolled in the US who previously received a 3-dose series of *Prevnar 13* only (i.e., no doses given as *Prevnar/Prevenar*), at least 60 days prior to study entry.

At the end of the study, GSK provided a second dose of HAV and/or VV vaccine to subjects enrolled in non-US countries if local health departments did not routinely provide hepatitis A and varicella vaccinations.

5.2. Study procedures

An overview of the study procedures performed on each group is provided in Table 4.

Table 4 List of study procedures

Age at enrollment	12-15 months		
Epoch	*Primary Epoch*		
Type of contact	Visit 1	Visit 2	Visit 3
Time points	Day 0	Day 42	Day 180
Sampling time points	Pre-Vacc	Post-Vacc	
Informed consent	●		
Check inclusion/exclusion criteria	●		
Check contraindications, warnings and precautions	O		O [1]
Collect demography data	●		
Medical history	●		
Physical examination	●	O [2]	O [2]
Measure/record height and weight	●		
Vaccination history (protocol specific vaccines) [3]	●		
Pre-vaccination body temperature	●		
Randomization and recording of treatment number	●		
Blood sampling for antibody determination (~5 mL)	●	●	
Study vaccinations	●		
Second dose of *Havrix* and/or varicella vaccine			x [1]
Distribution of Diary Cards	O	O	
Daily post-vaccination recording of solicited local adverse events by children's parent(s)/LAR(s) on Diary Cards (Day 0-3)	●		
Daily post-vaccination recording of solicited general adverse events by children's parent(s)/LAR(s) on Diary Cards for drowsiness, loss of appetite, and irritability (Day 0-14) and for fever, rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42) [4]	●		
Recording of the occurrence of any post-vaccination unsolicited symptoms by children's parent(s)/LAR(s) on Diary Cards (Day 0-42)	●		
Recording of concomitant medication/vaccination by children's parent(s)/LAR(s) on Diary Cards (Day 0-through study end)	●	O	O
Investigator/designee medical evaluation of any measles/rubella or varicella-like rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42)	●		
Recording of any medications/vaccinations through Visit 2	●	●	
Recording of any forbidden investigational product (through study end)	●	●	●
Return of Diary Cards by parent(s)/LAR(s) and transcription by investigator/designee		●	● [5]
Recording of any intercurrent medical condition	●	●	
Recording of all Serious Adverse Events (Day 0 through study end)	●	●	●
Recording of NOCD(s) and AEs prompting medically attended visits including ER visits (Day 0 through study end) [6]	●	●	●
Visit 2 investigator sign-off on data for the Day 42 analysis		●	
Study Conclusion			●
Final investigator signature			●

● is used to indicate a study procedure that required documentation in the individual eCRF
x is used to indicate a procedure (that was not part of the study) that required documentation in the individual eCRF
O is used to indicate a study procedure that did not require documentation in the individual eCRF
[1] At the end of the study or shortly after the study, depending on vaccine availability, GSK was to provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. The second dose of HAV and varicella vaccine was not part of the study procedures.
[2] Physical exam at Visit 2 and Visit 3 only required if deemed necessary based on child's interim medical history. Findings were to be recorded only if symptom/abnormality was present.
[3] For US children only, child that previously received a 3-dose series of PCV-13 at least 60 days prior to study entry
[4] Parent(s)/LAR(s) were to contact the investigator immediately for any suspected measles/rubella, varicella-like rash, parotid/salivary gland swelling or suspected signs of meningism, including febrile convulsions occurring between Day 0 and Day 42 and were to schedule a visit for evaluation by the investigator).
[5] Return of Diary Card for contraindicated medication / vaccination, any specific Adverse Events (AEs), and AEs prompting medically attended visits including Emergency Room (ER) visits until study end.
[6] Events recorded were new onset chronic disease(s) (NOCD(s)) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting medically attended visits including Emergency Room (ER) visits.

Table 5 Intervals between study visits

Visit	Optimal Visit Day*	Interval	Allowed interval
Visit 1	Day 0	---	---
Visit 2	Day 42	Visit 1 → Visit 2	35 - 77 days†
Visit 3	Day 180	Visit 1 → Visit 3	180 - 210 days

* Whenever possible, the investigator had to arrange study visits on this optimal visit day.
† Subjects were not eligible for inclusion in the ATP immunogenicity analyses if study visits were outside the allowed interval.

5.3. Selection of study population

5.3.1. Inclusion criteria for enrollment

All subjects had to satisfy all the following criteria at study entry:

- Male or female child between 12 and 15 months of age (e.g., from the 1 year birthday until the day before age 16 months) at the time of vaccination.
- Subjects' parent(s)/LARs who, in the opinion of the investigator, could and would comply, with the requirements of the protocol (e.g., completion of the diary cards, return for follow-up visits, respects intervals between visits).
- Written informed consent obtained from the parent(s)/LAR(s) of the child.
- Child was in stable health as determined by investigator's clinical examination and assessment of child's medical history.
- **For US subjects only:** a child who previously received a 3-dose series of *Prevnar 13* only (i.e., no doses given as *Prevnar/Prevenar*), with the last dose at least 60 days prior to study entry.

5.3.2. Exclusion criteria

The following criteria were to be checked at the time of study entry. If any exclusion criterion applied, the child was not to be included in the study:

- Child in care (refer to the glossary of terms for the definition of child in care).
- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the period starting 30 days before the day of study vaccination (i.e., 30 days prior to Day 0) or planned use during the entire study period.
- Concurrently participating in another clinical study, in which the child had been or would have been exposed to an investigational or a non-investigational product (pharmaceutical product or device).
- Chronic administration (defined as 14 or more consecutive days) of immunosuppressants, or other immune-modifying drugs during the period starting 180 days prior to the first vaccine dose or any planned administration of immunosuppressive and immune-modifying drugs during the entire study.
  - For corticosteroids, this will mean prednisone, ≥0.5 mg/kg/day or equivalent.
  - Inhaled and topical steroids are allowed.
- Planned administration/ administration of a vaccine not foreseen by the study protocol during the period starting 30 days prior to study vaccination at Visit 1 and ending at Visit 2. Please Note:
  - **Inactivated** influenza (Flu) vaccine and *Haemophilus influenzae* type b conjugate vaccine (Hib) could be given at any time, including the day of study vaccination (administered at a different location than the study vaccine/s).
  - Any other age appropriate vaccine could be given starting at Visit 2 and anytime thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting 180 days prior to study vaccination at Visit 1 or planned administration from the date of vaccination through the immunogenicity evaluation at Visit 2.
- History of measles, mumps, rubella, varicella/zoster and/or hepatitis A disease.
- Known exposure to measles, mumps, rubella and/or varicella/zoster during the period starting within 30 days prior to first study vaccination.
- Previous vaccination against measles, mumps, rubella, hepatitis A and/or varicella virus.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
- A family history of congenital or hereditary immunodeficiency.
- History of allergic disease or reactions likely to be exacerbated by any component of the vaccines, including hypersensitivity to neomycin, latex or gelatin.

- Blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- Acute disease at the time of enrollment (Acute disease was defined as the presence of a moderate or severe illness with or without fever). Fever was defined as temperature ≥38.0°C/100.4°F by any age appropriate route. All vaccines could be administered to persons with a minor illness such as diarrhea, mild upper respiratory infection without fever.
- Active untreated tuberculosis based on medical history.
- Any other condition which, in the opinion of the investigator, prevented the child from participating in the study.
- **For US subjects only:** a child that previously received a vaccination with heptavalent *Prevnar/Prevenar* (prior vaccination should have been with 3 doses of *Prevnar 13* only) and a child that previously received a fourth dose of any pneumococcal conjugate vaccine.

A list of criteria that may eliminate children from ATP analyses can be found in Sections 5.6.1, 5.6.2 and 5.10.5.

5.3.3. Withdrawal criteria

5.3.3.1. Subject completion

A subject who returned for the concluding Visit 3 (Day 180) was considered to have completed the study.

5.3.3.2. Subject withdrawal from the study

From an analysis perspective, a ‘withdrawal’ from the study referred to any subject who did not return for the concluding visit (Visit 3) or was not available for the concluding contact foreseen in the protocol.

All data collected until the date of withdrawal or last contact with the subject was used for analysis.

A child was considered a ‘withdrawal’ from the study when no study procedure had occurred, no follow-up had been performed and no further information had been collected for this subject from the date of withdrawal or last contact.

Investigators were to make an attempt to contact the parent(s)/LAR(s) of those subjects who did not return for scheduled visits or follow-up.

Information relative to the withdrawal was to be documented in the eCRF. The investigator was to document whether the decision to withdraw a subject from the study was made by the subject's parent(s) or LAR(s), or by the investigator, as well as which of the following possible reasons was responsible for withdrawal:

- Serious adverse event,
- Non-serious adverse event,
- Protocol violation (specify),
- Consent withdrawal, not due to an adverse event,
- Moved from the study area,
- Lost to follow-up,
- Other (specify).

5.3.3.3. Subject withdrawal from investigational vaccine

Not applicable in this study.

5.4. Composition and administration of vaccine(s)

5.4.1. Description of vaccine(s)

The candidate live, attenuated Inv_MMR vaccine was developed and manufactured by GSK Biologicals. The control vaccines Com_MMR_L1 and Com_MMR_L2 were manufactured by Sanofi Pasteur/Merck Sharp and Dohme (SPMSD).

The vaccines were labeled and packed according to applicable regulatory requirements. Commercial vaccines were assumed to comply with the specifications given in the manufacturer's Product Information. The formulation and lot numbers for the different study vaccines are given in Table 6.

Table 6 Study Vaccines

Treatment name	Vaccine/product name	Formulation	Presentation	Lot number	Volume	Number of doses
Inv_MMR_L1	Inv_MMR_L1	Measles virus (Schwarz strain) ≥10 $^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥10 $^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥10 $^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	AMJRC455A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	DD12A002A	0.5 mL	1
Inv_MMR_L2	Inv_MMR_L2	Measles virus (Schwarz strain) ≥10 $^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥10 $^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥10 $^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	AMJRC456A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	DD12A003A	0.5 mL	1
Inv_MMR_L3	Inv_MMR_L3	Measles virus (Schwarz strain) ≥10 $^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥10 $^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥10 $^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	AMJRC457A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	DD12A004B	0.5 mL	1
Com_MMR_L1	Com_MMR_L1	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg;	Lyophilized pellet in a vial for reconstitution with water for injection	H004594 J006933 H017980 J006564 0682AE H015824 J015488	0.5 mL†	1

Treatment name	Vaccine/product name	Formulation	Presentation	Lot number	Volume	Number of doses
		recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg				
	Com_MMR_L1 Diluent‡	water for injection	Vial or a Syringe (depending on the country)	G004842 J003177 J015955	0.5 mL	1
Com_MMR_L2	Com_MMR_L2	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	Lyophilized pellet in a vial for reconstitution with water for injection	G019547 J006564 H021002 H020866 J006933 0498AE H016132 J015222	0.5 mL†	1
	Com_MMR_L2 Diluent‡	water for injection	Vial or a Syringe (depending on the country)	0184AE J002990 J015955	0.5 mL	1
Varivax	*Varivax*	A minimum of 1350 pfu of Oka/Merck varicella virus; sucrose approximately 25 mg; hydrolyzed gelatin 12.5 mg, sodium chloride 3.2 mg; monosodium L-glutamate 0.5 mg; sodium phosphate dibasic 0.45 mg; potassium phosphate monobasic 0.08 mg; potassium chloride 0.08 mg; residual components of MRC-5 cells including DNA and protein; and trace quantities of sodium	Lyophilized pellet in a vial for reconstitution with water for injection	H004550; H019070 H012704 J004098 0603AE 0604AE	0.5 mL†	2§

Treatment name	Vaccine/product name	Formulation	Presentation	Lot number	Volume	Number of doses
		phosphate monobasic; EDTA; neomycin; and fetal bovine serum				
	Varivax Diluent	water for injection	Vial or Syringe (depending on the country)	H007994 H003763	0.5 mL	2§
Havrix	*Havrix*	720 EU of hepatitis A virus antigen; 0.25 mg aluminum (as hydroxide); amino acid supplement (0.3% w/v); in a phosphate-buffered saline solution and polysorbate 20 (0.05 mg/mL)	Suspension in vial/ pre-filled syringe	AHAVB666C AHAVB668A AHAVB573C AHAVB646BA AHAVVB738B	0.5 mL	2§
Prevnar 13	*Prevnar 13*	2.2 µg of the purified saccharides 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F; 4.4 mcg of the purified saccharide 6B; approximately 34 µg CRM_{197} carrier protein; 100 µg polysorbate 80; 295 µg succinate buffer; 125 µg aluminum as aluminum phosphate adjuvant	Suspension in vial/ pre-filled syringe	F94001; H17427	0.5 mL	1¥

L= Lot; CCID = Cell Culture Infectious Dose; TCID = Tissue Culture Infectious Dose; EU = ELISA Unit
ppm = Parts Per Million; pfu = Plaque Forming Unit; mL = Milliliter; mg = Milligram; mcg = Microgram; µg = Microgram
MRC = Medical Research Council; DNA = Deoxyribonucleic Acid; EDTA = Ethylenediamine-Tetraacetic Acid
CRM_{197} = Cross-Reactive Material (mutant diphtheria toxin)
† Volume after reconstitution
‡ The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
§ At the end of the study or shortly after the study, depending on vaccine availability, GSK was to provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. Not applicable for subjects enrolled in US. The second dose of HAV and varicella vaccine was not part of the study procedures.
¥ PCV-13 was administered to US children with a history of 3-doses of PCV-13 at least 60 days prior to study entry.

5.4.2. Dosage and administration of study vaccines

The dosage and administration of all the study vaccines is described in Table 7.

Table 7 Dosage and administration

Type of contact and time point	Dose	Treatment Group	Vaccine/Product	Route[1]	Site	Side
Visit 1 (Day 0)	1	Inv_MMR_L1	Inv_MMR_L1	SC	Triceps region	Left
	1	Inv_MMR_L2	Inv_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L3	Inv_MMR_L3	SC	Triceps region	Left
	1	Com_MMR_L1	Com_MMR_L1	SC	Triceps region	Left
	1	Com_MMR_L2	Com_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Varivax*	SC	Triceps region	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Havrix*	IM	Anterolateral thigh	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Prevnar 13**	IM	Anterolateral thigh	Left

[1] Intramuscular (IM)/ Subcutaneous (SC)
* For US children only.

The dose of Inv_MMR, Com_MMR was 0.5 mL administered subcutaneously in the upper regions ("Triceps") of the left arm. After reconstitution, the MMR vaccines were injected promptly (within 30 minutes).

Due to potential color differences between the reconstituted Inv_MMR and Com_MMR, dedicated unblinded staff in each investigational site was accountable for reconstitution and administration to each child.

Varivax was also administered subcutaneously in the Triceps region of the right arm. The dosage of this co-administered vaccine was 0.5 mL.

Havrix and *Prevnar 13* were administered by **intramuscular injection** in the right and left thigh, respectively. The dosage for these co-administered vaccines was 0.5 mL.

All vaccine recipients were to be observed closely for at least 30 minutes following the administration of vaccines with appropriate medical treatment readily available in case of a rare anaphylactic reaction. The contraindications and warnings/precautions to vaccination were specified in the protocol.

5.4.3. Treatment allocation and randomization

5.4.3.1. Randomization

Subjects:

At Visit 1, subject numbers were assigned sequentially to subjects participating in the study, according to the range of subject numbers allocated to each study center. Subjects were enrolled in a 2:2:2:1:1 ratio, with twice the number in the Inv_MMR vaccine lot groups (1250 subjects each) as in the active control Com_MMR vaccine lot groups, Com_MMR_L1 and Com_MMR_L2 (625 subjects each). Overall, the randomization was to be 3:1 (Inv_MMR: Com_MMR).

Supplies:

A first list based on a randomization blocking scheme using a 2:2:21:1 (Inv_MMR_L1: Inv_MMR_L2: Inv_MMR_L3: Com_MMR_L1: Com_MMR_L2) randomization ratio was to be used to number the MMR vaccines. The vaccines from this list were distributed to the study center while respecting the randomization block size. The co-administered vaccines were to be numbered separately using sequential lists.

To allow GSK Biologicals to take advantage of greater rates of recruitment than anticipated at individual centers in this multicenter study and to thus reduce the overall study recruitment period, a surplus of at least 20% of supplies was to be prepared.

5.4.3.2. Treatment allocation

The treatment allocation at the investigator site was to be performed using SBIR. The treatment numbers were to be allocated by MMR dose. The randomization algorithm used was stratified by country and within each country a minimization procedure accounting for center was be used. When SBIR was not available, the study staff was to refer to the SBIR user guide or the study procedures manual (SPM) for specific instructions.

After having checked the eligibility of the subject and obtaining the Informed Consent Form (ICF), the site staff accessed SBIR. Upon providing the child identification number, the randomization system used the randomization algorithm to determine the group allocation and the treatment number(s) to be used for the subject for MMR vaccination (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 or Com_MMR_L2). For replacement dose, the system would allocate a new treatment number according to the treatment initially allocated.

For allocation of co-administered vaccines (*Havrix* and *Varivax* to all subjects, and *Prevnar 13* to the subjects in the US), the site staff were to select a treatment number available for the vaccine dose to be used for the subject. See the SPM for further details. All treatment numbers had to be recorded in the eCRF on the ‘Vaccine Administration’ screen.

5.5. Blinding

The study was conducted in a double-blind fashion with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots (Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3) and in an observer-blind fashion for the comparison of the Inv_MMR vaccine versus the Com_MMR vaccine.

Data was collected in an observer-blind manner with the subjects and those responsible for the evaluation of any study endpoint (e.g., safety, reactogenicity, and immunogenicity) all unaware of which vaccine was administered. Vaccine preparation and administration was done by authorized medical personnel who did not participate in any of the clinical evaluations of the study.

The laboratory in charge of the laboratory testing was blinded to the treatment, and codes were used to link the subject and study (without any link to the treatment attributed to the child) to each sample.

Unblinding of a subject's individual treatment code was to occur only in the case of a medical emergency, or in the event of a serious medical condition, when knowledge of the study treatment would be essential for the clinical management or welfare of the subject, as judged by the investigator.

The emergency unblinding process was enabled by SBIR, which allowed the investigator to have unrestricted, immediate and direct access to the subject's individual study treatment.

Any emergency unblinding had to be fully documented by the investigator using the Emergency Unblinding Documentation Form and sent within 24 hours to GSK Biologicals.

Furthermore, GSK Biologicals' policy is to unblind the report of any SAE which was unexpected and attributable or suspected to be attributable to the investigational product, prior to regulatory reporting. The GSK Biologicals' Central Safety Physician was responsible for unblinding the treatment assignment in accordance with the specified timeframes for expedited reporting of SAEs (see Section 5.9.2).

5.6. Prior and concomitant medication/vaccinations

At each study visit, the investigator was to question the subjects' parent(s)/LAR(s) about any medication taken and vaccination received by the subject. All concomitant medications and vaccinations, with the exception of vitamins and/or dietary supplements, were to be recorded in the eCRF, within the window defined by the protocol (see protocol Section 6.7.2). This also applied to concomitant medication administered prophylactically in anticipation of reaction to the vaccination and any medication intended to treat an AE.

Similarly, concomitant medication administered for the treatment of a SAE, at any time, was recorded on the SAE Report / SAE screens in the eCRF, as applicable. Refer to protocol Section 8.1.2 for the definition of an SAE.

5.6.1. Medications/products that may lead to the elimination from ATP analyses

The following criteria were checked at each visit:

- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the entire study period.
- Chronic administration (defined as 14 or more consecutive days) of immunosuppressants, or other immune-modifying drugs, during the period starting at vaccination and ending at the immunogenicity evaluation at Visit 2.
  - For corticosteroids, this will mean prednisone ≥0.5 mg/kg/day, or equivalent.
  - Inhaled and topical steroids are allowed.
- Planned administration/ administration of a vaccine not foreseen by the study protocol during the study period starting at vaccination and ending at Visit 2.
  Please Note:
  - **Inactivated** Flu and Hib vaccines could be given at any time, including the day of study vaccination (administered at a different location than the study vaccine/s).
  - Any ***other*** age appropriate vaccine could be given starting at Visit 2 and any time thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting at vaccination through the immunogenicity evaluation at Visit 2.

If any became applicable during the study, it did not require withdrawal of the subject from the study but could have determined a subject's evaluability in the according-to-protocol (ATP) analysis. See Section 5.10.5 for definition of study cohorts to be evaluated.

5.6.2. Intercurrent medical conditions that may lead to elimination from the ATP cohort

Children were eliminated from the ATP cohort if they were confirmed as having an immunodeficiency condition, or if they developed measles, mumps, or rubella, in the interval between vaccination and the collection of the blood specimen for immunogenicity at the blood draw at Visit 2.

5.7. Assessment of efficacy variables

Not applicable as there were no efficacy assessments performed in this study.

5.8. Assessment of immunogenicity variables

Biological samples collected during the study consisted of 2 blood draws of approximately 5 mL each, at Visit 1 and Visit 2 respectively.

Serological assays for the determination of antibodies against measles, mumps and rubella viruses were performed by enzyme-linked immunosorbent assay (ELISA).

All testing was done at GSK Biologicals' laboratory or in a validated laboratory designated by GSK Biologicals using standardized and validated procedures (refer to Table 8).

Table 8 Summary of immunogenicity assessments

System	Component	Method	Kit / Manufacturer	Unit	Cut-off	Assay performed at
Serum	Measles Virus Ab.IgG	ELISA	Dade Behring Enzygnost	mIU/mL	150	NÉOMED-LABS Inc.
Serum	Rubella Virus Ab.IgG	ELISA	Dade Behring Enzygnost	IU/mL	4	NÉOMED-LABS Inc.
Serum	Mumps Virus Jeryl Lynn 135 Ab.IgG	ELISA	PPD	EU/mL	5	PPD
Serum	Varicella Zoster Virus Ab.IgG	ELISA	Dade Behring Enzygnost	mIU/mL	25	NÉOMED-LABS Inc.
Serum	Hepatitis A Virus Ab	ELISA	In-house	mIU/mL	15	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 01 Ab.IgG	ECL	In-house	μg/mL	0.08	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 03 Ab.IgG	ECL	In-house	μg/mL	0.075	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 04 Ab.IgG	ECL	In-house	μg/mL	0.061	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 05 Ab.IgG	ECL	In-house	μg/mL	0.198	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 06A Ab.IgG	ECL	In-house	μg/mL	0.111	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 06B Ab.IgG	ECL	In-house	μg/mL	0.102	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 07F Ab.IgG	ECL	In-house	μg/mL	0.063	GSK Biologicals

System	Component	Method	Kit / Manufacturer	Unit	Cut-off	Assay performed at
Serum	*Streptococcus pneumoniae*. Polysaccharide 09V Ab.IgG	ECL	In-house	μg/mL	0.066	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 14 Ab.IgG	ECL	In-house	μg/mL	0.16	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 18C Ab.IgG	ECL	In-house	μg/mL	0.111	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 19A Ab.IgG	ECL	In-house	μg/mL	0.199	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 19F Ab.IgG	ECL	In-house	μg/mL	0.163	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 23F Ab.IgG	ECL	In-house	μg/mL	0.073	GSK Biologicals

Ab = Antibody; IgG = Immunoglobulin class G
ELISA = Enzyme Linked Immunosorbent Assay
ECL = ElectroChemiLuminescence
PPD = Pharmaceutical Product Development
IU = International Unit; mIU = Milli International Unit; EU = ELISA Unit; mL = Milliliter; μg = micro-gram

The addresses of the clinical laboratories for sample analysis in this study are:

GlaxoSmithKline Biologicals
Clinical Immunology
Rue de l'Institut, 89
B-1330 Rixensart – Belgium

NÉOMED-LABS Inc.
Clinical Serology
525 Cartier Blvd West - Laval - Quebec - Canada - H7V 3S8

PPD, Inc.
466 Devon Park Drive
Wayne, PA 19087-1816 – USA

The central laboratory responsible for sample handling/processing for sites in the USA (including Puerto Rico) was BARC.

BARC USA Inc.
5 Delaware Drive
Lake Success, NY 11042-1114 - USA

For Estonia, Finland, Mexico and Spain, the sites shipped the samples directly to GlaxoSmithKline Biologicals, Global, Rue de l'Institut, 89 - B-1330 Rixensart, Belgium.

In case of insufficient blood sample volume to perform assays for all antibodies, the samples were analyzed according to priority ranking provided in Table 9.

Table 9 Immunological read outs

Blood sampling time point		Subset Name	Actual No. of children	Components	Priority rank
Type of contact and time point	Sampling time point				
Visit 1 (Day 0)	Pre-Vacc	Subset A	1234	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				Hepatitis A Virus Ab	3
		Subset B	1193	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG	3
		Subset C	2495	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG	2
Visit 2 (Day 42)	Post-Vacc	Subset A	1136	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				Hepatitis A Virus Ab	3
		Subset B	1113	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG	3
		Subset C	2479	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG	2

Vacc = vaccination; Ab = Antibody; IgG = Immunoglobulin class G
Subset A: the first 1250 children enrolled in the US
Subset B: the next 1250 children enrolled in the US
Subset C: the other 2500 children enrolled

5.8.1. Immunological correlates of protection

The following antibody thresholds for seroresponse are accepted by the Food and Drug Administration (FDA) as endpoints defining clinically meaningful change in antibody titer:

- Measles ≥200 mIU/mL
- Mumps ≥10 EU/mL
- Rubella ≥10 IU/mL

The blood sample taken at Visit 2 was the time point used to determine sub-optimal responders, i.e., an individual immunological assay result which is below the threshold accepted by the FDA.

The investigator, even though remaining blinded with respect to each subject's group attribution, was to be told which child had a sub-optimal response as confirmed by the results of blood samples. A list of sub-optimal responders was to be communicated to the investigators in a timely manner (no later than 12 months after the last sampling date of the last child enrolled).

The investigator was to share the immunological assay results for non-responders with the subjects' parent(s)/LAR(s). For the study subjects identified as non-responders**,** a rescue plan was to be implemented and re-vaccination with *M-M-R-II* (or *Priorix* in ex-US settings where the vaccine is licensed) was to be offered to subjects that fail to serorespond to measles, mumps or rubella virus components.

Children that received only one dose of varicella vaccine as part of this study (e.g., children enrolled in the US) and who failed to serorespond to the varicella virus (i.e. achieve a post-vaccination titer ≥75 mIU/mL) were offered re-vaccination with *Varivax.* Children in non-US countries that were provided with a second dose of varicella vaccine, because they were enrolled in countries where it is not routinely provided (see Table 4), were not considered sub-optimal responders based on their post dose immune response.

5.8.2. Sequence of analyses

The analysis was performed in 2 steps:

- A final analysis of immunogenicity data for measles, mumps and rubella and solicited symptoms up to Day 42 was performed as soon as all measles, mumps and rubella immunogenicity data and reactogenicity data (i.e. solicited symptoms) up to Visit 2 were available and cleaned. No clinical study report (CSR) was written at this time.
- A final analysis of immunogenicity data for the co-administered vaccines (i.e. VV, HAV and PCV-13) and unsolicited AEs from Day 0 to Day 42 following vaccination, and of SAEs and specific AEs covering the period from Day 0 to study end (including the 6-months safety follow-up) was performed at the end of the study.

These two analyses were combined in this final CSR.

Following unblinding for the analysis up to Day 42, accessibility to group attribution was limited to the statisticians until all study procedures pertaining to the active phase and the 6-months safety follow-up were completed for all subjects.

5.9. Assessment of safety variables

The investigator or site staff was/were responsible during the study for the detection and documentation of events meeting the criteria and definition of an AE or an SAE.

Each subject's parent(s)/LAR(s) were to be instructed to contact the investigator immediately should the subject manifest any signs or symptoms they perceived as serious.

5.9.1. Adverse events

5.9.1.1. Definition of adverse events and serious adverse events

An AE was any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also included failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse. Examples of possible AEs are given in protocol Section 8.1.1

AEs to be recorded as endpoints (solicited AEs) are described in Section 5.9.1.2, while all other AEs were to be recorded as unsolicited AEs.

An SAE was any untoward medical occurrence that:

- Resulted in death,
- Was life-threatening,
- Required hospitalization or prolongation of existing hospitalization,
- Resulted in disability/incapacity.

Further details are provided in protocol Section 8.1.2.

5.9.1.2. Solicited adverse events

The following local (injection-site) AE were solicited (Table 10):

Table 10 Solicited local adverse events at Inv_MMR and Com_MMR injection sites

Adverse Event	Solicited follow-up period
Pain at injection site	from Day 0 to Day 3 after vaccination
Redness at injection site	
Swelling at injection site	

These local AEs were recorded from Day 0 to Day 3 on the Diary Cards following vaccinations in both groups. Redness and swelling were measured in millimeters and the greatest surface diameter was recorded. Solicited local symptoms at the co-administration site were not assessed.

The solicited general AEs are shown in Table 11.

Table 11 Solicited general adverse events

Adverse Event	Solicited follow-up period
Drowsiness	from Day 0 to Day 14 after vaccination
Loss of appetite	
Irritability	
Varicella-like rash*	from Day 0 to Day 42 after vaccination
Measles/rubella-like rash*	
Other rash (not measles/rubella-like nor varicella-like)	
Fever (defined as temperature ≥38°C/100.4°F)**	
Parotid gland / Salivary gland swelling*	
Meningism including febrile convulsions*	

* To be confirmed by a physician.

** Fever is defined as temperature ≥38°C/100.4°F [Marcy, 2004]. The preferred route for recording temperature in this study was axillary. Temperature was recorded daily from Day 0 to Day 42 after vaccination. The child's parent(s)/LAR(s) were requested to record the child's body temperature each evening at bedtime. Should additional temperature measurements be performed at other times of day, the highest temperature was recorded.

Intensity of the following AEs was assessed as described in Table 12.

Table 12 Intensity scales for solicited adverse events

Adverse Event	Intensity Grade	Parameter
Pain at injection site	0	None
	1	Minor reaction to touch (digital pressure)
	2	Cries/protests on touch (digital pressure)
	3	Cries when limb is moved/spontaneously painful
Local injection site redness (Record greatest surface diameter in mm)	0	None
	1	> 0-≤ 5mm
	2	> 5-≤ 20mm
	3	>20mm
Local injection site swelling (Record greatest surface diameter in mm)	0	None
	1	> 0-≤ 5mm
	2	> 5-≤ 20mm
	3	>20mm
Fever* body temperature in °C or °F, (axillary route preferred)	Temperature will be analyzed in 0.5°C increments from ≥38°C (≥100.4°F) Grade 3 fever is defined as >39.5°C. (103.1°F)	
Measles/rubella-like rash and varicella-like rash	1	1-50 lesions
	2	51-150 lesions
	3	>150 lesions
Other rash	1	Rash which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities
	2	Rash which is sufficiently discomforting to interfere with normal everyday activities
	3	Rash which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day care and would cause the parent(s)/LAR(s) to seek medical advice)
Parotid/salivary gland swelling	1	Swelling without difficulty moving the jaw
	2	Swelling with difficulty moving the jaw
	3	Swelling with accompanying general symptoms
Irritability/Fussiness	0	Behavior as usual
	1	Crying more than usual/ no effect on normal activity
	2	Crying more than usual/ interferes with normal activity
	3	Crying that cannot be comforted/ prevents normal activity
Drowsiness	0	Behavior as usual
	1	Drowsiness easily tolerated
	2	Drowsiness that interferes with normal activity
	3	Drowsiness that prevents normal activity
Loss of appetite	0	Appetite as usual
	1	Eating less than usual/ no effect on normal activity
	2	Eating less than usual/ interferes with normal activity
	3	Not eating at all
Meningism (any suspected signs including febrile convulsions)	1	An event which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities
	2	An event which is sufficiently discomforting to interfere with normal everyday activities
	3	An event which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day care and would cause the parent(s)/LAR(s) to seek medical advice)

*Fever is defined as temperature ≥38°C/100.4°F.
mm = Millimeter; °C = Degree Celsius;°F = Degree Fahrenheit

The maximum intensity of local injection site redness/swelling was graded based on subject's parent(s)/LAR(s) measurements recorded on the Diary Card.

Temperature/ fever: Temperature was to be recorded daily, from Day 0 through Day 42. Parent(s)/LAR(s) were requested to record on the diary card the subject's body temperature measured each evening at bedtime (while at home ONLY one temperature route [axillary preferred] was to be used consistently for all measurements on a given subject). Should additional temperature measurements be performed at other times of day, the highest temperature was to be recorded.

Rash and parotid/salivary gland swelling and signs of meningism including febrile convulsions:

If any of the following symptoms below were suspected during the follow-up period after vaccination (Day 0-42), the parent(s)/LAR(s) had to perform daily post-vaccination recording on the Diary Card and contact the investigator's center.

- ***Rash/ exanthema:***

Parent(s)/LAR(s) were to be provided with a description of rashes and asked to contact the study site immediately if the subject developed a rash that could be a measles/rubella or varicella-like rash (Day 0-42). If the investigator/designee also suspected that the rash could possibly be a measles/rubella-like rash or varicella-like rash, a visit should be arranged as soon as possible; ideally within 48 hours after rash onset, or as soon as possible thereafter.

The investigator's assessment of the rash was recorded in the eCRF. If the investigator had not seen the rash, and other medically qualified person had assessed the rash during a medically attended visit, then this assessment was to be recorded in eCRF. If the subject was not seen by the investigator or other medically qualified person, the information about rash entered in eCRF was to be recorded by the parent in the diary card.

The investigator classified cases of the rash as follows:

- Measles/ rubella rashes (macular or maculopapular rashes): presence of macules, discolored small patches or spots of the skin, neither elevated nor depressed below the skin's surface and/or papules, raised bumps on the skin usually <1 cm in diameter.
- Varicella-like rash (papulo-vesicular): simultaneous presence of papules and vesicles raised above the skin's surface.
- Or other types of rash (heat rash, etc.).

Duration of rash episode was to be indicated, as well as the locality of the rash:

- Measles/rubella-like or varicella-like rash:
  - rash onset, i.e., date when the first lesion appears
  - rash ended, i.e., date of the first day when no new lesion appears.

- Other rash:
  - start date, i.e., date when first symptom appears
  - end date, i.e., date when the rash disappears/resolves.

Intensity of measles/rubella-like, or varicella-like rash was assessed according to the maximum number of overall lesions (Table 12).

The outcome of each rash was to be assessed as: recovered/resolved, recovering/resolving, not recovered/not resolved, recovered with sequelae/resolved with sequelae. The investigator was to assess the causality of rash episode.

- ***Parotid/salivary gland swelling:***

If parotitis was clinically suspected (swelling / tenderness in the mandibular / submandibular region) during Day 0 to Day 42 after vaccination, the child was to be seen by the investigator as soon as possible for an additional visit.

Only those cases diagnosed by the investigator/designee as parotitis were to be recorded as a solicited symptom in the eCRF. Other cases of swelling/tenderness in the mandibular/submandibular region that did not meet the criteria for parotitis clinically were to be reported as an unsolicited AE in the eCRF. Intensity was recorded as described in Table 12 and the outcome of each case was assessed as described in Section 5.9.1.5.

- ***Any suspected signs of meningism including febrile convulsions/seizures:***

If the subject experienced febrile convulsions or presented any other neurological signs or symptoms indicative of meningism (i.e., neck stiffness with or without light intolerance (photophobia) and headache; or convulsion/seizure) during Day 0 to Day 42 follow-up after vaccination, the parent(s)/LAR(s) had to contact the investigator immediately for follow-up. The investigator was requested to write a descriptive assessment of the case and evaluate the relationship to the study vaccination.

The investigator was requested to document full case details and to provide a diagnosis. In the case of all seizures, including febrile seizures, the investigator had to classify the level of diagnostic certainty regarding the seizure as guided by The Brighton Collaboration Seizure Working Group's case definitions of generalized convulsive seizure as an adverse event following immunization, as described in Table 13 [Bonhoeffer, 2004].

Table 13 Brighton Collaborative levels of diagnostic certainty

Level 1 of diagnostic certainty
witnessed sudden loss of consciousness AND generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations
Level 2 of diagnostic certainty
history of unconsciousness AND generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations
Level 3 of diagnostic certainty
history of unconsciousness AND other generalized motor manifestations
Level 4 of diagnostic certainty
reported generalized convulsive seizure with insufficient evidence to meet the case definitions for Level 1, 2 or 3 of diagnostic certainty above
Level 5 of diagnostic certainty
Not a case of generalized convulsive seizure

For any case of febrile convulsion, the investigator was also asked to classify the event based on the definitions below [American Academy of Pediatrics , 2008]:

- *Simple Febrile Convulsion/Seizure*: defined as a brief (<15 minutes in duration) generalized tonic-clonic seizure that occurs once during a 24 hour period in a febrile subject who does not have intracranial infection, metabolic disturbance or history of febrile seizures. The neurologic examination in the post-ictal period should be no different from baseline, i.e., there should be no newly acquired neurologic deficits.
- *Complex Febrile Convulsion/Seizure*: defined as a generalized tonic-clonic seizure that is not a simple febrile seizure. For instance, any seizure that has at least one of the following characteristics should be defined as a complex seizure:
  - lasts 15 minutes or longer, or
  - has a focal/localized component, or
  - recurs within 24 hours, or
  - is associated with an abnormal post-ictal neurologic examination.

5.9.1.3. Unsolicited adverse events and serious adverse events

All AEs starting from Day 0 through Visit 2 after the administration of study vaccine were recorded on the Adverse Event screen in the subject's eCRF, irrespective of intensity or whether or not they were considered vaccination-related. The standard time period for collecting and recording SAEs began at the first receipt of study vaccines and was collected throughout the entire study. See Section 5.9.2 for instructions on reporting of SAEs. SAEs that were related to the study vaccine(s) were collected and recorded from the time of the first study vaccination until the subject was discharged.

When an AE/SAE occurred, it was the responsibility of the investigator to review all documentation (e.g., hospital progress notes, laboratory, and diagnostics reports) relative to the event. The investigator would then record all relevant information regarding an AE/SAE on the eCRF or SAE Report screens as applicable. It was not acceptable for the investigator to send photocopies of the subject's medical records to GSK Biologicals

instead of the appropriate completed AE/SAE screens in the eCRF. However, there could be instances when copies of medical records for certain cases were requested by GSK Biologicals. In this instance, all subject identifiers were to be blinded on the copies of the medical records prior to submission to GSK Biologicals.

The investigator would attempt to establish a diagnosis pertaining to the event based on signs, symptoms, and/or other clinical information. In such cases, the diagnosis was to be documented as the AE/SAE and not the individual signs/symptoms. Treatment of any AE was at the sole discretion of the investigator and according to current good medical practices. Any medication administered for the treatment of an AE was recorded in the subject's eCRF.

In addition to the above-mentioned reporting requirements and in order to fulfill international reporting obligations, SAEs that were related to study participation (i.e., protocol-mandated procedures, invasive tests, a change from existing therapy) or were related to a concurrent GSK medication/vaccine or any fatal SAE were collected and recorded from the time the parent(s)/LAR(s) consented to have the subject participate in the study until she/he was discharged. The standard time period for collecting and recording AEs of specific interest, including NOCDs and AEs prompting emergency room (ER) visits, started at the first receipt of study vaccine and ended at the last study visit or contact. The standard time period for collecting and recording of AEs prompting a medically attended visit(s) started at the first receipt of study vaccine and ended at the last study visit or contact through study end. An overview of the protocol-required reporting periods for AEs, and SAEs is given in Table 14.

Table 14 Reporting periods and methods for adverse events and serious adverse events

	Visit 1 Vaccination			Visit 2 Follow-up	Visit 3 Conclusion
Optimal Visit Day	**Day 0**			**Day 42**	**Day 180**
Solicitation period	Day 0-3	Day 4-14	Day 15-42		
Study activity					
Reporting solicited local AEs	DC/RDE				
Reporting solicited drowsiness, loss of appetite or irritability	DC/RDE				
Reporting solicited fever, rash (measles / rubella or varicella-like rash, other rash), parotid/salivary gland swelling and any sign of meningism including febrile convulsions	DC/RDE				
Reporting unsolicited AEs	DC/RDE			DC	DC
Reporting NOCD(s) and AEs prompting a medically attended visit(s) (including ER visits)	DC/RDE			DC/RDE	DC/RDE
Reporting ALL SAEs	DC/RDE			DC/RDE	DC/RDE

AEs = Adverse Events; DC = Diary Card; RDE = Remote Data Entry; SAEs = Serious Adverse Events
NOCD = New Onset Chronic Disease; ER = Emergency Room.

A post-study AE/SAE was defined as any event that occurred outside of the AE/SAE reporting period defined in Table 14. Investigators were not obligated to actively seek AEs or SAEs in former study subjects. However, if the investigator learned of any SAE at any time after a subject had been discharged from the study, and he/she considered the event reasonably related to the investigational product, the investigator would promptly notify the Study Contact for reporting SAEs.

The investigator/designee would assess the maximum intensity that occurred over the duration of the event for all AEs and SAEs reported during the study, with the assessment based on the investigator's clinical judgment. The intensity of each AE and SAE recorded in the eCRF or SAE Report screens, as applicable, had to be assigned to one of the following categories:

1 (mild)	=	An AE which was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
2 (moderate)	=	An AE which was sufficiently discomforting to interfere with normal everyday activities.
3 (severe)	=	An AE which prevented normal, everyday activities (in a young subject, such an AE would, for example, prevent attendance at school/day-care and would cause the parent(s)/LAR(s) to seek medical advice.)

An AE that was assessed as Grade 3 (severe) was not to be confused with an SAE. Grade 3 is a category utilized for rating the intensity of an event; and both AEs and SAEs could be assessed as Grade 3. An event was defined as 'serious' when it met one of the pre-defined outcomes as described in protocol Section 8.1.2.

5.9.1.4. Assessment of causality

The investigator was also obligated to assess the relationship between study vaccine(s) and the occurrence of each AE/SAE, using his/her clinical judgment to determine the relationship. Alternative plausible causes based on natural history of the underlying diseases, concomitant therapy, other risk factors and the temporal relationship of the event to the investigational product were considered and investigated. The investigator would also consult the Investigator Brochure and/or Product Information for marketed products, in the determination of his/her assessment.

There may have been situations when an SAE had occurred and the investigator had minimal information to include in the initial report to GSK Biologicals. However, it was very important that the investigator always made an assessment of causality for every event prior to submission of the SAE to GSK Biologicals. The investigator could change his/her opinion of causality in light of follow-up information, amending the SAE information accordingly. The causality assessment was one of the criteria used when determining regulatory reporting requirements.

In case of concomitant administration of multiple vaccines, it might not have been possible to determine the causal relationship of general AEs to the individual vaccines administered. The investigator had to, therefore, assess whether the AE could be causally related to vaccination rather than to the individual vaccines/products.

All solicited local (injection site) AEs would be considered causally related to vaccination. Causality of all other AEs had to be assessed by the investigator using the following question:

Is there a reasonable possibility that the AE may have been caused by the investigational product?

NO	:	The AE was not causally related to administration of the study vaccine(s). There were other, more likely causes and administration of the study vaccine(s) was not suspected to have contributed to the AE.
YES	:	There was a reasonable possibility that the vaccine(s) contributed to the AE.

Non-serious and serious AEs were evaluated as two distinct events. If an event met criteria to be determined 'serious' (see protocol Section 8.1.2 for definition of an SAE), additional examinations/tests were performed by the investigator in order to determine all possible contributing factors applicable to each SAE.

Possible contributing factors included:

- Medical history;
- Concomitant medication;
- Protocol required procedure;
- Other procedure not required by the protocol;
- Lack of efficacy of the vaccine(s), if applicable;
- Erroneous administration;
- Other cause (specify).

5.9.1.5. Assessment of Outcomes

Outcome of any non-serious AE occurring within 42 days post-vaccination (i.e., unsolicited AE) or any SAE reported during the entire study were assessed as:

- Recovered/resolved.
- Recovering/resolving.
- Not recovered/not resolved.
- Recovered with sequelae/resolved with sequelae.
- Fatal (SAEs only).

5.9.2. Reporting of serious adverse events

SAEs that occurred in the time period defined in Table 14 were to be reported promptly to GSK within the timeframes described in Table 15, once the investigator determined that the event met the protocol definition of an SAE.

Table 15 Timeframes for submitting serious adverse event reports to GSK Biologicals

Type of Event	Initial Reports		Follow-up of Relevant Information on a Previous Report	
	Timeframe	Documents	Timeframe	Documents
All SAEs	24 hours*	SAE report/SAE screen	24 hours*	SAE report/SAE screen

* Timeframe allowed after receipt or awareness of the information.

5.9.2.1. Completion and transmission of SAE reports to GSK Biologicals

As soon as an investigator became aware of the occurrence of an SAE in a subject, the investigator (or designate) had to complete the information in the SAE screens of the eCRF within 24 hours. The SAE screens were always to be completed as thoroughly as possible with all available details of the event. Even if the investigator did not have all information regarding a SAE, the SAE screens had to be completed within 24 hours. Once additional relevant information was received, the SAE screens in the eCRF were to be updated, again within 24 hours.

The investigator would always provide an assessment of causality at the time of the initial report (see Section 5.9.1.4). The contact information for reporting SAEs to GSK Biologicals is provided in study protocol Section 8.3.2, with details on the back-up system to be used if the electronic SAE reporting system did not work are in protocol Section 8.3.3.1.

5.9.2.2. Updating of SAE information after freezing of the subjects' eCRF

When additional information was received on a SAE after freezing of the subject's eCRF, new or updated information had to be recorded on a SAE Report Form, with all changes signed and dated by the investigator. The updated form had to be faxed to the GSK Biologicals Clinical Safety and Pharmacovigilance department or to the Study Contact for Reporting SAEs within 24 hours of receipt of the follow-up information.

5.9.2.3. Regulatory reporting requirements for SAEs

The investigator would promptly report all SAEs to GSK in accordance with the procedures detailed above in Section 5.9.2.1. GSK Biologicals has a legal responsibility to promptly notify, as appropriate, both the local regulatory authority and other regulatory agencies about the safety of a product under clinical investigation. Prompt notification of SAEs by the investigator to the Study Contact for Reporting SAEs was essential so that legal obligations and ethical responsibilities towards the safety of other subjects are met.

Investigator safety reports were prepared according to the current GSK policy and were forwarded to investigators as necessary. An investigator safety report was prepared for a SAE(s) that was both attributable to the investigational product and unexpected. The purpose of the report was to fulfill specific regulatory and GCP requirements, regarding the product under investigation.

5.9.3. Medically attended visits

For each solicited and unsolicited AE the subject experienced, the parent(s)/LAR(s) were asked if the subject received medical attention defined as hospitalization, an ER visit or a visit to or from medical personnel (e.g., medical doctor) for any reason. This information was recorded in the eCRF; routine 'well child' visit information however was not to be recorded in the eCRF.

5.9.4. Clinical laboratory parameters and other abnormal assessments qualifying as adverse events or serious adverse events

Abnormal laboratory findings (e.g., clinical chemistry, hematology, urinalysis) or other abnormal assessments that were judged by the investigator to be clinically significant were recorded as AEs or SAEs if they met the definition of an AE, as defined in protocol Section 8.1.1 and Section 8.1.2. Clinically significant abnormal laboratory findings or other abnormal assessments that a) were detected during the study or b) were present at baseline and significantly worsened following the start of the study, were reported as AEs or SAEs. The investigator was to exercise his or her medical and scientific judgment in deciding whether an abnormal laboratory finding or other abnormal assessment was clinically significant.

5.9.5. Adverse events of specific interest

AEs of specific interest for safety monitoring included NOCDs (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting ER visits. Occurrences of AEs of specific interest, including NOCDs and AEs prompting ER visits, were reported throughout the study, through a minimum of six months post-vaccination, whether or not they were considered to be possibly related to the treatment administration. Medical documentation of the events was reported in appropriate places in the eCRF. These events also had to be reported as AEs or SAEs as appropriate in the eCRF.

5.9.6. Follow-up of adverse events and serious adverse events

After the initial AE/SAE report, the investigator was required to proactively follow each subject within the study and provide further information on the subject's condition to GSK Biologicals.

All AEs, SAEs, AEs of specific interest (including NOCDs such as autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies, and AEs prompting ER visits) documented at a previous visit and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until the end of the study.

Investigators would follow-up subjects:

- With SAEs or subjects withdrawn from the study as a result of an AE, until the event had resolved, subsided, stabilized, disappeared, or until the event was otherwise explained, or the subject was lost to follow-up.
- Or, in the case of other non-serious AEs, until resolution or study end or the subject was lost to follow-up.

Clinically significant laboratory abnormalities were followed up until they had returned to normal, or a satisfactory explanation had been provided. Additional information (including but not limited to laboratory results) relative to the subsequent course of such abnormalities noted for any subject was to be made available to the Site Monitor.

GSK Biologicals could request that the investigator performed or arranged for the conduct of additional clinical tests or evaluations to elucidate as fully as possible the nature and/or causality of the AE or SAE. The investigator was obliged to assist. If a subject died during participation in the study or during a recognized follow-up period, GSK Biologicals was to be provided with a copy of any available post-mortem findings, including histopathology.

5.10. Statistical methods

The statistical analyses were performed using the Statistical Analysis Systems (SAS) version 9.3 on SAS Drug Development 4.3.

Throughout this section, endpoints for the 2 lots of comparator Com_MMR vaccine (Com_MMR_L1 and Com_MMR_L2) were analyzed as pooled lots. In addition, apart from the endpoints related to clinical consistency, the 3 Inv_MMR lots (Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3) were analyzed as pooled lots and referred to as Inv_MMR throughout the report.

5.10.1. Primary endpoint

- Immunogenicity of the MMR vaccines at Day 42:
  - Seroresponse to measles, mumps and rubella viruses.
  - Measles, mumps and rubella virus antibody concentrations.

5.10.2. Secondary endpoints

- Immunogenicity of the *Varivax*, *Havrix* and *Prevnar 13* vaccines in a subset of children at Day 42:
  - Seroresponse to VZV.
  - VZV antibody concentrations.
  - HAV antibody concentrations.
  - Seroresponse to HAV.
  - Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.
- Complementary read-out for immunogenicity of the MMR vaccines at Day 42:
  - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
  - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms:
  - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
  - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
  - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.
- Unsolicited adverse events:
  - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest:
  - Occurrence of NOCD (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting ER visits from Day 0 through the end of study.
- Serious adverse events:
  - Occurrence of serious adverse events from Day 0 through the end of study.

5.10.3. Determination of sample size

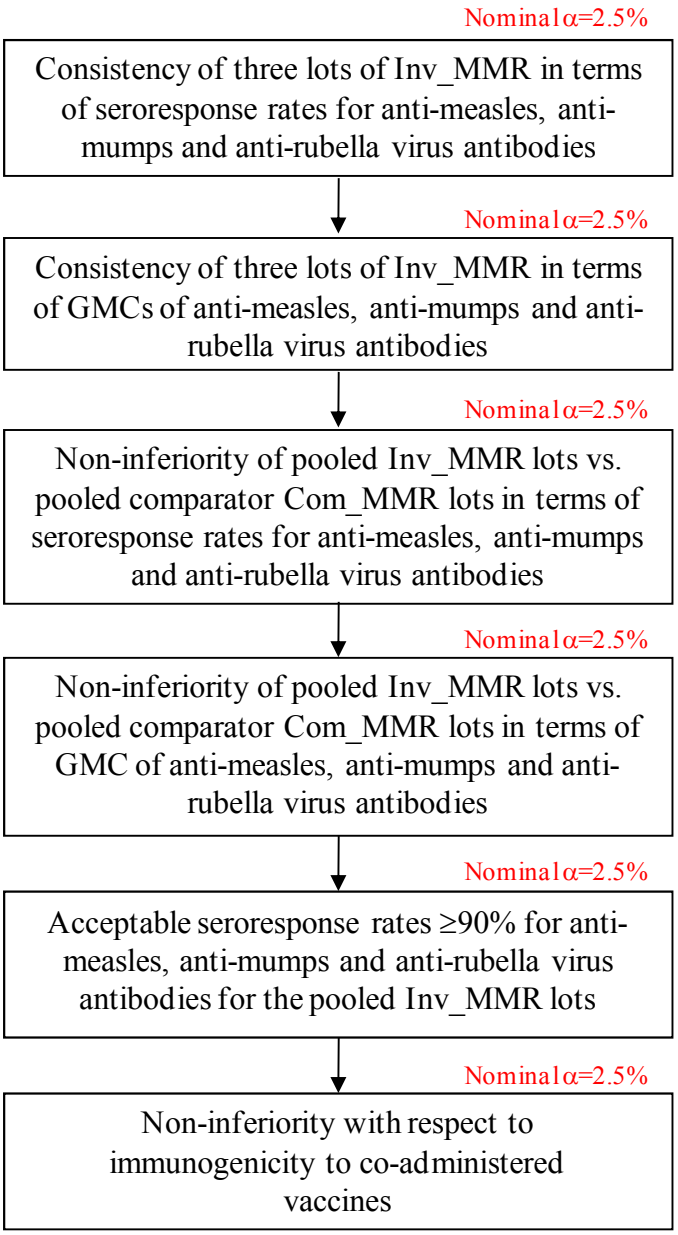
The target was to enroll 5000 subjects to be randomly assigned to 5 study groups (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 and Com_MMR_L2) in a 2:2:2:1:1 ratio. There would be approximately 1250 children in each Inv_MMR lot group; and approximately 625 children in each Com_MMR lot group. Assuming a 20% non-evaluable rate, the planned enrollment would result in 4000 evaluable children (1000 per Inv_MMR lot group; and 500 in each Com_MMR lot group).

5.10.3.1. Control on type I error

To control the type I error below 2.5%, a hierarchical procedure was used for the primary and secondary objectives, i.e., each co-primary objective could only be reached if all the associated criteria were met and all previous co-primary objectives were reached, and the secondary objectives (to evaluate non-inferiority of the immune response to the co-administered vaccines) were only assessed when all co-primary objectives were met. No hierarchy between secondary objectives was made (see Figure 2).

Figure 2 Sequence for evaluating the primary study objectives in order to control the overall type I error below 2.5%

An objective was reached if its associated criterion was met and the previous objectives were reached



5.10.3.2. Power for lot-to-lot consistency

The lot-to-lot consistency of the Inv_MMR groups was demonstrated if the lot-to-lot consistency criteria specific to each MMR antigen were met simultaneously (p-value <2.5%). Table 16 and Table 17 show that the probability to reach the lot-to-lot consistency criterion was at least 97.46% [=100%-sum of type II errors].

Table 16 Probability to meet the consistency criteria with respect to seroresponse rates for antibodies to measles, mumps and rubella viruses among the three Inv_MMR groups

Vaccine component	Endpoints	Reference values*	Clinically acceptable bounds for consistency	Power N= 1000 vs. 1000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98%	[-5%,5%]	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94%	[-5%,5%]	99.58%	2.54%
Rubella	Seroresponse (≥ 10 IU/mL)	98%	[-5%,5%]	>99.99%	<0.01%
			Total	97.46%	2.54%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** Power obtained using the Power Analysis and Sample Size software (PASS 2005) (Likelihood Score [Miettinen and Nurminen approach [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value for the 3 lots & alpha=2.5%; the type II error was multiplied by 6 to account for the 6 pairwise lot comparisons.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

Table 17 Probability to meet the consistency criteria with respect to GMCs of antibodies to measles, mumps and rubella viruses among the three Inv_MMR lot groups

Vaccine component	Endpoints	Reference SD*	Clinically acceptable bounds for consistency	Power N= 1000 vs. 1000**	Type II error
Measles	GMC	0.50	[0.67,1.50]	>99.99%	<0.01%
Mumps	GMC	0.50	[0.67,1.50]	>99.99%	<0.01%
Rubella	GMC	0.44	[0.67,1.50]	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
SD = Standard Deviation (of the $\log_{10}$ transformed titer); GMC = Geometric Mean Concentration
Observed SDs for measles for the three lots of *Priorix* were 0.33, 0.34, and 0.34
Observed SDs for mumps for the three lots of *Priorix* were 0.41, 0.40, and 0.44
Observed SDs for rubella for the three lots of *Priorix* were 0.33, 0.34, and 0.34
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of equal means & alpha=2.5%; the type II error was multiplied by 6 to account for the 6 pairwise lot comparisons.

5.10.3.3. Power for Non-inferiority to Com_MMR

The non-inferiority of the Inv_MMR groups compared to Com_MMR was demonstrated if the non-inferiority criteria specific to each MMR antigen were met simultaneously (p-value <2.5%) and lot-to-lot consistency was demonstrated. Table 18 and Table 19 show that the probability to reach the non-inferiority criteria was at least 97.46% [= 100% - sum of type II error from Table 16, Table 17, Table 18 and Table 19].

Table 18 Probability to meet the non-inferiority criteria with respect to seroresponse rate for antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups compared to the pooled Com_MMR lot groups

Vaccine component	Endpoints	Reference values* Pooled Inv_MMR vs. Com_MMR	Clinically acceptable limit for non-inferiority	Power N= 3000 vs. 1000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98% vs. 98%	-5%	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94% vs. 94%	-5%	>99.99%	<0.01%
Rubella	Seroresponse (≥ 10 IU/mL)	98% vs. 98%	-5%	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** Power obtained using PASS 2005 (Likelihood Score [Miettinen and Nurminen approach, [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value & alpha=2.5%.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

Table 19 Probability to meet the non-inferiority criteria with respect to GMCs of antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups compared to the pooled Com_MMR lot groups

Vaccine component	Endpoints	Reference ratio (Com_MMR over Inv_MMR lots)*	Reference SD*	Clinically acceptable limit for non-inferiority	Power N= 3000 vs. 1000**	Type II error
Measles	GMC	1	0.50	0.67	>99.99%	<0.01%
Mumps	GMC	1	0.53	0.67	>99.99%	<0.01%
Rubella	GMC	1	0.44	0.67	>99.99%	<0.01%
				Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
SD = Standard Deviation (of the log10 transformed titer); GMC = Geometric Mean Concentration
Observed SDs for measles for three lots of *Priorix* were 0.33, 0.34, and 0.34
Observed SDs for mumps (PPD ELISA) for the three lots of *Priorix* were 0.41, 0.40, and 0.44
Observed SDs for rubella for three lots of *Priorix* were 0.33, 0.34, and 0.34
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of a 1.2-fold difference in means & alpha=2.5%.

5.10.3.4. Power for a minimal seroresponse rate of pooled Inv_MMR lots

Assuming 20% of children were non-evaluable, an estimated 3000 children were to be evaluable in the Inv_MMR groups. Table 20 shows the probability to reach the immunogenicity criterion that the MMR seroresponse rate was at least 90% for measles, mumps and rubella.

Considering this was conditional to previous primary objectives the power to conclude on minimal MMR-seroresponse rate was at least 97.46% [= 100% - sum of type II error from Table 16, Table 17, Table 18, Table 19 and Table 20].

Table 20 Probability to meet the minimum level of seroresponse rate for antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups

Vaccine component	Endpoints	Reference values*	Acceptable lower limit	Power N= 3000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98%	90%	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94%	90%	>99.99%	<0.01%
Rubella	Seroresponse (≥ 10 IU/mL)	98%	90%	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** PASS 2005, 1-sided non-inferiority test on one proportion alpha = 2.5%, H0: p ≤ margin, Ha: p = reference value. The type II error was multiplied by 3 to account for the 3 lots.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

5.10.4. Power for the secondary objectives

Anti-VZV antibodies were to be tested in a subset of 2500 children enrolled in the US (subsets A and B). Assuming 20% were non-evaluable, this analysis would be based on 1500 children in the Inv_MMR groups and 500 children in the Com_MMR groups. Antibodies to HAV (subset A only) and anti-PS antibodies (subset B only) were to be tested in subsets of 1250 children enrolled in the US. Assuming 20% were non-evaluable, the analysis would be based on 750 children in the Inv_MMR groups and 250 children in the Com_MMR groups.

The probability to meet the non-inferiority criteria associated to immunogenicity to co-administered vaccine is shown in Table 21and Table 22 and would be demonstrated if the non-inferiority criteria specific to each antigen are met (p-value <2.5%) and non-inferiority and acceptability for MMR responses and lot-to-lot consistency have been demonstrated.

Table 21 Probability to meet the non-inferiority criteria with respect to VZV seroresponse rate

Vaccine component	Endpoints	Reference values*	Clinically acceptable limit for non-inferiority	Power N= 1500 vs. 500**	Type II error
VV	Seroresponse (≥ 75 mIU/mL)	95%	- 10%	>99.9%	<0.01%

VV = Varicella Vaccine *Varivax*
* Reference for sample size calculation: Study MMR-157 where the lowest observed seroresponse rate was 95% [92.5%; 98.0%]
** Power obtained using PASS 2005 (Likelihood Score [Miettinen and Nurminen approach, [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value for the 2 groups; N is based on the immuno subsets.
mIU = Milli International Unit; mL = Milliliter.

Table 22 Probability to meet the non-inferiority criteria with respect to GMC for antibodies associated to co-administered vaccines

Vaccine component	Reference SD*	Clinically acceptable limit for non-inferiority	N Inv_MMR lots vs. Com_MMR	Power**	Type II error
VV	0.4	1.5	1500 vs. 500	>99.99%	<0.01%
HAV	0.6	2	750 vs. 250	>99.99%	<0.01%

VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* Reference for sample size calculation: Study MMR-157
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of equal means & alpha=2.5%, N is based on the immuno subsets.
SD = Standard Deviation (of the $\log_{10}$ transformed titer)
Observed SDs for VZV for three lots of *Priorix* were 0.24, 0.26, and 0.27
Observed SDs for HAV for the three lots of *Priorix* were 0.38, 0.39, and 0.43

5.10.5. Study cohorts /data sets analyzed

5.10.5.1. Total vaccinated cohort

The TVC cohort included all vaccinated subjects.

- An immunogenicity analysis based on the Total Vaccinated cohort included all vaccinated subjects for whom immunogenicity data were available.
- A safety analysis based on the TVC included all vaccinated subjects with at least one vaccine administration of either Inv_MMR or Com_MMR lots documented.

5.10.5.2. According-to-protocol cohort for analysis of safety

The ATP cohort for analysis of safety included eligible subjects:

- who had received at least one MMR study vaccine/comparator as per protocol

- who had not received a vaccine leading to exclusion from the ATP cohort in the protocol as described in Section 6.7.1 up to Visit 2
- for whom the randomization code had not been broken
- for whom the administration route of study vaccine(s) was known and correct.

5.10.5.3. According-to-protocol cohort for analysis of immunogenicity

The ATP cohort for analysis of immunogenicity included all eligible subjects from the ATP cohort for safety:

- with pre-vaccination and post-dose serology results available for at least one antigen of measles, mumps, or rubella
- who were below the assay cut-off for at least one vaccine antigen for MMR at pre-vaccination
- who did not meet any elimination criteria up to the Visit 2 blood sample (see protocol Sections 6.7.1 and 6.8)
- who complied with the post-vaccination blood sample schedule, i.e., 35-77 days between vaccination at Visit 1 and the blood draw at Visit 2

5.10.6. Derived and transformed data

For the analysis of immunogenicity, the following definitions were applied:

- **Seroresponse for MMR vaccine was defined as follows**:
  - For measles virus, a seroresponse was defined as post-vaccination anti-measles virus antibody concentration ≥200 mIU/mL (ELISA, Enzygnost) among subjects who were seronegative (antibody concentration <150 mIU/mL) before vaccination.
  - For mumps virus, a seroresponse was defined as post-vaccination anti-mumps virus antibody concentration ≥10 EU/mL (ELISA, PPD) among subjects who were seronegative (antibody concentration <5 EU/mL) before vaccination.
  - For rubella virus, a seroresponse was defined as post-vaccination anti-rubella virus antibody concentration ≥10 IU/mL (ELISA, Enzygnost) among subjects who were seronegative (antibody concentration <4 IU/mL) before vaccination.
- **Seroresponse for *Varivax* was defined as follows**:
  - For VV, a seroresponse was defined as post-vaccination anti-VZV antibody concentration ≥75 mIU/mL among children who were seronegative (antibody concentration <25 mIU/mL) before vaccination.
- **Antibody response for *Havrix* was defined as follows**:
  - For HAV, an antibody response was defined as post-vaccination concentration equal to or above the cut-off of 15 mIU/mL in children below the assay cut-off of

15 mIU/mL before vaccination, or ≥ 2-fold increase in antibody concentration in children ≥ 15 mIU/mL before vaccination.

- **Antibody response for *Prevnar 13* is defined as follows**:
  - For each *S. Pneumoniae* serotype, an antibody response was defined as post-vaccination concentration equal to or above the ECL assay cut-off for the respective serotype. The ECL assay cut-off for each serotype is:
    - anti-PnPS 1 antibody =0.08 µg/mL
    - anti-PnPS 3 antibody =0.075 µg/mL
    - anti-PnPS 4 antibody =0.061 µg/mL
    - anti-PnPS 5 antibody =0.198 µg/mL
    - anti-PnPS 6A antibody =0.111 µg/mL
    - anti-PnPS 6B antibody =0.102 µg/mL
    - anti-PnPS 7F antibody =0.063 µg/mL
    - anti-PnPS 9V antibody =0.066 µg/mL
    - anti-PnPS 14 antibody =0.16 µg/mL
    - anti-PnPS 18C antibody =0.111 µg/mL
    - anti-PnPS 19A antibody =0.199 µg/mL
    - anti-PnPS 19F antibody =0.163 µg/mL
    - anti-PnPS 23F antibody =0.073 µg/mL

- **GMC/T calculation**:

  The GMC calculation for antibody to varicella virus was performed by taking the anti-log of the mean of the log concentration transformations of all values equal to or above Limit of Quantitation (LOQ) (40 mIU/mL), with anti-VZV antibody concentrations between LOQ and Limit of Detection (LOD) (25 mIU/mL) given a value of 25 mIU/mL. By convention, values <25 mIU/mL were given an arbitrary value of 12.5 mIU/mL.

  For the other assays, the GMC calculation was performed by taking the anti-log of the mean of the log concentration transformations. Antibody concentrations below the cut-off of the assay were given an arbitrary value of half the cut-off for the purpose of GMC calculation.

- **Handling of missing results or recordings**

  For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements were not replaced. Therefore, the analyses excluded subjects with missing or non-evaluable measurements.

  For the analysis of solicited symptoms, only subjects with a completed solicited AE section of the eCRF were considered.

  Missing or non-evaluable measurements were not replaced. Therefore the analysis of the solicited symptoms based on the TVC cohort included only subjects/doses with documented safety data (i.e., symptom screen/sheet completed).

  In the primary analysis of solicited symptoms, missing daily recordings were replaced by the maximum value recorded for the subject. For subjects reporting a symptom without a single daily recording (i.e., reporting fever as present in the

absence of temperature measurement), missing daily recordings were replaced by grade 1. A sensitivity analysis of the impact of missing data on the endpoints was to be conducted if the percentage of children reporting a symptom without a single daily recording is above 1%.

For the analyses of unsolicited AEs, SAEs and concomitant medication, all vaccinated subjects were considered, with those not reporting an event being considered as subjects without an event.

- **Methodology for computing CI**

  All CIs were 95% CI. The exact 95% CIs for a proportion within a group was calculated using SAS 9.3 [Clopper, 1934]. SAS 9.3 was also used to derive the standardized asymptotic 95% CI for the group difference in proportions (method 6 in [Newcombe, 1998]).

  The 95% CI for GMCs was obtained within each group separately. The 95% CI for the mean of log-transformed titer/concentration were first obtained assuming that log-transformed values were normally distributed with unknown variance. The 95% CI for the GMCs were then obtained by exponential-transformation of the 95% CI for the mean of log-transformed titer/concentration.

  The 95% CI for GMC group ratio was obtained using an ANOVA model on the logarithm-transformed titers. The ANOVA model included the vaccine group as the fixed effect, the country effect (only for measles, mumps & rubella) and, for pneumococcal immunogenicity, the pre-vaccination log-transformed titer as the regressor. The model assumed equal variance in the log concentrations post vaccination. The between group GMC ratios and their 95% CI were derived by exponential transformation of the corresponding group contrast in the model.

5.10.7. Analysis of demographics and other baseline characteristics

Demographic characteristics (age at Visit 1 in months, geographic ancestry (race), ethnicity and gender) were tabulated as a whole, for the Inv_MMR group and for the Com_MMR groups.

The distribution of subjects enrolled among the study sites/countries was tabulated as a whole, for each Inv_MMR group, for the Inv_MMR groups and for the Com_MMR groups.

5.10.8. Analysis of immunogenicity

The analysis of immunogenicity was based on the ATP cohort for immunogenicity. If, for any vaccine group, the percentage of enrolled children with serological results excluded from this ATP cohort was higher than 5%, a second analysis based on the TVC was required to complement the ATP analysis.

Except for anti-PS, and unless otherwise stated, the analysis post-vaccination of an assay described below was based on the children seronegative for the assay at pre-vaccination. The following descriptive analyses were performed for each Inv_MMR group, for the Inv_MMR groups, and for the Com_MMR groups at each blood sampling time point for which a serological result was available:

- Percentage of subjects above each specific cut-off and their exact 95% CIs were tabulated. See Section 5.10.6. for thresholds of all antigens evaluated for seroresponse.
- Antibody concentrations were also summarized by GMCs with their 95% CIs after vaccination.
- Antibody concentration distributions were displayed as reverse cumulative curves for each antigen and each treatment group after vaccination.

5.10.8.1. Between Inv_MMR lots analysis

At the Day 42 post-vaccination blood sampling, for measles, mumps and rubella:

- The 95% CIs for the GMC ratio of each pair of Inv_MMR lots were computed using an ANOVA model on the logarithm-transformed concentrations. The ANOVA model included the three Inv_MMR lot groups and the country as fixed effects.
- The asymptotic standardized 95% CIs for the pair-wise differences in seroresponse across the three Inv_MMR lots were computed.

5.10.8.2. Between Inv_MMR and Com_MMR group analysis

At the Day 42 post-vaccination blood sampling, for each antibody for which results were available:

- The asymptotic standardized 95% CIs for the difference in seroresponse rate and percentage of subjects with concentration/titer above each specific cut-off [Inv_MMR lot group minus the Com_MMR lot group] were computed.
- The 95% CIs for each GMC/T group ratio [Inv_MMR lot group over the Com_MMR lot group] were computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model included the vaccine group and the country (only for measles, mumps & rubella) as fixed effects and, for pneumococcal immunogenicity, the pre-vaccination log-transformed concentration as the regressor. The vaccine groups were the Inv_MMR lot group and the Com_MMR lot group.

5.10.8.2.1. Subgroup analysis of immunogenicity

All descriptive analyses for anti-measles, anti-mumps, and anti-rubella antibodies were repeated for the following subgroups:

- By country, provided that the country had at least 50 subjects per treatment group (Inv_MMR or Com_MMR)
- By gender, provided that each gender had at least 50 subjects per treatment group (Inv_MMR or Com_MMR)
- By geographic ancestry (race) category, provided that the category had at least 50 subjects per treatment group (Inv_MMR or Com_MMR). Subjects from the 'other' category were split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

5.10.8.2.2. Interpretation of analyses

Except for analyses addressing criteria specified in the objectives, comparative analyses were exploratory with the aim to characterize the difference between groups in immunogenicity. These exploratory analyses should be interpreted with caution since there is no adjustment for multiplicity of endpoints.

With respect to primary and secondary objectives involving pre-specified criteria, the interpretation was done according to a hierarchical procedure described in Section 10.3.1 of the protocol and Section 5.10.3.1 of this report. For instance, the primary objective 3 could only be reached if all the associated criteria were met and the previous primary objectives had been reached. If an objective was not met, all subsequent comparisons would be purely descriptive.

5.10.9. Analysis of safety

The analysis of safety was based on the TVC. If more than 5% of the vaccinated subjects were excluded from the ATP cohort for the analysis of safety, a second analysis based on the ATP cohort was to be performed to complement the TVC analysis. All safety analyses were repeated by country.

5.10.9.1. Between groups assessment

For each group (each Inv_MMR lot group, the Inv_MMR lot group and the Com_MMR lot group), the following results were tabulated:

- the number and percentage of subjects (with exact 95% CIs) with at least one local, general, and any AE (solicited or unsolicited) during the 43-day follow-up period after vaccination (Day 0-42);
- the number and percentage of subjects (with exact 95% CIs) reporting each local solicited symptom during Days 0-3 for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically attended visit;

- the number and percentage of subjects (with exact 95% CIs) reporting general symptom (drowsiness, irritability and loss of appetite) during the 15-day follow-up period after vaccination (Days 0-14) for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically-attended visit;
- the number and percentage of subjects reporting fever by half degree (°C) cumulative increments from Days 0-14, from Days 5-12 and from Days 0-42 after vaccination. Similar tabulations were performed for any fever with a causal relationship to vaccination and for any fever resulting in a medically attended visit. In addition, the prevalence of any and grade 3 fevers was presented graphically over time after vaccination. The distribution of maximum temperature recorded over 43 days after vaccination was displayed as reverse cumulative curves for the Inv_MMR lots and Com_MMR lots;
- the number and percentage of subjects (with exact 95% CIs) reporting measles/rubella-like rash and varicella-like rash (Days 0-42, according to number of lesions), any rash (Days 0-42), parotid/salivary gland swelling (Days 0-42, according to intensity) and any sign of meningism/febrile convulsions (Days 0-42, according to intensity), after vaccination. Similar tabulations were performed for general solicited adverse events with a causal relationship to vaccination and for solicited AEs resulting in a medically-attended visit;
- the number and percentage of subjects (with exact 95% CIs) for whom unsolicited adverse events were reported from Days 0-42. The verbatim reports of unsolicited symptoms were reviewed by a physician and the signs and symptoms were coded according to MedDRA, the Medical Dictionary for Regulatory Activities. Every verbatim term was matched with the appropriate Preferred Term. Similar tabulations were done for grade 3 unsolicited AEs, for unsolicited AEs related to vaccination and for unsolicited AEs resulting in a medically attended visit;
- the number and percentage of subjects who received at least one concomitant medication from Days 0-14 and from Days 0-42 after vaccination. Additionally, the number and percentage of children receiving antipyretic drugs was also calculated by group from Days 0-14 and from Days 0-42 after vaccination.
- Discontinuations due to AEs were described in detail.
- The percentages of subjects who experienced at least one serious adverse event or who reported a NOCD (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies), or an AE leading to an ER visit, or an AE leading to a medically attended visit from Day 0 to study end, were calculated.
- Descriptive listing of SAEs, any related SAEs to study participation, study withdrawals and deaths post-vaccination(s) for the entire study.
- All safety results will also be produced by country.

5.10.9.2. Subgroup analysis of safety

All safety analyses on the treatment groups were repeated for the following subgroups:

- By country, provided that the country had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By gender, provided that each gender had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By geographic ancestry (race) category, provided that the category had at least 50 subjects per treatment group (Inv_MMR or Com_MMR). Subjects from the 'other' category were split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

5.10.10. Interim analysis

No interim analyses were performed.

5.11. Data quality assurance at study level

To ensure that the study procedures conformed across all investigator sites, the protocol, CRF/eCRF and safety reporting were reviewed with the investigator(s) and his/her/their personnel responsible for the conduct of the study by the Company representative(s) prior to study start**.** A multi-investigator meeting or a site initiation visit was held prior to the study start.

Adherence to the protocol requirements and verification of data generation accuracy were achieved through monitoring visits to each investigator site. Computer checks and blinded review of subject tabulations were performed to ensure consistency of CRF/eCRF completion. All procedures were performed according to methodologies detailed in GlaxoSmithKline Biologicals Standard Operating Procedures (SOPs).

Between April and May 2013, two technical problems were identified in the Electronic Data Capture system (e-N@ble Web system) used in this study. The first technical issue was related to the incorrect display of the investigator's signature on the electronic screens in the system. The second technical issue was that the reasons for change of the data noted in the audit trail were overwritten; the author, date and time of original entry as well as data changes were not affected. These technical issues were corrected in December 2013. This does not change the validity of the data collected nor have any impact on the data reported.

All protocol deviations collected during the study were reviewed by the GSK study team in order to identify important protocol deviations. Consistent with ICH E3 guidance, important deviations are defined as deviations that were likely to affect the interpretation of the results and/or led to exclusion of any subject data from an analysis. Important deviations include, but are not limited to, those related to study inclusion or exclusion criteria, adherence to the protocol, conduct of the study, subject management or subject assessment**.**

The following issues with regard to the conduct of the study were identified, either via site monitoring activities or were brought to GSK Biologicals' attention by other oversight mechanisms. These issues were investigated and where possible corrective and / preventive actions were taken as described in Section 6.3.2.

CROs were employed to perform the activities listed in Table 1 according to an agreed contract. The CRO responsibilities were conducted according to GSK's SOPs.

Independent Audit statement: This study was subject to audit by GlaxoSmithKline's R&D Global Quality Compliance (GQC) - Clinical Development Quality Assurance (CDQA) department.

5.12. Changes in the conduct of the study or planned analyses

5.12.1. Protocol amendments

There were two amendments to the study protocol issued on 14 May 2014 and 26 February 2015 respectively. Both were issued after study initiation (09 November 2012) but prior to completion (16 April 2015). The main changes incorporated in these amendments are listed below:

Protocol Amendment 1 (14 May 2014)

- Vaccination against influenza (with inactivated influenza vaccine) and Haemophilus influenzae type b can be given at any time before, during, or after the study, including the day of study vaccination. This was to correct a prior exclusion criterion which stated that it could be given at any time during the study. The intent has always been to allow these vaccinations at any time regardless of whether or not it was before, during or after the study period.
- For other MMR US Phase III studies, the Center for Biologics Evaluation and Research (CBER) requested that all conditions leading to non-routine medically attended visits be collected for the entire study in the eCRF. It has been clarified throughout the protocol that from Visit 1 (Day 0) to study end (Day 180), all medically attended events will be recorded in the eCRF. Subjects' routine 'well child' doctor visits will not be recorded in the eCRF.
- Other minor corrections were implemented.

Protocol Amendment 2 (26 February 2015)

- Based on comments from CBER, the *Streptococcus pneumoniae* testing will not be the 22F ELISA currently listed but a validated assay accepted by CBER. The assessment of this assay is ongoing. As such, the secondary endpoint related to assessment of the percentage of subjects with *Streptococcus pneumoniae* antibody concentrations ≥0.05, 0.2, 0.5, and 1.0 µg/mL with the 22F ELISA has been removed. The need for any additional endpoints related to *Streptococcus pneumoniae* antibody testing will be reassessed once a CBER validated assay is selected.

- Serological assays for the determination of antibodies against measles, rubella and varicella viruses now will be performed by GSK Biologicals' laboratory in Laval, Canada. Note: In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party CRO.
- Serological testing for the co-administered vaccines (i.e. VV, HAV and PCV-13) will be completed much later than the antibody determination for measles, mumps and rubella. Therefore, the immunogenicity data analysis for the co-administered vaccines will be included in the final analysis performed at the end of the study.
- Other minor corrections were implemented.

5.12.2. Other changes

This study was conducted according to the protocol and all analyses were performed as planned in the protocol and the statistical analysis plan (SAP).

In accordance with other studies conducted with *Priorix* (Inv_MMR), subjects enrolled in Puerto Rico were analyzed together with the US subjects.

6. STUDY POPULATION RESULTS

6.1. Study dates

The first subject was enrolled in the study on 09 November 2012 and the last study visit was on 16 April 2015.

6.2. Subject disposition

A total of 5003 subjects were vaccinated in the study: 1239 subjects in the Inv_MMR_Lot 1 group, 1232 subjects in the Inv_MMR_Lot 2 group, 1243 subjects in the Inv_MMR_Lot 3 group and 1289 subjects in the Com_MMR group (Table 23).

The most common reasons for withdrawal were lost to follow-up subjects with complete vaccination course (133 subjects) and consent withdrawal (68 subjects). Two subjects were withdrawn due to experiencing an AE, and four subjects due to protocol violations.

Table 23 Number of subjects vaccinated, completed and withdrawn with reason for withdrawal (Total vaccinated cohort)

	INV_MMR_1	INV_MMR_2	INV_MMR_3	COM_MMR	Total
Number of subjects vaccinated	1239	1232	1243	1289	5003
Number of subjects completed	1175	1162	1190	1232	4759
Number of subjects withdrawn	64	70	53	57	244
Reasons for withdrawal					
Serious Adverse Event	0	0	0	0	0
Non-Serious Adverse Event	2	0	0	0	2
Protocol violation	3	0	1	0	4
Consent withdrawal (not due to an adverse event)	21	23	14	10	68
Migrated/moved from study area	7	3	6	6	22
Lost to follow-up (subjects with incomplete vaccination course)	0	0	0	0	0
Lost to follow-up (subjects with complete vaccination course)	26	38	31	38	133
Sponsor study termination	0	0	0	0	0
Others	5	6	1	3	15

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Vaccinated = number of subjects who were vaccinated in the study
Completed = number of subjects who completed last study visit
Withdrawn = number of subjects who did not come back for the last visit

The number of subjects enrolled in each study center is given in Table 6.1. The number of subjects at each visit and a list of withdrawn subjects are given in Table 6.2.

6.3. Important protocol deviations at subject level

6.3.1. Protocol deviations leading to elimination from ATP analyses

The total number of subjects included in each data cohort and the deviations leading to elimination from a particular cohort are shown in Table 24. A total of 5016 subjects were enrolled, with 5003 receiving a study vaccination and eligible to be included in the TVC.

A total of 4958 subjects (99.1%) were included in the ATP cohort for safety. The most common reason for exclusion from the safety analysis was administration of vaccines forbidden in the protocol (22 subjects).

A total of 4498 subjects (89.9%) were included in the ATP cohort for immunogenicity. The primary reason for exclusion from the ATP immunogenicity analysis was due to ‘essential serological data missing’ (276 subjects).

Note: On 21 May 2014, it was noted that a total of 17 blood samples were collected using expired “Vacutainer tubes”. Subjects impacted by the use of this material were excluded from the ATP analyses and were part of those eliminated due to ‘essential serological data missing’.

Table 24 Number of subjects enrolled into the study as well as the number excluded from ATP analyses with reasons for exclusion

	Total			INV_MMR_1		INV_MMR_2		INV_MMR_3		COM_MMR		NOGRP	
Title	**n**	**s**	**%**	**n**	**s**	**n**	**s**	**n**	**s**	**n**	**s**	**n**	**s**
Total cohort	**5016**			**1239**		**1234**		**1246**		**1291**		**6**	
Study vaccine dose not administrated but subject number allocated (code 1030)	13	13		0	0	2	2	3	3	2	2	6	6
Total vaccinated cohort	**5003**		**100**	**1239**		**1232**		**1243**		**1289**		**0**	
Administration of vaccine(s) forbidden in the protocol (code 1040)	22	22		8	8	4	4	5	5	5	5	0	0
Randomization code broken at the investigator site (code 1060)	1	1		0	0	1	1	0	0	0	0	0	0
Study vaccine dose not administered according to protocol (code 1070)	4	4		1	1	1	1	2	2	0	0	0	0
Vaccine temperature deviation (code 1080)	12	12		2	2	3	3	2	2	5	5	0	0
Expired vaccine administered (code 1090)	3	3		1	1	1	1	0	0	1	1	0	0
Others (reacto) (code 1500)	3	3		1	1	0	0	1	1	1	1	0	0
ATP cohort for safety	**4958**		**99.1**	**1226**		**1222**		**1233**		**1277**		**0**	
Protocol violation (inclusion/exclusion criteria) (code 2010)	4	5		1	1	1	1	2	3	0	0	0	0
Initially seropositive or initially unknown antibody status (code 2020)	139	144		40	42	34	35	28	30	37	37	0	0
Administration of any medication forbidden by the protocol (code 2040)	1	1		0	0	0	0	0	0	1	1	0	0
Underlying medical condition forbidden by the protocol (code 2050)	1	1		1	1	0	0	0	0	0	0	0	0
Non-compliance with blood sampling schedule (including wrong and unknown dates (code 2090)	39	42		8	8	10	10	11	11	10	13	0	0
Essential serological data missing (code 2100)	276	312		68	79	79	83	62	69	67	81	0	0
ATP cohort for immunogenicity	**4498**		**89.9**	**1108**		**1098**		**1130**		**1162**		**0**	

NOGRP = No assigned group
INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Note: Subjects may have more than one elimination code assigned
n = number of subjects with the elimination code assigned excluding subjects who have been assigned a lower elimination code number
s = number of subjects with the elimination code assigned
% = percentage of subjects in the considered ATP cohort relative to the Total vaccinated cohort

6.3.2. Protocol deviations not leading to elimination from ATP analyses

Deviations from specifications for subject age and intervals between study visits are provided for each treatment group in Table 6.3.

Deviations related to study vaccines

The *Varivax* vaccine was stored at a temperature colder than advised by the manufacturer at a US site, and administered to five study subjects. The affected subjects were notified, and one consenting subject was re-vaccinated at the site.

Deviations related to randomization process

Two subjects from a site in the US were entered and/or randomized in the Randomization System on Internet (SBIR) before the subject's parent(s)/ LAR signed or thumb-printed the ICF. No other study procedure was performed on these subjects until a signed Informed Consent/thumb impression was obtained for them. After acquiring a valid ICF, the subjects were included in the study, and data from the impacted subjects were used for the analysis(es) of the study.

6.4. Demographic characteristics and other baseline characteristics

Demographic and other baseline characteristics of the ATP cohort for immunogenicity cohort are presented by treatment group and overall in Table 25.

The mean age of subjects included in the ATP cohort for immunogenicity was 12.3 months at the time of the first study vaccination. Overall, majority of the subjects were White/Caucasian (76.6%) and male (51.5%); this distribution was reflected in the study groups. Overall, all demographic and baseline characteristics were similar among the study groups.

Summary of demographic characteristics of the TVC are given in Table 6.5, and reflected what was observed for the ATP cohort for immunogenicity.

Table 25 Summary of demographic characteristics (ATP cohort for immunogenicity

		INV_MMR_1 N = 1108		INV_MMR_2 N = 1098		INV_MMR_3 N = 1130		INV_MMR N = 3336		COM_MMR N = 1162		Total N = 4498	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-

		INV_MMR_1 N = 1108		INV_MMR_2 N = 1098		INV_MMR_3 N = 1130		INV_MMR N = 3336		COM_MMR N = 1162		Total N = 4498	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Gender	Female	542	48.9	529	48.2	550	48.7	1621	48.6	562	48.4	2183	48.5
	Male	566	51.1	569	51.8	580	51.3	1715	51.4	600	51.6	2315	51.5
Ethnicity	American Hispanic or Latino	184	16.6	215	19.6	210	18.6	609	18.3	209	18.0	818	18.2
	Not American Hispanic or Latino	924	83.4	883	80.4	920	81.4	2727	81.7	953	82.0	3680	81.8
Geographic Ancestry	African Heritage / African American	49	4.4	36	3.3	44	3.9	129	3.9	56	4.8	185	4.1
	American Indian or Alaskan Native	21	1.9	32	2.9	27	2.4	80	2.4	23	2.0	103	2.3
	Asian - Central/South Asian Heritage	12	1.1	6	0.5	7	0.6	25	0.7	8	0.7	33	0.7
	Asian - East Asian Heritage	7	0.6	8	0.7	8	0.7	23	0.7	9	0.8	32	0.7
	Asian - Japanese Heritage	1	0.1	2	0.2	2	0.2	5	0.1	1	0.1	6	0.1
	Asian - South East Asian Heritage	18	1.6	23	2.1	18	1.6	59	1.8	22	1.9	81	1.8
	Native Hawaiian or Other Pacific Islander	2	0.2	0	0.0	4	0.4	6	0.2	1	0.1	7	0.2
	White - Arabic / North African Heritage	3	0.3	6	0.5	2	0.2	11	0.3	7	0.6	18	0.4
	White - Caucasian / European Heritage	847	76.4	841	76.6	869	76.9	2557	76.6	889	76.5	3446	76.6
	Other	148	13.4	144	13.1	149	13.2	441	13.2	146	12.6	587	13.1
Country	Estonia	115	10.4	115	10.5	119	10.5	349	10.5	119	10.2	468	10.4
	Spain	56	5.1	56	5.1	55	4.9	167	5.0	61	5.2	228	5.1
	Finland	326	29.4	318	29.0	330	29.2	974	29.2	330	28.4	1304	29.0
	Mexico	86	7.8	93	8.5	94	8.3	273	8.2	93	8.0	366	8.1
	United States	525	47.4	516	47.0	532	47.1	1573	47.2	559	48.1	2132	47.4
Subset	VZV and HAV subset	265	23.9	263	24.0	267	23.6	795	23.8	286	24.6	1081	24.0
	VZV and PCV subset	257	23.2	249	22.7	263	23.3	769	23.1	270	23.2	1039	23.1
	Not in subset	586	52.9	586	53.4	600	53.1	1772	53.1	606	52.2	2378	52.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

7. IMMUNOGENICITY RESULTS

The primary analysis of immunogenicity was performed on the ATP cohort for immunogenicity. A second analysis based on the TVC was not performed because less than 5% of subjects were eliminated from each group in the ATP cohort.

Co-primary objectives 1 and 2 of the study were to demonstrate the consistency of 3 manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates and GMCs of anti-measles, anti-mumps and anti-rubella antibodies at Day 42.

Co-primary objectives 3 and 4 were to demonstrate the non-inferiority of Inv_MMR (for the 3 pooled lots) compared to Com_MMR (for the 2 pooled lots) vaccine in terms of seroresponse rates and GMCs of anti-measles, anti-mumps and anti-rubella antibodies at Day 42.

Co-primary objective 5 was to demonstrate acceptable immune response for Inv_MMR in terms of seroresponse rates to anti-measles, anti-mumps and anti-rubella antibodies at Day 42.

The secondary objectives 1, 2 and 3 were to demonstrate the non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of seroresponse rates and GMC ratio of antibodies to the VZV at Day 42 (in a subset of subjects enrolled in the US), to demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of GMC for antibodies to hepatitis A virus at Day 42 (in a subset of subjects enrolled in the US), and to demonstrate the non-inferiority of the Inv_MMR groups compared to Com_MMR groups in terms of antibodies to *S.pneumoniae* (13 serotypes) at Day 42 (in a subset of subjects administered *Prevnar 13* in the US), respectively.

Secondary objective 4 was to assess the immunogenicity of *Havrix* with respect to the seroresponse rates for antibodies to HAV in the Inv_MMR groups in contrast to the Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US). Finally, secondary objective 5 was to assess the safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to subjects enrolled in the US).

7.1. According-to-protocol analysis

The ATP cohort for immunogenicity consisted of 4498 subjects; 1108 subjects in the Inv_MMR_1 group, 1098 subjects in the Inv_MMR_2 group, 1130 subjects in the Inv_MMR_3 group and 1162 subjects in the Com_MMR group.

The co-primary objectives of the study were to demonstrate the consistency of three manufacturing lots of Inv_MMR, to demonstrate the non-inferiority of the Inv_MMR vaccine compared to the Com_MMR, and to demonstrate acceptable immune response of Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses. To control the risk of erroneous conclusions, a hierarchical procedure (Figure 2) was used

for the primary and secondary objectives. Thus, each objective could only be reached if all the associated criteria were met and all previous objectives were reached.
The pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies in the study groups is given in Table 7.1. The majority of subjects in both groups (≥95%) were seronegative at baseline prior to vaccination, against anti-measles, anti-mumps and anti-rubella antibodies.

7.1.1. Consistency of the three manufacturing lots of Inv_MMR (Co-primary objectives 1 and 2)

Consistency of the immune response after one dose of GSK MMR was demonstrated (See Table 26 and Table 27):

- For each pair-wise comparison, the two sided 95% CI for the difference in lots seroresponse rates was within the [-5%; 5%] margin for anti-measles, anti-mumps and anti-rubella antibodies.
- For each pair-wise comparison, the two sided 95% CI for the adjusted GMC ratio was between 0.67 and 1.5 for anti-measles, anti-mumps and anti-rubella antibodies.

Table 26 Consistency of INV_MMR lots in terms of seroresponse rate for measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

					Difference (First group minus Second group)		
	First group		Second group			95% CI	
Antibody	INV_MMR Lot	SR rate	INV_MMR Lot	SR rate	%	LL	UL
anti-Measles antibody	1	98.1	2	98.6	-0.54	-1.69	0.58
	1	98.1	3	97.8	0.25	-0.98	1.50
	2	98.6	3	97.8	0.79	-0.35	1.98
anti-Mumps (PPD) antibody	1	98.6	2	98.6	0.02	-1.05	1.09
	1	98.6	3	98.0	0.63	-0.50	1.81
	2	98.6	3	98.0	0.61	-0.53	1.79
anti-Rubella antibody	1	97.2	2	97.1	0.14	-1.30	1.58
	1	97.2	3	97.7	-0.49	-1.86	0.86
	2	97.1	3	97.7	-0.62	-2.02	0.74

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay -
seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively)
95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Table 27 Consistency of INV_MMR lots in terms of adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

					Adjusted GMC ratio (First group over Second group)		
	First group		Second group			95% CI	
Antibody	Lot	Adjusted GMC	Lot	Adjusted GMC	Value	LL	UL
anti-Measles antibody (mIU/mL)	INV_MMR_1	3128.5	INV_MMR_2	3174.4	0.99	0.91	1.06
	INV_MMR_1	3128.5	INV_MMR_3	3217.7	0.97	0.90	1.05
	INV_MMR_2	3174.4	INV_MMR_3	3217.7	0.99	0.91	1.06
anti-Mumps (PPD) antibody (EU/mL)	INV_MMR_1	75.2	INV_MMR_2	80.5	0.93	0.87	1.00
	INV_MMR_1	75.2	INV_MMR_3	72.3	1.04	0.97	1.11
	INV_MMR_2	80.5	INV_MMR_3	72.3	1.11	1.04	1.19
anti-Rubella antibody (IU/mL)	INV_MMR_1	54.5	INV_MMR_2	50.5	1.08	1.01	1.15
	INV_MMR_1	54.5	INV_MMR_3	54.3	1.00	0.94	1.07
	INV_MMR_2	50.5	INV_MMR_3	54.3	0.93	0.87	0.99

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for Country
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country - pooled variance with more than 2 groups), LL = lower limit, UL = upper limit

7.1.2. Non-inferiority of the immune response of Inv_MMR vs. Com_MMR (Co-primary objectives 3 and 4)

Since co-primary objectives 1 and 2 were met, this allowed for the hierarchical analyses to continue evaluating the subsequent co-primary objectives. The acceptance criteria for both co-primary objectives 3 and 4 for Inv_MMR i.e. demonstrating the non-inferiority of Inv_MMR vaccines compared to Com_MMR in terms of seroresponse rates and GMCs of anti-measles, anti-mumps and anti-rubella antibodies at Day 42 (see Table 28 and Table 29) were met:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps and anti-rubella antibodies.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps and anti-rubella antibodies.

Table 28 NI of INV_MMR vs COM_MMR in terms of seroresponse rate to measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

			Difference (INV_MMR minus COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	SR rate	SR rate	%	LL	UL
anti-Measles antibody	98.2	98.0	0.18	-0.68	1.25
anti-Mumps (PPD) antibody	98.4	97.6	0.81	-0.10	1.96
anti-Rubella antibody	97.3	98.5	-1.15	-2.00	-0.15

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay -
seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively)
95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Table 29 NI of INV_MMR vs COM_MMR in terms of post-vaccination adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

			Adjusted GMC ratio (INV_MMR over COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	Adjusted GMC	Adjusted GMC	Value	LL	UL
anti-Measles antibody (mIU/mL)	3165.2	3215.4	0.98	0.93	1.05
anti-Mumps (PPD) antibody (EU/mL)	76.4	73.0	1.05	0.99	1.11
anti-Rubella antibody (IU/mL)	52.5	60.0	0.87	0.83	0.92

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for Country
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country – pooled variance), LL = lower limit, UL = upper limit

7.1.3. Acceptable Immune response of Inv_MMR to measles, mumps and rubella viruses (Co-primary objective 5)

The final co-primary objective was to demonstrate an acceptable immune response of Inv_MMR in terms of seroresponse rates for anti-MMR virus antibodies at Day 42 (Table 30, Table 31 and Table 32) and this objective was met:

- The lower limit of the two sided 95% CI for the seroresponse rate for the Inv_MMR lots was ≥90% for anti-measles, anti-mumps and anti-rubella antibodies.

Table 30 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 mIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3196	98.4	97.9	98.8	3188	98.2	97.6	98.6	3017.4	2923.9	3113.8
	COM_MMR	PI(D42)	1137	1115	98.1	97.1	98.8	1114	98.0	97.0	98.7	3074.4	2911.0	3246.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 31 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 EU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 5 EU/ml				≥ 10 EU/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3187	3168	99.4	99.1	99.6	3135	98.4	97.9	98.8	72.4	70.4	74.5
	COM_MMR	PI(D42)	1107	1099	99.3	98.6	99.7	1080	97.6	96.5	98.4	69.1	65.7	72.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 32 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 4 IU/ml				≥ 10 IU/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3245	3229	99.5	99.2	99.7	3159	97.3	96.7	97.9	55.7	54.2	57.3
	COM_MMR	PI(D42)	1135	1130	99.6	99.0	99.9	1118	98.5	97.6	99.1	64.0	61.1	67.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

7.1.4. Antibody responses against each of the vaccine components

7.1.4.1. Anti-measles antibody responses

The percentages of subjects with concentrations equal to or above thresholds of 150 and 200 mIU/mL and GMCs of anti-measles antibodies in initially seronegative subjects are given in Table 30.

The percentages of subjects with anti-measles virus antibody concentrations ≥ 150 and concentrations ≥200 mIU/mL were observed in ≥98% of subjects in both Inv_MMR and Com_MMR groups.

At Day 42, GMCs were 3017.4 mIU/mL in Inv_MMR group and 3074.4 mIU/mL in Com_MMR group.

The distribution of anti-measles antibody concentrations in initially seronegative subjects is given in Table 7.14. Figure 7.1 depicts the reverse cumulative distribution curve of anti-measles antibody concentrations.

7.1.4.2. Anti-mumps antibody response

The percentages of subjects with concentrations equal to or above thresholds of 5 and 10 EU/mL and GMCs of anti-mumps antibodies in initially seronegative subjects are given in Table 31.

The percentages of subjects with anti-mumps virus antibody concentrations ≥ 5 EU/mL and concentrations ≥ 10 EU/mL were observed in ≥97.6% of subjects in both Inv_MMR and Com_MMR.

At Day 42, GMCs were 72.4 EU/mL in Inv_MMR group and 69.1 EU/mL in Com_MMR group.

The distribution of anti-mumps antibody concentrations in initially seronegative subjects is given in Table 7.20. Figure 7.2 depicts the reverse cumulative distribution curve of anti-mumps antibody concentrations.

7.1.4.3. Anti-rubella antibody response

The percentages of subjects with concentrations equal to or above thresholds of 4 and 1 IU/ml and GMCs of anti-rubella antibodies in initially seronegative subjects are given in Table 32.

The percentages of subjects with anti-rubella virus antibody concentrations ≥ 4 IU/mL and concentrations ≥ 10 IU/mL were observed in ≥97.3% of subjects in both Inv_MMR and Com_MMR groups.

At Day 42, GMCs were 55.7 IU/mL in Inv_MMR group and 64.0 IU/mL in Com_MMR group.

The distribution of anti-rubella antibody concentrations in initially seronegative subjects is given in Table 7.26. Figure 7.3 depicts the reverse cumulative distribution curve of anti-rubella antibody concentrations.

7.1.5. Non-inferiority of the immune response to varicella virus in terms of seroresponse rates and GMCs for anti-VZV antibodies (Secondary objective 1)

Since co-primary objectives 1 to 5 were met, this allowed for the hierarchical analyses to continue evaluating the subsequent secondary objectives i.e. to assess non-inferiority of the immune response to the co-administered vaccines.

The percentages of subjects with anti-VZV antibodies equal to or above the thresholds were at least 92.2% of subjects in the Inv_MMR group and at least 88.2% in the Com_MMR group. The GMCs were 169.6 in the Inv_MMR group and 167.2 in the Com_MMR group (See Table 33).

The acceptance criteria for secondary objective 1, demonstrating non-inferiority of the Inv_MMR groups to the Com_MMR groups in terms of the seroresponse rates and GMC of anti-VZV antibodies in a subset of children enrolled in the US (subsets A and B) were met (See Table 34 and Table 35):

- The lower limit of the two-sided 95% CI for the group difference (Inv_MMR minus Com_MMR) in seroresponse rates for anti-VZV antibodies was ≥-10%.
- The lower limit of the two-sided 95% CI on the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies.

Table 33 Number and percentage of subjects with an Anti-VZV antibody concentration equal to or above 25 and 75 mIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				≥ 25 mIU/mL				≥ 75 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-VZV antibody	INV_MMR	PI(D42)	1492	1488	99.7	99.3	99.9	1376	92.2	90.7	93.5	169.6	164.3	175.0
	COM_MMR	PI(D42)	540	538	99.6	98.7	100	491	90.9	88.2	93.2	167.2	158.2	176.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 34 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an VZV antibody concentration equal to or above 75 mIU/ML - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-VZV antibody	75 mIU/mL	1492	1376	92.2	540	491	90.9	1.30	-1.31	4.29

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 35 Ratios of Anti-VZV antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	GMC	N	GMC	Value	LL	UL
1492	169.6	540	167.2	1.01	0.95	1.08

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

7.1.6. Non-inferiority of the immune response to Hepatitis A Virus in terms of antibodies to HAV GMCs (Secondary objective 2)

The percentages of subjects with antibodies to HAV equal to or above the threshold of 15 mIU/mL were ≥91.4% of seropositive subjects on Day 42 for both the Inv_MMR and Com_MMR groups, and >87.1% in seronegative subjects on Day 42 for both the Inv_MMR and Com_MMR groups. The corresponding GMCs for each group are 42.0 for Inv_MMR and 42.4 for Com_MMR, respectively (see Table 36).

The acceptance criterion for secondary objective 2, demonstrating non-inferiority of Inv_MMR groups to Com_MMR groups in terms of the GMC of antibodies to HAV in a subset of children enrolled in the US (subset A) was met (see Table 37):

- The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was >0.5 for antibodies to HAV.

Table 36 Number and percentage of subjects with an Anti-HAV concentration equal to or above 15 mIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset)

					≥ 15 mIU/mL				GMC		
							95% CI			95% CI	
Antibody	Group	Pre-vacc status	Timing	N	n	%	LL	UL	value	LL	UL
anti-HAV	INV_MMR	S-	PI(D42)	748	664	88.8	86.3	90.9	41.8	39.2	44.7
		S+	PI(D42)	35	32	91.4	76.9	98.2	44.9	32.7	61.6
		Total	PI(D42)	783	696	88.9	86.5	91.0	42.0	39.3	44.8
	COM_MMR	S-	PI(D42)	271	236	87.1	82.5	90.8	42.8	38.3	47.9
		S+	PI(D42)	14	13	92.9	66.1	99.8	35.2	23.9	51.9
		Total	PI(D42)	285	249	87.4	82.9	91.0	42.4	38.1	47.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 15 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL) prior to vaccination
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 37 Ratios of Anti-HAV GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	GMC	N	GMC	Value	LL	UL
748	41.8	271	42.8	0.98	0.86	1.11

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

7.1.7. Non-inferiority of the immune response to PCV-13 in terms of anti-PS GMCs (Secondary objective 3)

The acceptance criterion for secondary objective 3, demonstrating non-inferiority of the Inv_MMR groups to Com_MMR groups in terms of GMCs for anti-PS antibodies (13 serotypes) at Day 42 in a subset of children administered *Prevnar 13* in the US (subset B) was met (see Table 38):

- The lower limit of the two-sided 95% CI for the group GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for each of the 13 PS serotypes.

The percentages of subjects with anti-PS antibodies equal to or above the respective assay cut offs for each of the 13 serotypes were at least 82.5% in the Inv_MMR group and at least 80.8% in the Com_MMR group at pre-vaccination, while the percentages of subjects with anti-PS antibodies equal to or above the threshold of 0.35 µg/mL were at least 70.1% and 69.4% for Inv_MMR and Com_MMR groups, respectively on Day 42 (see Table 39). The corresponding lower limit of the 95% CI of the adjusted GMC ratio ranged from 0.79 to 0.92 on Day 42 (see Table 38, Table 41). Antibody GMCs were within the same ranges for both groups thus meeting objective 3.

Table 38 Adjusted Ratios of Anti-S.Pneu GMCs at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

					Adjusted GMC ratio (INV_MMR / COM_MMR)		
	INV_MMR		COM_MMR			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PnPS 1 antibody (ECL) (µg/mL)	740	2.258	256	2.392	0.94	0.85	1.05
anti-PnPS 3 antibody (ECL) (µg/mL)	739	0.499	255	0.503	0.99	0.91	1.08
anti-PnPS 4 antibody (ECL) (µg/mL)	732	1.620	255	1.844	0.88	0.79	0.98
anti-PnPS 5 antibody (ECL) (µg/mL)	738	2.092	256	2.280	0.92	0.83	1.01
anti-PnPS 6A antibody (ECL) (µg/mL)	740	5.815	256	5.761	1.01	0.92	1.11
anti-PnPS 6B antibody (ECL) (µg/mL)	739	5.812	256	5.924	0.98	0.89	1.09
anti-PnPS 7F antibody (ECL) (µg/mL)	739	3.658	256	3.887	0.94	0.86	1.03
anti-PnPS 9V antibody (ECL) (µg/mL)	740	2.295	256	2.324	0.99	0.90	1.08
anti-PnPS 14 antibody (ECL) (µg/mL)	738	6.512	256	7.151	0.91	0.81	1.02
anti-PnPS 18C antibody (ECL) (µg/mL)	740	2.082	255	2.255	0.92	0.84	1.02
anti-PnPS 19A antibody (ECL) (µg/mL)	739	4.708	255	4.876	0.97	0.87	1.07
anti-PnPS 19F antibody (ECL) (µg/mL)	740	4.186	256	4.367	0.96	0.87	1.06
anti-PnPS 23F antibody (ECL) (µg/mL)	701	2.178	240	2.301	0.95	0.85	1.06

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for baseline concentration
N = Number of subjects with both pre- and post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Ancova model: adjustment for baseline concentration - pooled variance); LL = lower limit, UL = upper limit

Table 39 Number and percentage of subjects with an Anti-S.Pneu antibody concentration equal to or above the specified assay cut-off and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**Value**	**LL**	**UL**
anti-PnPS 1 antibody(ECL)(assay cut-off=0.08 µg/ml)	INV_MMR	PRE	750	743	99.1	98.1	99.6	469	62.5	59.0	66.0	0.476	0.449	0.505
		PI(D42)	759	755	99.5	98.7	99.9	751	98.9	97.9	99.5	2.257	2.121	2.402
	COM_MMR	PRE	260	260	100	98.6	100	173	66.5	60.4	72.2	0.491	0.450	0.535
		PI(D42)	266	266	100	98.6	100	264	99.2	97.3	99.9	2.425	2.195	2.679
anti-PnPS 3 antibody(ECL)(assay cut-off=0.075 µg/ml)	INV_MMR	PRE	750	619	82.5	79.6	85.2	116	15.5	13.0	18.3	0.151	0.141	0.162
		PI(D42)	758	754	99.5	98.7	99.9	531	70.1	66.7	73.3	0.506	0.481	0.533
	COM_MMR	PRE	260	210	80.8	75.4	85.4	35	13.5	9.6	18.2	0.143	0.127	0.161
		PI(D42)	265	264	99.6	97.9	100	184	69.4	63.5	74.9	0.496	0.454	0.542
anti-PnPS 4 antibody(ECL)(assay cut-off=0.061 µg/ml)	INV_MMR	PRE	748	726	97.1	95.6	98.1	292	39.0	35.5	42.6	0.272	0.256	0.289
		PI(D42)	753	749	99.5	98.6	99.9	738	98.0	96.7	98.9	1.618	1.518	1.725
	COM_MMR	PRE	259	255	98.5	96.1	99.6	98	37.8	31.9	44.0	0.279	0.253	0.308
		PI(D42)	266	266	100	98.6	100	258	97.0	94.2	98.7	1.872	1.676	2.091
anti-PnPS 5 antibody(ECL)(assay cut-off=0.198 µg/ml)	INV_MMR	PRE	750	677	90.3	87.9	92.3	510	68.0	64.5	71.3	0.490	0.462	0.520
		PI(D42)	757	753	99.5	98.7	99.9	748	98.8	97.8	99.5	2.106	1.991	2.228
	COM_MMR	PRE	260	239	91.9	87.9	94.9	182	70.0	64.0	75.5	0.485	0.443	0.532
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	2.280	2.085	2.493
anti-PnPS 6A antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	750	737	98.3	97.1	99.1	619	82.5	79.6	85.2	0.719	0.677	0.764
		PI(D42)	759	755	99.5	98.7	99.9	755	99.5	98.7	99.9	5.840	5.508	6.192
	COM_MMR	PRE	260	257	98.8	96.7	99.8	214	82.3	77.1	86.7	0.710	0.643	0.783
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	5.743	5.233	6.304
anti-PnPS 6B antibody(ECL)(assay cut-off=0.102 µg/ml)	INV_MMR	PRE	750	695	92.7	90.6	94.4	495	66.0	62.5	69.4	0.534	0.493	0.577
		PI(D42)	758	754	99.5	98.7	99.9	754	99.5	98.7	99.9	5.872	5.504	6.265
	COM_MMR	PRE	260	240	92.3	88.4	95.2	171	65.8	59.7	71.5	0.507	0.442	0.580
		PI(D42)	266	266	100	98.6	100	265	99.6	97.9	100	5.838	5.239	6.505
anti-PnPS 7F antibody(ECL)(assay cut-off=0.063 µg/ml)	INV_MMR	PRE	750	750	100	99.5	100	671	89.5	87.0	91.6	0.862	0.819	0.907
		PI(D42)	758	754	99.5	98.7	99.9	754	99.5	98.7	99.9	3.691	3.489	3.905
	COM_MMR	PRE	260	260	100	98.6	100	236	90.8	86.6	94.0	0.813	0.749	0.882
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	3.814	3.484	4.176

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**Value**	**LL**	**UL**
anti-PnPS 9V antibody(ECL)(assay cut-off=0.066 µg/ml)	INV_MMR	PRE	750	734	97.9	96.6	98.8	378	50.4	46.8	54.0	0.359	0.336	0.383
		PI(D42)	759	755	99.5	98.7	99.9	748	98.6	97.4	99.3	2.318	2.183	2.461
	COM_MMR	PRE	260	256	98.5	96.1	99.6	126	48.5	42.2	54.7	0.343	0.310	0.378
		PI(D42)	266	266	100	98.6	100	264	99.2	97.3	99.9	2.282	2.065	2.521
anti-PnPS 14 antibody(ECL)(assay cut-off=0.16 µg/ml)	INV_MMR	PRE	750	740	98.7	97.6	99.4	704	93.9	91.9	95.5	1.702	1.589	1.823
		PI(D42)	757	753	99.5	98.7	99.9	752	99.3	98.5	99.8	6.578	6.155	7.029
	COM_MMR	PRE	260	255	98.1	95.6	99.4	249	95.8	92.6	97.9	1.668	1.490	1.867
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	7.053	6.368	7.811
anti-PnPS 18C antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	750	675	90.0	87.6	92.1	307	40.9	37.4	44.5	0.286	0.268	0.304
		PI(D42)	759	755	99.5	98.7	99.9	749	98.7	97.6	99.4	2.102	1.973	2.241
	COM_MMR	PRE	260	230	88.5	83.9	92.1	108	41.5	35.5	47.8	0.274	0.247	0.304
		PI(D42)	265	265	100	98.6	100	262	98.9	96.7	99.8	2.217	1.990	2.470
anti-PnPS 19A antibody(ECL)(assay cut-off=0.199 µg/ml)	INV_MMR	PRE	749	652	87.0	84.4	89.4	475	63.4	59.9	66.9	0.511	0.475	0.550
		PI(D42)	759	755	99.5	98.7	99.9	753	99.2	98.3	99.7	4.731	4.461	5.017
	COM_MMR	PRE	260	224	86.2	81.3	90.1	168	64.6	58.5	70.4	0.475	0.423	0.534
		PI(D42)	265	265	100	98.6	100	265	100	98.6	100	4.821	4.372	5.317
anti-PnPS 19F antibody(ECL)(assay cut-off=0.163 µg/ml)	INV_MMR	PRE	750	724	96.5	95.0	97.7	577	76.9	73.7	79.9	0.654	0.612	0.699
		PI(D42)	759	755	99.5	98.7	99.9	754	99.3	98.5	99.8	4.251	4.013	4.504
	COM_MMR	PRE	260	251	96.5	93.5	98.4	189	72.7	66.8	78.0	0.591	0.533	0.656
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	4.260	3.872	4.687
anti-PnPS 23F antibody(ECL)(assay cut-off=0.073 µg/ml)	INV_MMR	PRE	728	644	88.5	85.9	90.7	266	36.5	33.0	40.2	0.251	0.231	0.273
		PI(D42)	742	738	99.5	98.6	99.9	730	98.4	97.2	99.2	2.198	2.051	2.355
	COM_MMR	PRE	254	223	87.8	83.1	91.6	91	35.8	29.9	42.1	0.244	0.212	0.281
		PI(D42)	256	255	99.6	97.8	100	251	98.0	95.5	99.4	2.291	2.025	2.592

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

7.1.8. Immune response to HAV in terms of seroresponse rates (Secondary objective 4)

For secondary objective 4, the immunogenicity of HAV with respect to the seroresponse rate for antibodies to HAV was assessed in the Inv_MMR groups and Com_MMR groups at Day 42 in a subset of children enrolled in the US. The results show that the percentages of subjects with antibodies to HAV equal to or above the threshold of 15 mIU/mL were 86.5% and 84.9% of subjects in the Inv_MMR and Com_MMR groups respectively (see Table 40).

Table 40 Vaccine response for Anti-HAV at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset)

			Vaccine response			
					95% CI	
Group	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR	S-	748	664	88.8	86.3	90.9
	S+	35	13	37.1	21.5	55.1
	Total	783	677	86.5	83.9	88.8
COM_MMR	S-	271	236	87.1	82.5	90.8
	S+	14	6	42.9	17.7	71.1
	Total	285	242	84.9	80.2	88.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 15 mIU/mL for anti-HAV antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL for anti-HAV antibody) prior to vaccination
Total = subjects either seropositive or seronegative at pre-vaccination
Vaccine response defined as:
For initially seronegative subjects, antibody concentration ≥ 15 mIU/mL at PI(D42)
For initially seropositive subjects: antibody concentration at PI(D42) ≥ 2 fold the pre-vaccination antibody concentration
N = number of subjects with both pre- and post-vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

7.2. Analysis by sub-groups

The analyses of immunogenicity were also repeated for subjects in each country, by gender and by geographic ancestry. These results can be found in Table 7.29 through Table 7.35. The immune responses in these categories were generally similar to what has been reported above for the overall groups.

7.3. Immunogenicity summary

Primary analyses of anti-measles, anti-mumps, and anti-rubella antibody responses at Day 42 showed that all 5 co-primary objectives were met.

The consistency of three manufacturing lots of Inv_MMR was demonstrated. For the comparison of Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3:

- For each pair-wise comparison, the two sided 95% CI for the difference in lots seroresponse rates was within the [-5%; 5%] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 1.
- For each pair-wise comparison, the two sided 95% CI for the adjusted GMC ratio was within the [0.67; 1.5] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 2.

The co-primary objectives of the non-inferiority of Inv_MMR compared to Com_MMR were met.

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 3.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 4.

The co-primary objective of acceptable immune response for Inv_MMR in terms of seroresponse rates to anti-measles, anti-mumps and anti-rubella antibodies was met.

- The lower limit of the two sided 95% CI for the seroresponse rate for the Inv_MMR lots was ≥90% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 5.

With respect to secondary objectives, analyses of anti-VZV, anti-HAV and anti-PS responses at Day 42 showed that all secondary objectives related to the non-inferiority of Inv_MMR compared to Com_MMR in terms of co-administered vaccines were met.

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies, and
- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies, thus meeting secondary objective 1.
- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV, thus meeting secondary objective 2.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to each of the 13 *S. pneumoniae* serotypes, thus meeting secondary objective 3.

Assessment of the immunogenicity of *Havrix* with respect to the seroresponse rates of antibodies to HAV showed a comparable vaccine response in both the Inv_MMR and Com_MMR groups (secondary objective 4).

8. SAFETY RESULTS

The analysis of safety was performed on the TVC. See Section 5.10.5 for the definition of the cohorts identified for analyses. A second analysis was not performed on the ATP cohort to complement the TVC analysis because less than 5% of subjects were eliminated from each group in the ATP cohort for the analysis of safety.

8.1. Total vaccinated cohort analysis

A total of 1239 subjects in the Inv_MMR_1 group, 1232 subjects in the Inv_MMR_2 group, 1243 subjects in the Inv_MMR_3 group and 1289 subjects in the Com_MMR group received study vaccine. At least 99.6% of the subjects in the 4 groups received HAV and VV but only about 50% of subjects received PCV-13 concomitantly, as the latter was administered only to subjects enrolled in US study sites (Table 41).

Compliance was ≥ 95.4% in returning symptom sheets for collection of local and general solicited AEs with regard to administered doses (Table 42).

Table 41 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort)

	INV_MMR_1 HAVRIX N = 1239		INV_MMR_1 MEMURU N = 1239		INV_MMR_1 PREVENAR 13 N = 1239		INV_MMR_1 VARIVAX VACCINE N = 1239		INV_MMR_2 HAVRIX N = 1234		INV_MMR_2 MEMURU N = 1234		INV_MMR_2 PREVENAR 13 N = 1234		INV_MMR_2 VARIVAX VACCINE N = 1234		INV_MMR_3 HAVRIX N = 1246		INV_MMR_3 MEMURU N = 1246	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	1	0.1	0	0.0	621	50.1	0	0.0	2	0.2	2	0.2	622	50.4	2	0.2	5	0.4	3	0.2
1	1238	99.9	1239	100	618	49.9	1239	100	1232	99.8	1232	99.8	612	49.6	1232	99.8	1241	99.6	1243	99.8

	INV_MMR_3 PREVENAR 13 N = 1246		INV_MMR_3 VARIVAX VACCINE N = 1246		INV_MMR HAVRIX N = 3719		INV_MMR MEMURU N = 3719		INV_MMR PREVENAR 13 N = 3719		INV_MMR VARIVAX VACCINE N = 3719		COM_MMR HAVRIX N = 1291		COM_MMR MMR II VACCINE N = 1291		COM_MMR PREVENAR 13 N = 1291		COM_MMR VARIVAX VACCINE N = 1291	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	629	50.5	4	0.3	8	0.2	5	0.1	1872	50.3	6	0.2	2	0.2	2	0.2	637	49.3	2	0.2
1	617	49.5	1242	99.7	3711	99.8	3714	99.9	1847	49.7	3713	99.8	1289	99.8	1289	99.8	654	50.7	1289	99.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose
Note: A second dose of HAV or VV was provided by GSK in Finland, Estonia and Mexico at the end of the study or shortly after the study.

Table 42 Compliance in returning symptom information (Total vaccinated cohort)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	1239	5	1190	96.0	1186	95.7
INV_MMR_2	1232	5	1176	95.5	1175	95.4
INV_MMR_3	1243	6	1200	96.5	1194	96.1
INV_MMR	3714	16	3566	96.0	3555	95.7
COM_MMR	1289	5	1243	96.4	1242	96.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

8.1.1. Overall incidence of adverse events

The incidence and nature of solicited and unsolicited symptoms reported by subjects from Day 0 to Day 42 following the study vaccination is presented in Table 43.

Overall, at least one solicited or unsolicited symptom was reported by 84.1% of subjects in the Inv_MMR group and by 85.3% in the Com_MMR group.

General symptoms were reported by 80.5% of subjects in Inv_MMR and 82.3% in Com_MMR groups. Local symptoms were reported by 40.2% and 41.9% of subjects in the Inv_MMR and Com_MMR groups, respectively.

Table 43 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	1239	1052	84.9	82.8	86.9	1239	1008	81.4	79.1	83.5	1239	513	41.4	38.6	44.2
INV_MMR_2	1232	1027	83.4	81.2	85.4	1232	992	80.5	78.2	82.7	1232	487	39.5	36.8	42.3
INV_MMR_3	1243	1044	84.0	81.8	86.0	1243	990	79.6	77.3	81.9	1243	493	39.7	36.9	42.4
INV_MMR	3714	3123	84.1	82.9	85.2	3714	2990	80.5	79.2	81.8	3714	1493	40.2	38.6	41.8
COM_MMR	1289	1099	85.3	83.2	87.2	1289	1061	82.3	80.1	84.4	1289	540	41.9	39.2	44.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.1.2. Solicited local adverse events

The percentages of subjects reporting solicited local symptoms within 4 days post-vaccination are presented in Table 44.

The incidences of solicited local symptoms were comparable among the groups. The most frequently reported solicited local symptoms post vaccination in the Inv_MMR and Com_MMR groups were pain and redness. Overall, 25.9% of subjects in the Inv_MMR group reported pain compared to 28.1% in the Com_MMR group, and 24.5% of the Inv_MMR group reported redness compared to the 25.2% of subjects in the Com_MMR group.

Redness >20 mm was reported in 0.4% of subjects in the Inv_MMR group, and 0.6% in the Com_MMR group, while pain (grade 3) was experienced by 0.7% and 1.0% of subjects in the Inv_MMR and Com_MMR groups, respectively. In addition, medical advice for pain and redness was sought by up to 0.2% of subjects in the Inv_MMR group and Com_MMR group.

Table 44 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	1186	331	27.9	25.4	30.6	1175	315	26.8	24.3	29.4	1194	273	22.9	20.5	25.4	3555	919	25.9	24.4	27.3	1242	349	28.1	25.6	30.7
	Grade 2 or 3	1186	76	6.4	5.1	8.0	1175	71	6.0	4.7	7.6	1194	73	6.1	4.8	7.6	3555	220	6.2	5.4	7.0	1242	89	7.2	5.8	8.7
	Grade 3	1186	6	0.5	0.2	1.1	1175	9	0.8	0.4	1.4	1194	9	0.8	0.3	1.4	3555	24	0.7	0.4	1.0	1242	12	1.0	0.5	1.7
	Medical advice	1186	1	0.1	0.0	0.5	1175	0	0.0	0.0	0.3	1194	1	0.1	0.0	0.5	3555	2	0.1	0.0	0.2	1242	2	0.2	0.0	0.6
Redness (mm)	All	1186	296	25.0	22.5	27.5	1175	273	23.2	20.8	25.8	1194	301	25.2	22.8	27.8	3555	870	24.5	23.1	25.9	1242	313	25.2	22.8	27.7
	>5	1186	46	3.9	2.9	5.1	1175	45	3.8	2.8	5.1	1194	49	4.1	3.1	5.4	3555	140	3.9	3.3	4.6	1242	41	3.3	2.4	4.5
	>20	1186	6	0.5	0.2	1.1	1175	2	0.2	0.0	0.6	1194	6	0.5	0.2	1.1	3555	14	0.4	0.2	0.7	1242	8	0.6	0.3	1.3
	Medical advice	1186	2	0.2	0.0	0.6	1175	1	0.1	0.0	0.5	1194	0	0.0	0.0	0.3	3555	3	0.1	0.0	0.2	1242	0	0.0	0.0	0.3
Swelling (mm)	All	1186	116	9.8	8.1	11.6	1175	99	8.4	6.9	10.2	1194	103	8.6	7.1	10.4	3555	318	8.9	8.0	9.9	1242	133	10.7	9.0	12.6
	>5	1186	16	1.3	0.8	2.2	1175	19	1.6	1.0	2.5	1194	19	1.6	1.0	2.5	3555	54	1.5	1.1	2.0	1242	25	2.0	1.3	3.0
	>20	1186	1	0.1	0.0	0.5	1175	5	0.4	0.1	1.0	1194	6	0.5	0.2	1.1	3555	12	0.3	0.2	0.6	1242	5	0.4	0.1	0.9
	Medical advice	1186	1	0.1	0.0	0.5	1175	0	0.0	0.0	0.3	1194	0	0.0	0.0	0.3	3555	1	0.0	0.0	0.2	1242	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

8.1.3. Solicited general adverse events

The percentages of subjects reporting solicited general symptoms within 15 days post-vaccination only are presented in Table 45.

Overall, the incidences of solicited general symptoms were similar between the groups. The most commonly reported general symptom post vaccination was irritability or fussiness, reported in 63.3% in the Inv_MMR group compared to 65.9% in Com_MMR group.

Drowsiness (44.9% and 47.1%) and loss of appetite (45.1% and 44.1%) were the next most commonly reported general symptoms in the Inv_MMR and Com_MMR groups, respectively.

Severe irritability or fussiness (grade 3) was reported in up to 4.9% of subjects in the Inv_MMR and Com_MMR groups. Grade 3 drowsiness and loss of appetite occurred in up to 2.5% of subjects in the Inv_MMR and Com_MMR groups, with overall medical advice being sought by a maximum of 3.0 and 3.4% of subjects in the Inv_MMR and Com_MMR groups, respectively for any solicited general symptom.

Table 45 Incidence of solicited general symptoms reported during the 15-day (Days 0-14) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**N**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	1190	533	44.8	41.9	47.7	1176	535	45.5	42.6	48.4	1200	533	44.4	41.6	47.3	3566	1601	44.9	43.3	46.5	1243	586	47.1	44.3	50.0
	Grade 2 or 3	1190	161	13.5	11.6	15.6	1176	181	15.4	13.4	17.6	1200	169	14.1	12.2	16.2	3566	511	14.3	13.2	15.5	1243	175	14.1	12.2	16.1
	Grade 3	1190	23	1.9	1.2	2.9	1176	39	3.3	2.4	4.5	1200	23	1.9	1.2	2.9	3566	85	2.4	1.9	2.9	1243	22	1.8	1.1	2.7
	Medical advice	1190	19	1.6	1.0	2.5	1176	15	1.3	0.7	2.1	1200	23	1.9	1.2	2.9	3566	57	1.6	1.2	2.1	1243	17	1.4	0.8	2.2
Irritability / fussiness	All	1190	764	64.2	61.4	66.9	1176	729	62.0	59.1	64.8	1200	765	63.8	61.0	66.5	3566	2258	63.3	61.7	64.9	1243	819	65.9	63.2	68.5
	Grade 2 or 3	1190	326	27.4	24.9	30.0	1176	324	27.6	25.0	30.2	1200	338	28.2	25.6	30.8	3566	988	27.7	26.2	29.2	1243	371	29.8	27.3	32.5
	Grade 3	1190	56	4.7	3.6	6.1	1176	63	5.4	4.1	6.8	1200	57	4.8	3.6	6.1	3566	176	4.9	4.2	5.7	1243	58	4.7	3.6	6.0
	Medical advice	1190	35	2.9	2.1	4.1	1176	32	2.7	1.9	3.8	1200	40	3.3	2.4	4.5	3566	107	3.0	2.5	3.6	1243	42	3.4	2.4	4.5
Loss of appetite	All	1190	546	45.9	43.0	48.8	1176	536	45.6	42.7	48.5	1200	526	43.8	41.0	46.7	3566	1608	45.1	43.4	46.7	1243	548	44.1	41.3	46.9
	Grade 2 or 3	1190	164	13.8	11.9	15.9	1176	168	14.3	12.3	16.4	1200	146	12.2	10.4	14.2	3566	478	13.4	12.3	14.6	1243	164	13.2	11.4	15.2
	Grade 3	1190	24	2.0	1.3	3.0	1176	29	2.5	1.7	3.5	1200	19	1.6	1.0	2.5	3566	72	2.0	1.6	2.5	1243	31	2.5	1.7	3.5
	Medical advice	1190	27	2.3	1.5	3.3	1176	22	1.9	1.2	2.8	1200	33	2.8	1.9	3.8	3566	82	2.3	1.8	2.8	1243	24	1.9	1.2	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

The percentages of subjects reporting fever (temperature ≥38.0°C/100.4°F) during the period from Day 5 to Day 12 post vaccination are given in Table 46.

In both the Inv_MMR and Com_MMR groups, up to 24.3% of subjects reported fever post dose. Medical advice for fever was sought by 4.6% of subjects in the Inv_MMR group and 4.4% in Com_MMR group.

Incidences of grade 3 fever (temperature >39.5°C) were reported in 1.4% and 1.1% of subjects in the Inv_MMR and Com_MMR groups, respectively.

The percentages of subjects reporting grade 3 fever (temperature >39.5°C), that was considered related to the study vaccination, were 1.0% and 0.7% of subjects in the Inv_MMR and Com_MMR groups, respectively.

The daily prevalence of any fever and grade 3 fever between Day 0 and Day 42 after vaccination are represented graphically in Figure 8.2 and Figure 8.3, respectively. As seen in the graphs, the peak prevalence of fever was observed approximately from Day 5 to Day 12 after vaccination, with the sharpest peak from Day 8 to Day 10.

Percentages of subjects reporting fever in the 43 days post-vaccination period are given in Table 8.44. Occurrences of fever ≥38.0°C/100.4°F in the 43-day post-vaccination period were reported by 34.7% and 33.1% of subjects in the Inv_MMR and Com_MMR groups, respectively. Occurrences of fever ≥39.5°C in the 43-day post-vaccination period were reported by 2.9% and 2.6% of subjects in the Inv_MMR and Com_MMR groups, respectively.

Table 46 Incidence of fever reported during the day 5 to day 12 post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1190	281	23.6	21.2	26.1	1176	287	24.4	22.0	27.0	1200	297	24.8	22.3	27.3	3566	865	24.3	22.9	25.7	1243	284	22.8	20.5	25.3
	≥38	1190	226	19.0	16.8	21.3	1176	242	20.6	18.3	23.0	1200	236	19.7	17.5	22.0	3566	704	19.7	18.4	21.1	1243	226	18.2	16.1	20.4
	>38.5	1190	103	8.7	7.1	10.4	1176	116	9.9	8.2	11.7	1200	114	9.5	7.9	11.3	3566	333	9.3	8.4	10.3	1243	103	8.3	6.8	10.0
	>39.0	1190	44	3.7	2.7	4.9	1176	47	4.0	3.0	5.3	1200	48	4.0	3.0	5.3	3566	139	3.9	3.3	4.6	1243	39	3.1	2.2	4.3
	>39.5	1190	16	1.3	0.8	2.2	1176	16	1.4	0.8	2.2	1200	17	1.4	0.8	2.3	3566	49	1.4	1.0	1.8	1243	14	1.1	0.6	1.9
	>40.0	1190	2	0.2	0.0	0.6	1176	6	0.5	0.2	1.1	1200	4	0.3	0.1	0.9	3566	12	0.3	0.2	0.6	1243	5	0.4	0.1	0.9
	≥38 Related	1190	164	13.8	11.9	15.9	1176	167	14.2	12.3	16.3	1200	165	13.8	11.9	15.8	3566	496	13.9	12.8	15.1	1243	159	12.8	11.0	14.8
	>38.5 Related	1190	71	6.0	4.7	7.5	1176	78	6.6	5.3	8.2	1200	87	7.3	5.8	8.9	3566	236	6.6	5.8	7.5	1243	73	5.9	4.6	7.3
	>39.0 Related	1190	29	2.4	1.6	3.5	1176	28	2.4	1.6	3.4	1200	37	3.1	2.2	4.2	3566	94	2.6	2.1	3.2	1243	23	1.9	1.2	2.8
	>39.5 Related	1190	11	0.9	0.5	1.6	1176	9	0.8	0.4	1.4	1200	14	1.2	0.6	1.9	3566	34	1.0	0.7	1.3	1243	9	0.7	0.3	1.4
	>40.0 Related	1190	1	0.1	0.0	0.5	1176	3	0.3	0.1	0.7	1200	4	0.3	0.1	0.9	3566	8	0.2	0.1	0.4	1243	4	0.3	0.1	0.8
	Medical advice	1190	49	4.1	3.1	5.4	1176	53	4.5	3.4	5.9	1200	62	5.2	4.0	6.6	3566	164	4.6	3.9	5.3	1243	55	4.4	3.4	5.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Solicited general symptoms specific to MMR vaccination were also collected from subjects. The percentages of subjects reporting the occurrence of febrile convulsion and parotid gland swelling during the 43-day post-vaccination period are presented in Table 47.

A total of 10 subjects (0.3%) in the Inv_MMR group and 3 (0.2%) in the Com_MMR group reported febrile convulsions within the 43-day reporting period post-vaccination. Nine out of 10 in the Inv_MMR group and 1 out of 3 in the Com_MMR group sought medical advice. Four of the 10 events in the Inv_MMR group and 2 of the 3 events in the Com_MMR group were considered related to vaccination.

No subject reported parotid gland swelling in any of the groups.

Table 47 Incidence of MMR specific solicited general symptoms reported during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**N**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	1190	4	0.3	0.1	0.9	1176	1	0.1	0.0	0.5	1200	5	0.4	0.1	1.0	3566	10	0.3	0.1	0.5	1243	3	0.2	0.0	0.7
	Grade 2 or 3	1190	3	0.3	0.1	0.7	1176	1	0.1	0.0	0.5	1200	3	0.3	0.1	0.7	3566	7	0.2	0.1	0.4	1243	1	0.1	0.0	0.4
	Grade 3	1190	2	0.2	0.0	0.6	1176	0	0.0	0.0	0.3	1200	2	0.2	0.0	0.6	3566	4	0.1	0.0	0.3	1243	0	0.0	0.0	0.3
	Related	1190	1	0.1	0.0	0.5	1176	1	0.1	0.0	0.5	1200	2	0.2	0.0	0.6	3566	4	0.1	0.0	0.3	1243	2	0.2	0.0	0.6
	Medical advice	1190	4	0.3	0.1	0.9	1176	1	0.1	0.0	0.5	1200	4	0.3	0.1	0.9	3566	9	0.3	0.1	0.5	1243	1	0.1	0.0	0.4
Parotid gland	All	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Grade 2 or 3	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Grade 3	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Related	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Medical advice	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

The percentages of subjects with any incidence of rash post vaccination, regardless of whether localized or generalized, were similar among the groups: 29.2% in Inv_MMR and 30.4% in Com_MMR groups. Fever along with rash was reported in up to 9.7% of subjects across the Inv_MMR and Com_MMR groups. Measles/rubella-like rash was seen in 6.6% of the Inv_MMR and 6.2% in Com_MMR groups (Table 48).

Medical advice for any rash post vaccination was sought by 12.5% and 13.2% of subjects in the Inv_MMR and Com_MMR groups, respectively, and a maximum of 13.7% of subjects had a rash considered by the investigator to be related to the study vaccination across the Inv_MMR and Com_MMR groups. A severe (grade 3) rash was reported in up to 3.0% of subjects across the Inv_MMR and Com_MMR groups.

Table 48 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95% CI					95% CI					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	1190	352	29.6	27.0	32.3	1176	331	28.1	25.6	30.8	1200	360	30.0	27.4	32.7	3566	1043	29.2	27.8	30.8	1243	378	30.4	27.9	33.1
	With fever	1190	106	8.9	7.4	10.7	1176	123	10.5	8.8	12.4	1200	118	9.8	8.2	11.7	3566	347	9.7	8.8	10.8	1243	104	8.4	6.9	10.1
	Varicella like	1190	87	7.3	5.9	8.9	1176	78	6.6	5.3	8.2	1200	85	7.1	5.7	8.7	3566	250	7.0	6.2	7.9	1243	85	6.8	5.5	8.4
	Measles/Rubella like	1190	71	6.0	4.7	7.5	1176	88	7.5	6.0	9.1	1200	76	6.3	5.0	7.9	3566	235	6.6	5.8	7.5	1243	77	6.2	4.9	7.7
	Grade 3	1190	33	2.8	1.9	3.9	1176	37	3.1	2.2	4.3	1200	36	3.0	2.1	4.1	3566	106	3.0	2.4	3.6	1243	25	2.0	1.3	3.0
	Related	1190	153	12.9	11.0	14.9	1176	165	14.0	12.1	16.2	1200	171	14.3	12.3	16.4	3566	489	13.7	12.6	14.9	1243	162	13.0	11.2	15.0
	Med adv	1190	160	13.4	11.6	15.5	1176	136	11.6	9.8	13.5	1200	150	12.5	10.7	14.5	3566	446	12.5	11.4	13.6	1243	164	13.2	11.4	15.2
Localized	Any	1190	230	19.3	17.1	21.7	1176	224	19.0	16.8	21.4	1200	251	20.9	18.7	23.3	3566	705	19.8	18.5	21.1	1243	266	21.4	19.2	23.8
	Administration site	1190	10	0.8	0.4	1.5	1176	16	1.4	0.8	2.2	1200	12	1.0	0.5	1.7	3566	38	1.1	0.8	1.5	1243	16	1.3	0.7	2.1
	Other site	1190	225	18.9	16.7	21.3	1176	213	18.1	16.0	20.4	1200	242	20.2	17.9	22.6	3566	680	19.1	17.8	20.4	1243	252	20.3	18.1	22.6
	With fever	1190	48	4.0	3.0	5.3	1176	67	5.7	4.4	7.2	1200	67	5.6	4.4	7.0	3566	182	5.1	4.4	5.9	1243	54	4.3	3.3	5.6
	Varicella like	1190	68	5.7	4.5	7.2	1176	57	4.8	3.7	6.2	1200	55	4.6	3.5	5.9	3566	180	5.0	4.4	5.8	1243	61	4.9	3.8	6.3
	Measles/Rubella like	1190	25	2.1	1.4	3.1	1176	34	2.9	2.0	4.0	1200	34	2.8	2.0	3.9	3566	93	2.6	2.1	3.2	1243	35	2.8	2.0	3.9
	Grade 3	1190	6	0.5	0.2	1.1	1176	10	0.9	0.4	1.6	1200	9	0.8	0.3	1.4	3566	25	0.7	0.5	1.0	1243	5	0.4	0.1	0.9
	Related	1190	87	7.3	5.9	8.9	1176	101	8.6	7.1	10.3	1200	101	8.4	6.9	10.1	3566	289	8.1	7.2	9.1	1243	103	8.3	6.8	10.0
	Med adv	1190	84	7.1	5.7	8.7	1176	77	6.5	5.2	8.1	1200	80	6.7	5.3	8.2	3566	241	6.8	6.0	7.6	1243	95	7.6	6.2	9.3
Generalized	Any	1190	143	12.0	10.2	14.0	1176	138	11.7	10.0	13.7	1200	133	11.1	9.4	13.0	3566	414	11.6	10.6	12.7	1243	143	11.5	9.8	13.4
	With fever	1190	66	5.5	4.3	7.0	1176	65	5.5	4.3	7.0	1200	55	4.6	3.5	5.9	3566	186	5.2	4.5	6.0	1243	55	4.4	3.4	5.7
	Varicella like	1190	20	1.7	1.0	2.6	1176	23	2.0	1.2	2.9	1200	31	2.6	1.8	3.7	3566	74	2.1	1.6	2.6	1243	25	2.0	1.3	3.0
	Measles/Rubella like	1190	47	3.9	2.9	5.2	1176	55	4.7	3.5	6.0	1200	44	3.7	2.7	4.9	3566	146	4.1	3.5	4.8	1243	42	3.4	2.5	4.5
	Grade 3	1190	29	2.4	1.6	3.5	1176	27	2.3	1.5	3.3	1200	27	2.3	1.5	3.3	3566	83	2.3	1.9	2.9	1243	20	1.6	1.0	2.5
	Related	1190	74	6.2	4.9	7.7	1176	74	6.3	5.0	7.8	1200	75	6.3	5.0	7.8	3566	223	6.3	5.5	7.1	1243	69	5.6	4.3	7.0
	Med adv	1190	83	7.0	5.6	8.6	1176	68	5.8	4.5	7.3	1200	76	6.3	5.0	7.9	3566	227	6.4	5.6	7.2	1243	80	6.4	5.1	8.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.1.4. Unsolicited adverse events

The percentages of subjects with the most frequently occurring unsolicited AEs reported during the 43-day reporting period post-vaccination are listed in Table 49. All unsolicited AEs reported by subjects in this period in each system organ class by preferred term are given in Table 8.81.

Overall, 50.0% of subjects in the Inv_MMR group and 47.9% in the Com_MMR group reported at least one unsolicited AE. The most commonly occurring MedDRA system organ class of AEs was 'infections and infestations', followed by 'gastrointestinal disorders' (Table 49). The most common AE by MedDRA preferred term was upper respiratory tract infection, reported in 9.5% of subjects in the Inv_MMR and 9.5% in Com_MMR groups, respectively (Table 49).

Table 49 Number (%) of subjects with adverse events during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

System Organ Class	Most frequent adverse events - On-Therapy (occurring within day 0-42 following vaccination)	INV_MMR_1 N = 1239	INV_MMR_2 N = 1232	INV_MMR_3 N = 1243	INV_MMR N = 3714	COM_MMR N = 1289
	Subjects with any AE(s), n (%)	615 (49.6)	633 (51.4)	609 (49.0)	1857 (50.0)	618 (47.9)
Infections and infestations	Upper respiratory tract infection	106 (8.6)	124 (10.1)	122 (9.8)	352 (9.5)	122 (9.5)
Gastrointestinal disorders	Teething	91 (7.3)	92 (7.5)	77 (6.2)	260 (7.0)	95 (7.4)
Infections and infestations	Otitis media	80 (6.5)	75 (6.1)	63 (5.1)	218 (5.9)	87 (6.7)
Infections and infestations	Nasopharyngitis	74 (6.0)	75 (6.1)	74 (6.0)	223 (6.0)	65 (5.0)
Gastrointestinal disorders	Diarrhea	64 (5.2)	58 (4.7)	49 (3.9)	171 (4.6)	64 (5.0)

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

8.2. Serious adverse events

All SAEs were collected throughout the entire study period (Days 0 to 180). The listing of SAEs for the TVC can be found in Table 8.136, and the SAE clinical narratives are in Section 12.

8.2.1. Fatal events

There were no fatal events reported.

8.2.2. Non-fatal events

The number and percentages of subjects that experienced an SAE during the study period are given in Table 50.

A total of 102 subjects reported one or more SAEs in this study. A total of 98 SAEs were reported in 77 subjects (2.1%) in the Inv_MMR group and 40 were reported in 25 subjects (1.9%) in the Com_MMR group.

Two of these SAEs in the Inv_MMR group were considered by the investigator to be related to the study vaccination. One subject in the Inv_MMR_2 group had gastroenteritis, occurring on the day of vaccination, for a duration of 14 days, and one subject in the Inv_MMR_3 group had febrile convulsion on Day 9 post dose lasting one day.

The most frequently occurring SAE during the study period was bronchitis reported by 8 subjects (0.2%) in the Inv_MMR group and by 2 subjects (0.2%) in the Com_MMR group. Overall, the safety results were consistent between the 3 lots of Inv_MMR used in this study

Table 50 Number (%) of subjects with serious adverse events including number of events reported during the study period (Total vaccinated cohort)

			INV_MMR_1 N = 1239			INV_MMR_2 N = 1232			INV_MMR_3 N = 1243			INV_MMR N = 3714			COM_MMR N = 1289		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**
SAE	At least one symptom		26	21	1.7	34	28	2.3	38	28	2.3	98	77	2.1	40	25	1.9
	Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	2	2	0.2
	Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	1	1	0.1
		Enterocolitis (10014893)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Gastritis (10017853)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
	General disorders and administration site conditions (10018065)	Pyrexia (10037660)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
	Immune system disorders (10021428)	Milk allergy (10027633)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
	Infections and infestations (10021881)	Abscess (10000269)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Bronchiolitis (10006448)	1	1	0.1	2	2	0.2	1	1	0.1	4	4	0.1	2	2	0.2
		Bronchitis (10006451)	3	3	0.2	2	2	0.2	3	3	0.2	8	8	0.2	3	2	0.2
		Cellulitis (10007882)	1	1	0.1	0	0	0.0	2	2	0.2	3	3	0.1	0	0	0.0
		Conjunctivitis (10010741)	1	1	0.1	0	0	0.0	1	1	0.1	2	2	0.1	1	1	0.1
		Croup infectious (10011416)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Escherichia urinary tract infection (10052238)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Gastroenteritis (10017888)	1	1	0.1	1	1	0.1	2	2	0.2	4	4	0.1	2	2	0.2
		Gastroenteritis adenovirus (10017889)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	1	1	0.1
		Gastroenteritis rotavirus (10017913)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	1	1	0.1
		Gastroenteritis viral (10017918)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Herpangina (10019936)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Laryngitis (10023874)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Mycoplasma infection (10061300)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Nasopharyngitis (10028810)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Neutropenic infection (10059482)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
		Otitis media (10033078)	0	0	0.0	0	0	0.0	4	4	0.3	4	4	0.1	2	2	0.2
		Otitis media acute (10033079)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
		Pharyngitis (10034835)	1	1	0.1	1	1	0.1	0	0	0.0	2	2	0.1	0	0	0.0
		Pneumococcal sepsis (10054047)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Pneumonia (10035664)	2	2	0.2	1	1	0.1	3	3	0.2	6	6	0.2	0	0	0.0

			INV_MMR_1 N = 1239			INV_MMR_2 N = 1232			INV_MMR_3 N = 1243			INV_MMR N = 3714			COM_MMR N = 1289		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**
		Pneumonia bacterial (10060946)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Pneumonia respiratory syncytial viral (10035732)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	1	1	0.1
		Pneumonia viral (10035737)	1	1	0.1	2	2	0.2	1	1	0.1	4	4	0.1	0	0	0.0
		Pyelonephritis acute (10037597)	1	1	0.1	0	0	0.0	1	1	0.1	2	2	0.1	0	0	0.0
		Respiratory syncytial virus bronchiolitis (10038718)	1	1	0.1	1	1	0.1	1	1	0.1	3	3	0.1	1	1	0.1
		Respiratory tract infection viral (10062106)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Rotavirus infection (10067470)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Subcutaneous abscess (10042343)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Tonsillitis (10044008)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	1	1	0.1
		Upper respiratory tract infection (10046306)	1	1	0.1	1	1	0.1	0	0	0.0	2	2	0.1	0	0	0.0
		Viral infection (10047461)	0	0	0.0	0	0	0.0	2	2	0.2	2	2	0.1	3	3	0.2
		Viral pharyngitis (10047473)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Viral upper respiratory tract infection (10047482)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
	Injury, poisoning and procedural complications (10022117)	Burns second degree (10006802)	0	0	0.0	1	1	0.1	1	1	0.1	2	2	0.1	0	0	0.0
		Concussion (10010254)	1	1	0.1	1	1	0.1	0	0	0.0	2	2	0.1	0	0	0.0
		Femur fracture (10016454)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Foot fracture (10016970)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Head injury (10019196)	2	2	0.2	0	0	0.0	0	0	0.0	2	2	0.1	0	0	0.0
	Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0	0.0	2	2	0.2	3	3	0.2	5	5	0.1	3	3	0.2
		Hypoglycaemia (10020993)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
		Type 1 diabetes mellitus (10067584)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
	Nervous system disorders (10029205)	Epilepsy (10015037)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Febrile convulsion (10016284)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	5	5	0.4
		Loss of consciousness (10024855)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Seizure (10039906)	0	0	0.0	0	0	0.0	2	2	0.2	2	2	0.1	0	0	0.0
	Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	2	0.2	2	2	0.2	0	0	0.0	4	4	0.1	2	2	0.2
		Bronchial hyperreactivity (10066091)	0	0	0.0	3	3	0.2	0	0	0.0	3	3	0.1	3	3	0.2
		Hypoxia (10021143)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0

			INV_MMR_1 N = 1239			INV_MMR_2 N = 1232			INV_MMR_3 N = 1243			INV_MMR N = 3714			COM_MMR N = 1289		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**
	Skin and subcutaneous tissue disorders (10040785)	Urticaria (10046735)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	2	2	0.2
	Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
Related SAE	At least one symptom		0	0	0.0	1	1	0.1	1	1	0.1	2	2	0.1	0	0	0.0
	Infections and infestations (10021881)	Gastroenteritis (10017888)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
	Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
Fatal SAE	At least one symptom		0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0
Related fatal SAE	At least one symptom		0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the symptom at least once

8.3. Adverse events leading to premature discontinuation of study

Two AEs occurred that led to subjects prematurely discontinuing the study (Table 6.2). Both subjects belonged to the Inv_MMR_1 group, and their cases were reported as non-serious adverse events.

8.4. Other significant adverse events

8.4.1. New Onset of Chronic Disease

The percentages of subjects reporting NOCDs during the entire study period are given in Table 51. At least one NOCD was reported in 3.4% of subjects in the Inv_MMR group and 3.7% in the Com_MMR group. The most frequent NOCD reported in 33 subjects was dermatitis atopic (0.7% in Inv_MMR and 0.5% in Com_MMR).

Table 51 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		40	3.2	2.3	4.4	39	3.2	2.3	4.3	49	3.9	2.9	5.2	128	3.4	2.9	4.1	48	3.7	2.8	4.9
Blood and lymphatic system disorders (10005329)	Thrombocytopenia (10043554)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Coeliac disease (10009839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Immune system disorders (10021428)	Allergy to animal (10001742)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	6	0.5	0.2	1.0	9	0.2	0.1	0.5	6	0.5	0.2	1.0
	Food allergy (10016946)	5	0.4	0.1	0.9	3	0.2	0.1	0.7	8	0.6	0.3	1.3	16	0.4	0.2	0.7	7	0.5	0.2	1.1
	Hypersensitivity (10020751)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Milk allergy (10027633)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Multiple allergies (10028164)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Seasonal allergy (10048908)	2	0.2	0.0	0.6	5	0.4	0.1	0.9	0	0.0	0.0	0.3	7	0.2	0.1	0.4	2	0.2	0.0	0.6
Infections and infestations (10021881)	Viral rash (10047476)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Metabolism and nutrition disorders (10027433)	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	3	0.2	0.0	0.7	4	0.3	0.1	0.8	7	0.6	0.2	1.2	14	0.4	0.2	0.6	8	0.6	0.3	1.2
	Bronchial hyperreactivity (10066091)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinitis allergic (10039085)	10	0.8	0.4	1.5	5	0.4	0.1	0.9	4	0.3	0.1	0.8	19	0.5	0.3	0.8	7	0.5	0.2	1.1
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	3	0.2	0.0	0.7	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Dermatitis atopic (10012438)	5	0.4	0.1	0.9	10	0.8	0.4	1.5	11	0.9	0.4	1.6	26	0.7	0.5	1.0	7	0.5	0.2	1.1
	Dermatitis contact (10012442)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug eruption (10013687)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eczema (10014184)	4	0.3	0.1	0.8	5	0.4	0.1	0.9	7	0.6	0.2	1.2	16	0.4	0.2	0.7	10	0.8	0.4	1.4
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Henoch-schonlein purpura (10019617)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urticaria (10046735)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled

COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

8.4.2. Emergency Room Visit

The percentage of subjects reporting AEs that required an ER visit throughout the study is given in Table 52. Overall, 10.1% in the Inv_MMR and 10.4% in Com_MMR groups experienced an AE that required an ER visit. The most frequent AEs that required an ER visit were otitis media reported in 80 subjects (1.6% in Inv_MMR and 1.5% in Com_MMR); upper respiratory tract infection reported in 60 subjects (1.1% in Inv_MMR and 1.4% in Com_MMR); and pyrexia reported in 45 subjects (0.8% in Inv_MMR and 1.3% in Com_MMR).

Table 52 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		123	9.9	8.3	11.7	116	9.4	7.8	11.2	136	10.9	9.3	12.8	375	10.1	9.1	11.1	134	10.4	8.8	12.2
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
Eye disorders (10015919)	Eyelid oedema (10015993)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Colitis (10009887)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Constipation (10010774)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Diarrhoea (10012735)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	12	0.9	0.5	1.6
	Gastritis (10017853)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Stomatitis (10042128)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Teething (10043183)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	3	0.2	0.0	0.7
	Vomiting (10047700)	7	0.6	0.2	1.2	2	0.2	0.0	0.6	6	0.5	0.2	1.0	15	0.4	0.2	0.7	9	0.7	0.3	1.3
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gait disturbance (10017577)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyrexia (10037660)	15	1.2	0.7	2.0	5	0.4	0.1	0.9	8	0.6	0.3	1.3	28	0.8	0.5	1.1	17	1.3	0.8	2.1
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Food allergy (10016946)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Hypersensitivity (10020751)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.2	0.0	0.7	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Seasonal allergy (10048908)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abscess neck (10053576)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchiolitis (10006448)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	1	0.1	0.0	0.4	9	0.2	0.1	0.5	2	0.2	0.0	0.6
	Bronchitis (10006451)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	6	0.5	0.2	1.0	13	0.4	0.2	0.6	5	0.4	0.1	0.9
	Burn infection (10051548)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Candida nappy rash (10007135)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cellulitis (10007882)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cellulitis orbital (10007918)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Conjunctivitis (10010741)	3	0.2	0.0	0.7	5	0.4	0.1	0.9	6	0.5	0.2	1.0	14	0.4	0.2	0.6	4	0.3	0.1	0.8
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Croup infectious (10011416)	3	0.2	0.0	0.7	12	1.0	0.5	1.7	5	0.4	0.1	0.9	20	0.5	0.3	0.8	8	0.6	0.3	1.2
	Ear infection (10014011)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	2	0.2	0.0	0.6	7	0.2	0.1	0.4	5	0.4	0.1	0.9
	Enterovirus infection (10014909)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Exanthema subitum (10015586)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Fungal skin infection (10017543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis (10017888)	3	0.2	0.0	0.7	5	0.4	0.1	0.9	7	0.6	0.2	1.2	15	0.4	0.2	0.7	9	0.7	0.3	1.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hand-foot-and-mouth disease (10019113)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	1	0.1	0.0	0.4	7	0.2	0.1	0.4	4	0.3	0.1	0.8
	Herpangina (10019936)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Herpes simplex (10019948)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Impetigo (10021531)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Influenza (10022000)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Laryngitis (10023874)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	4	0.3	0.1	0.8	14	0.4	0.2	0.6	3	0.2	0.0	0.7
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	3	0.2	0.0	0.7	6	0.5	0.2	1.1	5	0.4	0.1	0.9	14	0.4	0.2	0.6	3	0.2	0.0	0.7
	Oral herpes (10067152)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Otitis externa (10033072)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	17	1.4	0.8	2.2	23	1.9	1.2	2.8	21	1.7	1.0	2.6	61	1.6	1.3	2.1	19	1.5	0.9	2.3
	Otitis media acute (10033079)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	4	0.3	0.1	0.8	14	0.4	0.2	0.6	5	0.4	0.1	0.9
	Pharyngitis (10034835)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	4	0.3	0.1	0.8	14	0.4	0.2	0.6	4	0.3	0.1	0.8

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngitis streptococcal (10034839)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Pharyngotonsillitis (10049140)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pneumonia (10035664)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	5	0.4	0.1	0.9	11	0.3	0.1	0.5	0	0.0	0.0	0.3
	Pyelonephritis (10037596)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory tract infection (10062352)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Rhinitis (10039083)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Sinusitis (10040753)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Skin candida (10054152)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Streptococcal infection (10061372)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tonsillitis (10044008)	4	0.3	0.1	0.8	1	0.1	0.0	0.5	3	0.2	0.0	0.7	8	0.2	0.1	0.4	4	0.3	0.1	0.8
	Upper respiratory tract infection (10046306)	14	1.1	0.6	1.9	15	1.2	0.7	2.0	13	1.0	0.6	1.8	42	1.1	0.8	1.5	18	1.4	0.8	2.2
	Urinary tract infection (10046571)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral infection (10047461)	1	0.1	0.0	0.4	4	0.3	0.1	0.8	6	0.5	0.2	1.0	11	0.3	0.1	0.5	7	0.5	0.2	1.1
	Viral rash (10047476)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Animal bite (10002515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Arthropod bite (10003399)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	5	0.4	0.1	0.9	9	0.2	0.1	0.5	2	0.2	0.0	0.6
	Arthropod sting (10003402)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical eye injury (10055116)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Concussion (10010254)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Contusion (10050584)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	6	0.5	0.2	1.0
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Craniocerebral injury (10070976)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Eye injury (10061128)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eyelid injury (10069200)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Fall (10016173)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Foreign body in eye (10017012)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Head injury (10019196)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	6	0.5	0.2	1.0	10	0.3	0.1	0.5	2	0.2	0.0	0.6
	Humerus fracture (10020462)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Joint dislocation (10023204)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Laceration (10023572)	7	0.6	0.2	1.2	2	0.2	0.0	0.6	7	0.6	0.2	1.2	16	0.4	0.2	0.7	3	0.2	0.0	0.7
	Limb injury (10061225)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Lip injury (10055082)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Mouth injury (10049294)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Poisoning (10061355)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Wound (10052428)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	3	0.2	0.0	0.7
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pain in extremity (10033425)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Pyogenic granuloma (10037649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Nervous system disorders (10029205)	Febrile convulsion (10016284)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	3	0.2	0.0	0.7	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tremor (10044565)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Breath holding (10006322)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Irritability (10022998)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Renal and urinary disorders (10038359)	Pollakiuria (10036018)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Perineal cyst (10066058)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Aspiration (10003504)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Asthma (10003553)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Bronchospasm (10006482)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.2	0.0	0.7	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Catarrh (10007774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cough (10011224)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	3	0.2	0.0	0.7	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Dyspnoea (10013968)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rhinitis allergic (10039085)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinorrhoea (10039101)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Stridor (10042241)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	2	0.2	0.0	0.6	5	0.1	0.0	0.3	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dermatitis allergic (10012434)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dermatitis contact (10012442)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Miliaria (10027627)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pityriasis (10035110)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash (10037844)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	5	0.4	0.1	0.9	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Rash generalised (10037858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rash scarlatiniform (10037890)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin burning sensation (10054786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Urticaria (10046735)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	4	0.3	0.1	0.8	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Urticaria vesiculosa (10046755)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Vascular disorders (10047065)	Haematoma (10018852)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

8.4.3. Medically Attended Visits

The percentage of subjects reporting AEs that led to a medically attended visit throughout the study period are given in Table 53. A total of 59.4% of subjects in the Inv_MMR group and 60.4% in Com_MMR group had 1 or more symptoms that required medical attention; the most commonly reported AEs with a medically attended visit in both the Inv_MMR and Com_MMR groups were: otitis media (17.0% and 19.2%), upper respiratory tract infection (13.4% and 13.5%), nasopharyngitis (8.4% and 7.6%) and conjunctivitis (6.6% and 7.2%).

Table 53 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		743	60.0	57.2	62.7	736	59.7	56.9	62.5	727	58.5	55.7	61.2	2206	59.4	57.8	61.0	779	60.4	57.7	63.1
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	7	0.6	0.2	1.2	9	0.2	0.1	0.5	3	0.2	0.0	0.7
	Iron deficiency anaemia (10022972)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.8
	Leukocytosis (10024378)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	5	0.4	0.1	0.9
	Leukopenia (10024384)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	4	0.3	0.1	0.8
	Thrombocytopenia (10043554)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Supraventricular extrasystoles (10042602)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Congenital, familial and genetic disorders (10010331)	Ankyloglossia congenital (10049244)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Atrial septal defect (10003664)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cerebral palsy (10008129)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Cleft uvula (10053507)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Congenital cardiovascular anomaly (10061054)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cryptorchism (10011498)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Imperforate hymen (10021529)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Microcephaly (10027534)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Phimosis (10034878)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Supernumerary nipple (10042571)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Talipes (10043101)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Tibial torsion (10064515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Ear and labyrinth disorders (10013993)	Auricular swelling (10003800)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cerumen impaction (10050337)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Conductive deafness (10010280)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Deafness (10011878)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Ear pain (10014020)	13	1.0	0.6	1.8	4	0.3	0.1	0.8	13	1.0	0.6	1.8	30	0.8	0.5	1.2	10	0.8	0.4	1.4
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Excessive cerumen production (10076897)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Middle ear effusion (10062545)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otorrhoea (10033101)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Endocrine disorders (10014698)	Hypothyroidism (10021114)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Eye disorders (10015919)	Astigmatism (10003569)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Blepharitis (10005148)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Conjunctivitis allergic (10010744)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Dacryostenosis acquired (10053990)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Entropion (10061842)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye discharge (10015915)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye swelling (10015967)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eyelid oedema (10015993)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Hypermetropia (10020675)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Lacrimation increased (10023644)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Panophthalmitis (10033683)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pseudostrabismus (10072123)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Scleral haemorrhage (10050508)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Strabismus (10042159)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abdominal distension (10000060)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.2	0.0	0.7	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Abdominal pain upper (10000087)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Anal fissure (10002153)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Anal skin tags (10002172)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Aphthous ulcer (10002959)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Chapped lips (10049047)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chronic gastritis (10008882)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Coeliac disease (10009839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Colitis (10009887)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Constipation (10010774)	11	0.9	0.4	1.6	8	0.6	0.3	1.3	15	1.2	0.7	2.0	34	0.9	0.6	1.3	14	1.1	0.6	1.8
	Dental caries (10012318)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Diarrhoea (10012735)	59	4.8	3.6	6.1	45	3.7	2.7	4.9	51	4.1	3.1	5.4	155	4.2	3.6	4.9	62	4.8	3.7	6.1
	Dyspepsia (10013946)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Dysphagia (10013950)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Enterocolitis (10014893)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastritis (10017853)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastrooesophageal reflux disease (10017885)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	1	0.1	0.0	0.4	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Gingival hypertrophy (10018284)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gingival pain (10018286)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Haematochezia (10018836)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Inguinal hernia (10022016)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Melaena (10027141)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mouth cyst (10028020)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mucous stools (10028140)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Oral disorder (10067621)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Proctitis (10036774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ranula (10037838)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Stomatitis (10042128)	1	0.1	0.0	0.4	13	1.1	0.6	1.8	6	0.5	0.2	1.0	20	0.5	0.3	0.8	2	0.2	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Teething (10043183)	12	1.0	0.5	1.7	17	1.4	0.8	2.2	14	1.1	0.6	1.9	43	1.2	0.8	1.6	14	1.1	0.6	1.8
	Tongue ulceration (10043991)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tooth discolouration (10044032)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Toothache (10044055)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Umbilical hernia (10045458)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Vomiting (10047700)	29	2.3	1.6	3.3	17	1.4	0.8	2.2	20	1.6	1.0	2.5	66	1.8	1.4	2.3	29	2.2	1.5	3.2
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Asthenia (10003549)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Developmental delay (10012559)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Fatigue (10016256)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Feeling hot (10016334)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gait disturbance (10017577)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Gait inability (10017581)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ill-defined disorder (10061520)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza like illness (10022004)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Injection site erythema (10022061)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	0	0.0	0.0	0.3	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Injection site rash (10022094)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site swelling (10053425)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mucosal inflammation (10028116)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain (10033371)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pyrexia (10037660)	55	4.4	3.4	5.7	54	4.4	3.3	5.7	41	3.3	2.4	4.4	150	4.0	3.4	4.7	52	4.0	3.0	5.3
Immune system disorders (10021428)	Allergy to animal (10001742)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Allergy to arthropod bite (10058285)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	5	0.4	0.1	0.9	9	0.2	0.1	0.5	6	0.5	0.2	1.0
	Food allergy (10016946)	6	0.5	0.2	1.1	6	0.5	0.2	1.1	8	0.6	0.3	1.3	20	0.5	0.3	0.8	7	0.5	0.2	1.1
	Hypersensitivity (10020751)	2	0.2	0.0	0.6	5	0.4	0.1	0.9	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Immunisation reaction (10021432)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Milk allergy (10027633)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	2	0.2	0.0	0.6

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Multiple allergies (10028164)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Seasonal allergy (10048908)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	0	0.0	0.0	0.3	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Selective iga immunodeficiency (10039915)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Abscess limb (10050473)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Abscess neck (10053576)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acarodermatitis (10063409)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Acute sinusitis (10001076)	7	0.6	0.2	1.2	3	0.2	0.1	0.7	6	0.5	0.2	1.0	16	0.4	0.2	0.7	2	0.2	0.0	0.6
	Adenoiditis (10051223)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Adenovirus infection (10060931)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body tinea (10005913)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	2	0.2	0.0	0.6	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Borrelia infection (10061591)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Bronchiolitis (10006448)	22	1.8	1.1	2.7	30	2.4	1.6	3.5	19	1.5	0.9	2.4	71	1.9	1.5	2.4	27	2.1	1.4	3.0
	Bronchitis (10006451)	30	2.4	1.6	3.4	37	3.0	2.1	4.1	43	3.5	2.5	4.6	110	3.0	2.4	3.6	42	3.3	2.4	4.4
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchitis viral (10053160)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bullous impetigo (10006563)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Burn infection (10051548)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	10	0.8	0.4	1.5	5	0.4	0.1	0.9	3	0.2	0.0	0.7	18	0.5	0.3	0.8	12	0.9	0.5	1.6
	Candida nappy rash (10007135)	12	1.0	0.5	1.7	8	0.6	0.3	1.3	4	0.3	0.1	0.8	24	0.6	0.4	1.0	9	0.7	0.3	1.3
	Cellulitis (10007882)	5	0.4	0.1	0.9	4	0.3	0.1	0.8	8	0.6	0.3	1.3	17	0.5	0.3	0.7	3	0.2	0.0	0.7
	Cellulitis orbital (10007918)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clostridium difficile infection (10054236)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	71	5.7	4.5	7.2	88	7.1	5.8	8.7	86	6.9	5.6	8.5	245	6.6	5.8	7.4	93	7.2	5.9	8.8
	Conjunctivitis bacterial (10061784)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Coxsackie viral infection (10011261)	8	0.6	0.3	1.3	6	0.5	0.2	1.1	5	0.4	0.1	0.9	19	0.5	0.3	0.8	4	0.3	0.1	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Croup infectious (10011416)	28	2.3	1.5	3.2	37	3.0	2.1	4.1	31	2.5	1.7	3.5	96	2.6	2.1	3.1	33	2.6	1.8	3.6
	Cutaneous larva migrans (10059547)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cystitis (10011781)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Diarrhoea infectious (10012742)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Ear infection (10014011)	30	2.4	1.6	3.4	34	2.8	1.9	3.8	18	1.4	0.9	2.3	82	2.2	1.8	2.7	35	2.7	1.9	3.8
	Eczema herpeticum (10014197)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eczema infected (10014199)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Enteritis infectious (10058839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Enterovirus infection (10014909)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	2	0.2	0.0	0.6	7	0.2	0.1	0.4	5	0.4	0.1	0.9
	Epstein-barr virus infection (10015108)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Erythema infectiosum (10015214)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Escherichia urinary tract infection (10052238)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exanthema subitum (10015586)	8	0.6	0.3	1.3	7	0.6	0.2	1.2	4	0.3	0.1	0.8	19	0.5	0.3	0.8	7	0.5	0.2	1.1
	External ear cellulitis (10015729)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye infection (10015929)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	1	0.1	0.0	0.4	6	0.2	0.1	0.4	4	0.3	0.1	0.8
	Folliculitis (10016936)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	5	0.4	0.1	0.9	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Fungal infection (10017533)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Fungal skin infection (10017543)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	5	0.4	0.1	0.9
	Gastroenteritis (10017888)	68	5.5	4.3	6.9	57	4.6	3.5	6.0	61	4.9	3.8	6.3	186	5.0	4.3	5.8	58	4.5	3.4	5.8
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis enteroviral (10017901)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Gastroenteritis viral (10017918)	8	0.6	0.3	1.3	5	0.4	0.1	0.9	4	0.3	0.1	0.8	17	0.5	0.3	0.7	5	0.4	0.1	0.9

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gingivitis (10018292)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Hand-foot-and-mouth disease (10019113)	19	1.5	0.9	2.4	24	1.9	1.3	2.9	20	1.6	1.0	2.5	63	1.7	1.3	2.2	24	1.9	1.2	2.8
	Herpangina (10019936)	8	0.6	0.3	1.3	8	0.6	0.3	1.3	8	0.6	0.3	1.3	24	0.6	0.4	1.0	6	0.5	0.2	1.0
	Herpes dermatitis (10062639)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Herpes simplex (10019948)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Herpes zoster (10019974)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hordeolum (10020377)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Impetigo (10021531)	14	1.1	0.6	1.9	8	0.6	0.3	1.3	5	0.4	0.1	0.9	27	0.7	0.5	1.1	12	0.9	0.5	1.6
	Infected bite (10076911)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Influenza (10022000)	5	0.4	0.1	0.9	12	1.0	0.5	1.7	4	0.3	0.1	0.8	21	0.6	0.4	0.9	8	0.6	0.3	1.2
	Laryngitis (10023874)	14	1.1	0.6	1.9	23	1.9	1.2	2.8	20	1.6	1.0	2.5	57	1.5	1.2	2.0	19	1.5	0.9	2.3
	Lice infestation (10024424)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Localised infection (10024774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Lower respiratory tract infection (10024968)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Lyme disease (10025169)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	3	0.2	0.0	0.7	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Mycoplasma infection (10061300)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Nasopharyngitis (10028810)	105	8.5	7.0	10.2	101	8.2	6.7	9.9	106	8.5	7.0	10.2	312	8.4	7.5	9.3	98	7.6	6.2	9.2
	Neonatal candida infection (10028924)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Neutropenic infection (10059482)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Onychomycosis (10030338)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Oral candidiasis (10030963)	1	0.1	0.0	0.4	4	0.3	0.1	0.8	3	0.2	0.0	0.7	8	0.2	0.1	0.4	6	0.5	0.2	1.0
	Oral herpes (10067152)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	1	0.1	0.0	0.4	7	0.2	0.1	0.4	4	0.3	0.1	0.8
	Oral infection (10048685)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis externa (10033072)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	6	0.5	0.2	1.0
	Otitis media (10033078)	216	17.4	15.4	19.7	220	17.9	15.8	20.1	195	15.7	13.7	17.8	631	17.0	15.8	18.2	247	19.2	17.0	21.4

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	Otitis media acute (10033079)	28	2.3	1.5	3.2	18	1.5	0.9	2.3	38	3.1	2.2	4.2	84	2.3	1.8	2.8	42	3.3	2.4	4.4
	Otitis media chronic (10033081)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Otosalpingitis (10033102)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Parasitic gastroenteritis (10067720)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Paronychia (10034016)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Parotitis (10034038)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Periorbital cellulitis (10057182)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Pertussis (10034738)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pharyngitis (10034835)	65	5.2	4.1	6.6	72	5.8	4.6	7.3	65	5.2	4.1	6.6	202	5.4	4.7	6.2	68	5.3	4.1	6.6
	Pharyngitis bacterial (10057869)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pharyngitis streptococcal (10034839)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	8	0.6	0.3	1.3	16	0.4	0.2	0.7	6	0.5	0.2	1.0
	Pharyngotonsillitis (10049140)	7	0.6	0.2	1.2	5	0.4	0.1	0.9	4	0.3	0.1	0.8	16	0.4	0.2	0.7	7	0.5	0.2	1.1
	Pneumococcal sepsis (10054047)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	12	1.0	0.5	1.7	20	1.6	1.0	2.5	10	0.8	0.4	1.5	42	1.1	0.8	1.5	9	0.7	0.3	1.3
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia viral (10035737)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pyelonephritis (10037596)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pyelonephritis acute (10037597)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pyoderma (10037632)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	2	0.2	0.0	0.6	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Respiratory syncytial virus infection (10061603)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Respiratory tract infection (10062352)	13	1.0	0.6	1.8	16	1.3	0.7	2.1	15	1.2	0.7	2.0	44	1.2	0.9	1.6	16	1.2	0.7	2.0
	Respiratory tract infection viral (10062106)	5	0.4	0.1	0.9	1	0.1	0.0	0.5	1	0.1	0.0	0.4	7	0.2	0.1	0.4	6	0.5	0.2	1.0
	Rhinitis (10039083)	26	2.1	1.4	3.1	20	1.6	1.0	2.5	19	1.5	0.9	2.4	65	1.8	1.4	2.2	33	2.6	1.8	3.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Roseola (10039222)	5	0.4	0.1	0.9	6	0.5	0.2	1.1	6	0.5	0.2	1.0	17	0.5	0.3	0.7	2	0.2	0.0	0.6
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Scarlet fever (10039587)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	4	0.3	0.1	0.8	8	0.2	0.1	0.4	4	0.3	0.1	0.8
	Sinusitis (10040753)	23	1.9	1.2	2.8	11	0.9	0.4	1.6	12	1.0	0.5	1.7	46	1.2	0.9	1.6	17	1.3	0.8	2.1
	Skin bacterial infection (10052891)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin candida (10054152)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	3	0.2	0.0	0.7	9	0.2	0.1	0.5	1	0.1	0.0	0.4
	Skin infection (10040872)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Staphylococcal infection (10058080)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Streptococcal infection (10061372)	2	0.2	0.0	0.6	8	0.6	0.3	1.3	5	0.4	0.1	0.9	15	0.4	0.2	0.7	9	0.7	0.3	1.3
	Subcutaneous abscess (10042343)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Tinea capitis (10043866)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tinea cruris (10043868)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tinea infection (10060889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tinea nigra (10043871)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillitis (10044008)	42	3.4	2.5	4.6	31	2.5	1.7	3.6	32	2.6	1.8	3.6	105	2.8	2.3	3.4	42	3.3	2.4	4.4
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tracheitis (10044302)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Upper respiratory tract infection (10046306)	155	12.5	10.7	14.5	174	14.1	12.2	16.2	169	13.6	11.7	15.6	498	13.4	12.3	14.5	174	13.5	11.7	15.5
	Urethritis (10046480)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary tract infection (10046571)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.4	0.1	0.9	9	0.2	0.1	0.5	7	0.5	0.2	1.1
	Vaginal infection (10046914)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Varicella (10046980)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.2	0.0	0.6	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Viral infection (10047461)	53	4.3	3.2	5.6	48	3.9	2.9	5.1	55	4.4	3.4	5.7	156	4.2	3.6	4.9	47	3.6	2.7	4.8
	Viral pharyngitis (10047473)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	1	0.1	0.0	0.4	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Viral rash (10047476)	11	0.9	0.4	1.6	13	1.1	0.6	1.8	15	1.2	0.7	2.0	39	1.1	0.7	1.4	12	0.9	0.5	1.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral tonsillitis (10047480)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	7	0.6	0.2	1.2	8	0.6	0.3	1.3	9	0.7	0.3	1.4	24	0.6	0.4	1.0	8	0.6	0.3	1.2
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vulvovaginitis (10047794)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Animal bite (10002515)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	3	0.2	0.0	0.7	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Arthropod bite (10003399)	9	0.7	0.3	1.4	11	0.9	0.4	1.6	16	1.3	0.7	2.1	36	1.0	0.7	1.3	11	0.9	0.4	1.5
	Arthropod sting (10003402)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Bite (10004966)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Burns first degree (10006797)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Burns second degree (10006802)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Chemical eye injury (10055116)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Concussion (10010254)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Contusion (10050584)	8	0.6	0.3	1.3	4	0.3	0.1	0.8	6	0.5	0.2	1.0	18	0.5	0.3	0.8	13	1.0	0.5	1.7
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	3	0.2	0.0	0.7
	Craniocerebral injury (10070976)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Ear canal injury (10056319)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear injury (10057446)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye burns (10015911)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye contusion (10073354)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye injury (10061128)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eyelid injury (10069200)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Face injury (10050392)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Fall (10016173)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Foot fracture (10016970)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in eye (10017012)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Gingival injury (10049300)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Head injury (10019196)	10	0.8	0.4	1.5	14	1.1	0.6	1.9	12	1.0	0.5	1.7	36	1.0	0.7	1.3	10	0.8	0.4	1.4
	Heat stroke (10019345)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Humerus fracture (10020462)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injury (10022116)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Joint dislocation (10023204)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Joint injury (10060820)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Laceration (10023572)	8	0.6	0.3	1.3	2	0.2	0.0	0.6	9	0.7	0.3	1.4	19	0.5	0.3	0.8	10	0.8	0.4	1.4
	Ligament sprain (10024453)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Limb crushing injury (10064031)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Limb injury (10061225)	4	0.3	0.1	0.8	2	0.2	0.0	0.6	4	0.3	0.1	0.8	10	0.3	0.1	0.5	3	0.2	0.0	0.7
	Lip injury (10055082)	4	0.3	0.1	0.8	1	0.1	0.0	0.5	5	0.4	0.1	0.9	10	0.3	0.1	0.5	3	0.2	0.0	0.7
	Mouth injury (10049294)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Nail avulsion (10028686)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Poisoning (10061355)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Post vaccination syndrome (10036242)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Procedural pain (10064882)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	3	0.2	0.0	0.7	8	0.2	0.1	0.4	5	0.4	0.1	0.9
	Radius fracture (10037802)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	5	0.4	0.1	0.9	1	0.1	0.0	0.4	6	0.2	0.1	0.4	3	0.2	0.0	0.7
	Skin wound (10072170)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skull fracture (10061365)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Splinter (10041662)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Sunburn (10042496)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	6	0.5	0.2	1.0	11	0.3	0.1	0.5	2	0.2	0.0	0.6
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Upper limb fracture (10061394)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wound (10052428)	1	0.1	0.0	0.4	4	0.3	0.1	0.8	1	0.1	0.0	0.4	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Wrist fracture (10048049)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Investigations (10022891)	Blood lead increased (10005642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body height below normal (10056811)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cardiac murmur (10007586)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Cardiac murmur functional (10007587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight decreased (10047895)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	3	0.2	0.0	0.7
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.2	0.0	0.7	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Dehydration (10012174)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	3	0.2	0.0	0.7	8	0.2	0.1	0.4	6	0.5	0.2	1.0
	Failure to thrive (10016165)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Hypoglycaemia (10020993)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Iron deficiency (10022970)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Lactose intolerance (10023681)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Malnutrition (10061273)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Overweight (10033307)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight gain poor (10047897)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Foot deformity (10061159)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Knee deformity (10062061)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Limb asymmetry (10070670)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain in extremity (10033425)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	1	0.1	0.0	0.4
	Synovial cyst (10042858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Synovitis (10042868)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Toe walking (10068872)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Trigger finger (10044654)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma of skin (10018823)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphangioma (10025219)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mycosis fungoides (10028483)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Skin papilloma (10040907)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Epilepsy (10015037)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Exaggerated startle response (10066482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Febrile convulsion (10016284)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	5	0.4	0.1	0.9	10	0.3	0.1	0.5	8	0.6	0.3	1.2
	Gross motor delay (10069118)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Headache (10019211)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lethargy (10024264)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Loss of consciousness (10024855)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Motor developmental delay (10070302)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Nystagmus (10029864)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Seizure (10039906)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Speech disorder (10041466)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Speech disorder developmental (10041467)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	5	0.4	0.1	0.9	12	0.3	0.2	0.6	2	0.2	0.0	0.6
	Tremor (10044565)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Psychiatric disorders (10037175)	Breath holding (10006322)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Insomnia (10022437)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Irritability (10022998)	7	0.6	0.2	1.2	4	0.3	0.1	0.8	3	0.2	0.0	0.7	14	0.4	0.2	0.6	2	0.2	0.0	0.6
	Pica (10035001)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Sleep disorder (10040984)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Sleep terror (10041010)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
Renal and urinary disorders (10038359)	Dysuria (10013990)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	4	0.3	0.1	0.8	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Haematuria (10018867)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pollakiuria (10036018)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Urinary tract disorder (10046566)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Balanoposthitis (10004078)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	5	0.4	0.1	0.9	12	0.3	0.2	0.6	3	0.2	0.0	0.7
	Bilateral breast buds (10004557)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Genital labial adhesions (10064162)	4	0.3	0.1	0.8	2	0.2	0.0	0.6	1	0.1	0.0	0.4	7	0.2	0.1	0.4	1	0.1	0.0	0.4
	Oedema genital (10030104)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Penile adhesion (10059636)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Perineal cyst (10066058)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prepuce redundant (10036624)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Testicular retraction (10043348)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vulval disorder (10047754)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vulvovaginal discomfort (10047786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Respiratory, thoracic and mediastinal disorders (10038738)	Adenoidal hypertrophy (10001229)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Apnoea (10002974)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Aspiration (10003504)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Asthma (10003553)	5	0.4	0.1	0.9	6	0.5	0.2	1.1	12	1.0	0.5	1.7	23	0.6	0.4	0.9	12	0.9	0.5	1.6
	Bronchial hyperreactivity (10066091)	8	0.6	0.3	1.3	8	0.6	0.3	1.3	9	0.7	0.3	1.4	25	0.7	0.4	1.0	11	0.9	0.4	1.5
	Bronchitis chronic (10006458)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Bronchospasm (10006482)	4	0.3	0.1	0.8	9	0.7	0.3	1.4	7	0.6	0.2	1.2	20	0.5	0.3	0.8	7	0.5	0.2	1.1
	Catarrh (10007774)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	4	0.3	0.1	0.8
	Cough (10011224)	44	3.6	2.6	4.7	38	3.1	2.2	4.2	37	3.0	2.1	4.1	119	3.2	2.7	3.8	55	4.3	3.2	5.5
	Dyspnoea (10013968)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	1	0.1	0.0	0.4	6	0.2	0.1	0.4	3	0.2	0.0	0.7
	Epistaxis (10015090)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Increased bronchial secretion (10062530)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	4	0.3	0.1	0.8	4	0.3	0.1	0.8	6	0.5	0.2	1.0	14	0.4	0.2	0.6	5	0.4	0.1	0.9
	Nasal discomfort (10052437)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Nasal obstruction (10028748)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Oropharyngeal pain (10068319)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Productive cough (10036790)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory disorder (10038683)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis allergic (10039085)	14	1.1	0.6	1.9	10	0.8	0.4	1.5	10	0.8	0.4	1.5	34	0.9	0.6	1.3	12	0.9	0.5	1.6
	Rhinorrhoea (10039101)	3	0.2	0.0	0.7	5	0.4	0.1	0.9	3	0.2	0.0	0.7	11	0.3	0.1	0.5	2	0.2	0.0	0.6
	Stridor (10042241)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tachypnoea (10043089)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillar hypertrophy (10044003)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Upper respiratory tract congestion (10052252)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vasomotor rhinitis (10047145)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	5	0.4	0.1	0.9	19	1.5	0.9	2.4	9	0.7	0.3	1.4	33	0.9	0.6	1.2	6	0.5	0.2	1.0
Skin and subcutaneous tissue disorders (10040785)	Blister (10005191)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dermatitis (10012431)	15	1.2	0.7	2.0	10	0.8	0.4	1.5	7	0.6	0.2	1.2	32	0.9	0.6	1.2	10	0.8	0.4	1.4
	Dermatitis allergic (10012434)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	3	0.2	0.0	0.7
	Dermatitis atopic (10012438)	11	0.9	0.4	1.6	19	1.5	0.9	2.4	29	2.3	1.6	3.3	59	1.6	1.2	2.0	16	1.2	0.7	2.0
	Dermatitis contact (10012442)	4	0.3	0.1	0.8	8	0.6	0.3	1.3	6	0.5	0.2	1.0	18	0.5	0.3	0.8	6	0.5	0.2	1.0
	Dermatitis diaper (10012444)	28	2.3	1.5	3.2	29	2.4	1.6	3.4	35	2.8	2.0	3.9	92	2.5	2.0	3.0	43	3.3	2.4	4.5
	Drug eruption (10013687)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dry skin (10013786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dyshidrotic eczema (10013913)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ecchymosis (10014080)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eczema (10014184)	9	0.7	0.3	1.4	4	0.3	0.1	0.8	9	0.7	0.3	1.4	22	0.6	0.4	0.9	19	1.5	0.9	2.3
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Erythema (10015150)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Erythema multiforme (10015218)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Granuloma annulare (10018692)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hair disorder (10019037)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Henoch-schonlein purpura (10019617)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hyperkeratosis (10020649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ingrowing nail (10022013)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Keratosis pilaris (10066295)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Lichen sclerosus (10024434)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Lichen striatus (10066945)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Miliaria (10027627)	6	0.5	0.2	1.1	2	0.2	0.0	0.6	1	0.1	0.0	0.4	9	0.2	0.1	0.5	2	0.2	0.0	0.6
	Nail disorder (10028694)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Onychomalacia (10058673)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pityriasis (10035110)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pityriasis rosea (10035114)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prurigo (10037083)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash (10037844)	17	1.4	0.8	2.2	14	1.1	0.6	1.9	20	1.6	1.0	2.5	51	1.4	1.0	1.8	14	1.1	0.6	1.8
	Rash erythematous (10037855)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rash generalised (10037858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash macular (10037867)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rash maculo-papular (10037868)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash papular (10037876)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash scarlatiniform (10037890)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rash vesicular (10037898)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seborrhoea (10039792)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Seborrhoeic dermatitis (10039793)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Skin burning sensation (10054786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Skin disorder (10040831)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin fissures (10040849)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin hypopigmentation (10040868)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin irritation (10040880)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Skin lesion (10040882)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin mass (10067868)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urticaria (10046735)	13	1.0	0.6	1.8	5	0.4	0.1	0.9	6	0.5	0.2	1.0	24	0.6	0.4	1.0	13	1.0	0.5	1.7
	Urticaria vesiculosa (10046755)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Vitiligo (10047642)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	1	0.1	0.0	0.4
Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Myringotomy (10028662)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Vascular disorders (10047065)	Haematoma (10018852)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

8.5. Concomitant medications /vaccinations

The number and percentage of subjects who were given a concomitant medication during the 43-day and 15-day post-vaccination reporting periods are given in Table 8.105 and Table 8.113, respectively. Incidences of subjects that were given antipyretics are depicted graphically in Figure 8.4. The highest percentages of antipyretic use were reported on the day of vaccination and within 6-12 days post-vaccination.

8.6. Clinical laboratory evaluations

No clinical laboratory evaluations with regard to safety were performed in this study.

8.7. Analysis by sub-groups

Analysis of safety was based on the TVC. No safety analyses were performed for subjects by gender or geographic ancestry.

8.8. Safety summary

The study results are supportive of an acceptable safety profile of the Inv_MMR study vaccine that is similar to the US standard of care (Com_MMR vaccine) in healthy subjects aged 12 to 15 months of age. Safety results were consistent between the 3 lots of Inv_MMR used in this study. Reactogenicity and safety of the study vaccine was found to be acceptable when co-administered with VV, HAV and PCV-13 (in the US), and also in line with what has been previously reported for Inv_MMR globally.

- Overall, during the 43-day post-vaccination period, at least one solicited or unsolicited symptom was reported by 84.1% of subjects in the Inv_MMR group and by 85.3% in the Com_MMR group. General symptoms were reported by 80.5% and 82.3% of subjects in Inv_MMR and Com_MMR groups, respectively. Local symptoms were reported by 40.2% and 41.9% of subjects in the Inv_MMR and Com_MMR groups, respectively.
- Within the 4-day post-vaccination period, the most frequently reported solicited local symptoms in the Inv_MMR and Com_MMR groups were pain (25.9% and 28.1%) and redness (24.5% and 25.2%), respectively. Solicited local symptoms of grade 3 were reported in up to 1.0% of subjects in any group.
- Within the 15-day post-vaccination period, the most commonly reported general symptom in the Inv_MMR group and Com_MMR groups was irritability or fussiness reported in 63.3% and 65.9% of subjects respectively. This was followed by drowsiness (44.9% and 47.1%) and loss of appetite (45.1% and 44.1%). Solicited general AEs of grade 3 were reported in a maximum of 4.9% of subjects in the Inv_MMR and Com_MMR groups.
- Within the 43-day post-vaccination period, the following solicited general symptoms were reported in both the Inv_MMR and Com_MMR groups, respectively: fever ≥ 38.0°C/100.4°F (34.7% and 33.1%), rash (29.2% and 30.4%) and febrile convulsions

(10 subjects [0.3%] and 3 subjects [0.2%]; 4 of these 10 events in the Inv_MMR group and 2 of the 3 events in the Com_MMR group were considered related to vaccination). No subject reported parotid gland swelling in any of the groups.

- Within the 43-day post-vaccination period, 50.0% of subjects in the Inv_MMR group and 47.9% in the Com_MMR group reported at least one unsolicited AE. The most common AE by MedDRA preferred term was upper respiratory tract infection, reported in 9.5% of subjects in both the Inv_MMR and Com_MMR groups.
- During the entire study period, 102 subjects reported one or more SAEs in this study. A total of 98 SAEs were reported in 77 subjects (2.1%) in the Inv_MMR group and 40 were reported in 25 subjects (1.9%) in the Com_MMR group. Two of these SAEs in the Inv_MMR group were considered by the investigator to be related to the study vaccination. One subject in the Inv_MMR_2 group had gastroenteritis, and another subject in the Inv_MMR_3 group had febrile convulsion. There were no fatal SAEs in the study.
- The most frequently occurring SAE during the study period was bronchitis reported by 8 subjects (0.2%) in the Inv_MMR group and by 2 subjects (0.2%) in the Com_MMR group.
- Two subjects were withdrawn from the study due to an AE.

9. OVERALL CONCLUSIONS

All co-primary study objectives were met.

The lot-to-lot consistency of the immune response to each of the three vaccine components after one dose of *Priorix*, out of three consistency lots, was demonstrated:

- All 95% CIs for the pair-wise lot differences in seroresponse rates were between -5% and +5% for anti-measles, anti-mumps, and anti-rubella antibodies.
- All 95% CIs for the pair-wise adjusted GMC ratios were between 0.67 and 1.50 for anti-measles, anti-mumps, and anti-rubella antibodies.

Non-inferiority of the immune response of the Inv_MMR lots versus *M-M-R-II* was demonstrated:

- The lower limit of the 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps, and anti-rubella antibodies.
- The lower limit of the 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps, and anti-rubella antibodies.

The acceptability of the immune response of the Inv_MMR lots was demonstrated:

- The lower limit of the 95% CI for the seroresponse rate in the Inv_MMR group was ≥90% for anti-measles, anti-mumps, and anti-rubella antibodies.

All secondary study objectives related to immunogenicity were met.

Non-inferiority of the immune response of the Inv_MMR lots versus Com_MMR lots, in terms of co-administered vaccines, was demonstrated:

- The lower limit of the two-sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies.
- The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies.
- The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV.
- The lower limit of the two-sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to each of the 13 *S. pneumoniae* serotypes.

An acceptable safety profile was observed for the Inv_MMR groups when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US) which was similar to that observed with Com_MMR.

10. REFERENCES

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11. STUDY REPORT AUTHORS /CONTRIBUTING AUTHORS

Scientific Writers: PPD PPD PPD

Statistician(s): PPD

Study Delivery Lead/Study Delivery Manager: PPD PPD

Central Safety Contact: PPD

Clinical Research and Development Lead: PPD

Regulatory Affairs representative: PPD

N + 1 of Clinical Research and Development Lead: PPD

12. SERIOUS ADVERSE EVENTS / OTHER SIGNIFICANT ADVERSE EVENTS

12.1. SAE Listing(s)

The listing of individual SAEs that were reported during the course of this study is found in Table 8.136.

13. POST-TEXT TABLES AND FIGURES

Table 6.1 Number of subjects by center (Total vaccinated cohort)

	INV_MMR_1	INV_MMR_2	INV_MMR_3	INV_MMR	COM_MMR	Total	
Center	n	n	n	n	n	n	%
PPD	10	10	10	30	10	40	0.8
	8	7	6	21	8	29	0.6
	4	5	4	13	5	18	0.4
	38	37	37	112	38	150	3.0
	8	7	7	22	8	30	0.6
	12	12	12	36	12	48	1.0
	7	8	8	23	9	32	0.6
	4	3	3	10	3	13	0.3
	11	11	11	33	12	45	0.9
	1	0	1	2	2	4	0.1
	14	13	13	40	14	54	1.1
	20	20	20	60	20	80	1.6
	11	10	11	32	12	44	0.9
	21	21	20	62	21	83	1.7
	2	0	1	3	2	5	0.1
	12	12	12	36	14	50	1.0
	5	4	5	14	6	20	0.4
	8	9	9	26	8	34	0.7
	4	5	4	13	5	18	0.4
	7	7	6	20	7	27	0.5
	1	2	3	6	2	8	0.2
	22	21	22	65	22	87	1.7
	8	8	7	23	8	31	0.6
	7	6	7	20	7	27	0.5
	6	6	6	18	6	24	0.5
	9	9	9	27	10	37	0.7
	16	15	16	47	16	63	1.3
	10	10	11	31	11	42	0.8
	8	9	9	26	9	35	0.7
	2	2	2	6	4	10	0.2
	6	8	7	21	8	29	0.6
	0	0	1	1	1	2	0.0
	1	0	1	2	2	4	0.1
	8	8	9	25	8	33	0.7
	1	1	1	3	2	5	0.1
	4	4	5	13	4	17	0.3
	9	10	10	29	10	39	0.8
	26	26	25	77	26	103	2.1
	8	8	9	25	8	33	0.7
	6	6	6	18	8	26	0.5
	13	14	13	40	14	54	1.1
	0	0	0	0	1	1	0.0
	45	42	42	129	43	172	3.4
	49	50	50	149	50	199	4.0
	25	26	25	76	26	102	2.0
	24	24	24	72	24	96	1.9
	32	31	32	95	32	127	2.5
	35	35	36	106	36	142	2.8
	28	28	28	84	29	113	2.3
	36	36	36	108	36	144	2.9
	12	12	12	36	12	48	1.0
	26	25	26	77	26	103	2.1

	INV_MMR_1	INV_MMR_2	INV_MMR_3	INV_MMR	COM_MMR	Total	
Center	n	n	n	n	n	n	%
PPD	26	26	26	78	26	104	2.1
	1	2	2	5	2	7	0.1
	80	79	80	239	80	319	6.4
	12	12	12	36	12	48	1.0
	14	15	15	44	16	60	1.2
	11	11	10	32	11	43	0.9
	6	6	6	18	6	24	0.5
	0	0	1	1	0	1	0.0
	82	82	83	247	83	330	6.6
	4	4	4	12	4	16	0.3
	7	7	8	22	8	30	0.6
	13	14	15	42	14	56	1.1
	10	9	9	28	10	38	0.8
	12	12	13	37	13	50	1.0
	16	16	16	48	16	64	1.3
	34	33	33	100	34	134	2.7
	42	42	42	126	43	169	3.4
	30	29	29	88	30	118	2.4
	21	21	20	62	21	83	1.7
	14	15	14	43	14	57	1.1
	6	6	6	18	7	25	0.5
	6	6	5	17	7	24	0.5
	10	10	10	30	10	40	0.8
	5	4	5	14	6	20	0.4
	2	2	3	7	2	9	0.2
	16	15	16	47	16	63	1.3
	0	1	0	1	0	1	0.0
	4	5	5	14	6	20	0.4
	10	10	10	30	10	40	0.8
	5	5	5	15	6	21	0.4
	9	9	9	27	10	37	0.7
	1	2	2	5	3	8	0.2
	15	14	15	44	15	59	1.2
	5	5	5	15	6	21	0.4
	5	5	4	14	6	20	0.4
	4	5	5	14	6	20	0.4
	1	2	2	5	2	7	0.1
	3	2	2	7	3	10	0.2
	4	3	3	10	4	14	0.3
	3	3	3	9	4	13	0.3
All	1239	1232	1243	3714	1289	5003	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
n = number of subjects included in each group or in total for a given center or for all centers
All = sum of all subjects in each group or in total (sum of all groups)
% = n/All x 100
Center = GSK Biologicals assigned center number

Table 6.2 Number of subjects at each visit and list of withdrawn subjects (Total vaccinated cohort)

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
INV_MMR_1	VISIT 1 (D0)	1239		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Protocol violation
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Protocol violation
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				Non-serious adverse event
				Non-serious adverse event

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Migrated / moved from the study area
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up*Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
	VISIT 2 (D42)	1199		
			PPD	PARENTS TO BUSY. SPOKE TO MOTHER. INFO FROM HEALTH CONNECT
				LOST HEALTH PLAN
				Lost to follow-up
				Protocol violation
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				LOST HEALTH PLAN
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				BY JOB AND PERSONAL REASONS THE PARENTS CAN NOT ASSIST TO THE SITE
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				LOST HEALTH PLAN

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
	VISIT 3 (D180)	1175		
INV_MMR_2	VISIT 1 (D0)	1232		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
	VISIT 2 (D42)	1192		
			PPD	LOST HEALTH PLAN
				LOST HEALTH PLAN
				LOST HEALTH PLAN
				LOST HEALTH PLAN
				LOST HEALTH PLAN
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				MOTHER TRANSFERRED CARE AND DID NOT WANT TO COME IN BUT REVIEWED AE'S
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
	VISIT 3 (D180)	1162		
INV_MMR_3	VISIT 1 (D0)	1243		
			PPD	Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
	VISIT 2 (D42)	1211		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Protocol violation
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				BY LACK OF TIME, THE MOTHER CAN NOT ASSIST WITH THE SUBJECT TO THE SITE
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
	VISIT 3 (D180)	1190		
COM_MMR	VISIT 1 (D0)	1289		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
	VISIT 2 (D42)	1258		
			PPD	LOST HEALTH PLAN
				LOST COVERAGE
				LOST HEALTH PLAN
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
	VISIT 3 (D180)	1232		

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
N = Number of subjects who are still in the study up to the visit
Withdrawn = Subject who did not return after the visit

Table 6.3 Deviations from specifications for age and intervals between study visits (Total vaccinated cohort)

		Age	Dose:1-PI(D42)	VISIT 1 (D0)-VISIT 3 (D180)
Group		**Protocol**	**Protocol**	**Protocol**
		from 12 to 15 months	from 35 to 77 days	from 180 to 210 days
INV_MMR_1	N	1239	1166	1175
	n	1	8	51
	%	0.1	0.7	4.3
	range	12 to 16	35 to 160	137 to 337
INV_MMR_2	N	1232	1160	1162
	n	0	10	46
	%	0.0	0.9	4.0
	range	12 to 15	35 to 119	99 to 313
INV_MMR_3	N	1243	1183	1190
	n	1	11	51
	%	0.1	0.9	4.3
	range	12 to 16	35 to 243	152 to 264
COM_MMR	N	1289	1220	1232
	n	1	13	59
	%	0.1	1.1	4.8
	range	11 to 15	29 to 126	88 to 355

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Dose: 1 = study dose 1 received at Day 0
PI(D42) = Day 42 post-vaccination
N = total number of subjects with available results
n/% = number / percentage of subjects with results outside of the interval
range = minimum-maximum for age and intervals

Table 6.4 Study population (Total vaccinated cohort)

Number of subjects	INV_MMR_1	INV_MMR_2	INV_MMR_3	COM_MMR	Total
Planned, N	1250	1250	1250	1250	5000
Randomised, N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Completed, n (%)	1175 (94.8)	1162 (94.3)	1190 (95.7)	1232 (95.6)	4759 (95.1)
Demographics	INV_MMR_1	INV_MMR_2	INV_MMR_3	COM_MMR	Total
N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Females:Males	607:632	594:638	615:628	618:671	2434:2569
Mean Age, months (SD)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)
Median Age, months (minimum, maximum)	12 (12, 16)	12 (12, 15)	12 (12, 16)	12 (11, 15)	12 (11, 16)
White - Caucasian / European Heritage, n (%)	932 (75.2)	938 (76.1)	944 (75.9)	970 (75.3)	3784 (75.6)
Other, n (%)	170 (13.7)	155 (12.6)	162 (13.0)	163 (12.6)	650 (13.0)
African Heritage / African American, n (%)	60 (4.8)	52 (4.2)	57 (4.6)	70 (5.4)	239 (4.8)

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR

Table 6.5 Summary of demographic characteristics (Total vaccinated cohort)

		INV_MMR_1 N = 1239		INV_MMR_2 N = 1232		INV_MMR_3 N = 1243		INV_MMR N = 3714		COM_MMR N = 1289		Total N = 5003	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	11	-	11	-
	Maximum	16	-	15	-	16	-	16	-	15	-	16	-
Gender	Female	607	49.0	594	48.2	615	49.5	1816	48.9	618	47.9	2434	48.7
	Male	632	51.0	638	51.8	628	50.5	1898	51.1	671	52.1	2569	51.3
Ethnicity	American hispanic or latino	219	17.7	239	19.4	234	18.8	692	18.6	240	18.6	932	18.6
	Not american hispanic or latino	1020	82.3	993	80.6	1009	81.2	3022	81.4	1049	81.4	4071	81.4
Geographic Ancestry	African Heritage / African American	60	4.8	52	4.2	57	4.6	169	4.6	70	5.4	239	4.8
	American Indian or Alaskan Native	25	2.0	37	3.0	33	2.7	95	2.6	31	2.4	126	2.5
	Asian - Central/South Asian Heritage	14	1.1	6	0.5	7	0.6	27	0.7	9	0.7	36	0.7
	Asian - East Asian Heritage	8	0.6	10	0.8	10	0.8	28	0.8	10	0.8	38	0.8
	Asian - Japanese Heritage	1	0.1	2	0.2	2	0.2	5	0.1	1	0.1	6	0.1
	Asian - South East Asian Heritage	21	1.7	25	2.0	21	1.7	67	1.8	26	2.0	93	1.9
	Native Hawaiian or Other Pacific Islander	3	0.2	1	0.1	5	0.4	9	0.2	2	0.2	11	0.2
	White - Arabic / North African Heritage	5	0.4	6	0.5	2	0.2	13	0.4	7	0.5	20	0.4
	White - Caucasian / European Heritage	932	75.2	938	76.1	944	75.9	2814	75.8	970	75.3	3784	75.6
	Other	170	13.7	155	12.6	162	13.0	487	13.1	163	12.6	650	13.0
Country	Estonia	124	10.0	125	10.1	125	10.1	374	10.1	127	9.9	501	10.0
	Spain	61	4.9	62	5.0	64	5.1	187	5.0	69	5.4	256	5.1
	Finland	338	27.3	335	27.2	337	27.1	1010	27.2	340	26.4	1350	27.0
	Mexico	98	7.9	98	8.0	99	8.0	295	7.9	99	7.7	394	7.9
	United States	618	49.9	612	49.7	618	49.7	1848	49.8	654	50.7	2502	50.0
Subset	VZV and HAV subset	309	24.9	306	24.8	308	24.8	923	24.9	334	25.9	1257	25.1
	VZV and PCV subset	306	24.7	302	24.5	306	24.6	914	24.6	317	24.6	1231	24.6
	Not in subset	624	50.4	624	50.6	629	50.6	1877	50.5	638	49.5	2515	50.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.6 Summary of demographic characteristics (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124		INV_MMR_2 N = 125		INV_MMR_3 N = 125		INV_MMR N = 374		COM_MMR N = 127		Total N = 501	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.8	-	12.8	-	12.8	-	12.8	-	12.8	-	12.8	-
	SD	1.0	-	1.0	-	1.0	-	1.0	-	0.9	-	1.0	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	16	-	15	-	16	-	16	-	15	-	16	-
Gender	Female	71	57.3	54	43.2	68	54.4	193	51.6	57	44.9	250	49.9
	Male	53	42.7	71	56.8	57	45.6	181	48.4	70	55.1	251	50.1
Ethnicity	American hispanic or latino	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not american hispanic or latino	124	100	125	100	125	100	374	100	127	100	501	100
Geographic Ancestry	African Heritage / African American	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	1	0.8	0	0.0	1	0.3	0	0.0	1	0.2
	White - Caucasian / European Heritage	124	100	124	99.2	125	100	373	99.7	127	100	500	99.8
	Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Country	Estonia	124	100	125	100	125	100	374	100	127	100	501	100
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	124	100	125	100	125	100	374	100	127	100	501	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.7 Summary of demographic characteristics (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61		INV_MMR_2 N = 62		INV_MMR_3 N = 64		INV_MMR N = 187		COM_MMR N = 69		Total N = 256	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.2	-	12.1	-	12.2	-	12.1	-	12.1	-	12.1	-
	SD	0.5	-	0.3	-	0.4	-	0.4	-	0.4	-	0.4	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	11	-	11	-
	Maximum	14	-	13	-	14	-	14	-	13	-	14	-
Gender	Female	34	55.7	36	58.1	27	42.2	97	51.9	38	55.1	135	52.7
	Male	27	44.3	26	41.9	37	57.8	90	48.1	31	44.9	121	47.3
Ethnicity	American hispanic or latino	3	4.9	3	4.8	1	1.6	7	3.7	2	2.9	9	3.5
	Not american hispanic or latino	58	95.1	59	95.2	63	98.4	180	96.3	67	97.1	247	96.5
Geographic Ancestry	African Heritage / African American	1	1.6	1	1.6	0	0.0	2	1.1	0	0.0	2	0.8
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	3	4.9	0	0.0	1	1.6	4	2.1	0	0.0	4	1.6
	Asian - East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	1	1.6	0	0.0	0	0.0	1	0.5	0	0.0	1	0.4
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	1	1.6	1	1.6	0	0.0	2	1.1	2	2.9	4	1.6
	White - Caucasian / European Heritage	52	85.2	57	91.9	62	96.9	171	91.4	66	95.7	237	92.6
	Other	3	4.9	3	4.8	1	1.6	7	3.7	1	1.4	8	3.1
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	61	100	62	100	64	100	187	100	69	100	256	100
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	61	100	62	100	64	100	187	100	69	100	256	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.8 Summary of demographic characteristics (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338		INV_MMR_2 N = 335		INV_MMR_3 N = 337		INV_MMR N = 1010		COM_MMR N = 340		Total N = 1350	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.4	-	12.5	-	12.4	-	12.4	-	12.4	-	12.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	167	49.4	142	42.4	157	46.6	466	46.1	164	48.2	630	46.7
	Male	171	50.6	193	57.6	180	53.4	544	53.9	176	51.8	720	53.3
Ethnicity	American hispanic or latino	0	0.0	1	0.3	0	0.0	1	0.1	1	0.3	2	0.1
	Not american hispanic or latino	338	100	334	99.7	337	100	1009	99.9	339	99.7	1348	99.9
Geographic Ancestry	African Heritage / African American	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	0	0.0	0	0.0	1	0.3	1	0.1	0	0.0	1	0.1
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3	1	0.1
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	0	0.0	2	0.6	2	0.2	1	0.3	3	0.2
	White - Caucasian / European Heritage	329	97.3	329	98.2	329	97.6	987	97.7	333	97.9	1320	97.8
	Other	9	2.7	6	1.8	5	1.5	20	2.0	5	1.5	25	1.9
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	338	100	335	100	337	100	1010	100	340	100	1350	100
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	338	100	335	100	337	100	1010	100	340	100	1350	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.9 Summary of demographic characteristics (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98		INV_MMR_2 N = 98		INV_MMR_3 N = 99		INV_MMR N = 295		COM_MMR N = 99		Total N = 394	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.3	-	12.3	-	12.3	-	12.3	-	12.4	-	12.3	-
	SD	0.6	-	0.7	-	0.6	-	0.6	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	45	45.9	40	40.8	48	48.5	133	45.1	50	50.5	183	46.4
	Male	53	54.1	58	59.2	51	51.5	162	54.9	49	49.5	211	53.6
Ethnicity	American hispanic or latino	98	100	95	96.9	99	100	292	99.0	97	98.0	389	98.7
	Not american hispanic or latino	0	0.0	3	3.1	0	0.0	3	1.0	2	2.0	5	1.3
Geographic Ancestry	African Heritage / African American	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Caucasian / European Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Other	98	100	98	100	99	100	295	100	99	100	394	100
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	98	100	98	100	99	100	295	100	99	100	394	100
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	98	100	98	100	99	100	295	100	99	100	394	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.10 Summary of demographic characteristics (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618		INV_MMR_2 N = 612		INV_MMR_3 N = 618		INV_MMR N = 1848		COM_MMR N = 654		Total N = 2502	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.2	-	12.2	-	12.2	-	12.2	-	12.2	-	12.2	-
	SD	0.6	-	0.5	-	0.6	-	0.5	-	0.5	-	0.5	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	290	46.9	322	52.6	315	51.0	927	50.2	309	47.2	1236	49.4
	Male	328	53.1	290	47.4	303	49.0	921	49.8	345	52.8	1266	50.6
Ethnicity	American hispanic or latino	118	19.1	140	22.9	134	21.7	392	21.2	140	21.4	532	21.3
	Not american hispanic or latino	500	80.9	472	77.1	484	78.3	1456	78.8	514	78.6	1970	78.7
Geographic Ancestry	African Heritage / African American	59	9.5	51	8.3	57	9.2	167	9.0	70	10.7	237	9.5
	American Indian or Alaskan Native	25	4.0	37	6.0	33	5.3	95	5.1	31	4.7	126	5.0
	Asian - Central/South Asian Heritage	11	1.8	6	1.0	6	1.0	23	1.2	9	1.4	32	1.3
	Asian - East Asian Heritage	8	1.3	10	1.6	9	1.5	27	1.5	10	1.5	37	1.5
	Asian - Japanese Heritage	1	0.2	2	0.3	2	0.3	5	0.3	1	0.2	6	0.2
	Asian - South East Asian Heritage	20	3.2	25	4.1	21	3.4	66	3.6	25	3.8	91	3.6
	Native Hawaiian or Other Pacific Islander	3	0.5	1	0.2	5	0.8	9	0.5	2	0.3	11	0.4
	White - Arabic / North African Heritage	4	0.6	4	0.7	0	0.0	8	0.4	4	0.6	12	0.5
	White - Caucasian / European Heritage	427	69.1	428	69.9	428	69.3	1283	69.4	444	67.9	1727	69.0
	Other	60	9.7	48	7.8	57	9.2	165	8.9	58	8.9	223	8.9
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	618	100	612	100	618	100	1848	100	654	100	2502	100
Subset	VZV and HAV subset	309	50.0	306	50.0	308	49.8	923	49.9	334	51.1	1257	50.2
	VZV and PCV subset	306	49.5	302	49.3	306	49.5	914	49.5	317	48.5	1231	49.2
	Not in subset	3	0.5	4	0.7	4	0.6	11	0.6	3	0.5	14	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.11 Time between visits/vaccinations/blood samples (Total vaccinated cohort)

		INV_MMR_1 N = 1239	INV_MMR_2 N = 1232	INV_MMR_3 N = 1243	COM_MMR N = 1289	Total N = 5003
Characteristics	**Parameters**	**Value**	**Value**	**Value**	**Value**	**Value**
Time[Days] Dose:1-*PI[D42]	N	1166	1160	1183	1220	4729
	Mean	48.5	48.2	48.3	48.0	48.2
	SD	9.2	8.4	10.4	9.1	9.3
	Minimum	35.0	35.0	35.0	29.0	29.0
	Maximum	160.0	119.0	243.0	126.0	243.0
	Missing	73	72	60	69	274

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
PI(D42) = Post-vaccination blood sample at Day 42
Value = value of the considered parameter
SD = Standard deviation

Table 7.1 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity)

		INV_MMR_1 N=1108		INV_MMR_2 N=1098		INV_MMR_3 N=1130		INV_MMR N=3336		COM_MMR N=1162		Total N=4498	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	1090	99.9	1085	100	1112	100	3287	100	1147	100	4434	100
	S+	1	0.1	0	0.0	0	0.0	1	0.0	0	0.0	1	0.0
	Unknown	17	.	13	.	18	.	48	.	15	.	63	.
anti-Mumps (PPD) antibody (EU/mL)	S-	1062	95.8	1047	95.4	1078	95.4	3187	95.5	1107	95.3	4294	95.5
	S+	46	4.2	51	4.6	52	4.6	149	4.5	55	4.7	204	4.5
anti-Rubella antibody (IU/mL)	S-	1090	99.9	1083	99.8	1111	99.9	3284	99.9	1146	99.9	4430	99.9
	S+	1	0.1	2	0.2	1	0.1	4	0.1	1	0.1	5	0.1
	Unknown	17	.	13	.	18	.	48	.	15	.	63	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.2 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Estonia)

		INV_MMR_1 N=115		INV_MMR_2 N=115		INV_MMR_3 N=119		INV_MMR N=349		COM_MMR N=119		Total N=468	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	110	100	114	100	116	100	340	100	114	100	454	100
	Unknown	5	.	1	.	3	.	9	.	5	.	14	.
anti-Mumps (PPD) antibody (EU/mL)	S-	111	96.5	110	95.7	114	95.8	335	96.0	114	95.8	449	95.9
	S+	4	3.5	5	4.3	5	4.2	14	4.0	5	4.2	19	4.1
anti-Rubella antibody (IU/mL)	S-	110	100	114	100	116	100	340	100	114	100	454	100
	Unknown	5	.	1	.	3	.	9	.	5	.	14	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.3 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Spain)

		INV_MMR_1 N=56		INV_MMR_2 N=56		INV_MMR_3 N=55		INV_MMR N=167		COM_MMR N=61		Total N=228	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	52	98.1	54	100	55	100	161	99.4	60	100	221	99.5
	S+	1	1.9	0	0.0	0	0.0	1	0.6	0	0.0	1	0.5
	Unknown	3	.	2	.	-	.	5	.	1	.	6	.
anti-Mumps (PPD) antibody (EU/mL)	S-	53	94.6	54	96.4	52	94.5	159	95.2	57	93.4	216	94.7
	S+	3	5.4	2	3.6	3	5.5	8	4.8	4	6.6	12	5.3
anti-Rubella antibody (IU/mL)	S-	53	100	54	100	55	100	162	100	60	100	222	100
	Unknown	3	.	2	.	-	.	5	.	1	.	6	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.4 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Finland)

		INV_MMR_1 N=326		INV_MMR_2 N=318		INV_MMR_3 N=330		INV_MMR N=974		COM_MMR N=330		Total N=1304	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	324	100	317	100	330	100	971	100	330	100	1301	100
	Unknown	2	.	1	.	-	.	3	.	-	.	3	.
anti-Mumps (PPD) antibody (EU/mL)	S-	317	97.2	310	97.5	320	97.0	947	97.2	327	99.1	1274	97.7
	S+	9	2.8	8	2.5	10	3.0	27	2.8	3	0.9	30	2.3
anti-Rubella antibody (IU/mL)	S-	324	100	317	100	330	100	971	100	329	99.7	1300	99.9
	S+	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3	1	0.1
	Unknown	2	.	1	.	-	.	3	.	-	.	3	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.5 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Mexico)

		INV_MMR_1 N=86		INV_MMR_2 N=93		INV_MMR_3 N=94		INV_MMR N=273		COM_MMR N=93		Total N=366	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	86	100	93	100	93	100	272	100	93	100	365	100
	Unknown	-	.	-	.	1	.	1	.	-	.	1	.
anti-Mumps (PPD) antibody (EU/mL)	S-	84	97.7	87	93.5	87	92.6	258	94.5	85	91.4	343	93.7
	S+	2	2.3	6	6.5	7	7.4	15	5.5	8	8.6	23	6.3
anti-Rubella antibody (IU/mL)	S-	86	100	92	98.9	93	100	271	99.6	93	100	364	99.7
	S+	0	0.0	1	1.1	0	0.0	1	0.4	0	0.0	1	0.3
	Unknown	-	.	-	.	1	.	1	.	-	.	1	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.6 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, United States)

		INV_MMR_1 N=525		INV_MMR_2 N=516		INV_MMR_3 N=532		INV_MMR N=1573		COM_MMR N=559		Total N=2132	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	518	100	507	100	518	100	1543	100	550	100	2093	100
	Unknown	7	.	9	.	14	.	30	.	9	.	39	.
anti-Mumps (PPD) antibody (EU/mL)	S-	497	94.7	486	94.2	505	94.9	1488	94.6	524	93.7	2012	94.4
	S+	28	5.3	30	5.8	27	5.1	85	5.4	35	6.3	120	5.6
anti-Rubella antibody (IU/mL)	S-	517	99.8	506	99.8	517	99.8	1540	99.8	550	100	2090	99.9
	S+	1	0.2	1	0.2	1	0.2	3	0.2	0	0.0	3	0.1
	Unknown	7	.	9	.	14	.	30	.	9	.	39	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.7 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, by gender)

		INV_MMR_1				INV_MMR_2				INV_MMR_3				INV_MMR			
		F N= 542		M N= 566		F N= 529		M N= 569		F N= 550		M N= 580		F N= 1621		M N= 1715	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	532	99.8	558	100	520	100	565	100	542	100	570	100	1594	99.9	1693	100
	S+	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1	0	0.0
	Unknown	9	.	8	.	9	.	4	.	8	.	10	.	26	.	22	.
anti-Mumps (PPD) antibody (EU/mL)	S-	517	95.4	545	96.3	502	94.9	545	95.8	523	95.1	555	95.7	1542	95.1	1645	95.9
	S+	25	4.6	21	3.7	27	5.1	24	4.2	27	4.9	25	4.3	79	4.9	70	4.1
anti-Rubella antibody (IU/mL)	S-	533	100	557	99.8	519	99.8	564	99.8	541	99.8	570	100	1593	99.9	1691	99.9
	S+	0	0.0	1	0.2	1	0.2	1	0.2	1	0.2	0	0.0	2	0.1	2	0.1
	Unknown	9	.	8	.	9	.	4	.	8	.	10	.	26	.	22	.

		COM_MMR				Total			
		F N= 562		M N= 600		F N= 2183		M N= 2315	
		n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	554	100	593	100	2148	100	2286	100
	S+	0	0.0	0	0.0	1	0.0	0	0.0
	Unknown	8	.	7	.	34	.	29	.
anti-Mumps (PPD) antibody (EU/mL)	S-	534	95.0	573	95.5	2076	95.1	2218	95.8
	S+	28	5.0	27	4.5	107	4.9	97	4.2
anti-Rubella antibody (IU/mL)	S-	553	99.8	593	100	2146	99.9	2284	99.9
	S+	1	0.2	0	0.0	3	0.1	2	0.1
	Unknown	8	.	7	.	34	.	29	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male

S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.8 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, by geographic ancestry)

		INV_MMR_1						INV_MMR_2						INV_MMR_3			
		WH N= 847		OT N= 108		AF N= 49		WH N= 841		OT N= 111		AF N= 36		WH N= 869		OT N= 111	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	832	100	107	100	49	100	830	100	111	100	35	100	855	100	110	100
	Unknown	15	.	1	.	-	.	11	.	-	.	1	.	14	.	1	.
anti-Mumps (PPD) antibody (EU/mL)	S-	814	96.1	106	98.1	45	91.8	800	95.1	105	94.6	35	97.2	836	96.2	102	91.9
	S+	33	3.9	2	1.9	4	8.2	41	4.9	6	5.4	1	2.8	33	3.8	9	8.1
anti-Rubella antibody (IU/mL)	S-	831	99.9	107	100	49	100	830	100	110	99.1	35	100	854	99.9	110	100
	S+	1	0.1	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.1	0	0.0
	Unknown	15	.	1	.	-	.	11	.	-	.	1	.	14	.	1	.

		INV_MMR_3		INV_MMR						COM_MMR						Total	
		AF N= 44		WH N= 2557		OT N= 330		AF N= 129		WH N= 889		OT N= 114		AF N= 56		WH N= 3446	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	41	100	2517	100	328	100	125	100	875	100	114	100	55	100	3392	100
	Unknown	3	.	40	.	2	.	4	.	14	.	-	.	1	.	54	.
anti-Mumps (PPD) antibody (EU/mL)	S-	41	93.2	2450	95.8	313	94.8	121	93.8	850	95.6	105	92.1	54	96.4	3300	95.8
	S+	3	6.8	107	4.2	17	5.2	8	6.2	39	4.4	9	7.9	2	3.6	146	4.2
anti-Rubella antibody (IU/mL)	S-	41	100	2515	99.9	327	99.7	125	100	874	99.9	114	100	55	100	3389	99.9
	S+	0	0.0	2	0.1	1	0.3	0	0.0	1	0.1	0	0.0	0	0.0	3	0.1
	Unknown	3	.	40	.	2	.	4	.	14	.	-	.	1	.	54	.

		Total			
		OT N= 444		AF N= 185	
		n	%	n	%
anti-Measles antibody (mIU/mL)	S-	442	100	180	100
	Unknown	2	.	5	.
anti-Mumps (PPD) antibody (EU/mL)	S-	418	94.1	175	94.6
	S+	26	5.9	10	5.4
anti-Rubella antibody (IU/mL)	S-	441	99.8	180	100
	S+	1	0.2	0	0.0
	Unknown	2	.	5	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.9 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Measles antibody	INV_MMR_1	PI(D42)	1083	1064	98.2	97.3	98.9	1062	98.1	97.1	98.8	2970.3	2813.2	3136.2
	INV_MMR_2	PI(D42)	1069	1057	98.9	98.0	99.4	1054	98.6	97.7	99.2	3023.6	2864.5	3191.6
	INV_MMR_3	PI(D42)	1096	1075	98.1	97.1	98.8	1072	97.8	96.8	98.6	3058.3	2893.9	3232.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.10 Difference between groups (INV_MMR_1 minus INV_MMR_2) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_2)		
		INV_MMR_1			INV_MMR_2				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	1083	1062	98.1	1069	1054	98.6	-0.54	-1.69	0.58

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.11 Difference between groups (INV_MMR_1 minus INV_MMR_3) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_3)		
		INV_MMR_1			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	1083	1062	98.1	1096	1072	97.8	0.25	-0.98	1.50

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.12 Difference between groups (INV_MMR_2 minus INV_MMR_3) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_2 minus INV_MMR_3)		
		INV_MMR_2			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	1069	1054	98.6	1096	1072	97.8	0.79	-0.35	1.98

INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.13 Ratios of Anti-Measles antibody GMCs at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

						Adjusted GMC ratio			
								95% CI	
Group description	N	Adjusted GMC	Group description	N	Adjusted GMC	Ratio order	Value	LL	UL
INV_MMR_1	1083	3128.5	INV_MMR_2	1069	3174.4	INV_MMR_1 /INV_MMR_2	0.99	0.91	1.06
INV_MMR_1	1083	3128.5	INV_MMR_3	1096	3217.7	INV_MMR_1 /INV_MMR_3	0.97	0.90	1.05
INV_MMR_2	1069	3174.4	INV_MMR_1	1083	3128.5	INV_MMR_2 /INV_MMR_1	1.01	0.94	1.09
INV_MMR_2	1069	3174.4	INV_MMR_3	1096	3217.7	INV_MMR_2 /INV_MMR_3	0.99	0.91	1.06
INV_MMR_3	1096	3217.7	INV_MMR_1	1083	3128.5	INV_MMR_3 /INV_MMR_1	1.03	0.95	1.11
INV_MMR_3	1096	3217.7	INV_MMR_2	1069	3174.4	INV_MMR_3 /INV_MMR_2	1.01	0.94	1.09

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit

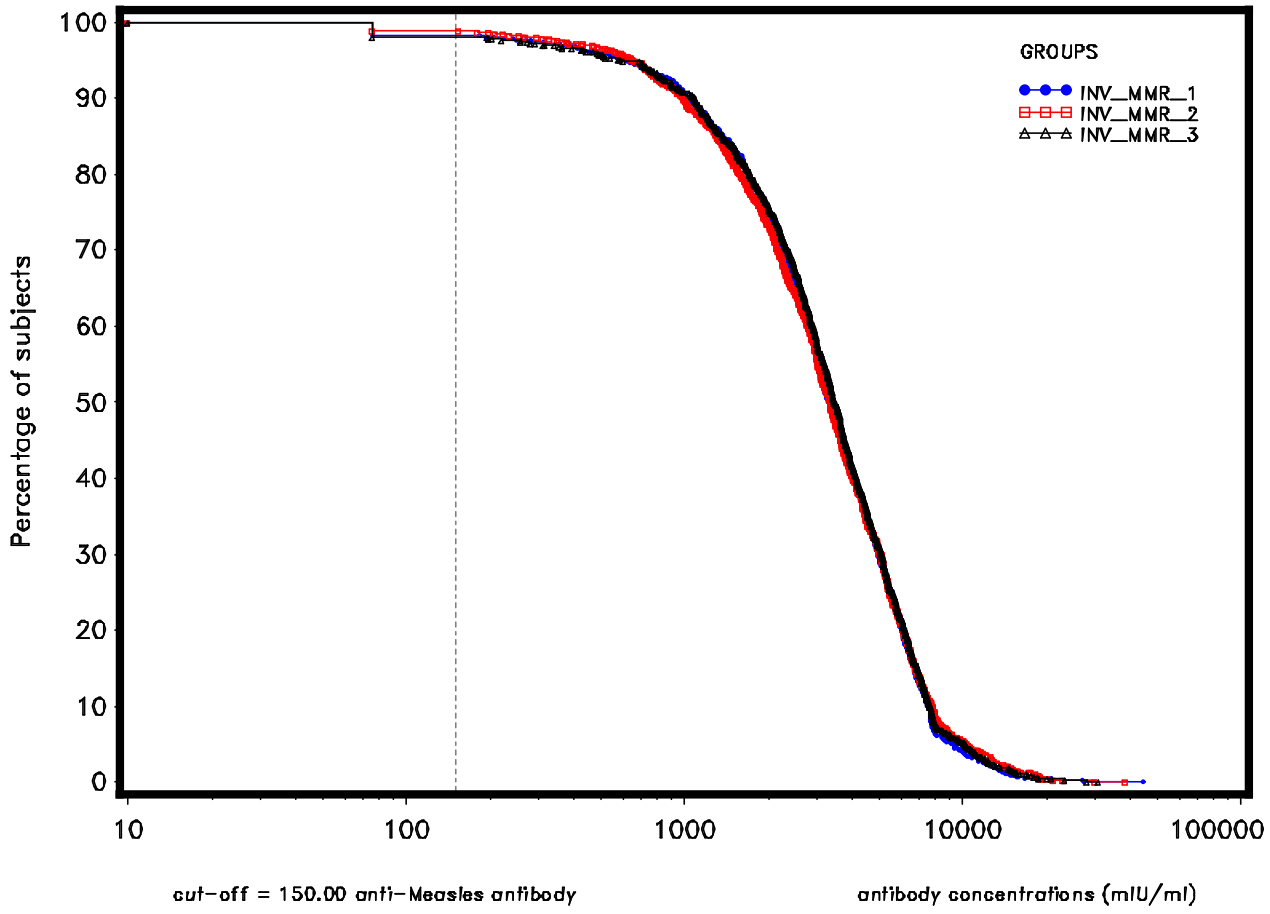
Table 7.14 Distribution of Anti-Measles antibody concentrations - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥150 mIU/mL				≥200 mIU/mL				≥300 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR_1	PI(D42)	1083	1064	98.2	97.3	98.9	1062	98.1	97.1	98.8	1055	97.4	96.3	98.3
	INV_MMR_2	PI(D42)	1069	1057	98.9	98.0	99.4	1054	98.6	97.7	99.2	1047	97.9	96.9	98.7
	INV_MMR_3	PI(D42)	1096	1075	98.1	97.1	98.8	1072	97.8	96.8	98.6	1065	97.2	96.0	98.1

				≥600 mIU/mL				≥1200 mIU/mL				≥2400 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR_1	PI(D42)	1083	1030	95.1	93.6	96.3	951	87.8	85.7	89.7	732	67.6	64.7	70.4
	INV_MMR_2	PI(D42)	1069	1024	95.8	94.4	96.9	928	86.8	84.6	88.8	702	65.7	62.7	68.5
	INV_MMR_3	PI(D42)	1096	1041	95.0	93.5	96.2	962	87.8	85.7	89.7	760	69.3	66.5	72.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.1 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3

Table 7.15 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR_1	PI(D42)	1062	1059	99.7	99.2	99.9	1047	98.6	97.7	99.2	71.7	68.3	75.2
	INV_MMR_2	PI(D42)	1047	1040	99.3	98.6	99.7	1032	98.6	97.6	99.2	76.9	73.2	80.8
	INV_MMR_3	PI(D42)	1078	1069	99.2	98.4	99.6	1056	98.0	96.9	98.7	69.0	65.5	72.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.16 Difference between groups (INV_MMR_1 minus INV_MMR_2) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_2)		
		INV_MMR_1			INV_MMR_2				95% CI	
Antibody	**Type**	**N**	**n**	**%**	**N**	**n**	**%**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	10 EU/mL	1062	1047	98.6	1047	1032	98.6	0.02	-1.05	1.09

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.17 Difference between groups (INV_MMR_1 minus INV_MMR_3) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_3)		
		INV_MMR_1			INV_MMR_3				95% CI	
Antibody	**Type**	**N**	**n**	**%**	**N**	**n**	**%**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	10 EU/mL	1062	1047	98.6	1078	1056	98.0	0.63	-0.50	1.81

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.18 Difference between groups (INV_MMR_2 minus INV_MMR_3) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_2 minus INV_MMR_3)		
		INV_MMR_2			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Mumps (PPD) antibody	10 EU/mL	1047	1032	98.6	1078	1056	98.0	0.61	-0.53	1.79

INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.19 Ratios of Anti-Mumps (PPD) antibody GMCs at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

						Adjusted GMC ratio			
								95% CI	
Group description	N	Adjusted GMC	Group description	N	Adjusted GMC	Ratio order	Value	LL	UL
INV_MMR_1	1062	75.2	INV_MMR_2	1047	80.5	INV_MMR_1 /INV_MMR_2	0.93	0.87	1.00
INV_MMR_1	1062	75.2	INV_MMR_3	1078	72.3	INV_MMR_1 /INV_MMR_3	1.04	0.97	1.11
INV_MMR_2	1047	80.5	INV_MMR_1	1062	75.2	INV_MMR_2 /INV_MMR_1	1.07	1.00	1.15
INV_MMR_2	1047	80.5	INV_MMR_3	1078	72.3	INV_MMR_2 /INV_MMR_3	1.11	1.04	1.19
INV_MMR_3	1078	72.3	INV_MMR_1	1062	75.2	INV_MMR_3 /INV_MMR_1	0.96	0.90	1.03
INV_MMR_3	1078	72.3	INV_MMR_2	1047	80.5	INV_MMR_3 /INV_MMR_2	0.90	0.84	0.96

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit

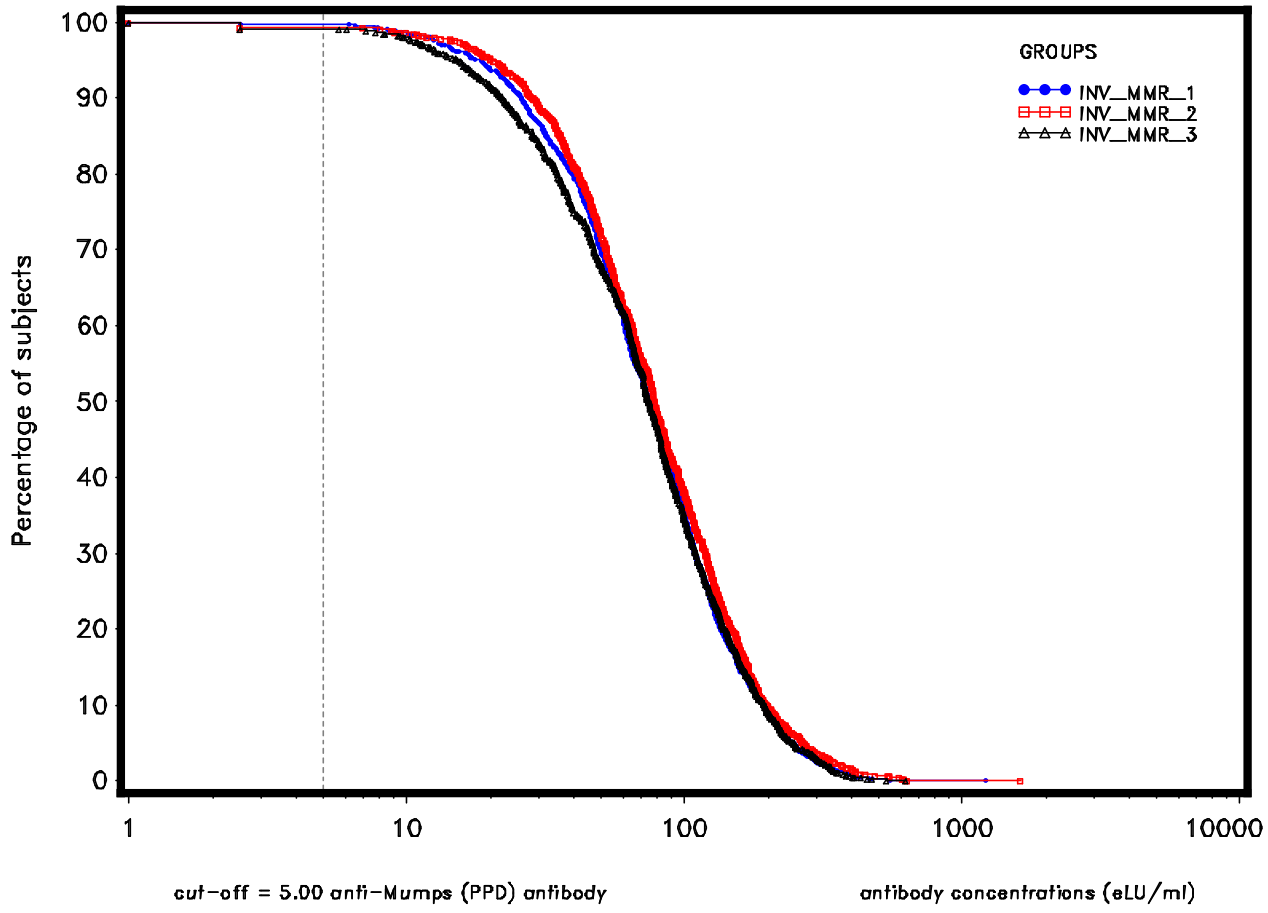
Table 7.20 Distribution of Anti-Mumps (PPD) antibody concentrations - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥5 EU/mL				≥10 EU/mL				≥15 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR_1	PI(D42)	1062	1059	99.7	99.2	99.9	1047	98.6	97.7	99.2	1023	96.3	95.0	97.4
	INV_MMR_2	PI(D42)	1047	1040	99.3	98.6	99.7	1032	98.6	97.6	99.2	1022	97.6	96.5	98.4
	INV_MMR_3	PI(D42)	1078	1069	99.2	98.4	99.6	1056	98.0	96.9	98.7	1028	95.4	93.9	96.5

				≥20 EU/mL				≥30 EU/mL				≥40 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR_1	PI(D42)	1062	996	93.8	92.2	95.2	920	86.6	84.4	88.6	846	79.7	77.1	82.0
	INV_MMR_2	PI(D42)	1047	999	95.4	94.0	96.6	933	89.1	87.1	90.9	851	81.3	78.8	83.6
	INV_MMR_3	PI(D42)	1078	988	91.7	89.8	93.2	907	84.1	81.8	86.3	812	75.3	72.6	77.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.2 Reverse cumulative distribution curve of Anti-Mumps (PPD) antibody concentrations at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3

Table 7.21 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Rubella antibody	INV_MMR_1	PI(D42)	1083	1077	99.4	98.8	99.8	1053	97.2	96.1	98.1	57.2	54.4	60.1
	INV_MMR_2	PI(D42)	1067	1064	99.7	99.2	99.9	1036	97.1	95.9	98.0	53.1	50.5	55.7
	INV_MMR_3	PI(D42)	1095	1088	99.4	98.7	99.7	1070	97.7	96.6	98.5	57.0	54.3	59.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.22 Difference between groups (INV_MMR_1 minus INV_MMR_2) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_2)		
		INV_MMR_1			INV_MMR_2				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	1083	1053	97.2	1067	1036	97.1	0.14	-1.30	1.58

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.23 Difference between groups (INV_MMR_1 minus INV_MMR_3) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_3)		
		INV_MMR_1			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	1083	1053	97.2	1095	1070	97.7	-0.49	-1.86	0.86

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.24 Difference between groups (INV_MMR_2 minus INV_MMR_3) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_2 minus INV_MMR_3)		
		INV_MMR_2			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	1067	1036	97.1	1095	1070	97.7	-0.62	-2.02	0.74

INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.25 Ratios of Anti-Rubella antibody GMCs at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

						Adjusted GMC ratio			
								95% CI	
Group description	N	Adjusted GMC	Group description	N	Adjusted GMC	Ratio order	Value	LL	UL
INV_MMR_1	1083	54.5	INV_MMR_2	1067	50.5	INV_MMR_1 /INV_MMR_2	1.08	1.01	1.15
INV_MMR_1	1083	54.5	INV_MMR_3	1095	54.3	INV_MMR_1 /INV_MMR_3	1.00	0.94	1.07
INV_MMR_2	1067	50.5	INV_MMR_1	1083	54.5	INV_MMR_2 /INV_MMR_1	0.93	0.87	0.99
INV_MMR_2	1067	50.5	INV_MMR_3	1095	54.3	INV_MMR_2 /INV_MMR_3	0.93	0.87	0.99
INV_MMR_3	1095	54.3	INV_MMR_1	1083	54.5	INV_MMR_3 /INV_MMR_1	1.00	0.93	1.07
INV_MMR_3	1095	54.3	INV_MMR_2	1067	50.5	INV_MMR_3 /INV_MMR_2	1.08	1.01	1.15

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit

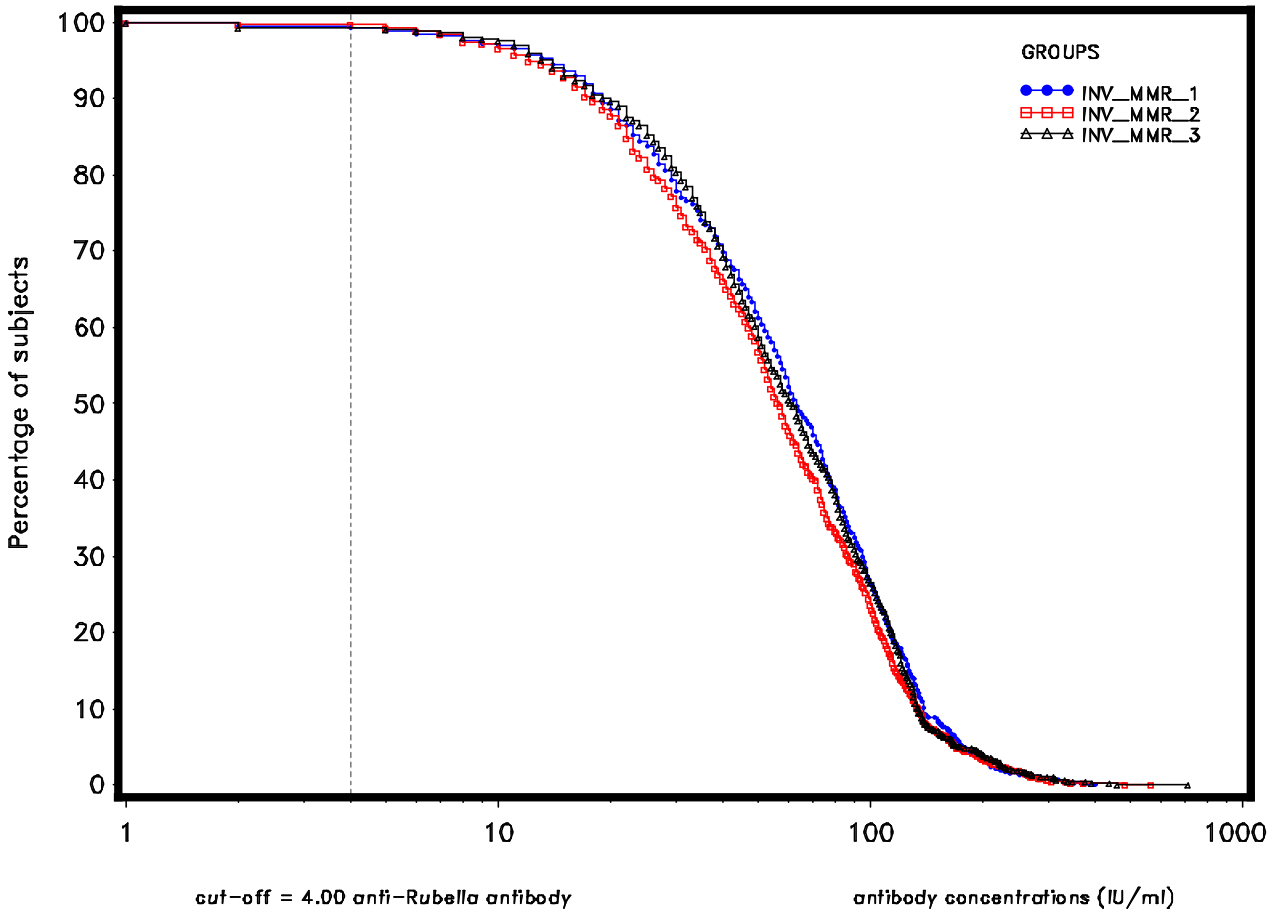
Table 7.26 Distribution of Anti-Rubella antibody concentrations - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥4 IU/mL				≥8 IU/mL				≥10 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR_1	PI(D42)	1083	1077	99.4	98.8	99.8	1063	98.2	97.2	98.9	1053	97.2	96.1	98.1
	INV_MMR_2	PI(D42)	1067	1064	99.7	99.2	99.9	1050	98.4	97.5	99.1	1036	97.1	95.9	98.0
	INV_MMR_3	PI(D42)	1095	1088	99.4	98.7	99.7	1080	98.6	97.8	99.2	1070	97.7	96.6	98.5

				≥16 IU/mL				≥32 IU/mL				≥64 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR_1	PI(D42)	1083	1014	93.6	92.0	95.0	835	77.1	74.5	79.6	539	49.8	46.7	52.8
	INV_MMR_2	PI(D42)	1067	990	92.8	91.1	94.3	796	74.6	71.9	77.2	476	44.6	41.6	47.7
	INV_MMR_3	PI(D42)	1095	1018	93.0	91.3	94.4	869	79.4	76.8	81.7	531	48.5	45.5	51.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.3 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3

Table 7.27 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	3248	3188	98.2	1137	1114	98.0	0.18	-0.68	1.25

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.28 Ratios of Anti-Measles antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				Adjusted GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
3248	3165.2	1137	3215.4	0.98	0.93	1.05

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance); LL = lower limit, UL = upper limit

Table 7.29 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Measles antibody	INV_MMR	PI(D42)	334	329	98.5	96.5	99.5	329	98.5	96.5	99.5	2858.2	2618.7	3119.6
	COM_MMR	PI(D42)	114	111	97.4	92.5	99.5	110	96.5	91.3	99.0	2694.6	2252.5	3223.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.30 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	164	161	98.2	94.7	99.6	160	97.6	93.9	99.3	3187.3	2735.0	3714.5
	COM_MMR	PI(D42)	60	60	100	94.0	100	60	100	94.0	100	3430.4	2692.1	4371.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.31 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	974	959	98.5	97.5	99.1	953	97.8	96.7	98.7	2409.7	2274.2	2553.2
	COM_MMR	PI(D42)	329	321	97.6	95.3	98.9	321	97.6	95.3	98.9	2414.2	2175.1	2679.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.32 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	273	271	99.3	97.4	99.9	271	99.3	97.4	99.9	4477.4	4058.9	4939.0
	COM_MMR	PI(D42)	93	91	97.8	92.4	99.7	91	97.8	92.4	99.7	4358.5	3656.3	5195.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.33 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	1549	1522	98.3	97.5	98.8	1521	98.2	97.4	98.8	3273.3	3129.6	3423.6
	COM_MMR	PI(D42)	554	545	98.4	96.9	99.3	545	98.4	96.9	99.3	3404.1	3159.7	3667.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.34 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by gender)

					≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	F	PI(D42)	1572	1548	98.5	97.7	99.0	1544	98.2	97.4	98.8	3180.4	3041.1	3326.1
		M	PI(D42)	1676	1648	98.3	97.6	98.9	1644	98.1	97.3	98.7	2872.0	2748.0	3001.6
	COM_MMR	F	PI(D42)	551	545	98.9	97.6	99.6	545	98.9	97.6	99.6	3276.0	3048.1	3520.9
		M	PI(D42)	586	570	97.3	95.6	98.4	569	97.1	95.4	98.3	2896.1	2670.0	3141.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.35 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by geographic ancestry)

					≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	WH	PI(D42)	2481	2440	98.3	97.8	98.8	2433	98.1	97.4	98.6	2784.9	2686.6	2886.8
		OT	PI(D42)	327	323	98.8	96.9	99.7	323	98.8	96.9	99.7	4401.4	4008.7	4832.6
		AF	PI(D42)	123	120	97.6	93.0	99.5	120	97.6	93.0	99.5	4211.8	3563.4	4978.1
	COM_MMR	WH	PI(D42)	866	849	98.0	96.9	98.9	848	97.9	96.7	98.8	2831.4	2658.2	3016.0
		OT	PI(D42)	114	112	98.2	93.8	99.8	112	98.2	93.8	99.8	4559.5	3941.8	5274.0
		AF	PI(D42)	54	54	100	93.4	100	54	100	93.4	100	4653.4	3798.8	5700.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

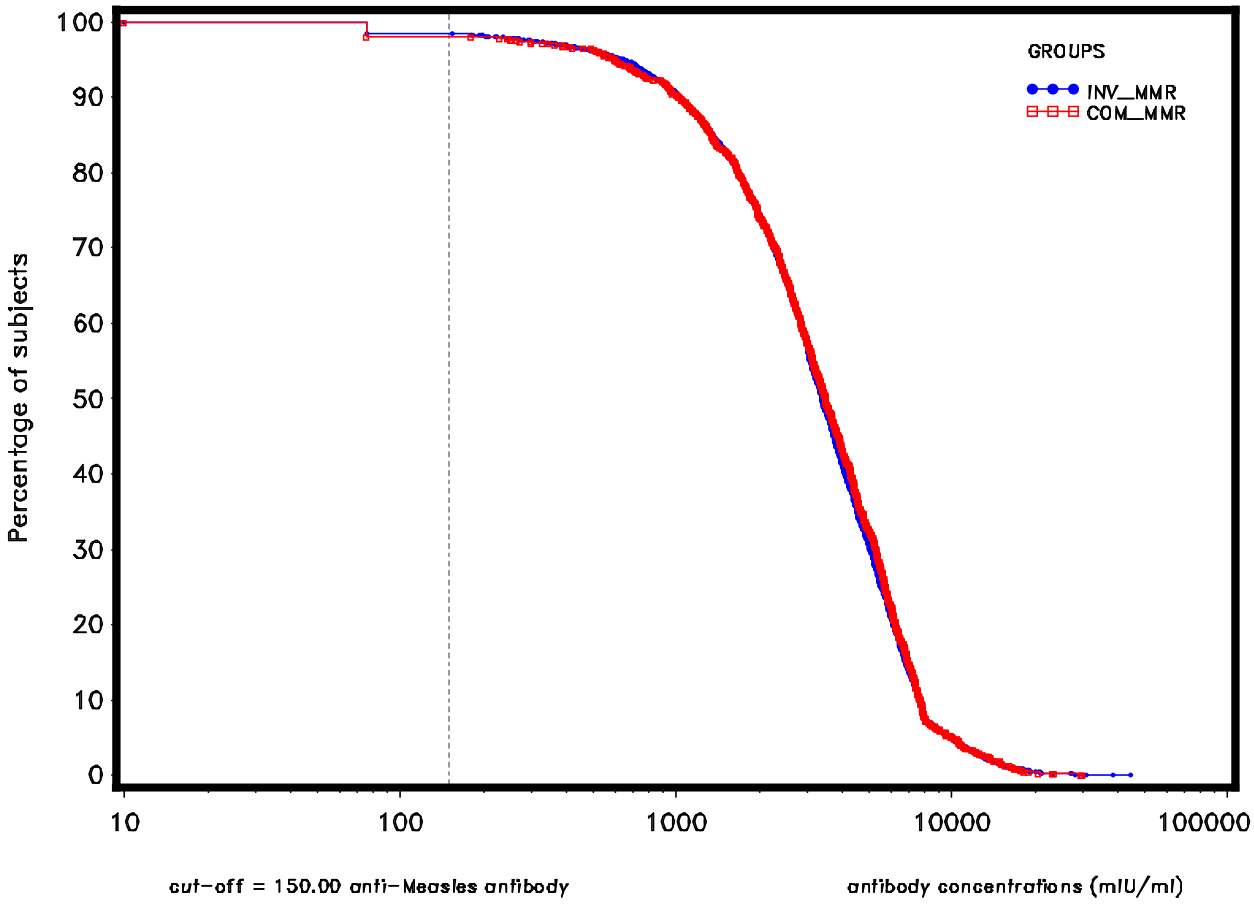
Table 7.36 Distribution of Anti-Measles antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥150 mIU/mL				≥200 mIU/mL				≥300 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3196	98.4	97.9	98.8	3188	98.2	97.6	98.6	3167	97.5	96.9	98.0
	COM_MMR	PI(D42)	1137	1115	98.1	97.1	98.8	1114	98.0	97.0	98.7	1107	97.4	96.3	98.2

				≥600 mIU/mL				≥1200 mIU/mL				≥2400 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3095	95.3	94.5	96.0	2841	87.5	86.3	88.6	2194	67.5	65.9	69.2
	COM_MMR	PI(D42)	1137	1083	95.3	93.8	96.4	998	87.8	85.7	89.6	779	68.5	65.7	71.2

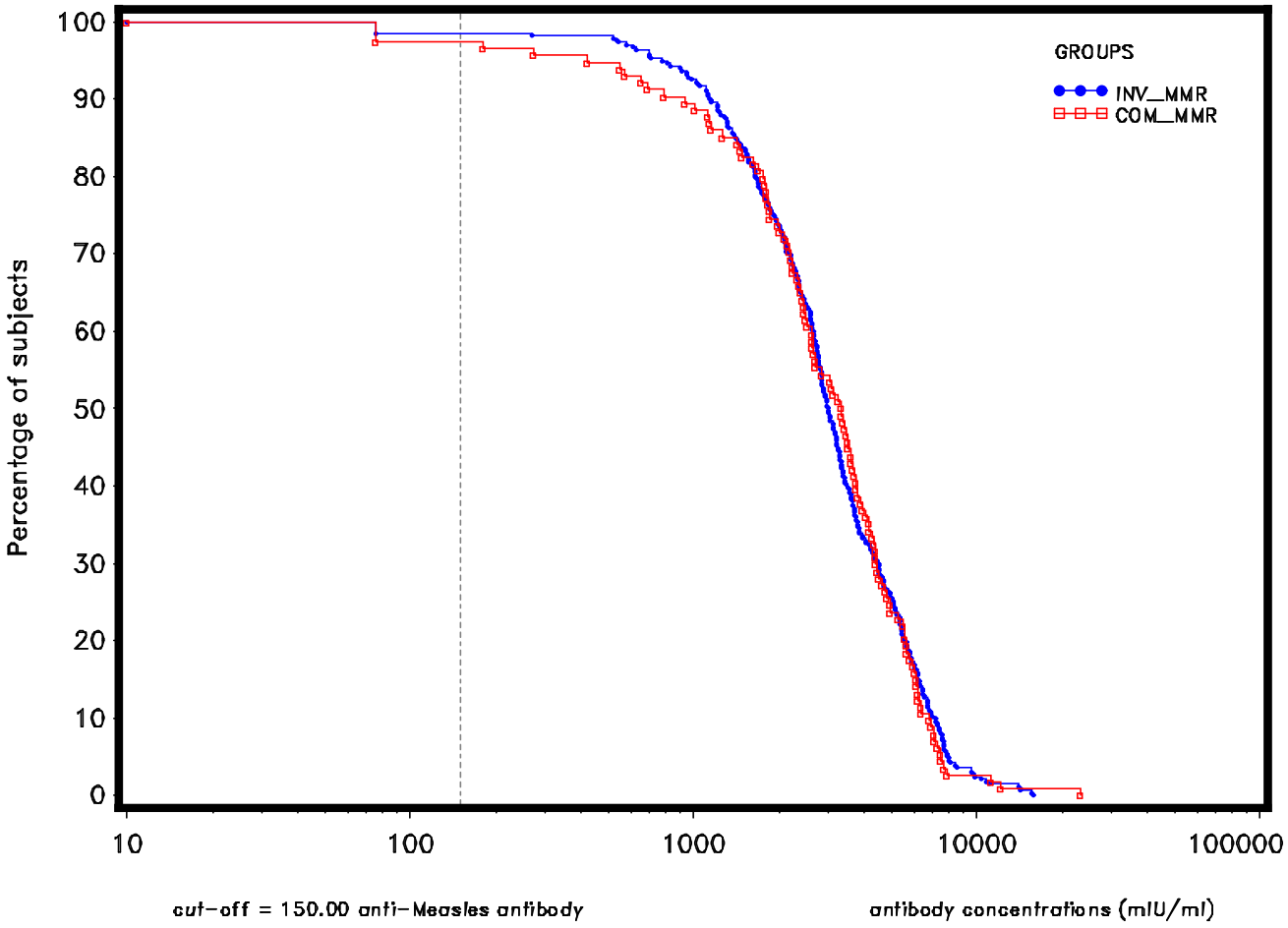
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.4 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)



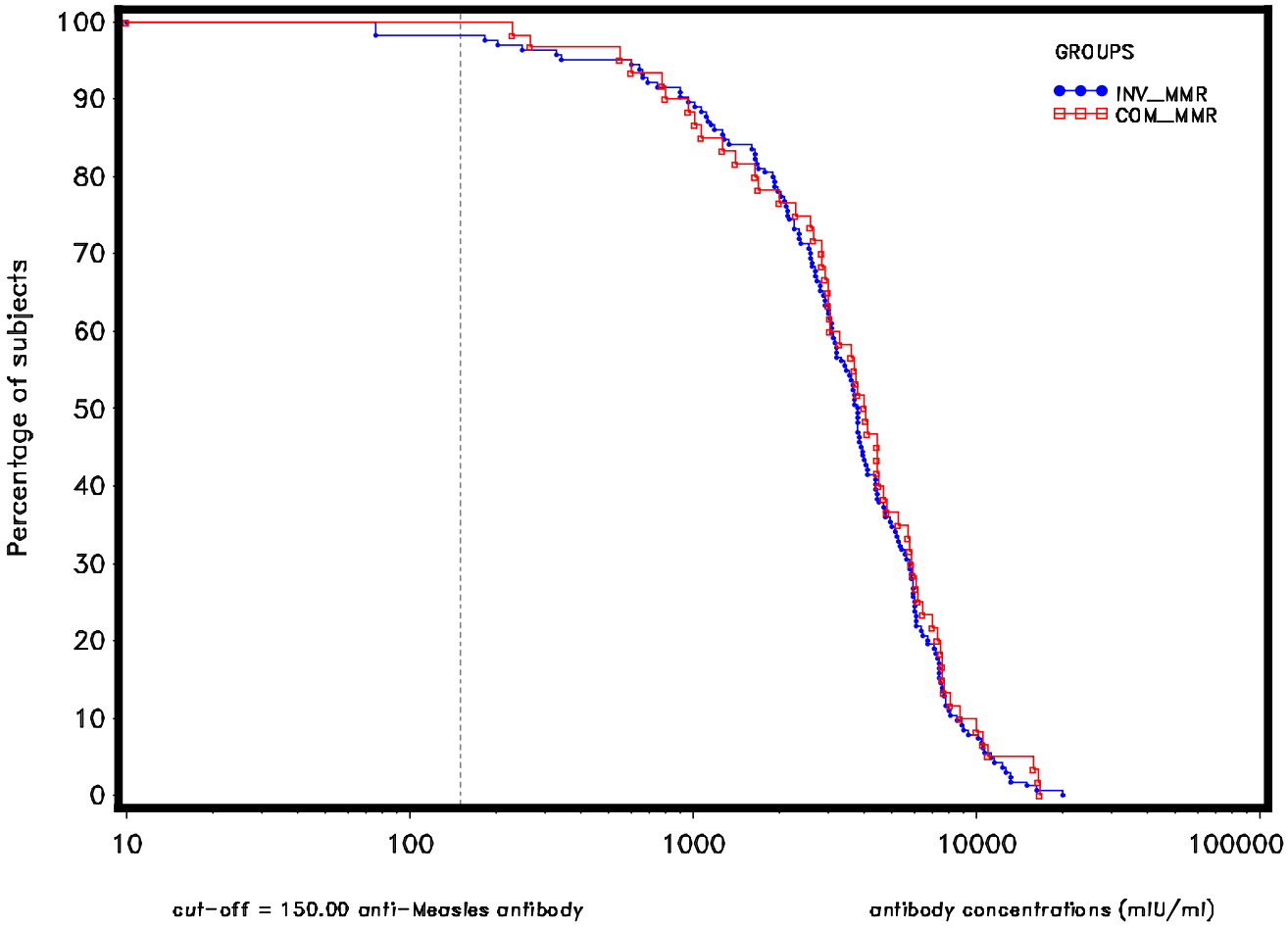
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.5 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)



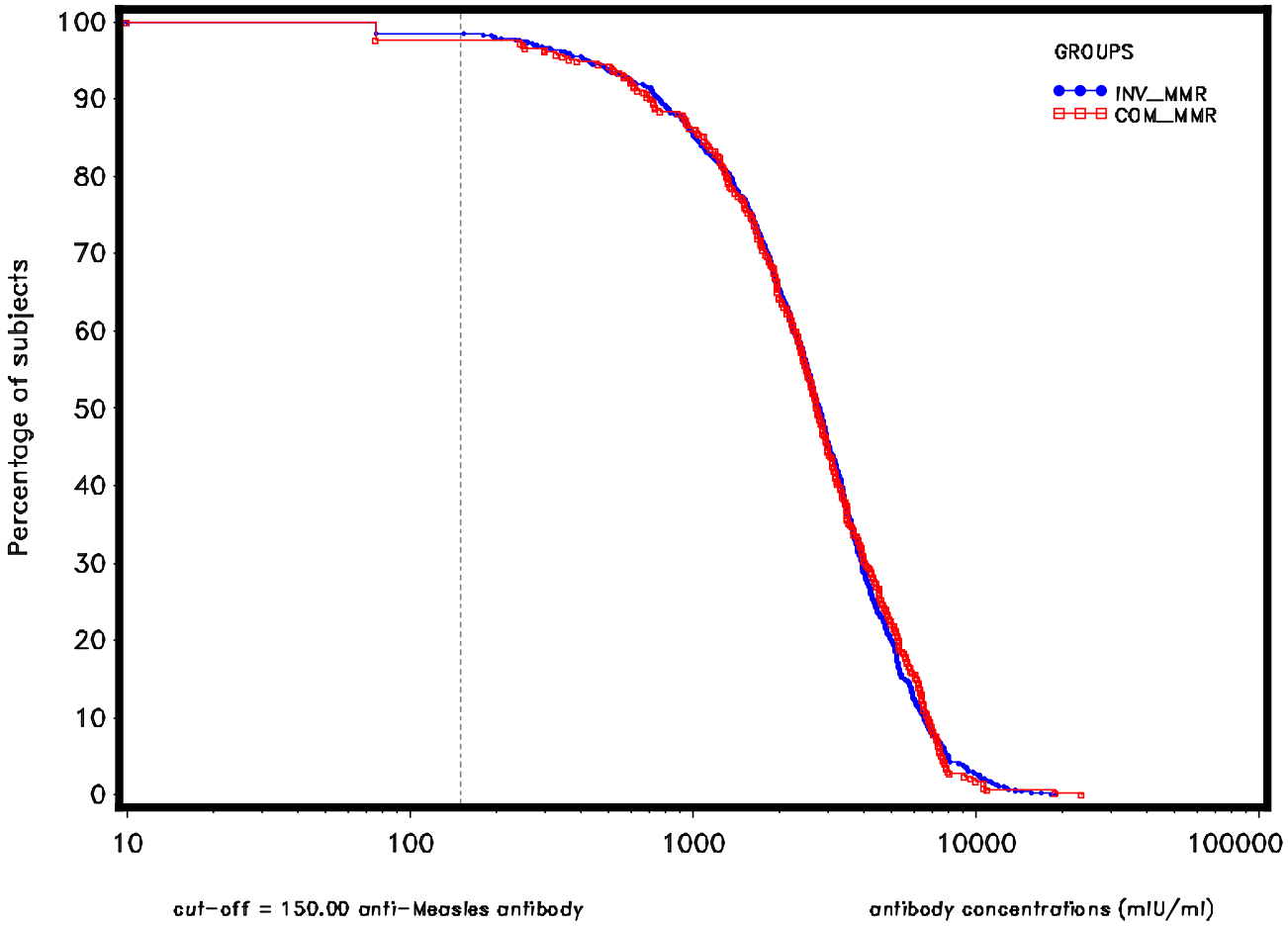
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.6 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)



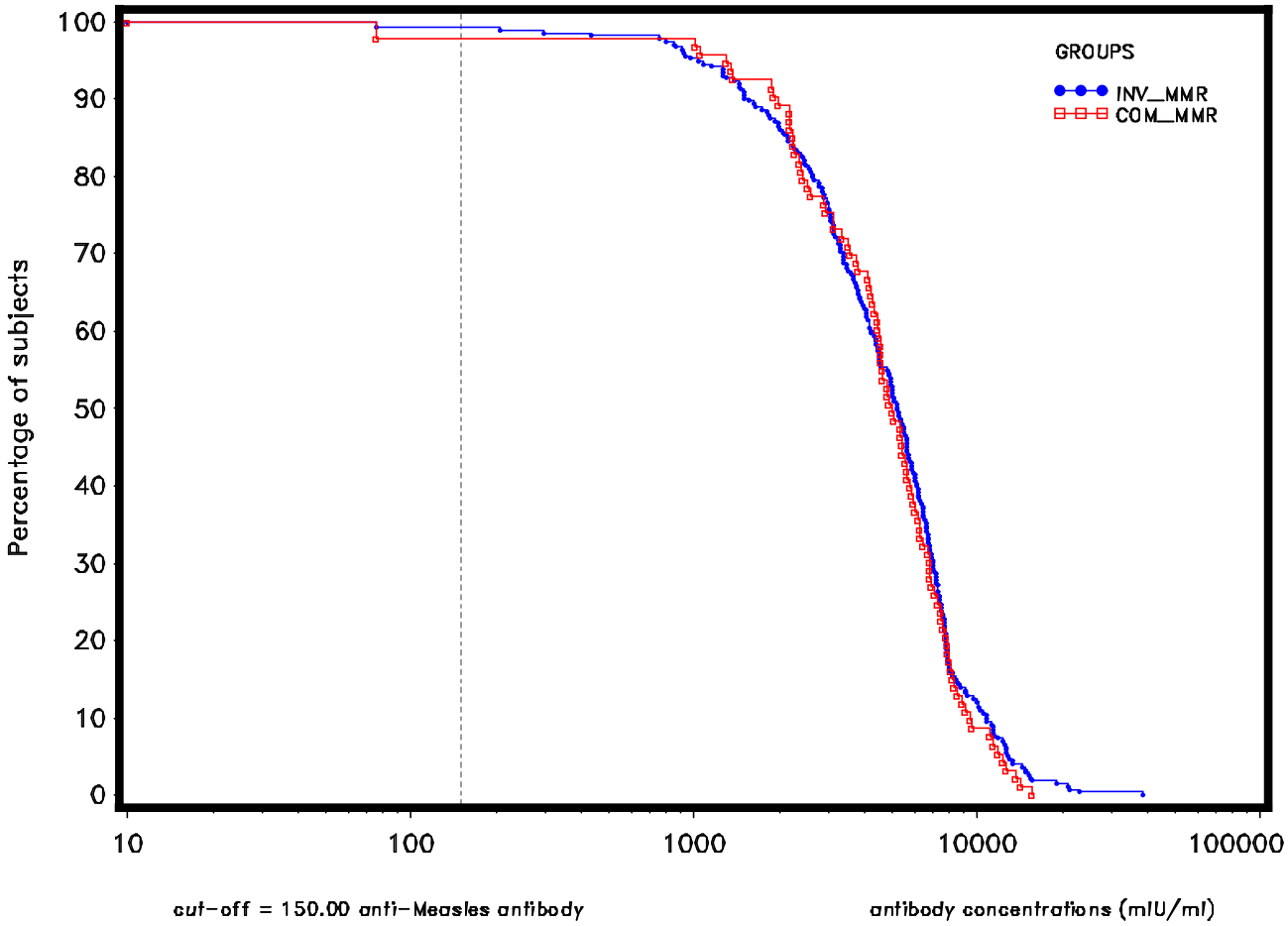
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.7 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)



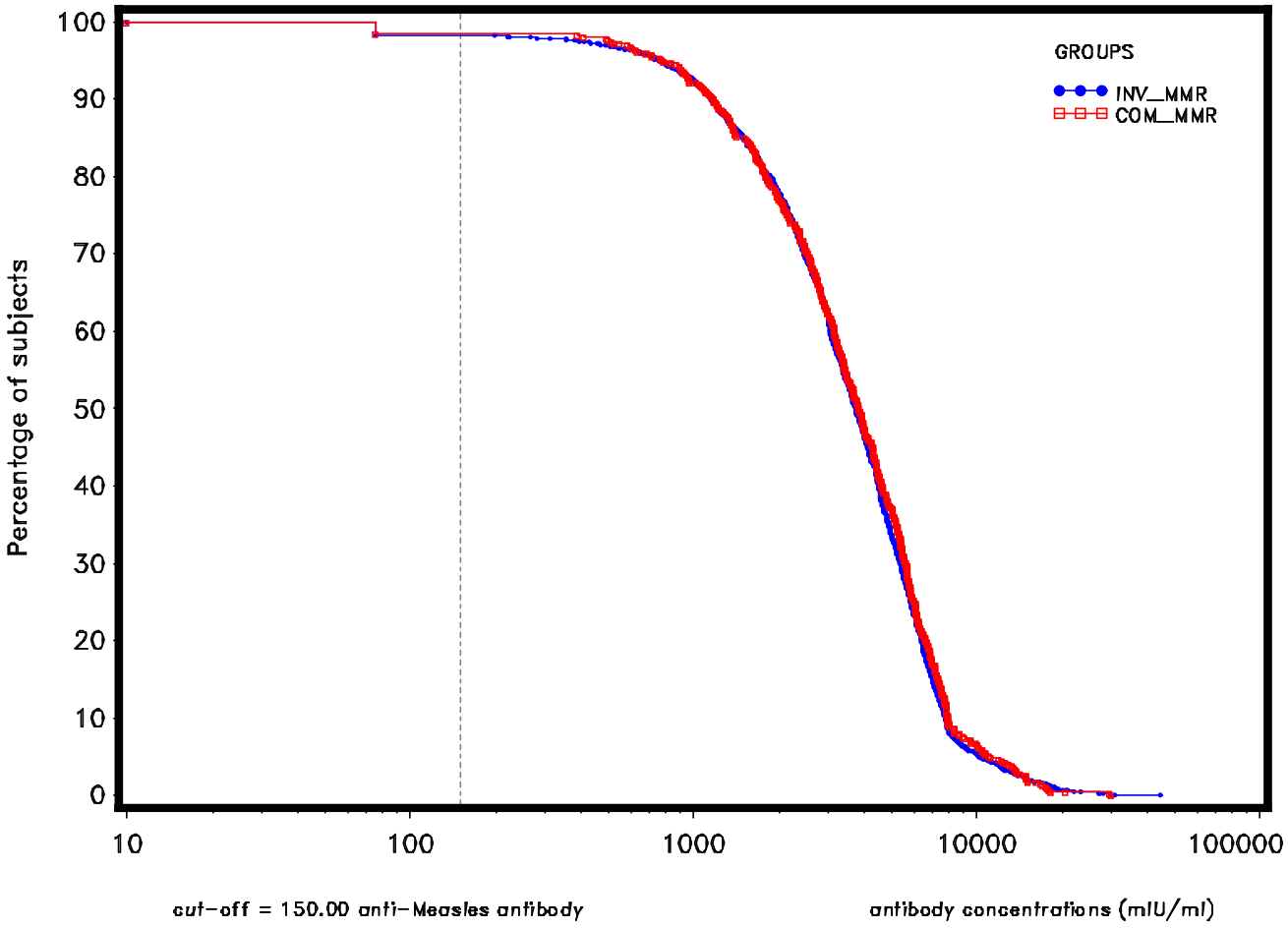
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.8 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.9 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.37 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Mumps (PPD) antibody	10 EU/mL	3187	3135	98.4	1107	1080	97.6	0.81	-0.10	1.96

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.38 Ratios of Anti-Mumps (PPD) antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				Adjusted GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
3187	76.4	1107	73.0	1.05	0.99	1.11

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance); LL = lower limit, UL = upper limit

Table 7.39 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	349	347	99.4	97.9	99.9	340	97.4	95.2	98.8	68.4	62.7	74.5
	COM_MMR	PI(D42)	119	116	97.5	92.8	99.5	113	95.0	89.3	98.1	64.4	54.3	76.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.40 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	167	166	99.4	96.7	100	166	99.4	96.7	100	77.8	68.9	87.8
	COM_MMR	PI(D42)	61	61	100	94.1	100	61	100	94.1	100	76.6	64.0	91.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.41 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	974	964	99.0	98.1	99.5	952	97.7	96.6	98.6	62.7	59.6	66.1
	COM_MMR	PI(D42)	330	330	100	98.9	100	323	97.9	95.7	99.1	62.0	56.9	67.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.42 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	273	273	100	98.7	100	271	99.3	97.4	99.9	101.3	91.8	111.8
	COM_MMR	PI(D42)	93	92	98.9	94.2	100	89	95.7	89.4	98.8	101.4	84.0	122.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.43 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	1573	1567	99.6	99.2	99.9	1555	98.9	98.2	99.3	76.7	73.7	79.9
	COM_MMR	PI(D42)	559	555	99.3	98.2	99.8	548	98.0	96.5	99.0	70.3	65.5	75.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.44 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by gender)

					≥ 5 EU/mL				≥ 10 EU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	F	PI(D42)	1542	1530	99.2	98.6	99.6	1517	98.4	97.6	98.9	74.0	70.9	77.2
		M	PI(D42)	1645	1638	99.6	99.1	99.8	1618	98.4	97.6	98.9	71.0	68.3	73.9
	COM_MMR	F	PI(D42)	534	532	99.6	98.7	100	519	97.2	95.4	98.4	72.7	67.6	78.2
		M	PI(D42)	573	567	99.0	97.7	99.6	561	97.9	96.4	98.9	65.9	61.5	70.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.45 Number and percentage of subjects with an Anti-Mumps PPD antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by geographic ancestry)

					≥ 5 EU/mL				≥ 10 EU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	WH	PI(D42)	2450	2433	99.3	98.9	99.6	2406	98.2	97.6	98.7	68.9	66.7	71.2
		OT	PI(D42)	313	313	100	98.8	100	311	99.4	97.7	99.9	99.1	90.5	108.5
		AF	PI(D42)	121	120	99.2	95.5	100	118	97.5	92.9	99.5	72.3	61.4	85.1
	COM_MMR	WH	PI(D42)	850	846	99.5	98.8	99.9	830	97.6	96.4	98.6	65.7	62.1	69.5
		OT	PI(D42)	105	104	99.0	94.8	100	102	97.1	91.9	99.4	101.9	86.1	120.5
		AF	PI(D42)	54	53	98.1	90.1	100	52	96.3	87.3	99.5	83.1	65.2	106.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

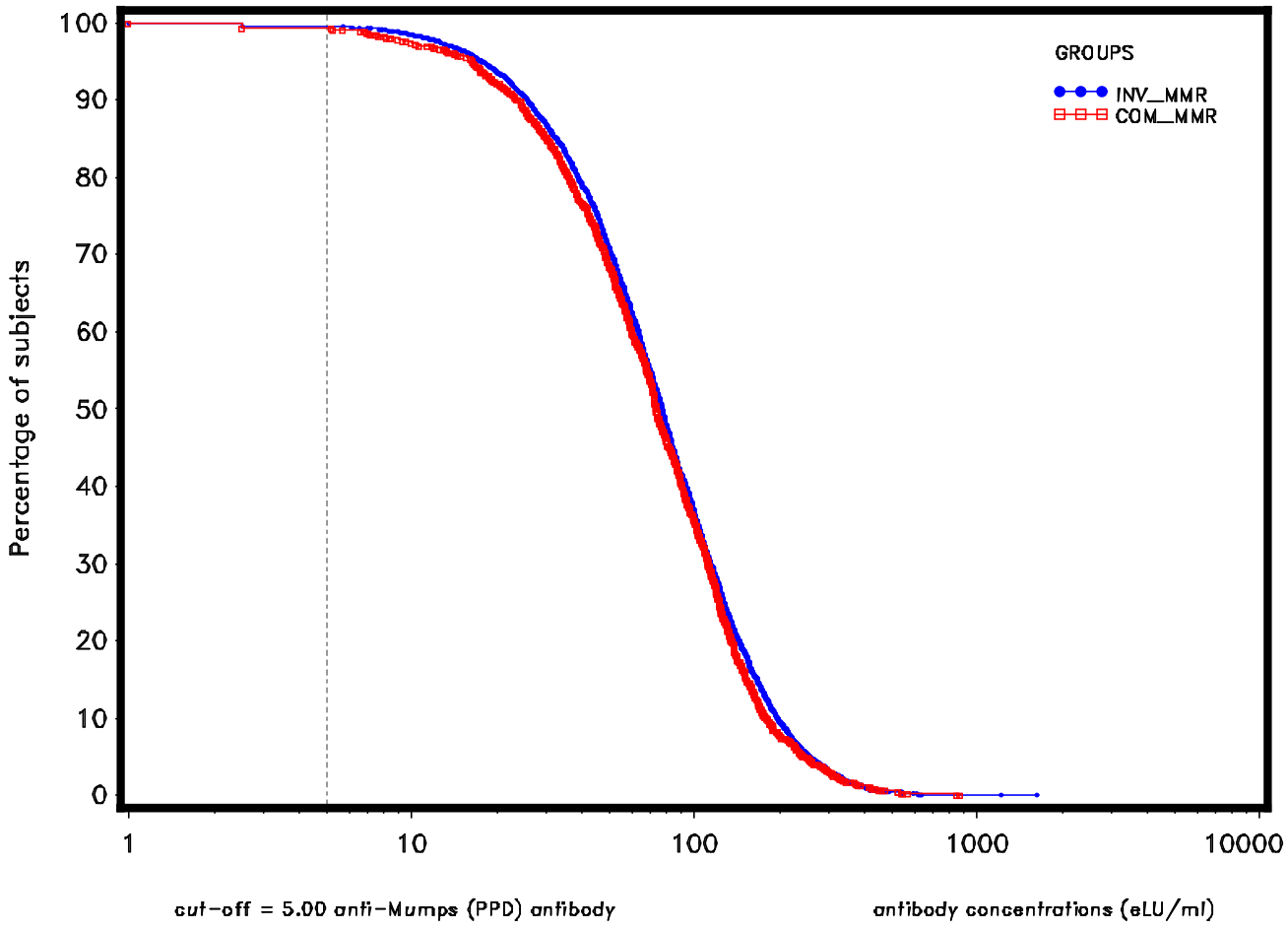
Table 7.46 Distribution of Anti-Mumps (PPD) antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥5 EU/mL				≥10 EU/mL				≥15 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3336	3317	99.4	99.1	99.7	3284	98.4	98.0	98.8	3219	96.5	95.8	97.1
	COM_MMR	PI(D42)	1162	1154	99.3	98.6	99.7	1134	97.6	96.5	98.4	1113	95.8	94.5	96.9

				≥20 EU/mL				≥30 EU/mL				≥40 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3336	3125	93.7	92.8	94.5	2896	86.8	85.6	87.9	2637	79.0	77.6	80.4
	COM_MMR	PI(D42)	1162	1072	92.3	90.6	93.7	991	85.3	83.1	87.3	894	76.9	74.4	79.3

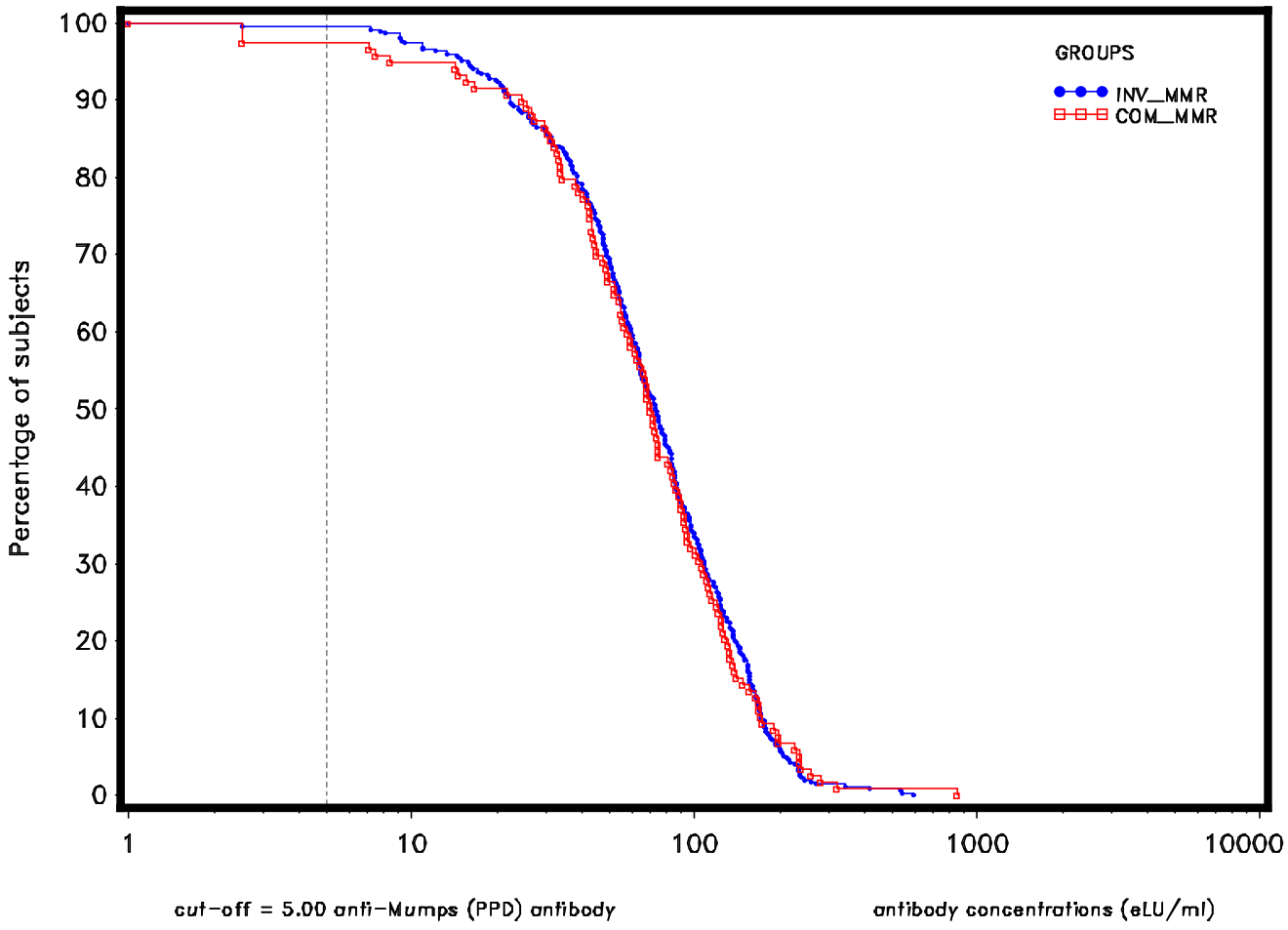
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.10 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)



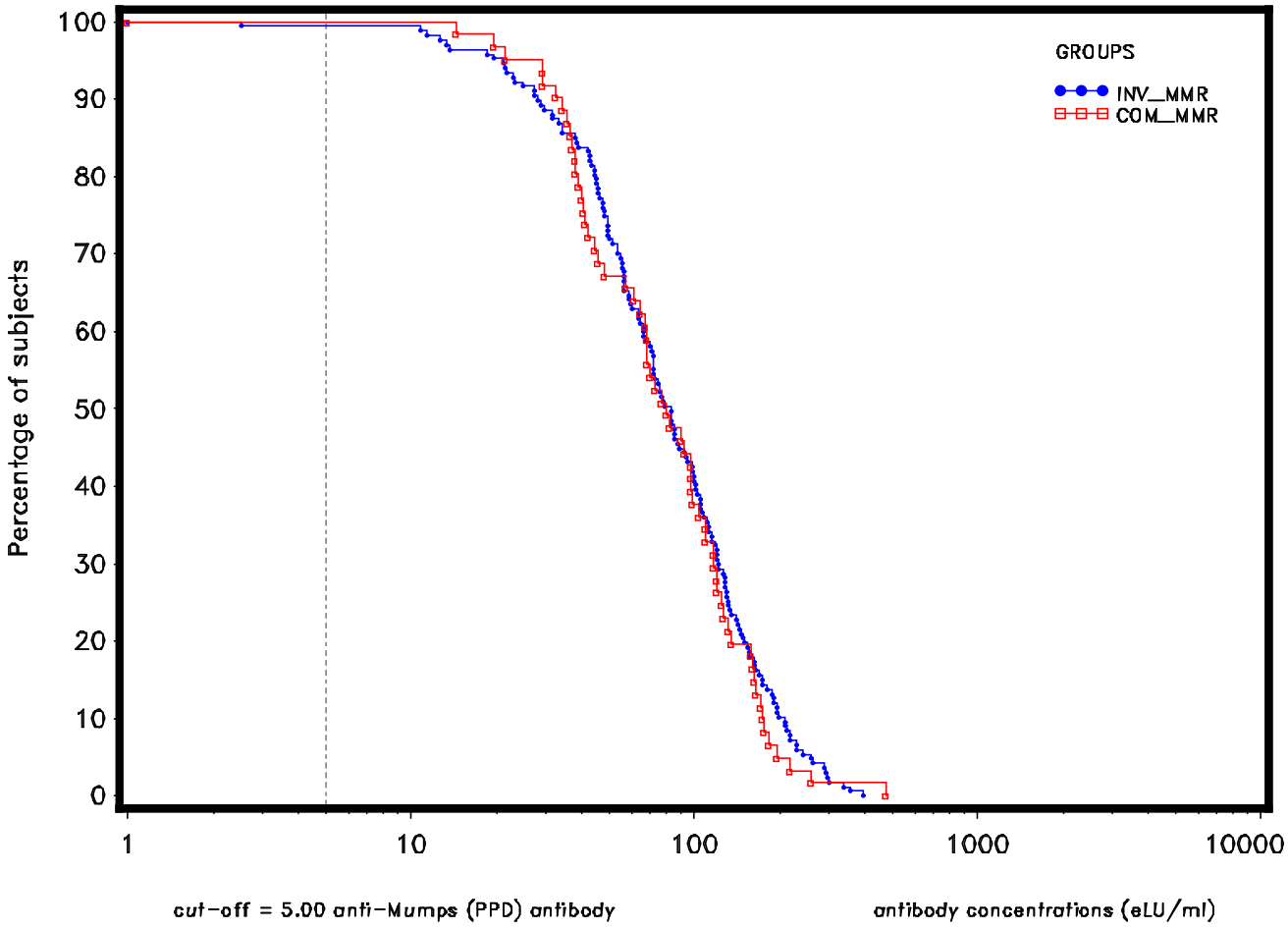
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.11 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Estonia)



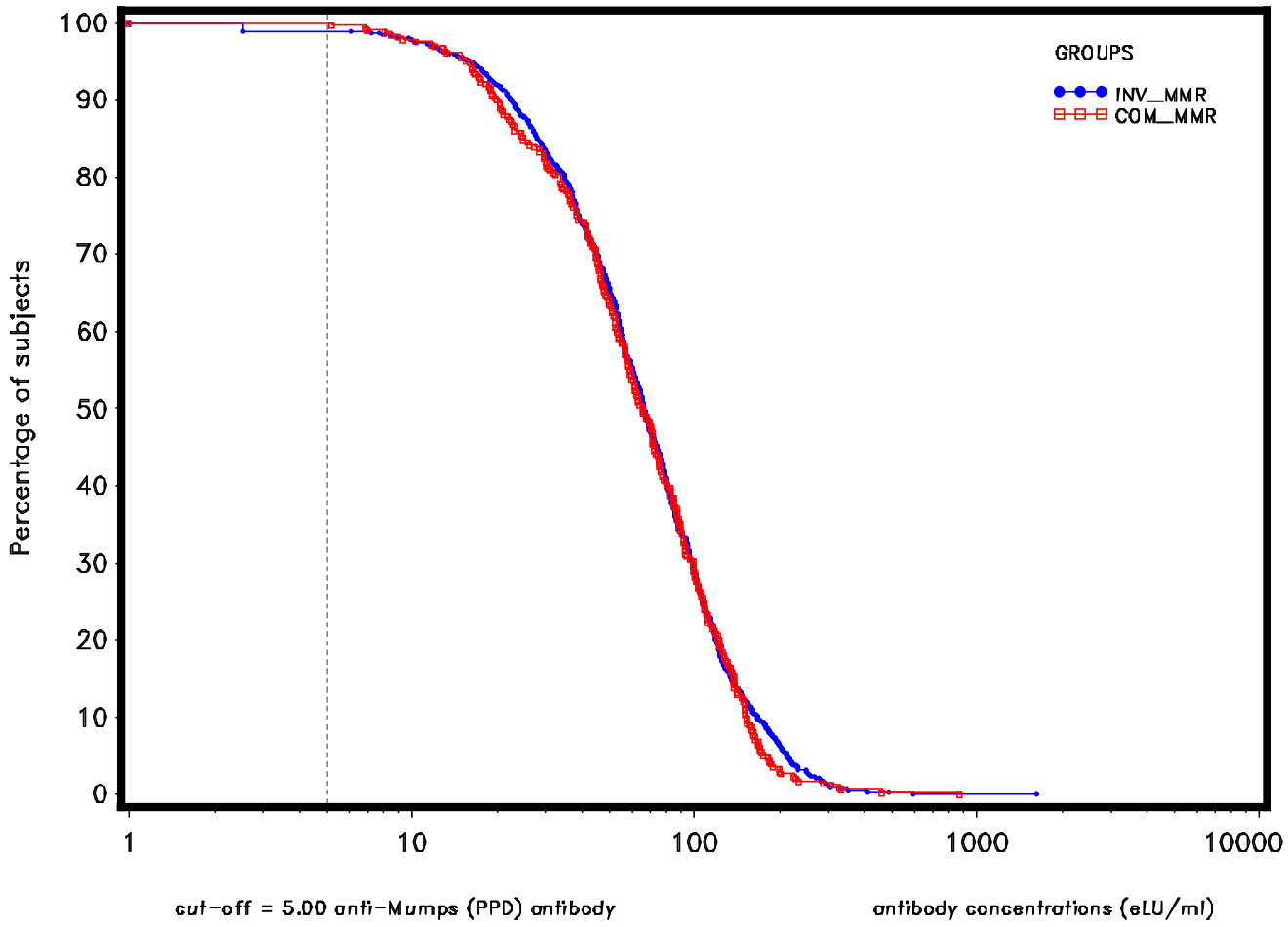
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.12 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Spain)



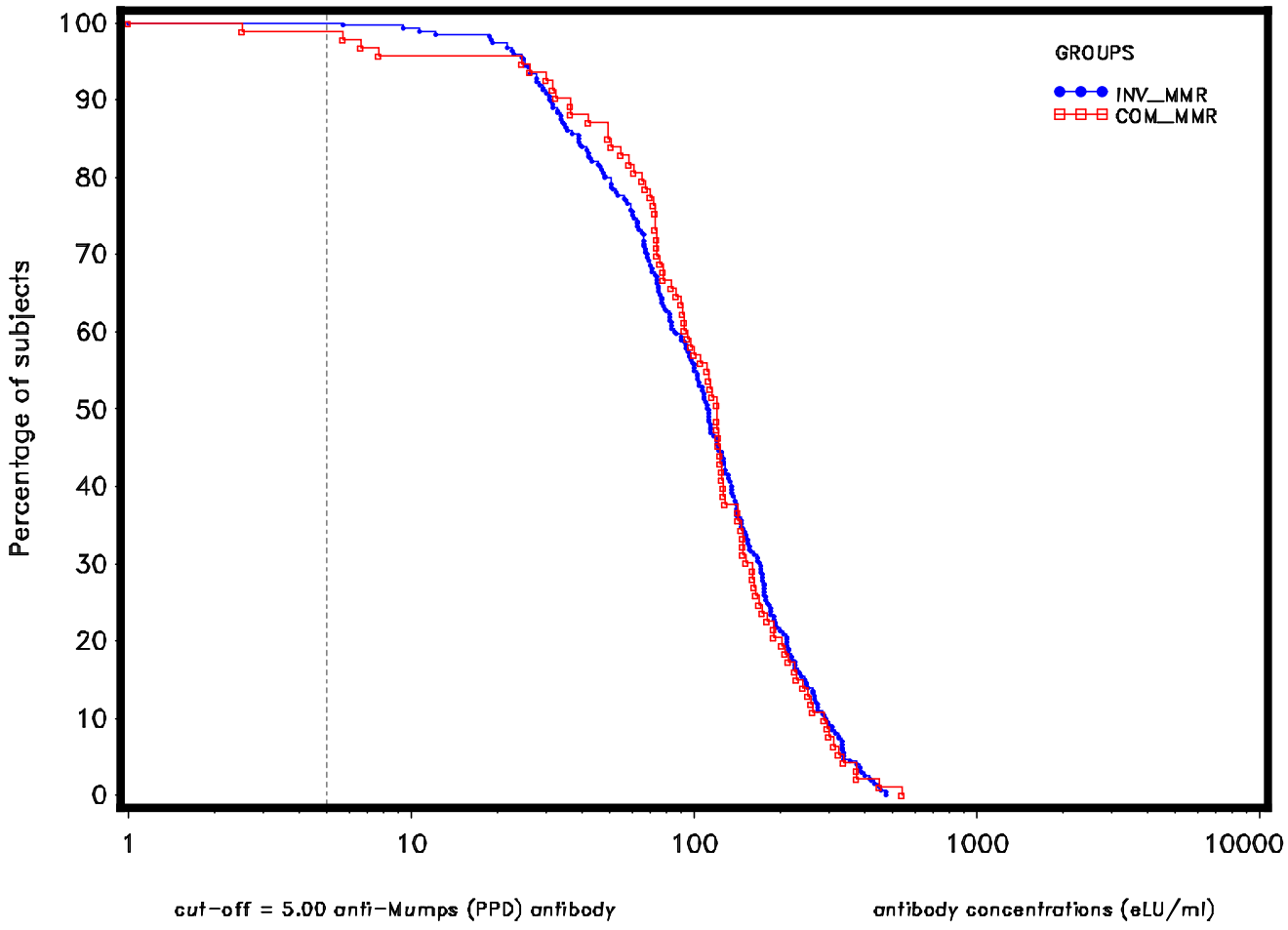
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.13 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Finland)



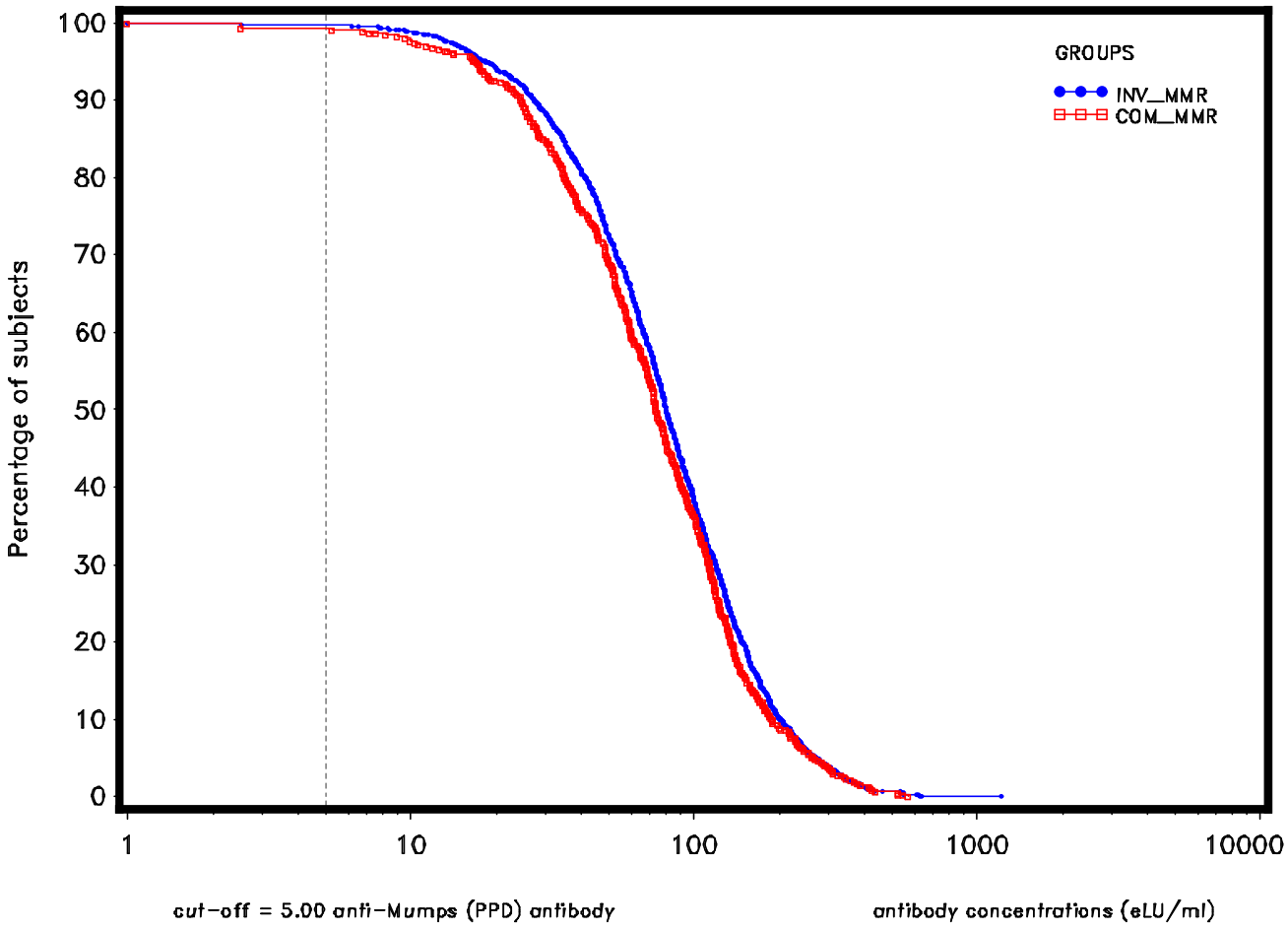
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.14 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Mexico)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.15 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, UnitedStates)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.47 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	3245	3159	97.3	1135	1118	98.5	-1.15	-2.00	-0.15

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.48 Ratios of Anti-Rubella antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				Adjusted GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
3245	52.5	1135	60.0	0.87	0.83	0.92

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance); LL = lower limit, UL = upper limit

Table 7.49 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Estonia)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Rubella antibody	INV_MMR	PI(D42)	334	330	98.8	97.0	99.7	316	94.6	91.6	96.8	41.6	37.8	45.7
	COM_MMR	PI(D42)	114	113	99.1	95.2	100	112	98.2	93.8	99.8	42.5	36.9	49.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.50 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Spain)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	164	162	98.8	95.7	99.9	157	95.7	91.4	98.3	54.5	47.1	63.0
	COM_MMR	PI(D42)	60	59	98.3	91.1	100	57	95.0	86.1	99.0	54.6	41.7	71.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.51 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Finland)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	974	967	99.3	98.5	99.7	943	96.8	95.5	97.8	45.6	43.4	47.9
	COM_MMR	PI(D42)	329	328	99.7	98.3	100	324	98.5	96.5	99.5	56.0	51.8	60.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.52 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Mexico)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	273	273	100	98.7	100	266	97.4	94.8	99.0	61.2	55.5	67.5
	COM_MMR	PI(D42)	93	92	98.9	94.2	100	91	97.8	92.4	99.7	67.7	57.0	80.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.53 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, United States)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	1549	1546	99.8	99.4	100	1526	98.5	97.8	99.1	66.5	64.0	69.1
	COM_MMR	PI(D42)	553	552	99.8	99.0	100	548	99.1	97.9	99.7	75.8	71.3	80.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.54 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by gender)

					≥ 4 IU/mL				≥ 10 IU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	F	PI(D42)	1571	1565	99.6	99.2	99.9	1537	97.8	97.0	98.5	60.0	57.6	62.5
		M	PI(D42)	1674	1664	99.4	98.9	99.7	1622	96.9	95.9	97.7	52.0	50.0	54.1
	COM_MMR	F	PI(D42)	550	548	99.6	98.7	100	544	98.9	97.6	99.6	67.2	63.0	71.8
		M	PI(D42)	585	582	99.5	98.5	99.9	574	98.1	96.7	99.1	61.1	57.3	65.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.55 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by geographic ancestry)

					≥ 4 IU/mL				≥ 10 IU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	WH	PI(D42)	2479	2463	99.4	99.0	99.6	2404	97.0	96.2	97.6	51.9	50.3	53.7
		OT	PI(D42)	326	326	100	98.9	100	318	97.5	95.2	98.9	64.1	58.6	70.2
		AF	PI(D42)	123	123	100	97.0	100	123	100	97.0	100	84.1	75.5	93.8
	COM_MMR	WH	PI(D42)	865	861	99.5	98.8	99.9	851	98.4	97.3	99.1	59.6	56.6	62.7
		OT	PI(D42)	114	113	99.1	95.2	100	112	98.2	93.8	99.8	71.4	61.1	83.4
		AF	PI(D42)	54	54	100	93.4	100	54	100	93.4	100	101.0	87.4	116.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

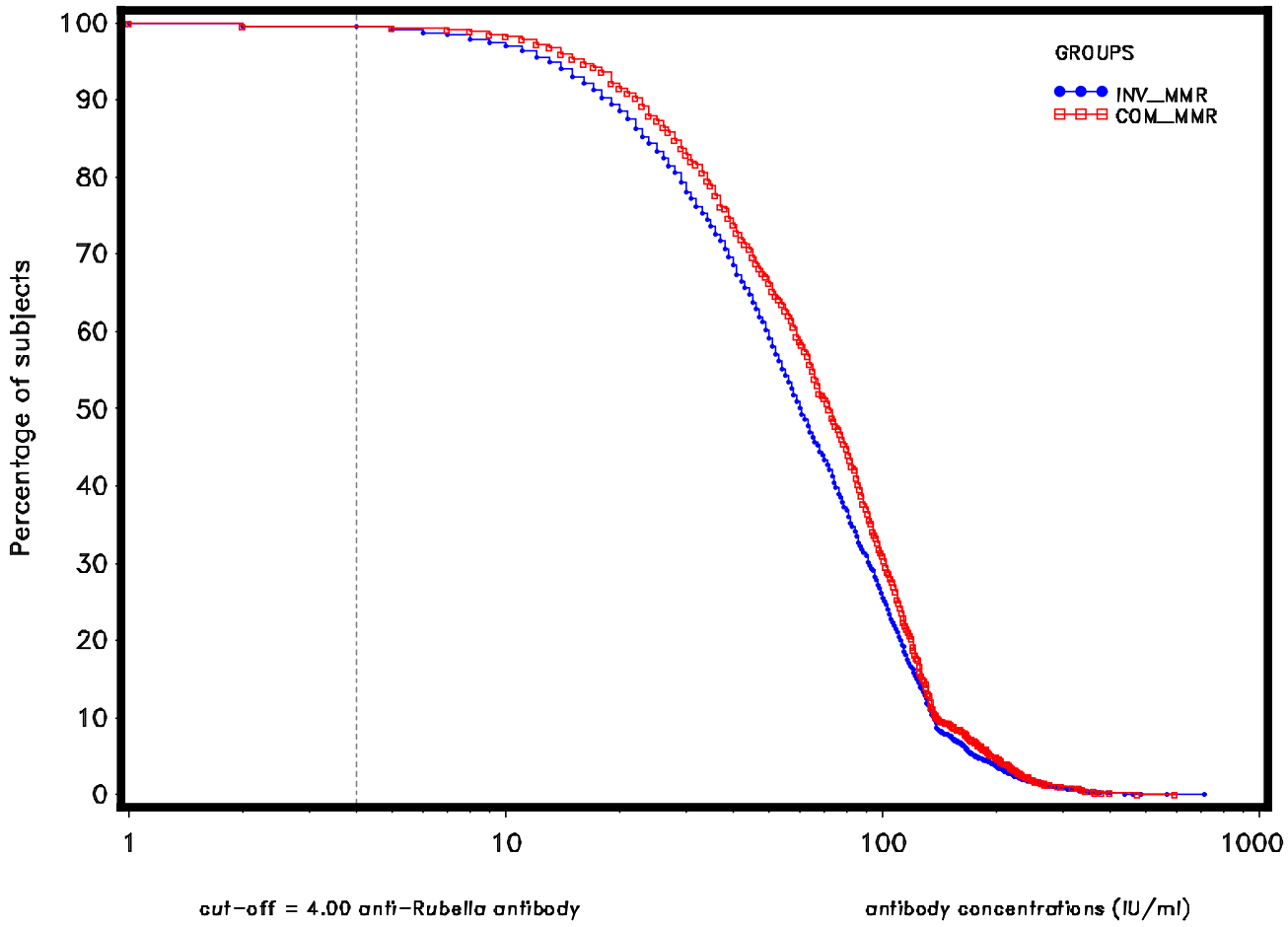
Table 7.56 Distribution of Anti-Rubella antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥4 IU/mL				≥8 IU/mL				≥10 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3294	3278	99.5	99.2	99.7	3242	98.4	97.9	98.8	3208	97.4	96.8	97.9
	COM_MMR	PI(D42)	1149	1144	99.6	99.0	99.9	1139	99.1	98.4	99.6	1132	98.5	97.6	99.1

				≥16 IU/mL				≥32 IU/mL				≥64 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3294	3066	93.1	92.2	93.9	2542	77.2	75.7	78.6	1575	47.8	46.1	49.5
	COM_MMR	PI(D42)	1149	1095	95.3	93.9	96.5	943	82.1	79.7	84.2	653	56.8	53.9	59.7

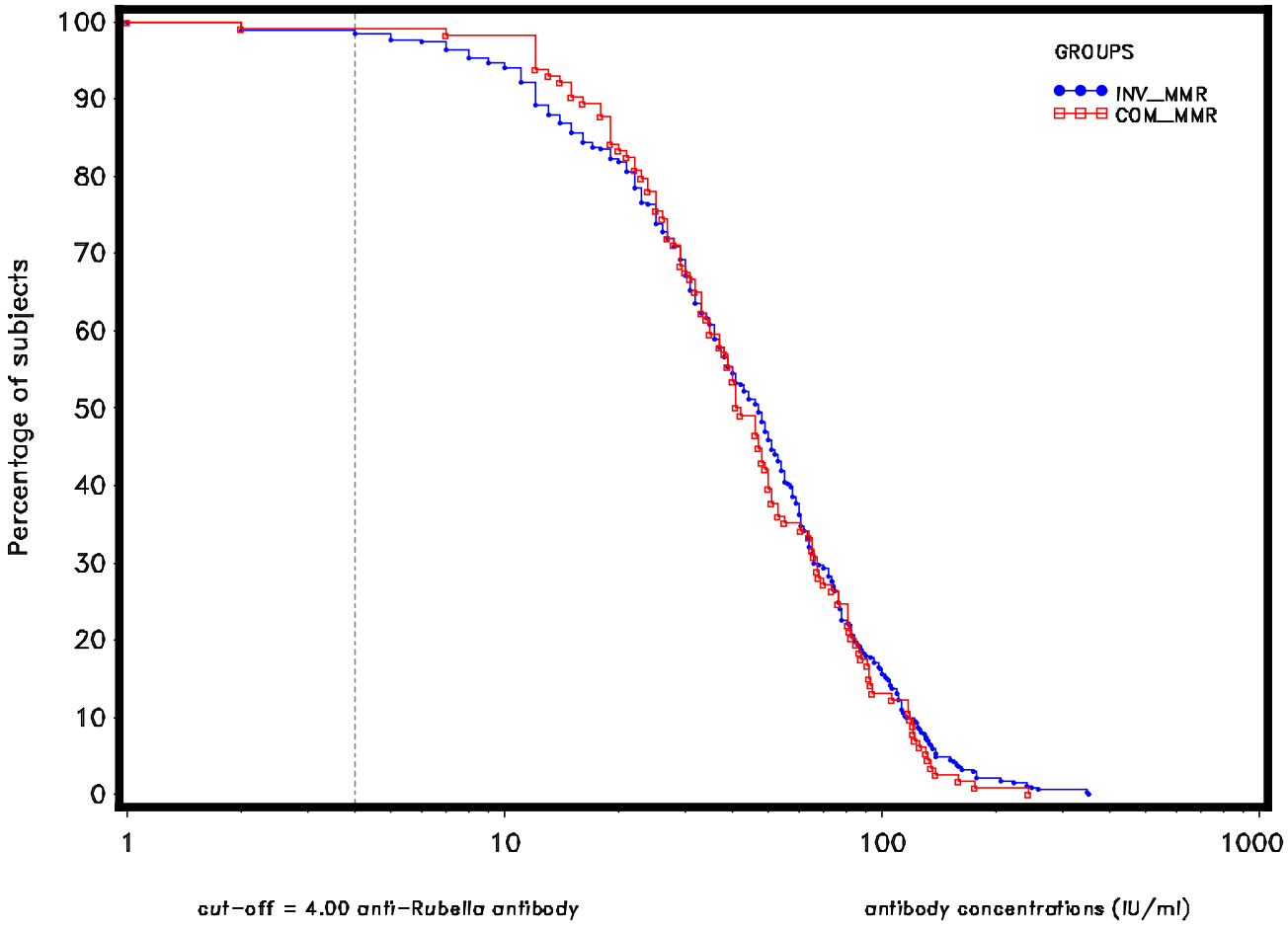
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.16 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)



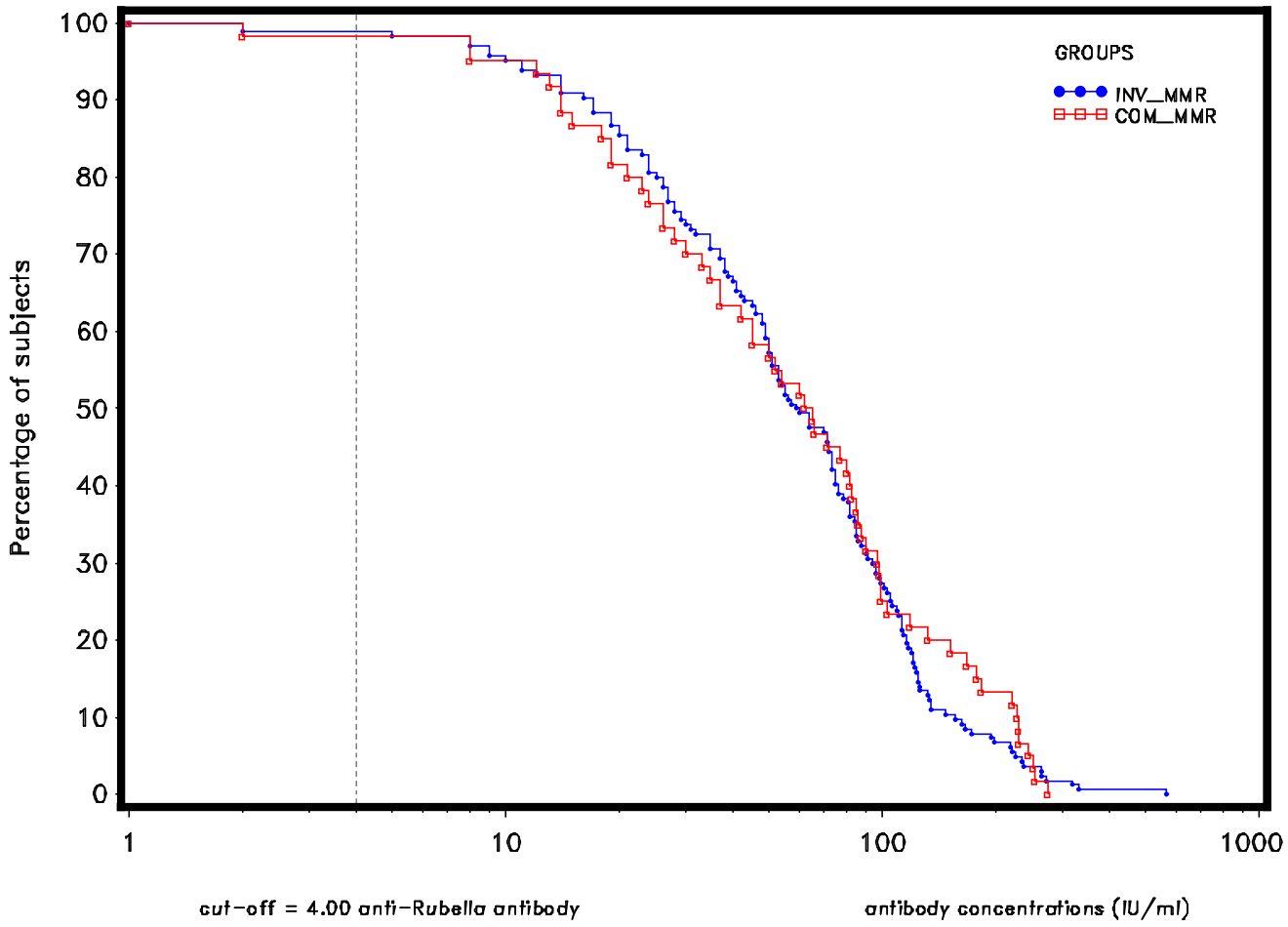
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.17 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)



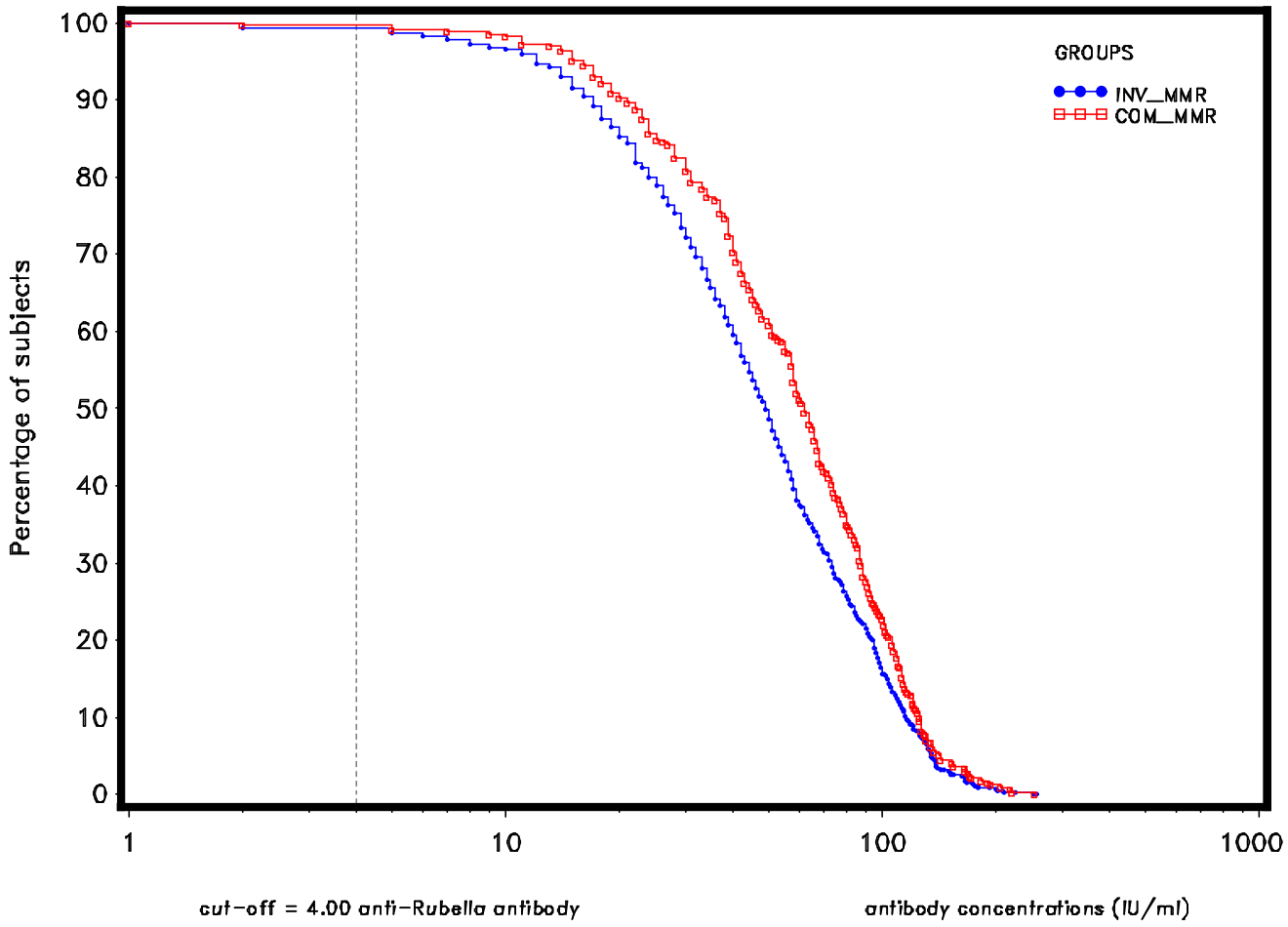
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.18 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)



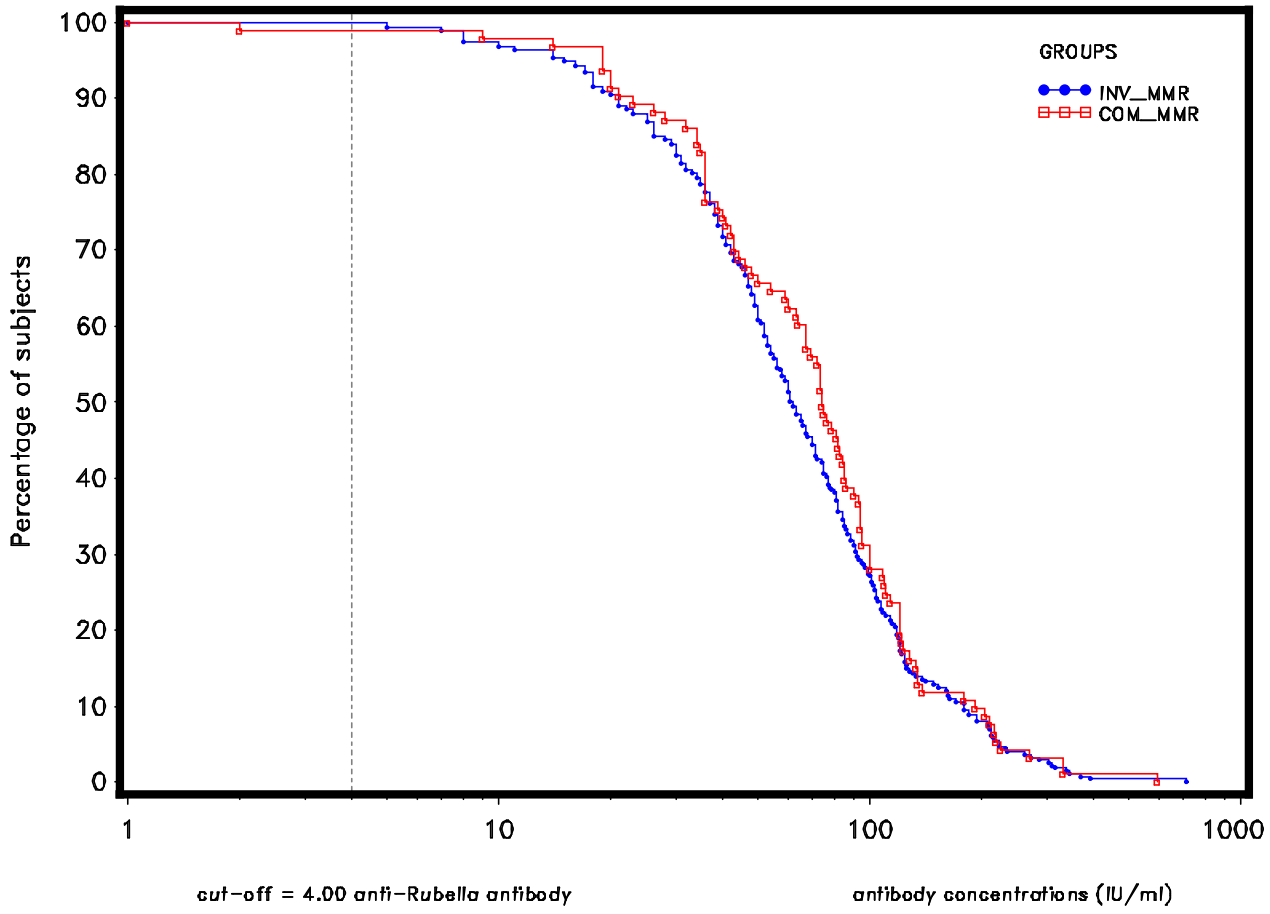
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.19 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)



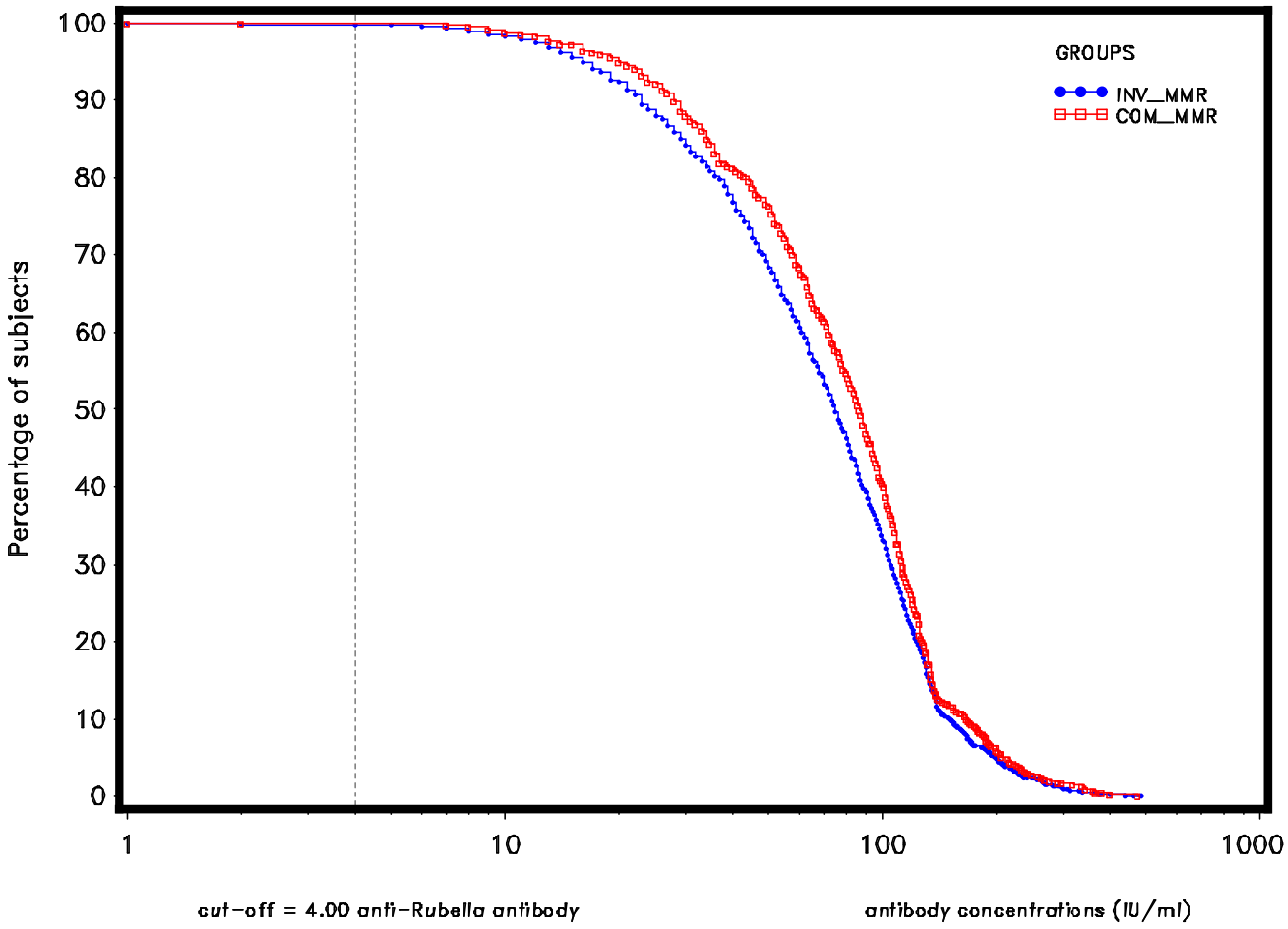
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.20 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.21 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.57 Pre-vaccination status for anti-VZV antibodies - pooled INV_MMR groups (ATP cohort for immunogenicity, VZV subset)

		INV_MMR N=1564		COM_MMR N=556		Total N=2120	
		n	%	n	%	n	%
anti-VZV antibody (mIU/mL)	S-	1514	98.7	544	99.5	2058	98.9
	S+	20	1.3	3	0.5	23	1.1
	Unknown	30	.	9	.	39	.

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 25 mIU/mL for anti-VZV antibody, titre < . for) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 25 mIU/mL for anti-VZV antibody, titre ≥ . for) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.58 Pre-vaccination status for anti-VZV antibodies - pooled INV_MMR groups (ATP cohort for immunogenicity, VZV subset, by gender)

		INV_MMR				COM_MMR				Total			
		F N= 779		M N= 785		F N= 264		M N= 292		F N= 1043		M N= 1077	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-VZV antibody (mIU/mL)	S-	758	99.2	756	98.2	258	99.6	286	99.3	1016	99.3	1042	98.5
	S+	6	0.8	14	1.8	1	0.4	2	0.7	7	0.7	16	1.5
	Unknown	15	.	15	.	5	.	4	.	20	.	19	.

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
S- = seronegative subjects (antibody concentration < 25 mIU/mL for anti-VZV antibody, titre < . for) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 25 mIU/mL for anti-VZV antibody, titre ≥ . for) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.59 Pre-vaccination status for anti-VZV antibodies - pooled INV_MMR groups (ATP cohort for immunogenicity, VZV subset, by geographic ancestry)

		INV_MMR						COM_MMR						Total			
		WH N= 1096		OT N= 52		AF N= 127		WH N= 386		OT N= 21		AF N= 56		WH N= 1482		OT N= 73	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-VZV antibody (mIU/mL)	S-	1059	98.8	50	98.0	121	98.4	376	99.5	21	100	54	98.2	1435	99.0	71	98.6
	S+	13	1.2	1	2.0	2	1.6	2	0.5	0	0.0	1	1.8	15	1.0	1	1.4
	Unknown	24	.	1	.	4	.	8	.	-	.	1	.	32	.	1	.

		Total AF N= 183	
		n	%
anti-VZV antibody (mIU/mL)	S-	175	98.3
	S+	3	1.7
	Unknown	5	.

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
S- = seronegative subjects (antibody concentration < 25 mIU/mL for anti-VZV antibody, titre < . for) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 25 mIU/mL for anti-VZV antibody, titre ≥ . for) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.60 Number and percentage of subjects with an Anti-VZV antibody concentration equal to or above 25 and 75 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset, by gender)

					≥ 25 mIU/mL				≥ 75 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-VZV antibody	INV_MMR	F	PI(D42)	744	741	99.6	98.8	99.9	689	92.6	90.5	94.4	175.5	167.7	183.7
		M	PI(D42)	748	747	99.9	99.3	100	687	91.8	89.6	93.7	163.9	156.9	171.2
	COM_MMR	F	PI(D42)	257	257	100	98.6	100	239	93.0	89.2	95.8	177.5	163.9	192.2
		M	PI(D42)	283	281	99.3	97.5	99.9	252	89.0	84.8	92.4	158.4	146.8	170.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.61 Number and percentage of subjects with an Anti-VZV antibody concentration equal to or above 25 and 75 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset, by geographic ancestry)

					≥ 25 mIU/mL				≥ 75 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-VZV antibody	INV_MMR	WH	PI(D42)	1040	1036	99.6	99.0	99.9	954	91.7	89.9	93.3	162.4	156.4	168.6
		OT	PI(D42)	49	49	100	92.7	100	46	93.9	83.1	98.7	187.8	157.5	224.0
		AF	PI(D42)	119	119	100	96.9	100	111	93.3	87.2	97.1	184.5	164.4	207.1
	COM_MMR	WH	PI(D42)	373	371	99.5	98.1	99.9	335	89.8	86.3	92.7	158.5	148.2	169.5
		OT	PI(D42)	21	21	100	83.9	100	21	100	83.9	100	213.9	157.3	290.9
		AF	PI(D42)	53	53	100	93.3	100	50	94.3	84.3	98.8	177.2	151.2	207.8

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

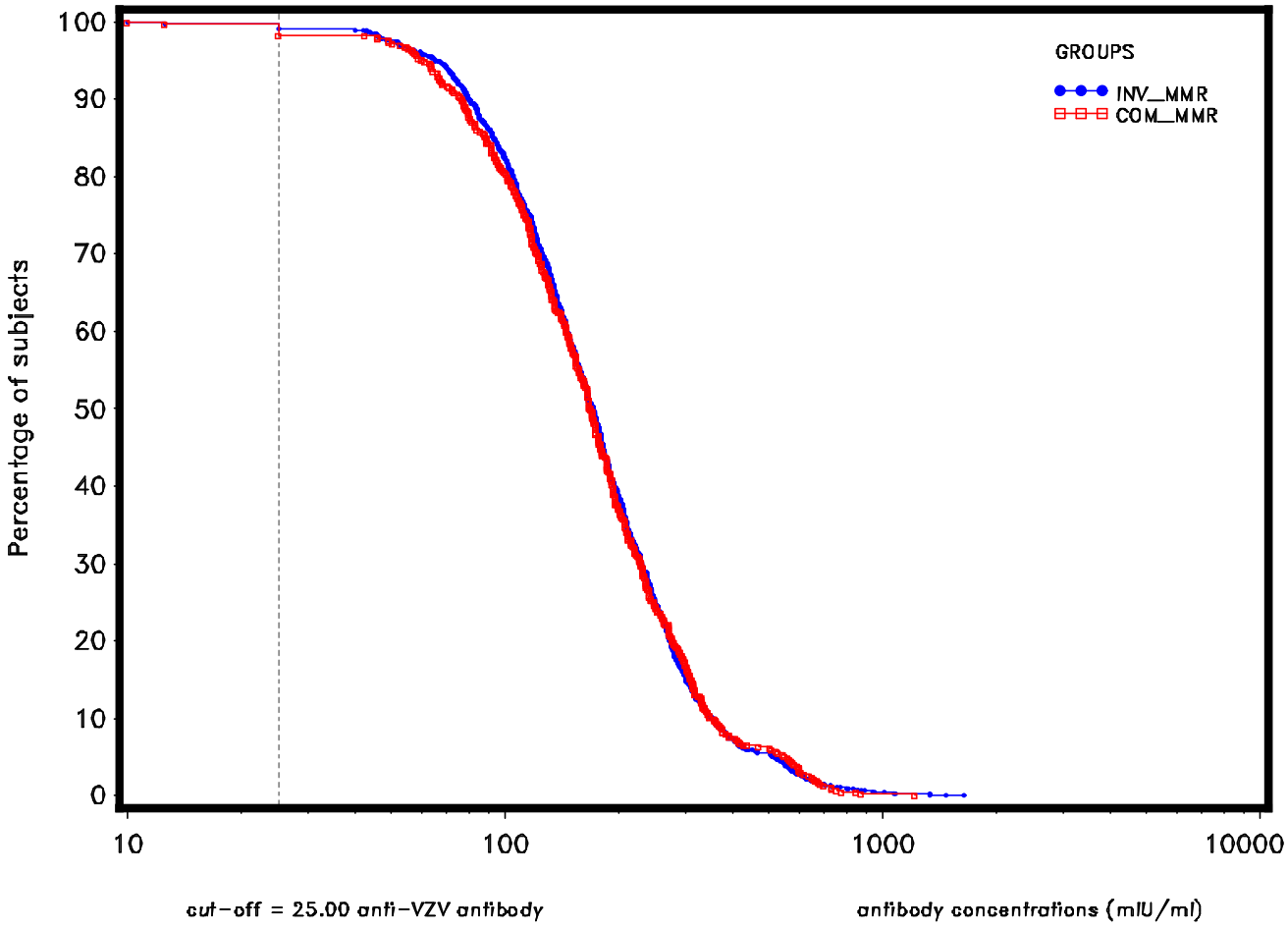
Table 7.62 Distribution of Anti-VZV antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				≥25 mIU/mL				≥50 mIU/mL				≥75 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
anti-VZV antibody	INV_MMR	PI(D42)	1492	1488	99.7	99.3	99.9	1455	97.5	96.6	98.2	1376	92.2	90.7	93.5
	COM_MMR	PI(D42)	540	538	99.6	98.7	100	526	97.4	95.7	98.6	491	90.9	88.2	93.2

				≥100 mIU/mL				≥200 mIU/mL				≥400 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
anti-VZV antibody	INV_MMR	PI(D42)	1492	1228	82.3	80.3	84.2	577	38.7	36.2	41.2	110	7.4	6.1	8.8
	COM_MMR	PI(D42)	540	436	80.7	77.2	84.0	202	37.4	33.3	41.6	41	7.6	5.5	10.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.22 Reverse cumulative distribution curve of Anti-VZV antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.63 Number and percentage of subjects with an Anti-HAV antibody concentration equal to or above 15 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset, by gender)

						≥ 15 mIU/mL				GMC		
								95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-HAV antibody	INV_MMR	F	S-	PI(D42)	353	315	89.2	85.5	92.3	43.7	39.7	48.2
			S+	PI(D42)	20	18	90.0	68.3	98.8	38.8	25.5	59.0
			Total	PI(D42)	373	333	89.3	85.7	92.2	43.5	39.6	47.7
		M	S-	PI(D42)	395	349	88.4	84.8	91.3	40.2	36.7	44.1
			S+	PI(D42)	15	14	93.3	68.1	99.8	54.4	32.1	92.3
			Total	PI(D42)	410	363	88.5	85.0	91.5	40.7	37.2	44.5
	COM_MMR	F	S-	PI(D42)	132	116	87.9	81.1	92.9	47.2	40.0	55.7
			S+	PI(D42)	6	6	100	54.1	100	51.8	31.7	84.6
			Total	PI(D42)	138	122	88.4	81.9	93.2	47.4	40.4	55.6
		M	S-	PI(D42)	139	120	86.3	79.5	91.6	39.0	33.5	45.4
			S+	PI(D42)	8	7	87.5	47.3	99.7	26.3	14.9	46.5
			Total	PI(D42)	147	127	86.4	79.8	91.5	38.2	33.0	44.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
S- = seronegative subjects (antibody concentration < 15 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL) prior to vaccination
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.64 Number and percentage of subjects with an Anti-HAV antibody concentration equal to or above 15 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset, by geographic ancestry)

						≥ 15 mIU/mL				GMC		
								95% CI			95% CI	
Antibody	Group	Sub-group	Pre-vacc status	Timing	N	n	%	LL	UL	value	LL	UL
anti-HAV antibody	INV_MMR	WH	S-	PI(D42)	547	478	87.4	84.3	90.1	37.7	35.0	40.6
			S+	PI(D42)	18	17	94.4	72.7	99.9	41.8	27.3	63.9
			Total	PI(D42)	565	495	87.6	84.6	90.2	37.8	35.1	40.7
		OT	S-	PI(D42)	24	23	95.8	78.9	99.9	46.4	32.0	67.4
			S+	PI(D42)	1	1	100	2.5	100	19.0	-	-
			Total	PI(D42)	25	24	96.0	79.6	99.9	44.8	31.1	64.5
		AF	S-	PI(D42)	56	53	94.6	85.1	98.9	58.7	45.9	75.1
			S+	PI(D42)	1	1	100	2.5	100	83.0	-	-
			Total	PI(D42)	57	54	94.7	85.4	98.9	59.1	46.4	75.3
	COM_MMR	WH	S-	PI(D42)	203	170	83.7	77.9	88.5	37.3	32.8	42.4
			S+	PI(D42)	5	5	100	47.8	100	30.6	21.1	44.3
			Total	PI(D42)	208	175	84.1	78.4	88.8	37.1	32.7	42.0
		OT	S-	PI(D42)	6	6	100	54.1	100	63.2	31.2	127.9
			S+	PI(D42)	3	2	66.7	9.4	99.2	29.2	1.4	613.2
			Total	PI(D42)	9	8	88.9	51.8	99.7	48.9	24.5	97.5
		AF	S-	PI(D42)	22	20	90.9	70.8	98.9	69.3	46.3	103.6
			S+	PI(D42)	1	1	100	2.5	100	18.0	-	-
			Total	PI(D42)	23	21	91.3	72.0	98.9	65.3	43.6	97.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
S- = seronegative subjects (antibody concentration < 15 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL) prior to vaccination
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

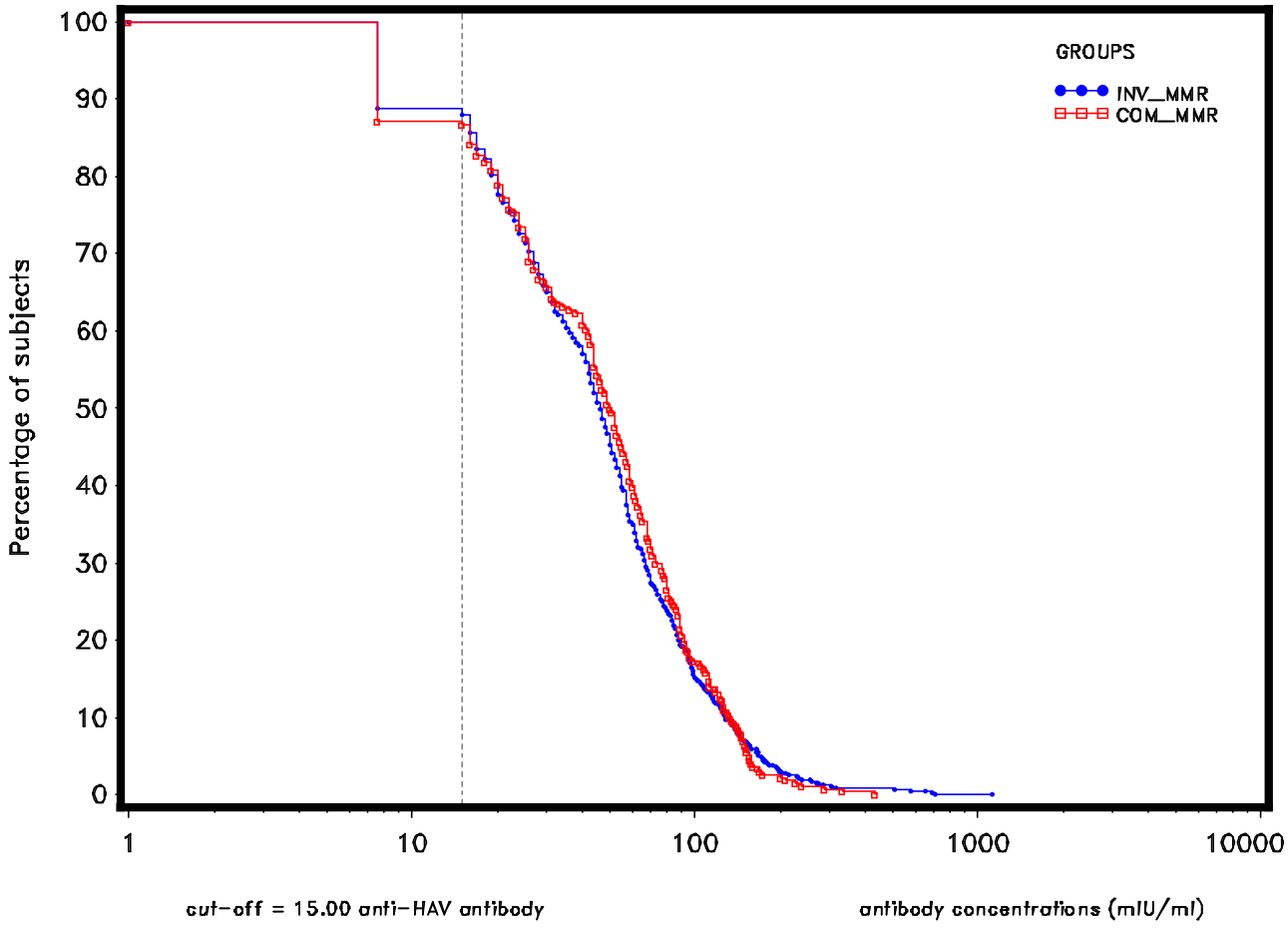
Table 7.65 Distribution of Anti-HAV antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)

				≥15 mIU/mL				≥20 mIU/mL				≥25 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-HAV antibody	INV_MMR	PI(D42)	748	664	88.8	86.3	90.9	600	80.2	77.2	83.0	543	72.6	69.2	75.8
	COM_MMR	PI(D42)	271	236	87.1	82.5	90.8	219	80.8	75.6	85.3	199	73.4	67.8	78.6

				≥30 mIU/mL				≥35 mIU/mL				≥40 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-HAV antibody	INV_MMR	PI(D42)	748	492	65.8	62.3	69.2	458	61.2	57.6	64.7	434	58.0	54.4	61.6
	COM_MMR	PI(D42)	271	180	66.4	60.5	72.0	171	63.1	57.1	68.9	169	62.4	56.3	68.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.23 Reverse cumulative distribution curve of Anti-HAV antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.66 Number and percentage of subjects with an Anti-S.Pneu antibody concentration equal to or above the specified assay cut-off and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset, by gender)

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-PnPS 1 antibody(ECL)(assay cut-off=0.08 µg/ml)	INV_MMR	F	PRE	393	391	99.5	98.2	99.9	275	70.0	65.2	74.5	0.526	0.487	0.568
			PI(D42)	393	390	99.2	97.8	99.8	388	98.7	97.1	99.6	2.520	2.306	2.754
		M	PRE	357	352	98.6	96.8	99.5	194	54.3	49.0	59.6	0.427	0.390	0.467
			PI(D42)	366	365	99.7	98.5	100	363	99.2	97.6	99.8	2.005	1.841	2.184
	COM_MMR	F	PRE	121	121	100	97.0	100	87	71.9	63.0	79.7	0.512	0.455	0.576
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.683	2.320	3.102
		M	PRE	139	139	100	97.4	100	86	61.9	53.3	70.0	0.473	0.417	0.537
			PI(D42)	142	142	100	97.4	100	140	98.6	95.0	99.8	2.220	1.936	2.546
anti-PnPS 3 antibody(ECL)(assay cut-off=0.075 µg/ml)	INV_MMR	F	PRE	393	341	86.8	83.0	90.0	66	16.8	13.2	20.9	0.165	0.150	0.180
			PI(D42)	392	389	99.2	97.8	99.8	285	72.7	68.0	77.1	0.547	0.508	0.589
		M	PRE	357	278	77.9	73.2	82.1	50	14.0	10.6	18.0	0.137	0.124	0.152
			PI(D42)	366	365	99.7	98.5	100	246	67.2	62.1	72.0	0.465	0.433	0.500
	COM_MMR	F	PRE	121	100	82.6	74.7	88.9	13	10.7	5.8	17.7	0.136	0.118	0.156
			PI(D42)	124	123	99.2	95.6	100	86	69.4	60.4	77.3	0.480	0.425	0.541
		M	PRE	139	110	79.1	71.4	85.6	22	15.8	10.2	23.0	0.150	0.125	0.179
			PI(D42)	141	141	100	97.4	100	98	69.5	61.2	77.0	0.511	0.449	0.582
anti-PnPS 4 antibody(ECL)(assay cut-off=0.061 µg/ml)	INV_MMR	F	PRE	392	384	98.0	96.0	99.1	169	43.1	38.2	48.2	0.298	0.275	0.323
			PI(D42)	390	387	99.2	97.8	99.8	382	97.9	96.0	99.1	1.876	1.711	2.057
		M	PRE	356	342	96.1	93.5	97.8	123	34.6	29.6	39.7	0.245	0.224	0.268
			PI(D42)	363	362	99.7	98.5	100	356	98.1	96.1	99.2	1.381	1.268	1.505
	COM_MMR	F	PRE	120	118	98.3	94.1	99.8	52	43.3	34.3	52.7	0.303	0.265	0.346
			PI(D42)	124	124	100	97.1	100	121	97.6	93.1	99.5	2.143	1.832	2.506
		M	PRE	139	137	98.6	94.9	99.8	46	33.1	25.4	41.6	0.260	0.225	0.300
			PI(D42)	142	142	100	97.4	100	137	96.5	92.0	98.8	1.663	1.425	1.942
anti-PnPS 5 antibody(ECL)(assay cut-off=0.198 µg/ml)	INV_MMR	F	PRE	393	366	93.1	90.2	95.4	288	73.3	68.6	77.6	0.543	0.502	0.587
			PI(D42)	392	389	99.2	97.8	99.8	388	99.0	97.4	99.7	2.356	2.182	2.544
		M	PRE	357	311	87.1	83.2	90.4	222	62.2	56.9	67.2	0.438	0.402	0.478
			PI(D42)	365	364	99.7	98.5	100	360	98.6	96.8	99.6	1.867	1.721	2.025
	COM_MMR	F	PRE	121	117	96.7	91.8	99.1	90	74.4	65.6	81.9	0.524	0.467	0.587
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.606	2.306	2.945

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
		M	PRE	139	122	87.8	81.1	92.7	92	66.2	57.7	74.0	0.454	0.394	0.524
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	2.029	1.788	2.303
anti-PnPS 6A antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	F	PRE	393	392	99.7	98.6	100	346	88.0	84.4	91.1	0.803	0.743	0.867
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	6.335	5.825	6.889
		M	PRE	357	345	96.6	94.2	98.3	273	76.5	71.7	80.8	0.637	0.581	0.700
			PI(D42)	366	365	99.7	98.5	100	365	99.7	98.5	100	5.352	4.937	5.801
	COM_MMR	F	PRE	121	119	98.3	94.2	99.8	104	86.0	78.5	91.6	0.804	0.695	0.930
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	6.372	5.551	7.313
		M	PRE	139	138	99.3	96.1	100	110	79.1	71.4	85.6	0.637	0.558	0.727
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	5.245	4.625	5.949
anti-PnPS 6B antibody(ECL)(assay cut-off=0.102 µg/ml)	INV_MMR	F	PRE	393	373	94.9	92.2	96.9	288	73.3	68.6	77.6	0.635	0.572	0.704
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	6.665	6.081	7.306
		M	PRE	357	322	90.2	86.6	93.1	207	58.0	52.7	63.2	0.441	0.393	0.495
			PI(D42)	365	364	99.7	98.5	100	364	99.7	98.5	100	5.123	4.686	5.602
	COM_MMR	F	PRE	121	113	93.4	87.4	97.1	90	74.4	65.6	81.9	0.630	0.516	0.770
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	6.930	5.987	8.023
		M	PRE	139	127	91.4	85.4	95.5	81	58.3	49.6	66.6	0.419	0.350	0.502
			PI(D42)	142	142	100	97.4	100	141	99.3	96.1	100	5.026	4.305	5.867
anti-PnPS 7F antibody(ECL)(assay cut-off=0.063 µg/ml)	INV_MMR	F	PRE	393	393	100	99.1	100	357	90.8	87.5	93.5	0.924	0.862	0.991
			PI(D42)	392	389	99.2	97.8	99.8	389	99.2	97.8	99.8	3.907	3.594	4.248
		M	PRE	357	357	100	99.0	100	314	88.0	84.1	91.1	0.798	0.740	0.860
			PI(D42)	366	365	99.7	98.5	100	365	99.7	98.5	100	3.473	3.222	3.743
	COM_MMR	F	PRE	121	121	100	97.0	100	111	91.7	85.3	96.0	0.859	0.770	0.958
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	4.041	3.615	4.518
		M	PRE	139	139	100	97.4	100	125	89.9	83.7	94.4	0.774	0.687	0.873
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	3.627	3.154	4.170
anti-PnPS 9V antibody(ECL)(assay cut-off=0.066 µg/ml)	INV_MMR	F	PRE	393	390	99.2	97.8	99.8	223	56.7	51.7	61.7	0.399	0.367	0.433
			PI(D42)	393	390	99.2	97.8	99.8	386	98.2	96.4	99.3	2.534	2.326	2.762
		M	PRE	357	344	96.4	93.9	98.0	155	43.4	38.2	48.7	0.320	0.289	0.354
			PI(D42)	366	365	99.7	98.5	100	362	98.9	97.2	99.7	2.106	1.940	2.287
	COM_MMR	F	PRE	121	120	99.2	95.5	100	60	49.6	40.4	58.8	0.361	0.315	0.414
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.445	2.145	2.787
		M	PRE	139	136	97.8	93.8	99.6	66	47.5	39.0	56.1	0.327	0.283	0.378

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
			PI(D42)	142	142	100	97.4	100	140	98.6	95.0	99.8	2.148	1.851	2.493
anti-PnPS 14 antibody(ECL)(assay cut-off=0.16 µg/ml)	INV_MMR	F	PRE	393	388	98.7	97.1	99.6	379	96.4	94.1	98.0	1.933	1.764	2.118
			PI(D42)	392	389	99.2	97.8	99.8	388	99.0	97.4	99.7	7.187	6.527	7.913
		M	PRE	357	352	98.6	96.8	99.5	325	91.0	87.6	93.8	1.479	1.336	1.638
			PI(D42)	365	364	99.7	98.5	100	364	99.7	98.5	100	5.981	5.463	6.548
	COM_MMR	F	PRE	121	120	99.2	95.5	100	119	98.3	94.2	99.8	1.848	1.593	2.144
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	7.950	6.822	9.264
		M	PRE	139	135	97.1	92.8	99.2	130	93.5	88.1	97.0	1.525	1.291	1.802
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	6.353	5.544	7.279
anti-PnPS 18C antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	F	PRE	393	366	93.1	90.2	95.4	182	46.3	41.3	51.4	0.316	0.290	0.343
			PI(D42)	393	390	99.2	97.8	99.8	389	99.0	97.4	99.7	2.234	2.042	2.444
		M	PRE	357	309	86.6	82.6	89.9	125	35.0	30.1	40.2	0.256	0.233	0.281
			PI(D42)	366	365	99.7	98.5	100	360	98.4	96.5	99.4	1.970	1.800	2.156
	COM_MMR	F	PRE	121	113	93.4	87.4	97.1	55	45.5	36.4	54.8	0.297	0.259	0.340
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.387	2.068	2.756
		M	PRE	139	117	84.2	77.0	89.8	53	38.1	30.0	46.7	0.256	0.220	0.299
			PI(D42)	141	141	100	97.4	100	138	97.9	93.9	99.6	2.077	1.771	2.437
anti-PnPS 19A antibody(ECL)(assay cut-off=0.199 µg/ml)	INV_MMR	F	PRE	392	358	91.3	88.1	93.9	273	69.6	64.8	74.2	0.567	0.516	0.624
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	5.467	5.045	5.925
		M	PRE	357	294	82.4	78.0	86.2	202	56.6	51.3	61.8	0.456	0.408	0.510
			PI(D42)	366	365	99.7	98.5	100	363	99.2	97.6	99.8	4.050	3.726	4.403
	COM_MMR	F	PRE	121	108	89.3	82.3	94.2	86	71.1	62.1	79.0	0.519	0.446	0.604
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	5.685	4.990	6.476
		M	PRE	139	116	83.5	76.2	89.2	82	59.0	50.3	67.3	0.440	0.370	0.524
			PI(D42)	141	141	100	97.4	100	141	100	97.4	100	4.171	3.623	4.802
anti-PnPS 19F antibody(ECL)(assay cut-off=0.163 µg/ml)	INV_MMR	F	PRE	393	385	98.0	96.0	99.1	317	80.7	76.4	84.4	0.725	0.663	0.794
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	4.841	4.464	5.249
		M	PRE	357	339	95.0	92.1	97.0	260	72.8	67.9	77.4	0.584	0.531	0.642
			PI(D42)	366	365	99.7	98.5	100	364	99.5	98.0	99.9	3.698	3.413	4.008
	COM_MMR	F	PRE	121	118	97.5	92.9	99.5	98	81.0	72.9	87.6	0.682	0.585	0.797
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	5.244	4.617	5.955
		M	PRE	139	133	95.7	90.8	98.4	91	65.5	56.9	73.3	0.522	0.455	0.599
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	3.554	3.106	4.065

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PnPS 23F antibody(ECL)(assay cut-off=0.073 µg/ml)	INV_MMR	F	PRE	381	347	91.1	87.8	93.7	146	38.3	33.4	43.4	0.286	0.255	0.320
			PI(D42)	385	382	99.2	97.7	99.8	380	98.7	97.0	99.6	2.424	2.206	2.665
		M	PRE	347	297	85.6	81.4	89.1	120	34.6	29.6	39.8	0.218	0.194	0.246
			PI(D42)	357	356	99.7	98.4	100	350	98.0	96.0	99.2	1.978	1.788	2.187
	COM_MMR	F	PRE	119	110	92.4	86.1	96.5	50	42.0	33.0	51.4	0.302	0.248	0.367
			PI(D42)	119	119	100	96.9	100	118	99.2	95.4	100	2.777	2.333	3.305
		M	PRE	135	113	83.7	76.4	89.5	41	30.4	22.8	38.9	0.202	0.166	0.246
			PI(D42)	137	136	99.3	96.0	100	133	97.1	92.7	99.2	1.938	1.633	2.300

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.67 Number and percentage of subjects with an Anti-S.Pneu antibody concentration equal to or above the specified assay cut-off and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset, by geographic ancestry)

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PnPS 1 antibody(ECL)(assay cut-off=0.08 µg/ml)	INV_MMR	PRE	598	592	99.0	97.8	99.6	361	60.4	56.3	64.3	0.448	0.420	0.478
		PI(D42)	607	604	99.5	98.6	99.9	601	99.0	97.9	99.6	2.114	1.977	2.261
	COM_MMR	PRE	214	214	100	98.3	100	139	65.0	58.2	71.3	0.467	0.425	0.514
		PI(D42)	218	218	100	98.3	100	216	99.1	96.7	99.9	2.293	2.055	2.560
anti-PnPS 3 antibody(ECL)(assay cut-off=0.075 µg/ml)	INV_MMR	PRE	598	477	79.8	76.3	82.9	82	13.7	11.1	16.7	0.139	0.129	0.151
		PI(D42)	607	604	99.5	98.6	99.9	416	68.5	64.7	72.2	0.492	0.464	0.521
	COM_MMR	PRE	214	170	79.4	73.4	84.6	30	14.0	9.7	19.4	0.139	0.122	0.159
		PI(D42)	217	216	99.5	97.5	100	148	68.2	61.6	74.3	0.495	0.446	0.548
anti-PnPS 4 antibody(ECL)(assay cut-off=0.061 µg/ml)	INV_MMR	PRE	596	574	96.3	94.5	97.7	215	36.1	32.2	40.1	0.252	0.235	0.269
		PI(D42)	602	599	99.5	98.6	99.9	588	97.7	96.1	98.7	1.533	1.430	1.644
	COM_MMR	PRE	213	209	98.1	95.3	99.5	73	34.3	27.9	41.1	0.264	0.236	0.294
		PI(D42)	218	218	100	98.3	100	211	96.8	93.5	98.7	1.774	1.571	2.003
anti-PnPS 5 antibody(ECL)(assay cut-off=0.198 µg/ml)	INV_MMR	PRE	598	533	89.1	86.4	91.5	386	64.5	60.6	68.4	0.462	0.433	0.493
		PI(D42)	605	602	99.5	98.6	99.9	597	98.7	97.4	99.4	2.009	1.887	2.138
	COM_MMR	PRE	214	194	90.7	85.9	94.2	146	68.2	61.5	74.4	0.467	0.421	0.518
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	2.213	2.006	2.441
anti-PnPS 6A antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	598	586	98.0	96.5	99.0	480	80.3	76.8	83.4	0.690	0.644	0.740
		PI(D42)	607	604	99.5	98.6	99.9	604	99.5	98.6	99.9	5.689	5.335	6.067
	COM_MMR	PRE	214	211	98.6	96.0	99.7	176	82.2	76.5	87.1	0.699	0.626	0.780
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	5.704	5.129	6.344
anti-PnPS 6B antibody(ECL)(assay cut-off=0.102 µg/ml)	INV_MMR	PRE	598	547	91.5	88.9	93.6	377	63.0	59.0	66.9	0.505	0.462	0.553
		PI(D42)	607	604	99.5	98.6	99.9	604	99.5	98.6	99.9	5.667	5.276	6.086
	COM_MMR	PRE	214	195	91.1	86.5	94.6	138	64.5	57.7	70.9	0.483	0.414	0.564
		PI(D42)	218	218	100	98.3	100	217	99.5	97.5	100	5.636	4.999	6.355
anti-PnPS 7F antibody(ECL)(assay cut-off=0.063 µg/ml)	INV_MMR	PRE	598	598	100	99.4	100	534	89.3	86.5	91.7	0.844	0.797	0.895
		PI(D42)	607	604	99.5	98.6	99.9	604	99.5	98.6	99.9	3.596	3.382	3.824
	COM_MMR	PRE	214	214	100	98.3	100	196	91.6	87.0	94.9	0.810	0.742	0.884
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	3.818	3.459	4.215
anti-PnPS 9V antibody(ECL)(assay cut-off=0.066 µg/ml)	INV_MMR	PRE	598	582	97.3	95.7	98.5	288	48.2	44.1	52.2	0.337	0.313	0.362

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
		PI(D42)	607	604	99.5	98.6	99.9	597	98.4	97.0	99.2	2.229	2.087	2.380
	COM_MMR	PRE	214	211	98.6	96.0	99.7	96	44.9	38.1	51.8	0.323	0.290	0.360
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	2.222	1.996	2.475
anti-PnPS 14 antibody(ECL)(assay cut-off=0.16 µg/ml)	INV_MMR	PRE	598	590	98.7	97.4	99.4	556	93.0	90.6	94.9	1.583	1.466	1.710
		PI(D42)	606	603	99.5	98.6	99.9	602	99.3	98.3	99.8	6.277	5.829	6.758
	COM_MMR	PRE	214	211	98.6	96.0	99.7	205	95.8	92.2	98.1	1.696	1.502	1.915
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	7.060	6.303	7.909
anti-PnPS 18C antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	598	530	88.6	85.8	91.1	230	38.5	34.5	42.5	0.271	0.252	0.291
		PI(D42)	607	604	99.5	98.6	99.9	598	98.5	97.2	99.3	1.992	1.857	2.137
	COM_MMR	PRE	214	187	87.4	82.2	91.5	85	39.7	33.1	46.6	0.262	0.233	0.293
		PI(D42)	217	217	100	98.3	100	215	99.1	96.7	99.9	2.143	1.902	2.414
anti-PnPS 19A antibody(ECL)(assay cut-off=0.199 µg/ml)	INV_MMR	PRE	597	512	85.8	82.7	88.5	366	61.3	57.3	65.2	0.485	0.447	0.526
		PI(D42)	607	604	99.5	98.6	99.9	602	99.2	98.1	99.7	4.597	4.306	4.908
	COM_MMR	PRE	214	181	84.6	79.0	89.1	129	60.3	53.4	66.9	0.442	0.391	0.500
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	4.648	4.177	5.172
anti-PnPS 19F antibody(ECL)(assay cut-off=0.163 µg/ml)	INV_MMR	PRE	598	573	95.8	93.9	97.3	442	73.9	70.2	77.4	0.615	0.572	0.663
		PI(D42)	607	604	99.5	98.6	99.9	603	99.3	98.3	99.8	4.099	3.843	4.373
	COM_MMR	PRE	214	205	95.8	92.2	98.1	147	68.7	62.0	74.8	0.553	0.492	0.623
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	4.199	3.771	4.676
anti-PnPS 23F antibody(ECL)(assay cut-off=0.073 µg/ml)	INV_MMR	PRE	582	509	87.5	84.5	90.0	202	34.7	30.8	38.7	0.237	0.216	0.260
		PI(D42)	593	590	99.5	98.5	99.9	583	98.3	96.9	99.2	2.127	1.973	2.293
	COM_MMR	PRE	208	179	86.1	80.6	90.5	69	33.2	26.8	40.0	0.231	0.196	0.271
		PI(D42)	210	209	99.5	97.4	100	205	97.6	94.5	99.2	2.158	1.881	2.475

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

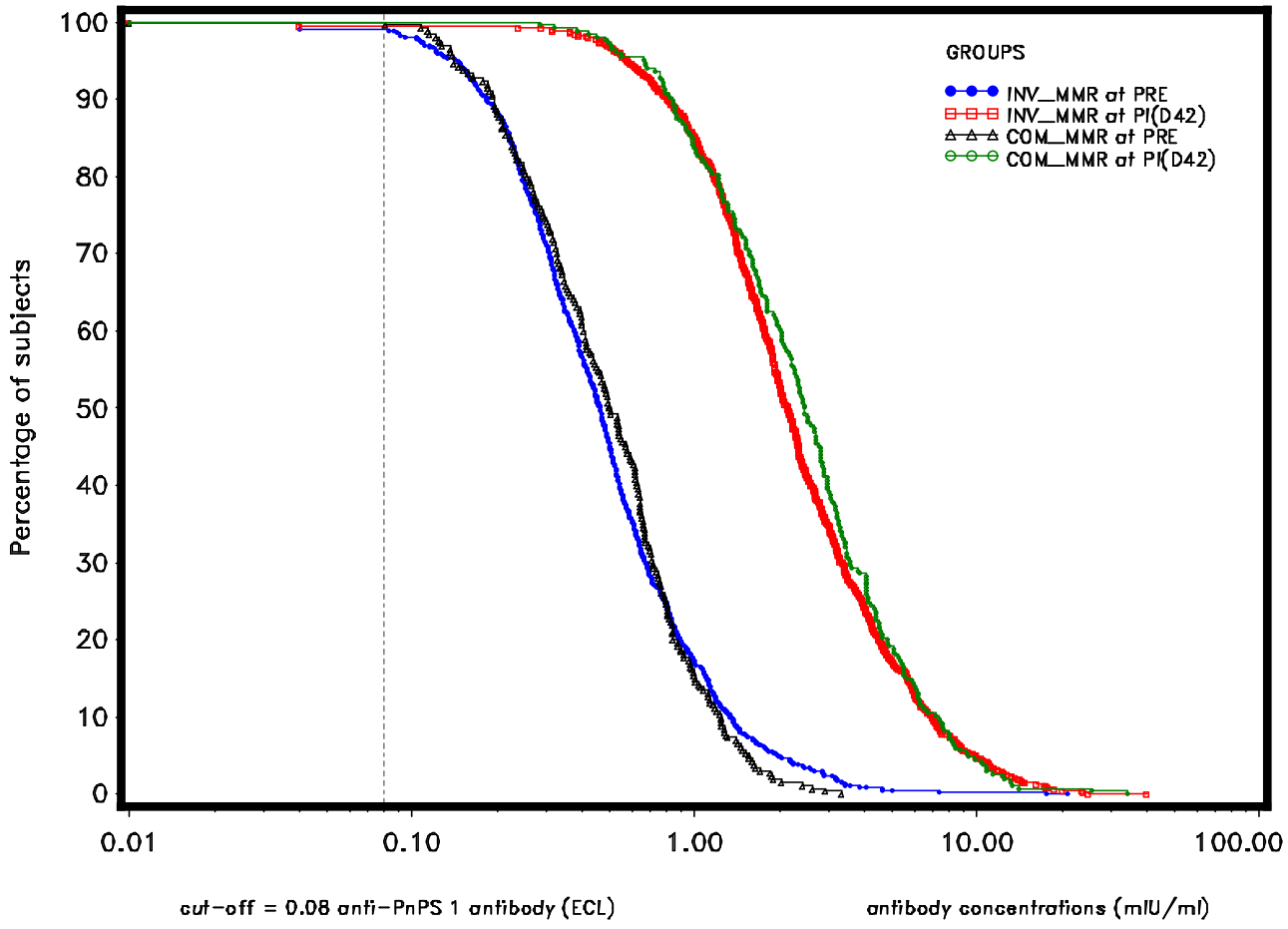
Table 7.68 Distribution of Anti-S.Pneu antibody concentrations - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

				≥0.1 µg/mL				≥1 µg/mL				≥10 µg/mL			
						95% CI				95% CI				95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
anti-PnPS 1 antibody (ECL)	INV_MMR	PRE	750	736	98.1	96.9	99.0	128	17.1	14.4	20.0	2	0.3	0.0	1.0
		PI(D42)	759	755	99.5	98.7	99.9	648	85.4	82.7	87.8	38	5.0	3.6	6.8
	COM_MMR	PRE	260	259	99.6	97.9	100	41	15.8	11.6	20.8	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	223	83.8	78.8	88.0	12	4.5	2.4	7.7
anti-PnPS 3 antibody (ECL)	INV_MMR	PRE	750	530	70.7	67.3	73.9	25	3.3	2.2	4.9	0	0.0	0.0	0.5
		PI(D42)	758	751	99.1	98.1	99.6	108	14.2	11.8	16.9	0	0.0	0.0	0.5
	COM_MMR	PRE	260	181	69.6	63.6	75.1	8	3.1	1.3	6.0	0	0.0	0.0	1.4
		PI(D42)	265	263	99.2	97.3	99.9	38	14.3	10.4	19.1	0	0.0	0.0	1.4
anti-PnPS 4 antibody (ECL)	INV_MMR	PRE	748	668	89.3	86.9	91.4	38	5.1	3.6	6.9	1	0.1	0.0	0.7
		PI(D42)	753	749	99.5	98.6	99.9	536	71.2	67.8	74.4	22	2.9	1.8	4.4
	COM_MMR	PRE	259	230	88.8	84.3	92.4	16	6.2	3.6	9.8	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	202	75.9	70.3	80.9	11	4.1	2.1	7.3
anti-PnPS 5 antibody (ECL)	INV_MMR	PRE	750	677	90.3	87.9	92.3	140	18.7	15.9	21.6	1	0.1	0.0	0.7
		PI(D42)	757	753	99.5	98.7	99.9	641	84.7	81.9	87.2	20	2.6	1.6	4.1
	COM_MMR	PRE	260	239	91.9	87.9	94.9	43	16.5	12.2	21.6	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	230	86.5	81.8	90.3	10	3.8	1.8	6.8
anti-PnPS 6A antibody (ECL)	INV_MMR	PRE	750	737	98.3	97.1	99.1	243	32.4	29.1	35.9	3	0.4	0.1	1.2
		PI(D42)	759	755	99.5	98.7	99.9	752	99.1	98.1	99.6	176	23.2	20.2	26.4
	COM_MMR	PRE	260	257	98.8	96.7	99.8	89	34.2	28.5	40.3	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	263	98.9	96.7	99.8	61	22.9	18.0	28.5
anti-PnPS 6B antibody (ECL)	INV_MMR	PRE	750	695	92.7	90.6	94.4	204	27.2	24.0	30.5	4	0.5	0.1	1.4
		PI(D42)	758	754	99.5	98.7	99.9	739	97.5	96.1	98.5	198	26.1	23.0	29.4
	COM_MMR	PRE	260	240	92.3	88.4	95.2	72	27.7	22.3	33.6	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	260	97.7	95.2	99.2	73	27.4	22.2	33.2
anti-PnPS 7F antibody (ECL)	INV_MMR	PRE	750	749	99.9	99.3	100	295	39.3	35.8	42.9	3	0.4	0.1	1.2
		PI(D42)	758	754	99.5	98.7	99.9	737	97.2	95.8	98.3	74	9.8	7.7	12.1
	COM_MMR	PRE	260	260	100	98.6	100	96	36.9	31.0	43.1	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	255	95.9	92.7	97.9	18	6.8	4.1	10.5
anti-PnPS 9V antibody (ECL)	INV_MMR	PRE	750	709	94.5	92.7	96.0	82	10.9	8.8	13.4	1	0.1	0.0	0.7
		PI(D42)	759	755	99.5	98.7	99.9	663	87.4	84.8	89.6	27	3.6	2.4	5.1
	COM_MMR	PRE	260	247	95.0	91.6	97.3	28	10.8	7.3	15.2	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	226	85.0	80.1	89.0	12	4.5	2.4	7.7
anti-PnPS 14 antibody (ECL)	INV_MMR	PRE	750	740	98.7	97.6	99.4	551	73.5	70.2	76.6	18	2.4	1.4	3.8
		PI(D42)	757	753	99.5	98.7	99.9	740	97.8	96.4	98.7	251	33.2	29.8	36.6
	COM_MMR	PRE	260	255	98.1	95.6	99.4	193	74.2	68.5	79.4	3	1.2	0.2	3.3
		PI(D42)	266	266	100	98.6	100	263	98.9	96.7	99.8	97	36.5	30.7	42.6
anti-PnPS 18C antibody (ECL)	INV_MMR	PRE	750	675	90.0	87.6	92.1	52	6.9	5.2	9.0	1	0.1	0.0	0.7
		PI(D42)	759	755	99.5	98.7	99.9	619	81.6	78.6	84.3	39	5.1	3.7	7.0
	COM_MMR	PRE	260	230	88.5	83.9	92.1	16	6.2	3.6	9.8	0	0.0	0.0	1.4
		PI(D42)	265	265	100	98.6	100	215	81.1	75.9	85.7	14	5.3	2.9	8.7
anti-PnPS 19A antibody (ECL)	INV_MMR	PRE	749	652	87.0	84.4	89.4	176	23.5	20.5	26.7	7	0.9	0.4	1.9
		PI(D42)	759	755	99.5	98.7	99.9	738	97.2	95.8	98.3	131	17.3	14.6	20.1
	COM_MMR	PRE	260	224	86.2	81.3	90.1	50	19.2	14.6	24.6	2	0.8	0.1	2.8
		PI(D42)	265	265	100	98.6	100	256	96.6	93.7	98.4	45	17.0	12.7	22.1
anti-PnPS 19F antibody (ECL)	INV_MMR	PRE	750	724	96.5	95.0	97.7	206	27.5	24.3	30.8	9	1.2	0.6	2.3
		PI(D42)	759	755	99.5	98.7	99.9	737	97.1	95.6	98.2	109	14.4	11.9	17.1
	COM_MMR	PRE	260	251	96.5	93.5	98.4	66	25.4	20.2	31.1	2	0.8	0.1	2.8
		PI(D42)	266	266	100	98.6	100	257	96.6	93.7	98.4	37	13.9	10.0	18.7
anti-PnPS 23F antibody (ECL)	INV_MMR	PRE	728	586	80.5	77.4	83.3	78	10.7	8.6	13.2	2	0.3	0.0	1.0
		PI(D42)	742	738	99.5	98.6	99.9	592	79.8	76.7	82.6	40	5.4	3.9	7.3

				≥0.1 µg/mL				≥1 µg/mL				≥10 µg/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	COM_MMR	PRE	254	199	78.3	72.8	83.3	31	12.2	8.4	16.9	0	0.0	0.0	1.4
		PI(D42)	256	255	99.6	97.8	100	209	81.6	76.3	86.2	18	7.0	4.2	10.9

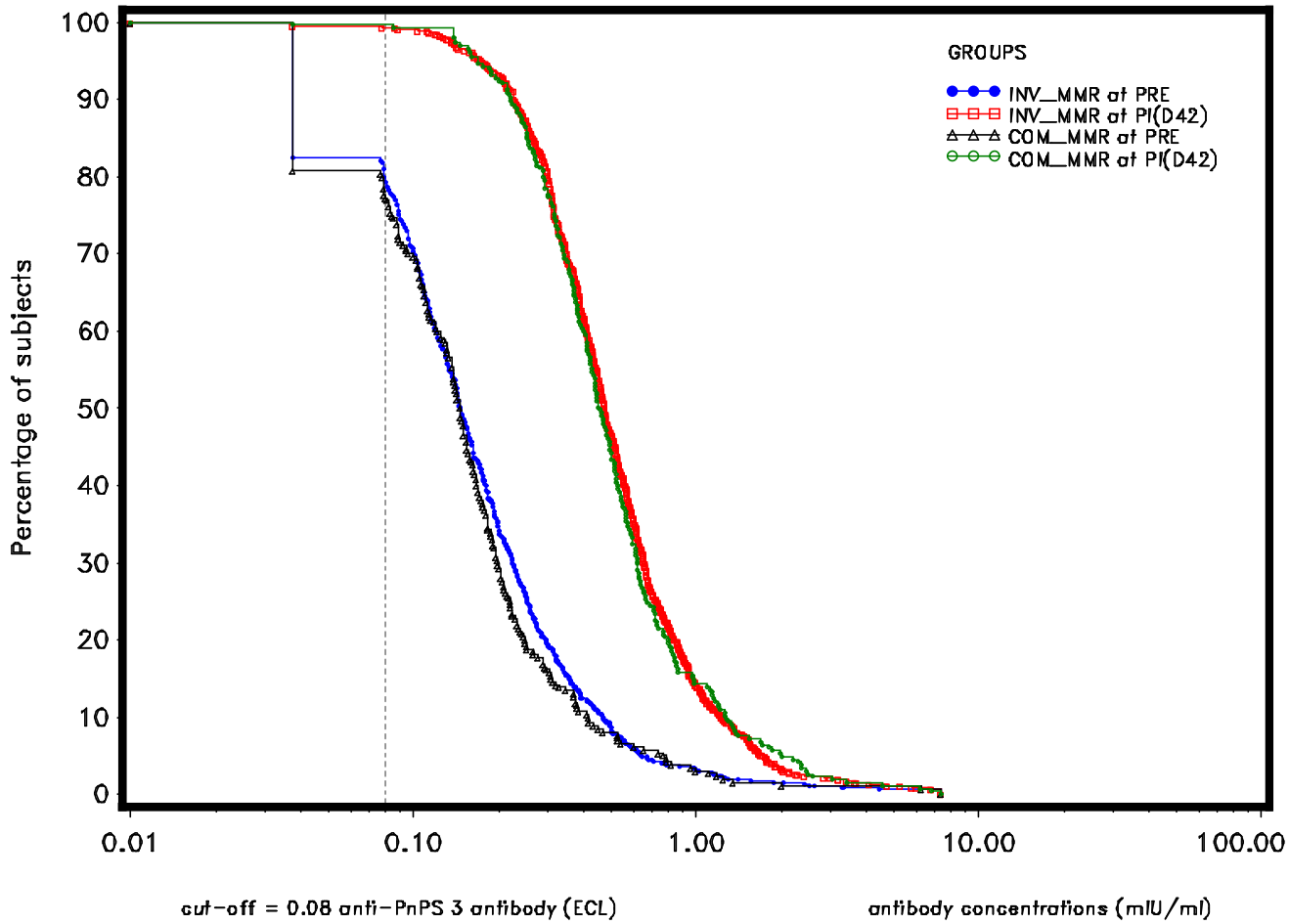
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.24 Reverse cumulative distribution curve of Anti-1 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



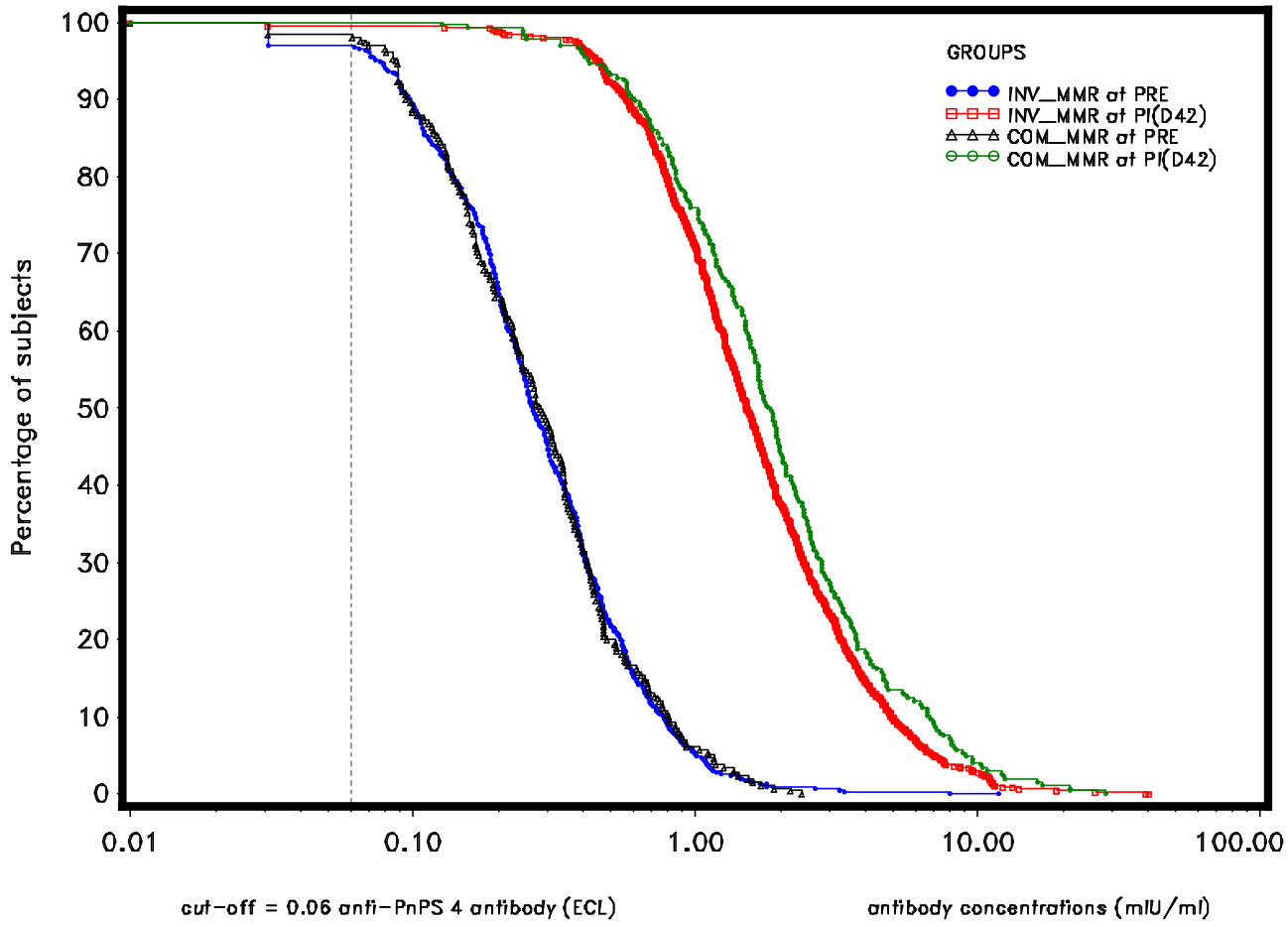
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.25 Reverse cumulative distribution curve of Anti-3 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



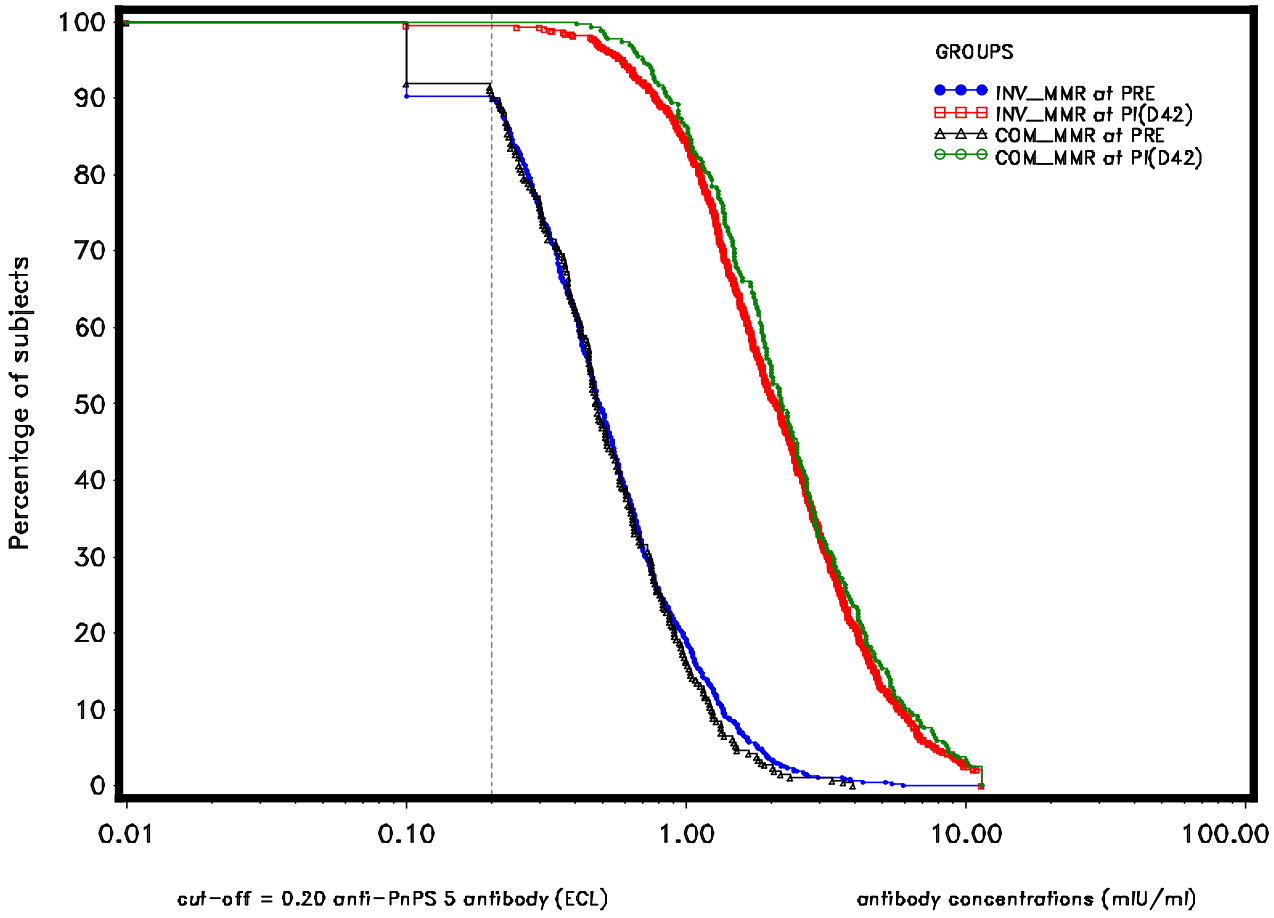
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.26 Reverse cumulative distribution curve of Anti-4 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



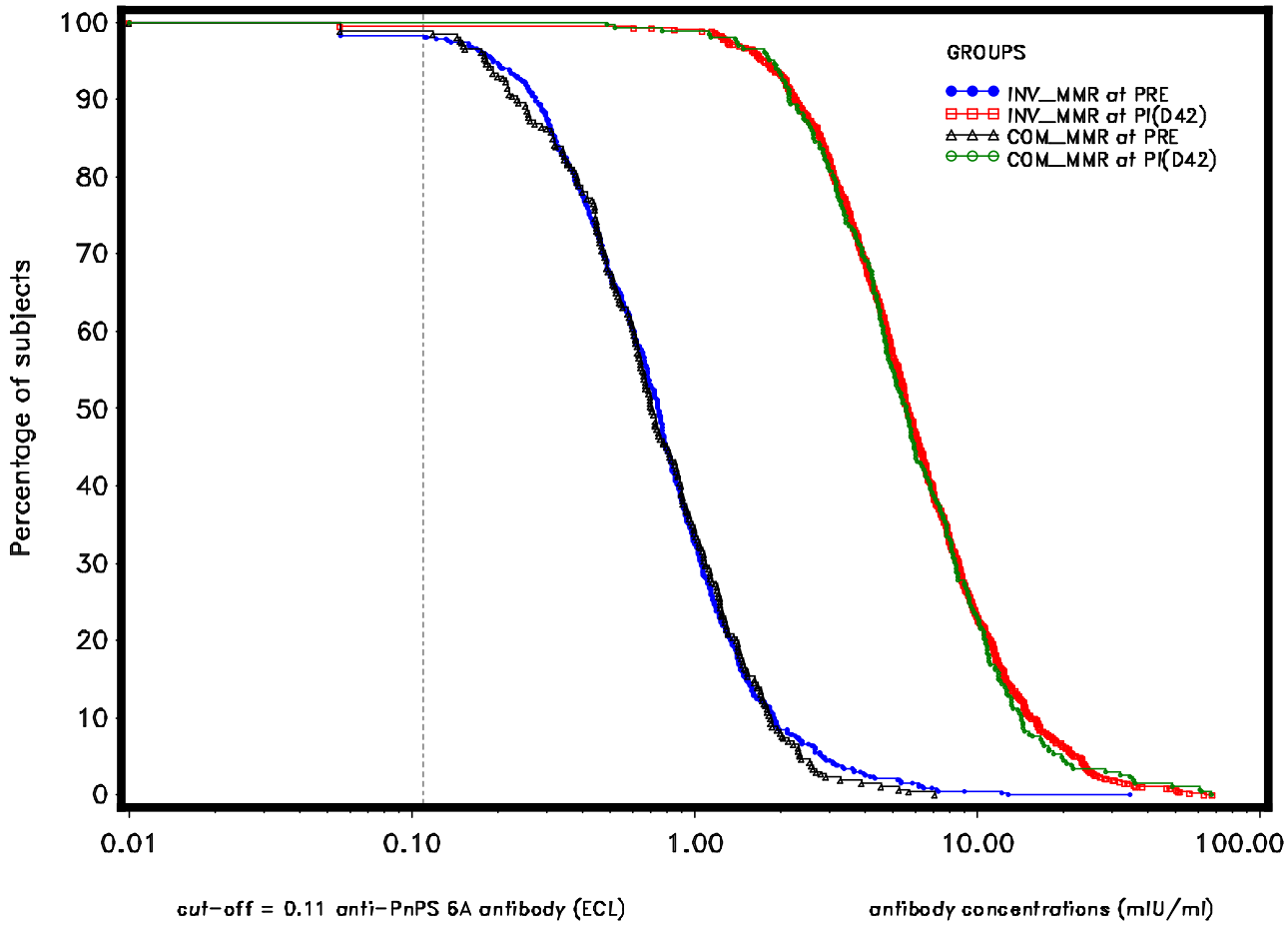
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.27 Reverse cumulative distribution curve of Anti-5 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



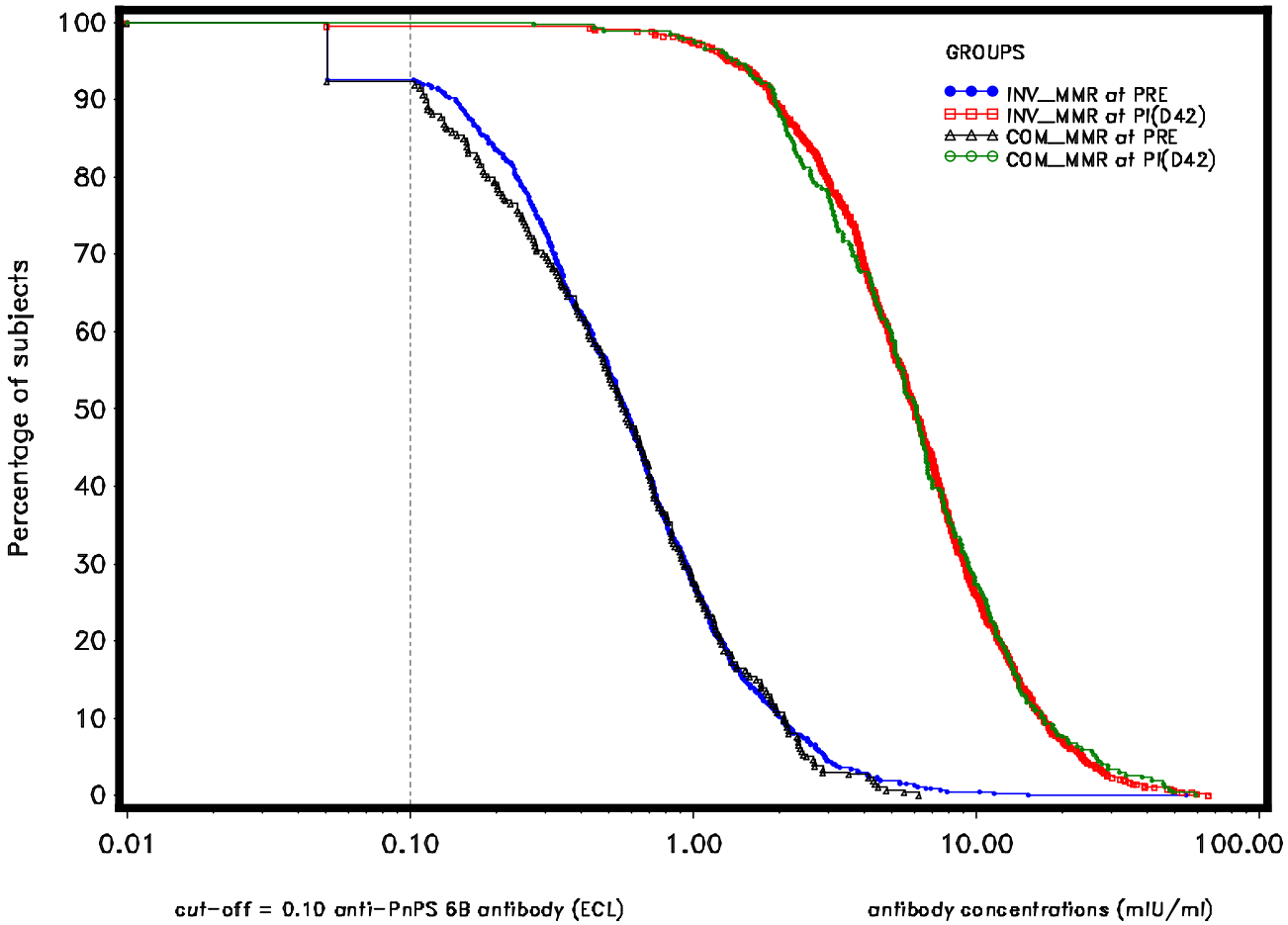
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.28 Reverse cumulative distribution curve of Anti-6A antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



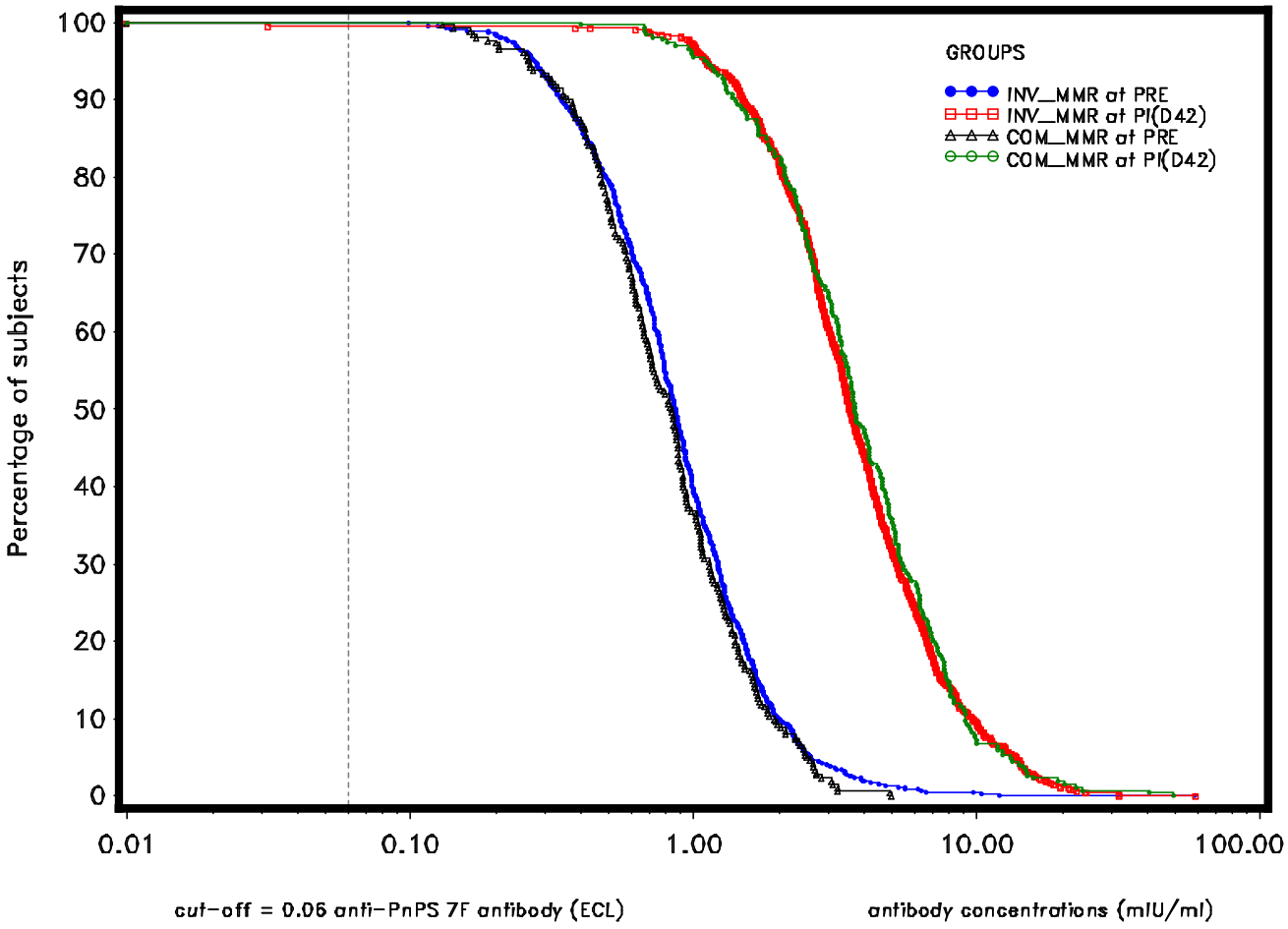
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.29 Reverse cumulative distribution curve of Anti-6B antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



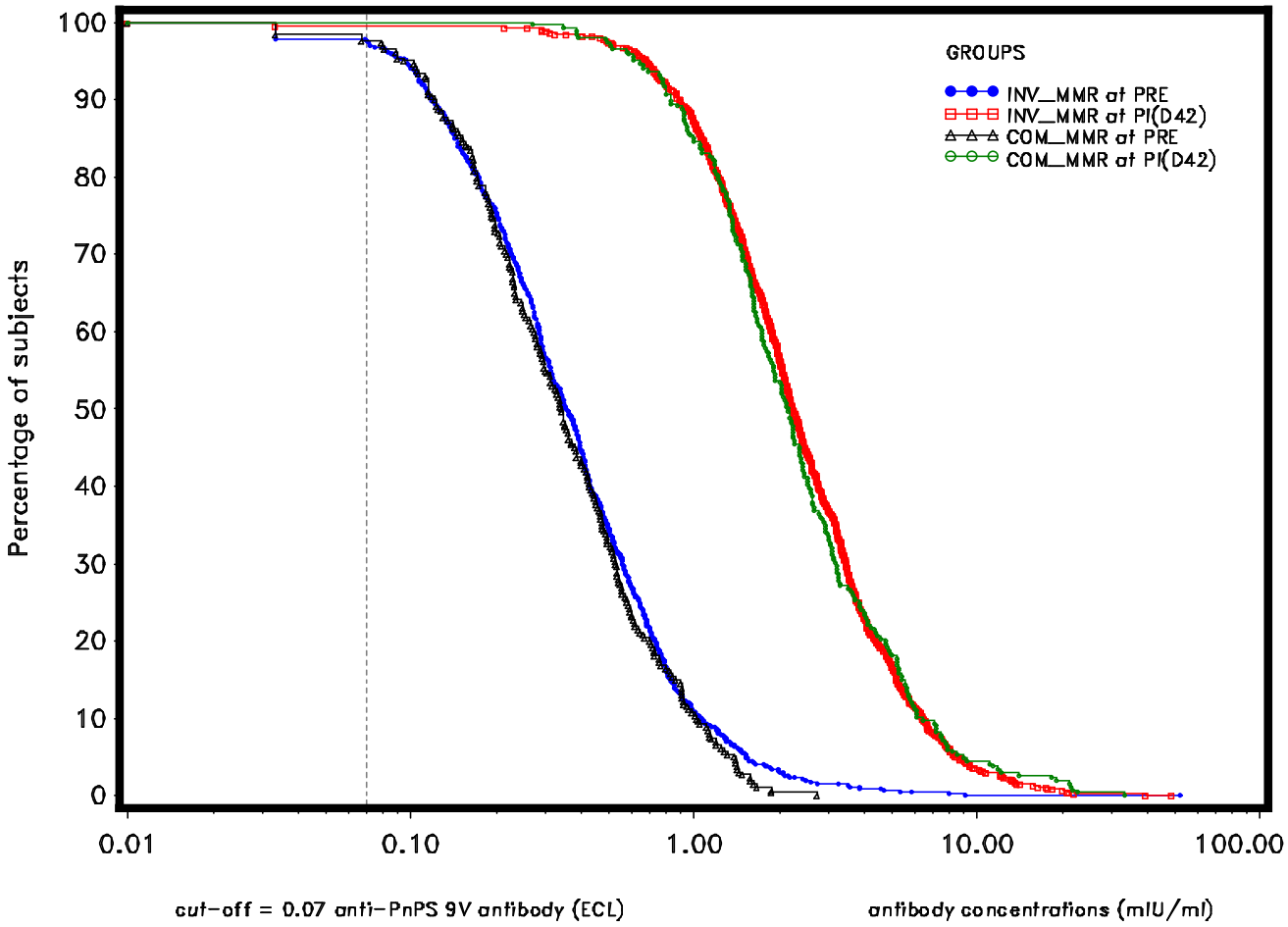
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.30 Reverse cumulative distribution curve of Anti-7F antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



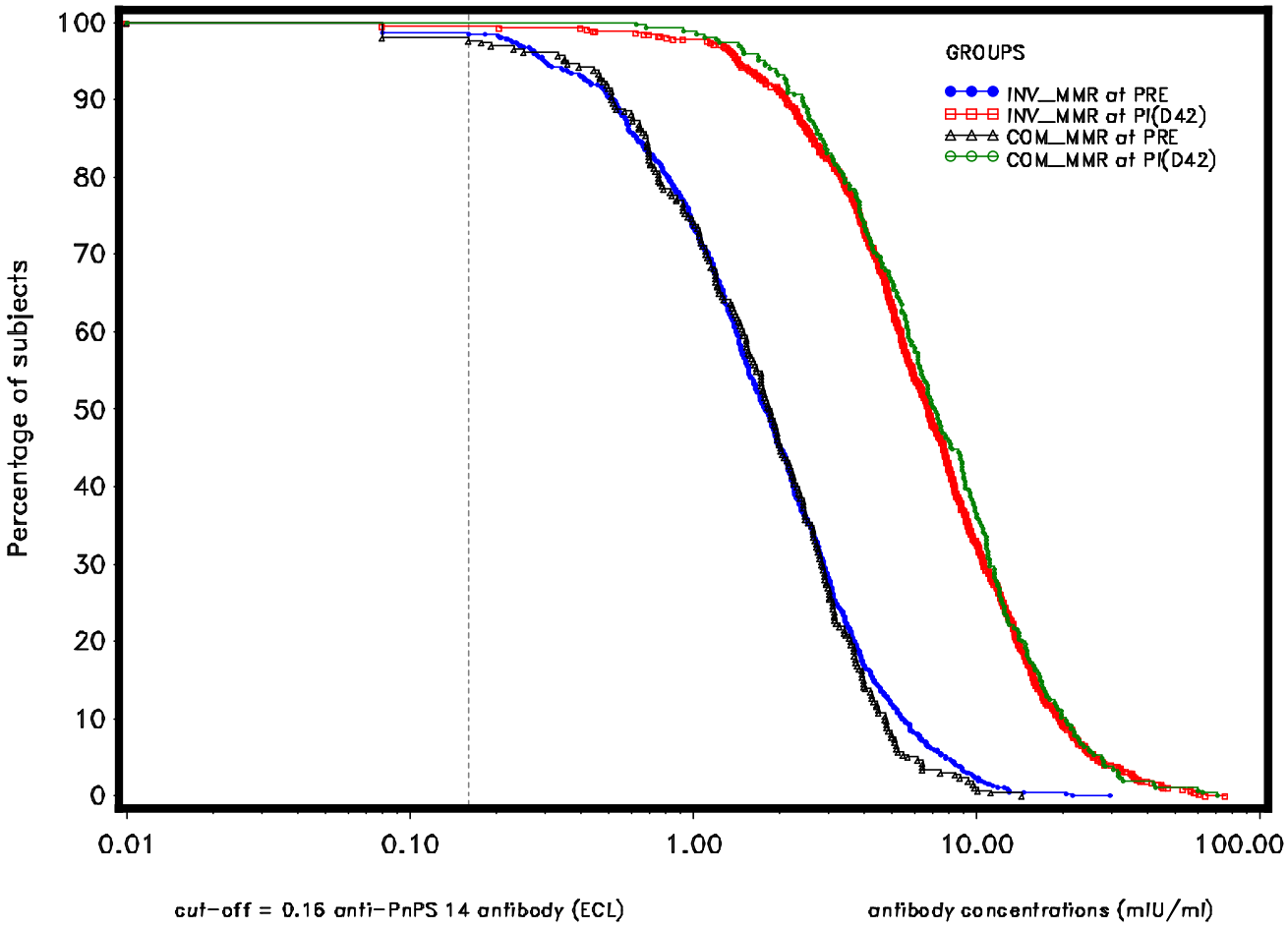
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.31 Reverse cumulative distribution curve of Anti-9V antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



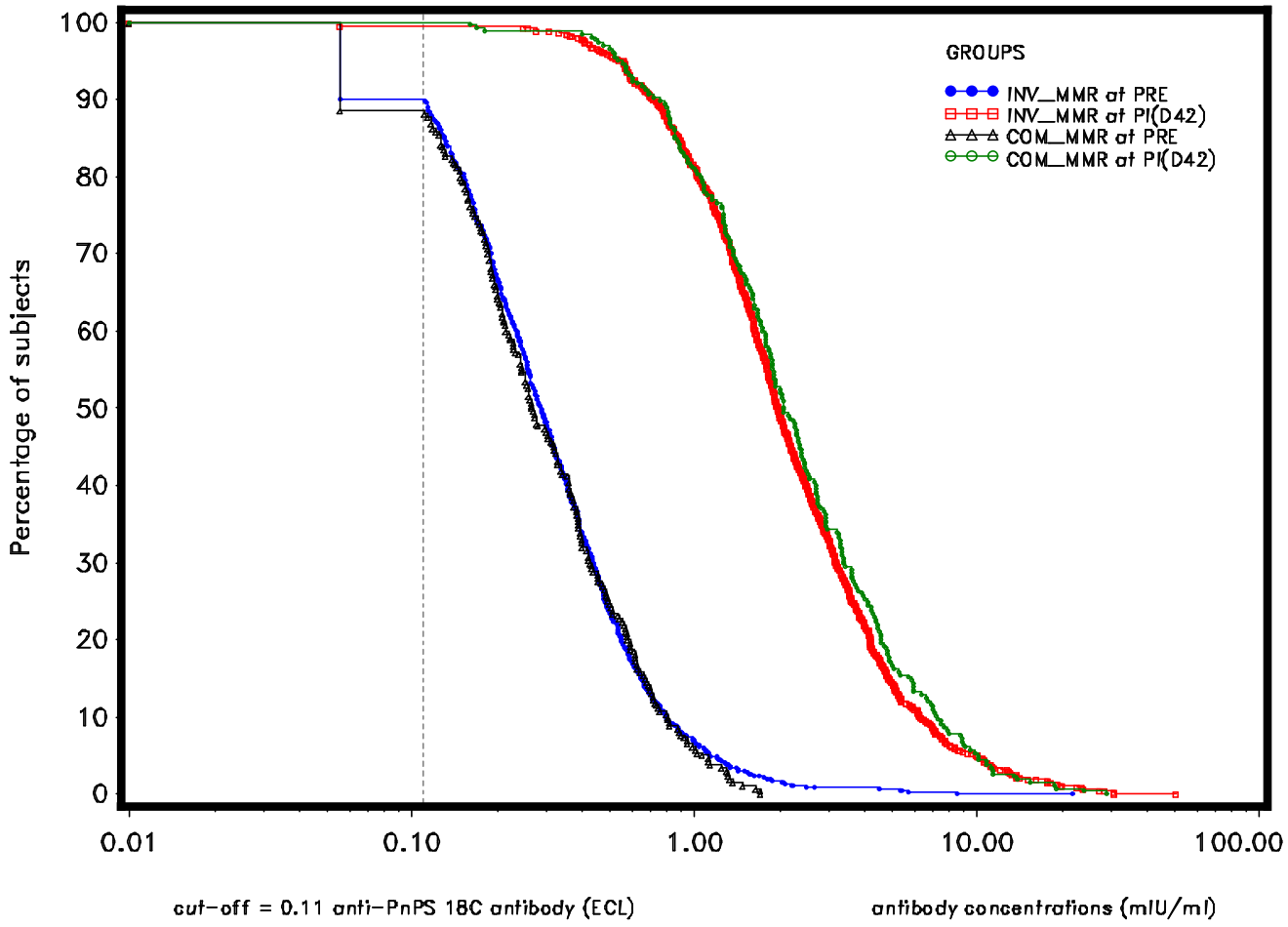
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.32 Reverse cumulative distribution curve of Anti-14 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



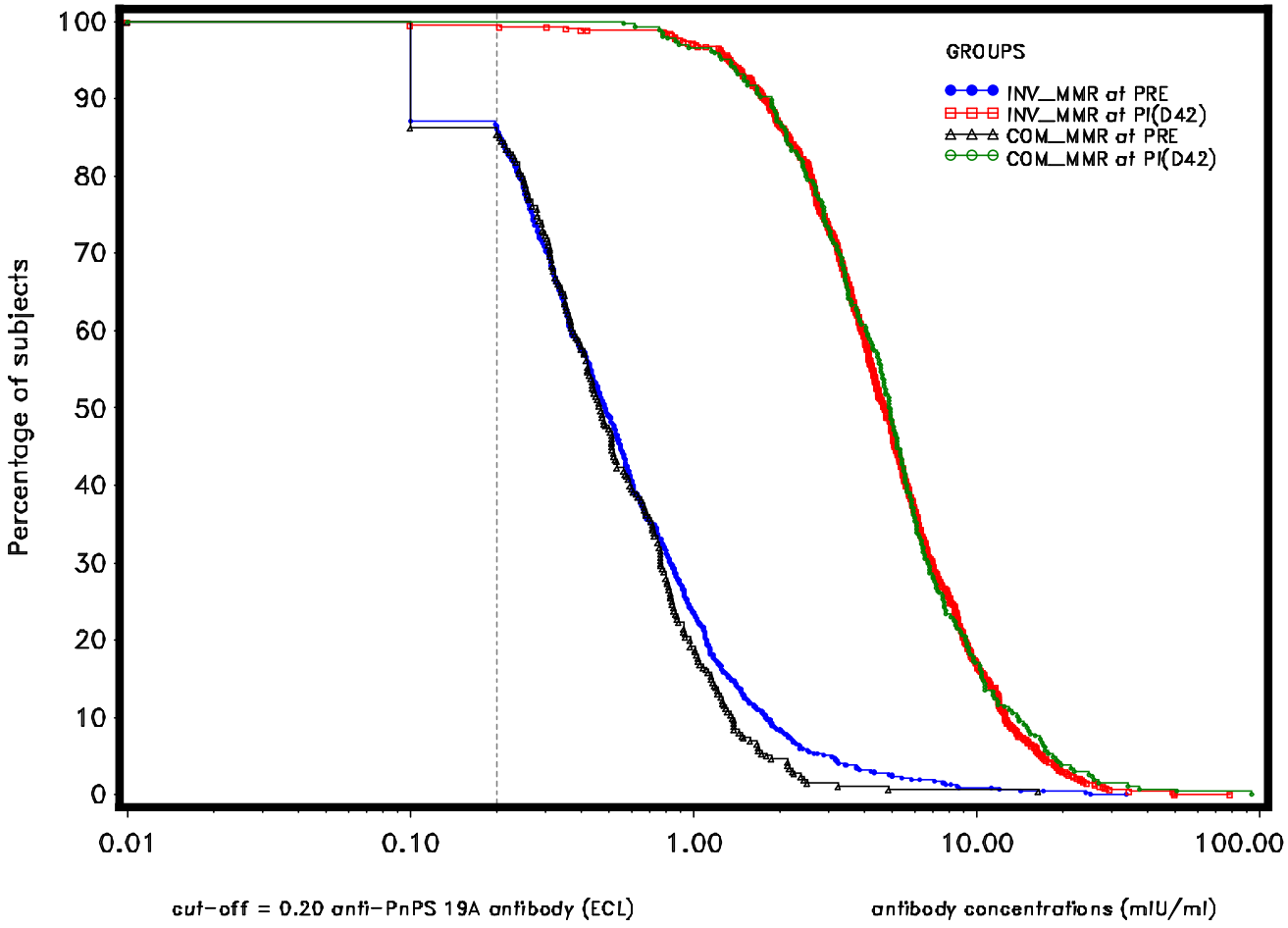
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.33 Reverse cumulative distribution curve of Anti-18C antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



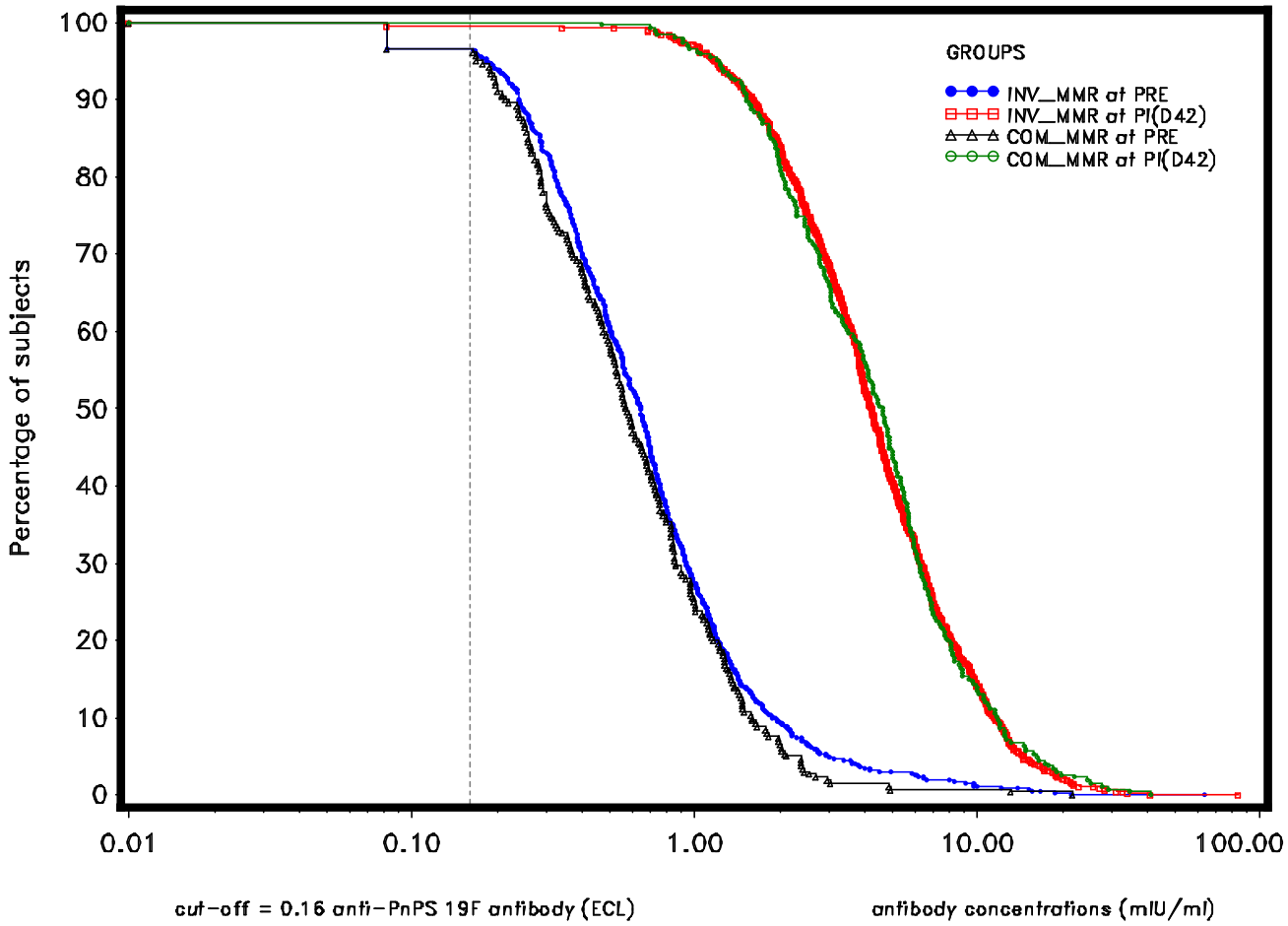
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.34 Reverse cumulative distribution curve of Anti-19A antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



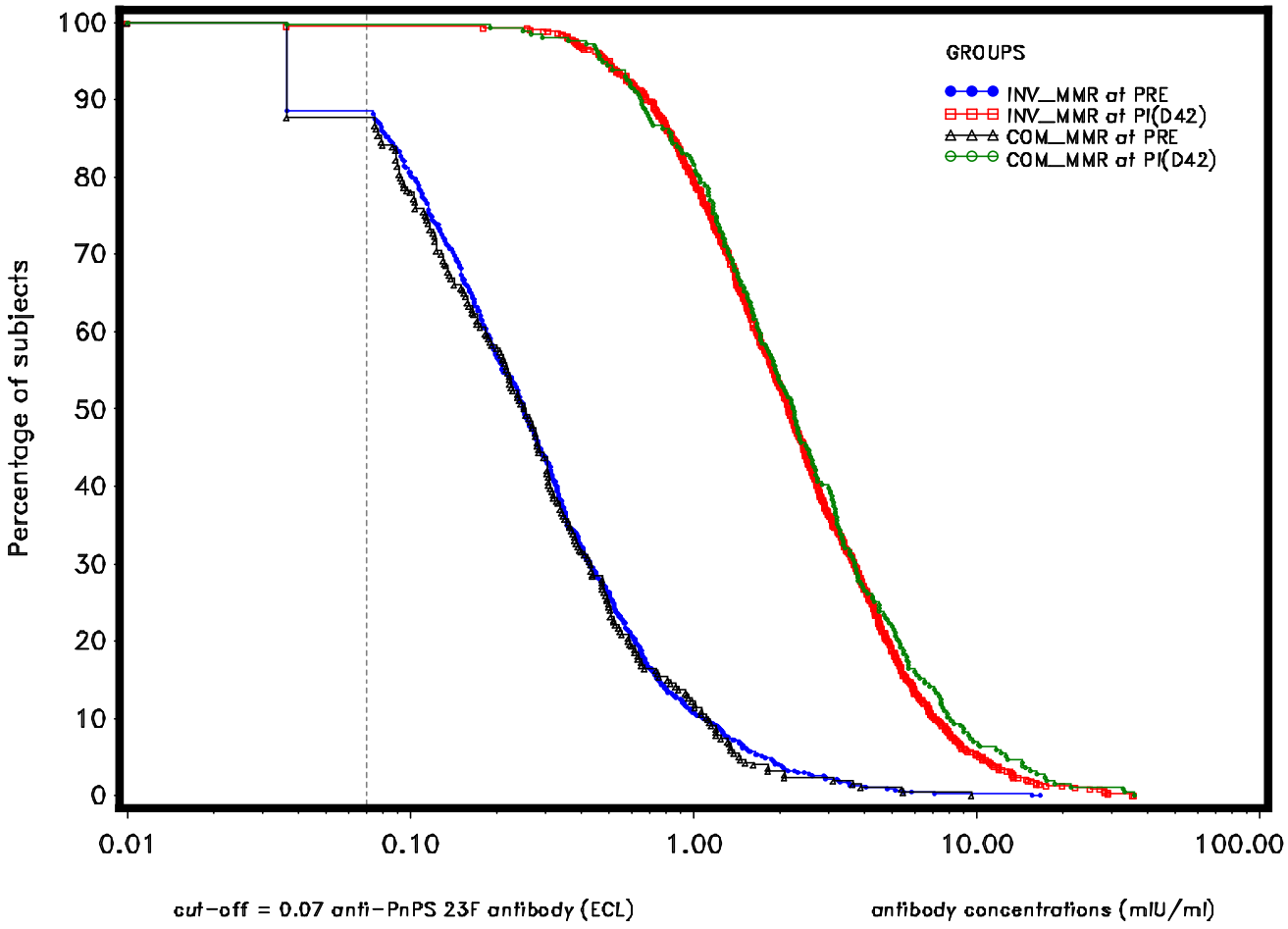
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.35 Reverse cumulative distribution curve of Anti-19F antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.36 Reverse cumulative distribution curve of Anti-23F antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 8.1 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Estonia)

INV_MMR_1 HAVRIX N = 124		INV_MMR_1 MEMURU N = 124		INV_MMR_1 VARIVAX VACCINE N = 124		INV_MMR_2 HAVRIX N = 125		INV_MMR_2 MEMURU N = 125		INV_MMR_2 VARIVAX VACCINE N = 125		INV_MMR_3 HAVRIX N = 125		INV_MMR_3 MEMURU N = 125		INV_MMR_3 VARIVAX VACCINE N = 125		INV_MMR HAVRIX N = 374		INV_MMR MEMURU N = 374		INV_MMR VARIVAX VACCINE N = 374		COM_MMR HAVRIX N = 127		COM_MMR MMR II VACCINE N = 127		COM_MMR VARIVAX VACCINE N = 127	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
124	100	124	100	124	100	125	100	125	100	125	100	125	100	125	100	125	100	374	100	374	100	374	100	127	100	127	100	127	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.2 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Spain)

INV_MMR_1 HAVRIX N = 61		INV_MMR_1 MEMURU N = 61		INV_MMR_1 VARIVAX VACCINE N = 61		INV_MMR_2 HAVRIX N = 62		INV_MMR_2 MEMURU N = 62		INV_MMR_2 VARIVAX VACCINE N = 62		INV_MMR_3 HAVRIX N = 64		INV_MMR_3 MEMURU N = 64		INV_MMR_3 VARIVAX VACCINE N = 64		INV_MMR HAVRIX N = 187		INV_MMR MEMURU N = 187		INV_MMR VARIVAX VACCINE N = 187		COM_MMR HAVRIX N = 69		COM_MMR MMR II VACCINE N = 69		COM_MMR VARIVAX VACCINE N = 69	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
61	100	61	100	61	100	62	100	62	100	62	100	64	100	64	100	64	100	187	100	187	100	187	100	69	100	69	100	69	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.3 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Finland)

INV_MMR_1 HAVRIX N = 338		INV_MMR_1 MEMURU N = 338		INV_MMR_1 VARIVAX VACCINE N = 338		INV_MMR_2 HAVRIX N = 335		INV_MMR_2 MEMURU N = 335		INV_MMR_2 VARIVAX VACCINE N = 335		INV_MMR_3 HAVRIX N = 337		INV_MMR_3 MEMURU N = 337		INV_MMR_3 VARIVAX VACCINE N = 337		INV_MMR HAVRIX N = 1010		INV_MMR MEMURU N = 1010		INV_MMR VARIVAX VACCINE N = 1010		COM_MMR HAVRIX N = 340		COM_MMR MMR II VACCINE N = 340		COM_MMR VARIVAX VACCINE N = 340	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
338	100	338	100	338	100	335	100	335	100	335	100	337	100	337	100	337	100	1010	100	1010	100	1010	100	340	100	340	100	340	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.4 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Mexico)

INV_MMR_1 HAVRIX N = 98		INV_MMR_1 MEMURU N = 98		INV_MMR_1 VARIVAX VACCINE N = 98		INV_MMR_2 HAVRIX N = 98		INV_MMR_2 MEMURU N = 98		INV_MMR_2 VARIVAX VACCINE N = 98		INV_MMR_3 HAVRIX N = 99		INV_MMR_3 MEMURU N = 99		INV_MMR_3 VARIVAX VACCINE N = 99		INV_MMR HAVRIX N = 295		INV_MMR MEMURU N = 295		INV_MMR VARIVAX VACCINE N = 295		COM_MMR HAVRIX N = 99		COM_MMR MMR II VACCINE N = 99		COM_MMR VARIVAX VACCINE N = 99	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
98	100	98	100	98	100	98	100	98	100	98	100	99	100	99	100	99	100	295	100	295	100	295	100	99	100	99	100	99	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.5 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, United States)

	INV_MMR_1 HAVRIX N = 618		INV_MMR_1 MEMURU N = 618		INV_MMR_1 PREVENAR 13 N = 618		INV_MMR_1 VARIVAX VACCINE N = 618		INV_MMR_2 HAVRIX N = 614		INV_MMR_2 MEMURU N = 614		INV_MMR_2 PREVENAR 13 N = 614		INV_MMR_2 VARIVAX VACCINE N = 614		INV_MMR_3 HAVRIX N = 621		INV_MMR_3 MEMURU N = 621		INV_MMR_3 PREVENAR 13 N = 621		INV_MMR_3 VARIVAX VACCINE N = 621		INV_MMR HAVRIX N = 1853		INV_MMR MEMURU N = 1853		INV_MMR PREVENAR 13 N = 1853	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	1	0.2	0	0.0	0	0.0	0	0.0	2	0.3	2	0.3	2	0.3	2	0.3	5	0.8	3	0.5	4	0.6	4	0.6	8	0.4	5	0.3	6	0.3
1	617	99.8	618	100	618	100	618	100	612	99.7	612	99.7	612	99.7	612	99.7	616	99.2	618	99.5	617	99.4	617	99.4	1845	99.6	1848	99.7	1847	99.7

	INV_MMR VARIVAX VACCINE N = 1853		COM_MMR HAVRIX N = 656		COM_MMR MMR II VACCINE N = 656		COM_MMR PREVENAR 13 N = 656		COM_MMR VARIVAX VACCINE N = 656	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	6	0.3	2	0.3	2	0.3	2	0.3	2	0.3
1	1847	99.7	654	99.7	654	99.7	654	99.7	654	99.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.6 Number and percentage of subjects who received the study vaccine dose (Total vaccinated cohort, by gender)

INV_MMR				COM_MMR			
F N = 1816		M N = 1898		F N = 618		M N = 671	
n	%	n	%	n	%	n	%
1816	100	1898	100	618	100	671	100

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.7 Number and percentage of subjects who received the study vaccine dose (Total vaccinated cohort, by geographic ancestry)

INV_MMR						COM_MMR					
WH N = 2814		OT N = 364		AF N = 169		WH N = 970		OT N = 124		AF N = 70	
n	%	n	%	n	%	n	%	n	%	n	%
2814	100	364	100	169	100	970	100	124	100	70	100

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.8 Compliance in returning symptom information (Total vaccinated cohort, Estonia)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	124	0	123	99.2	123	99.2
INV_MMR_2	125	0	125	100	125	100
INV_MMR_3	125	0	125	100	125	100
INV_MMR	374	0	373	99.7	373	99.7
COM_MMR	127	0	127	100	127	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.9 Compliance in returning symptom information (Total vaccinated cohort, Spain)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	61	0	61	100	61	100
INV_MMR_2	62	0	62	100	62	100
INV_MMR_3	64	0	63	98.4	63	98.4
INV_MMR	187	0	186	99.5	186	99.5
COM_MMR	69	0	68	98.6	68	98.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.10 Compliance in returning symptom information (Total vaccinated cohort, Finland)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	338	1	336	99.4	336	99.4
INV_MMR_2	335	2	332	99.1	332	99.1
INV_MMR_3	337	1	337	100	337	100
INV_MMR	1010	4	1005	99.5	1005	99.5
COM_MMR	340	0	340	100	340	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.11 Compliance in returning symptom information (Total vaccinated cohort, Mexico)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	98	0	93	94.9	93	94.9
INV_MMR_2	98	0	97	99.0	97	99.0
INV_MMR_3	99	0	98	99.0	98	99.0
INV_MMR	295	0	288	97.6	288	97.6
COM_MMR	99	0	96	97.0	96	97.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.12 Compliance in returning symptom information (Total vaccinated cohort, United States)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	618	4	577	93.4	573	92.7
INV_MMR_2	612	3	560	91.5	559	91.3
INV_MMR_3	618	5	577	93.4	571	92.4
INV_MMR	1848	12	1714	92.7	1703	92.2
COM_MMR	654	5	612	93.6	611	93.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.13 Compliance in returning symptom information (Total vaccinated cohort, by gender)

Group	Sub-group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR	F	1816	8	1734	95.5	1729	95.2
	M	1898	8	1832	96.5	1826	96.2
COM_MMR	F	618	2	598	96.8	597	96.6
	M	671	3	645	96.1	645	96.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.14 Compliance in returning symptom information (Total vaccinated cohort, by geographic ancestry)

Group	Sub-group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR	WH	2814	13	2720	96.7	2714	96.4
	OT	364	3	352	96.7	351	96.4
	AF	169	0	151	89.3	148	87.6
COM_MMR	WH	970	3	947	97.6	945	97.4
	OT	124	1	119	96.0	119	96.0
	AF	70	1	64	91.4	65	92.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.15 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	124	107	86.3	79.0	91.8	124	95	76.6	68.2	83.7	124	64	51.6	42.5	60.7
INV_MMR_2	125	104	83.2	75.5	89.3	125	100	80.0	71.9	86.6	125	54	43.2	34.4	52.4
INV_MMR_3	125	107	85.6	78.2	91.2	125	98	78.4	70.2	85.3	125	51	40.8	32.1	49.9
INV_MMR	374	318	85.0	81.0	88.5	374	293	78.3	73.8	82.4	374	169	45.2	40.1	50.4
COM_MMR	127	107	84.3	76.7	90.1	127	100	78.7	70.6	85.5	127	55	43.3	34.5	52.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.16 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	61	49	80.3	68.2	89.4	61	47	77.0	64.5	86.8	61	12	19.7	10.6	31.8
INV_MMR_2	62	52	83.9	72.3	92.0	62	51	82.3	70.5	90.8	62	14	22.6	12.9	35.0
INV_MMR_3	64	54	84.4	73.1	92.2	64	53	82.8	71.3	91.1	64	21	32.8	21.6	45.7
INV_MMR	187	155	82.9	76.7	88.0	187	151	80.7	74.4	86.1	187	47	25.1	19.1	32.0
COM_MMR	69	62	89.9	80.2	95.8	69	60	87.0	76.7	93.9	69	22	31.9	21.2	44.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.17 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	338	313	92.6	89.3	95.2	338	307	90.8	87.2	93.7	338	144	42.6	37.3	48.1
INV_MMR_2	335	308	91.9	88.5	94.6	335	300	89.6	85.8	92.6	335	152	45.4	40.0	50.9
INV_MMR_3	337	311	92.3	88.9	94.9	337	295	87.5	83.5	90.9	337	149	44.2	38.8	49.7
INV_MMR	1010	932	92.3	90.5	93.8	1010	902	89.3	87.2	91.1	1010	445	44.1	41.0	47.2
COM_MMR	340	320	94.1	91.1	96.4	340	305	89.7	86.0	92.7	340	152	44.7	39.3	50.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.18 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	98	88	89.8	82.0	95.0	98	85	86.7	78.4	92.7	98	37	37.8	28.2	48.1
INV_MMR_2	98	84	85.7	77.2	92.0	98	81	82.7	73.7	89.6	98	29	29.6	20.8	39.7
INV_MMR_3	99	86	86.9	78.6	92.8	99	80	80.8	71.7	88.0	99	38	38.4	28.8	48.7
INV_MMR	295	258	87.5	83.1	91.0	295	246	83.4	78.6	87.5	295	104	35.3	29.8	41.0
COM_MMR	99	81	81.8	72.8	88.9	99	80	80.8	71.7	88.0	99	35	35.4	26.0	45.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.19 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR_1	618	495	80.1	76.7	83.2	618	474	76.7	73.2	80.0	618	256	41.4	37.5	45.4
INV_MMR_2	612	479	78.3	74.8	81.5	612	460	75.2	71.5	78.5	612	238	38.9	35.0	42.9
INV_MMR_3	618	486	78.6	75.2	81.8	618	464	75.1	71.5	78.4	618	234	37.9	34.0	41.8
INV_MMR	1848	1460	79.0	77.1	80.8	1848	1398	75.6	73.6	77.6	1848	728	39.4	37.2	41.7
COM_MMR	654	529	80.9	77.7	83.8	654	516	78.9	75.6	82.0	654	276	42.2	38.4	46.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.20 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		Any symptom					General symptoms					Local symptoms				
					95% CI					95% CI					95% CI	
Group	**Sub-group**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR	F	1816	1522	83.8	82.0	85.5	1816	1459	80.3	78.4	82.1	1816	736	40.5	38.3	42.8
	M	1898	1601	84.4	82.6	86.0	1898	1531	80.7	78.8	82.4	1898	757	39.9	37.7	42.1
COM_MMR	F	618	518	83.8	80.7	86.6	618	494	79.9	76.6	83.0	618	257	41.6	37.7	45.6
	M	671	581	86.6	83.8	89.1	671	567	84.5	81.5	87.2	671	283	42.2	38.4	46.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.21 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		Any symptom					General symptoms					Local symptoms				
					95% CI					95% CI					95% CI	
Group	**Sub-group**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR	WH	2814	2407	85.5	84.2	86.8	2814	2311	82.1	80.7	83.5	2814	1194	42.4	40.6	44.3
	OT	364	315	86.5	82.6	89.9	364	301	82.7	78.4	86.4	364	130	35.7	30.8	40.9
	AF	169	121	71.6	64.2	78.3	169	114	67.5	59.8	74.5	169	47	27.8	21.2	35.2
COM_MMR	WH	970	854	88.0	85.8	90.0	970	824	84.9	82.5	87.1	970	430	44.3	41.2	47.5
	OT	124	102	82.3	74.4	88.5	124	100	80.6	72.6	87.2	124	46	37.1	28.6	46.2
	AF	70	52	74.3	62.4	84.0	70	51	72.9	60.9	82.8	70	24	34.3	23.3	46.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.22 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	123	34	27.6	20.0	36.4	125	32	25.6	18.2	34.2	125	20	16.0	10.1	23.6	373	86	23.1	18.9	27.7	127	32	25.2	17.9	33.7
	Grade 2 or 3	123	6	4.9	1.8	10.3	125	7	5.6	2.3	11.2	125	3	2.4	0.5	6.9	373	16	4.3	2.5	6.9	127	7	5.5	2.2	11.0
	Grade 3	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
Redness (mm)	All	123	45	36.6	28.1	45.7	125	35	28.0	20.3	36.7	125	35	28.0	20.3	36.7	373	115	30.8	26.2	35.8	127	35	27.6	20.0	36.2
	>5	123	9	7.3	3.4	13.4	125	7	5.6	2.3	11.2	125	6	4.8	1.8	10.2	373	22	5.9	3.7	8.8	127	6	4.7	1.8	10.0
	>20	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	1	0.8	0.0	4.3
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
Swelling (mm)	All	123	8	6.5	2.8	12.4	125	11	8.8	4.5	15.2	125	11	8.8	4.5	15.2	373	30	8.0	5.5	11.3	127	9	7.1	3.3	13.0
	>5	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	1	0.8	0.0	4.3
	>20	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.23 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	61	7	11.5	4.7	22.2	62	5	8.1	2.7	17.8	63	10	15.9	7.9	27.3	186	22	11.8	7.6	17.4	68	17	25.0	15.3	37.0
	Grade 2 or 3	61	2	3.3	0.4	11.3	62	1	1.6	0.0	8.7	63	2	3.2	0.4	11.0	186	5	2.7	0.9	6.2	68	2	2.9	0.4	10.2
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
Redness (mm)	All	61	9	14.8	7.0	26.2	62	10	16.1	8.0	27.7	63	15	23.8	14.0	36.2	186	34	18.3	13.0	24.6	68	17	25.0	15.3	37.0
	>5	61	0	0.0	0.0	5.9	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5	186	3	1.6	0.3	4.6	68	1	1.5	0.0	7.9
	>20	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
Swelling (mm)	All	61	2	3.3	0.4	11.3	62	4	6.5	1.8	15.7	63	5	7.9	2.6	17.6	186	11	5.9	3.0	10.3	68	9	13.2	6.2	23.6
	>5	61	0	0.0	0.0	5.9	62	2	3.2	0.4	11.2	63	0	0.0	0.0	5.7	186	2	1.1	0.1	3.8	68	0	0.0	0.0	5.3
	>20	61	0	0.0	0.0	5.9	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.24 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	336	73	21.7	17.4	26.5	332	82	24.7	20.2	29.7	337	55	16.3	12.5	20.7	1005	210	20.9	18.4	23.5	340	79	23.2	18.8	28.1
	Grade 2 or 3	336	17	5.1	3.0	8.0	332	9	2.7	1.2	5.1	337	12	3.6	1.9	6.1	1005	38	3.8	2.7	5.2	340	22	6.5	4.1	9.6
	Grade 3	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	1	0.3	0.0	1.6
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
Redness (mm)	All	336	83	24.7	20.2	29.7	332	84	25.3	20.7	30.3	337	94	27.9	23.2	33.0	1005	261	26.0	23.3	28.8	340	88	25.9	21.3	30.9
	>5	336	14	4.2	2.3	6.9	332	19	5.7	3.5	8.8	337	18	5.3	3.2	8.3	1005	51	5.1	3.8	6.6	340	13	3.8	2.1	6.4
	>20	336	1	0.3	0.0	1.6	332	1	0.3	0.0	1.7	337	4	1.2	0.3	3.0	1005	6	0.6	0.2	1.3	340	3	0.9	0.2	2.6
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
Swelling (mm)	All	336	24	7.1	4.6	10.4	332	28	8.4	5.7	12.0	337	28	8.3	5.6	11.8	1005	80	8.0	6.4	9.8	340	29	8.5	5.8	12.0
	>5	336	1	0.3	0.0	1.6	332	8	2.4	1.0	4.7	337	6	1.8	0.7	3.8	1005	15	1.5	0.8	2.4	340	9	2.6	1.2	5.0
	>20	336	0	0.0	0.0	1.1	332	2	0.6	0.1	2.2	337	3	0.9	0.2	2.6	1005	5	0.5	0.2	1.2	340	4	1.2	0.3	3.0
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.25 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	93	27	29.0	20.1	39.4	97	21	21.6	13.9	31.2	98	19	19.4	12.1	28.6	288	67	23.3	18.5	28.6	96	18	18.8	11.5	28.0
	Grade 2 or 3	93	6	6.5	2.4	13.5	97	5	5.2	1.7	11.6	98	5	5.1	1.7	11.5	288	16	5.6	3.2	8.9	96	3	3.1	0.6	8.9
	Grade 3	93	2	2.2	0.3	7.6	97	1	1.0	0.0	5.6	98	3	3.1	0.6	8.7	288	6	2.1	0.8	4.5	96	1	1.0	0.0	5.7
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	1	1.0	0.0	5.7
Redness (mm)	All	93	18	19.4	11.9	28.9	97	19	19.6	12.2	28.9	98	25	25.5	17.2	35.3	288	62	21.5	16.9	26.7	96	22	22.9	15.0	32.6
	>5	93	2	2.2	0.3	7.6	97	3	3.1	0.6	8.8	98	0	0.0	0.0	3.7	288	5	1.7	0.6	4.0	96	2	2.1	0.3	7.3
	>20	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
Swelling (mm)	All	93	11	11.8	6.1	20.2	97	5	5.2	1.7	11.6	98	9	9.2	4.3	16.7	288	25	8.7	5.7	12.5	96	16	16.7	9.8	25.6
	>5	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	3	3.1	0.6	8.9
	>20	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.26 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	573	190	33.2	29.3	37.2	559	175	31.3	27.5	35.3	571	169	29.6	25.9	33.5	1703	534	31.4	29.2	33.6	611	203	33.2	29.5	37.1
	Grade 2 or 3	573	45	7.9	5.8	10.4	559	49	8.8	6.6	11.4	571	51	8.9	6.7	11.6	1703	145	8.5	7.2	9.9	611	55	9.0	6.9	11.6
	Grade 3	573	4	0.7	0.2	1.8	559	7	1.3	0.5	2.6	571	6	1.1	0.4	2.3	1703	17	1.0	0.6	1.6	611	10	1.6	0.8	3.0
	Medical advice	573	1	0.2	0.0	1.0	559	0	0.0	0.0	0.7	571	1	0.2	0.0	1.0	1703	2	0.1	0.0	0.4	611	1	0.2	0.0	0.9
Redness (mm)	All	573	141	24.6	21.1	28.3	559	125	22.4	19.0	26.0	571	132	23.1	19.7	26.8	1703	398	23.4	21.4	25.5	611	151	24.7	21.3	28.3
	>5	573	21	3.7	2.3	5.5	559	14	2.5	1.4	4.2	571	24	4.2	2.7	6.2	1703	59	3.5	2.6	4.4	611	19	3.1	1.9	4.8
	>20	573	5	0.9	0.3	2.0	559	1	0.2	0.0	1.0	571	2	0.4	0.0	1.3	1703	8	0.5	0.2	0.9	611	3	0.5	0.1	1.4
	Medical advice	573	2	0.3	0.0	1.3	559	1	0.2	0.0	1.0	571	0	0.0	0.0	0.6	1703	3	0.2	0.0	0.5	611	0	0.0	0.0	0.6
Swelling (mm)	All	573	71	12.4	9.8	15.4	559	51	9.1	6.9	11.8	571	50	8.8	6.6	11.4	1703	172	10.1	8.7	11.6	611	70	11.5	9.0	14.3
	>5	573	14	2.4	1.3	4.1	559	8	1.4	0.6	2.8	571	13	2.3	1.2	3.9	1703	35	2.1	1.4	2.8	611	12	2.0	1.0	3.4
	>20	573	1	0.2	0.0	1.0	559	1	0.2	0.0	1.0	571	3	0.5	0.1	1.5	1703	5	0.3	0.1	0.7	611	1	0.2	0.0	0.9
	Medical advice	573	1	0.2	0.0	1.0	559	0	0.0	0.0	0.7	571	0	0.0	0.0	0.6	1703	1	0.1	0.0	0.3	611	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.27 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	1729	455	26.3	24.3	28.5	1826	464	25.4	23.4	27.5	597	174	29.1	25.5	33.0	645	175	27.1	23.7	30.7
	Grade 2 or 3	1729	118	6.8	5.7	8.1	1826	102	5.6	4.6	6.7	597	49	8.2	6.1	10.7	645	40	6.2	4.5	8.3
	Grade 3	1729	9	0.5	0.2	1.0	1826	15	0.8	0.5	1.4	597	7	1.2	0.5	2.4	645	5	0.8	0.3	1.8
	Medical advice	1729	0	0.0	0.0	0.2	1826	2	0.1	0.0	0.4	597	1	0.2	0.0	0.9	645	1	0.2	0.0	0.9
Redness (mm)	All	1729	437	25.3	23.2	27.4	1826	433	23.7	21.8	25.7	597	147	24.6	21.2	28.3	645	166	25.7	22.4	29.3
	>5	1729	67	3.9	3.0	4.9	1826	73	4.0	3.1	5.0	597	20	3.4	2.1	5.1	645	21	3.3	2.0	4.9
	>20	1729	7	0.4	0.2	0.8	1826	7	0.4	0.2	0.8	597	4	0.7	0.2	1.7	645	4	0.6	0.2	1.6
	Medical advice	1729	1	0.1	0.0	0.3	1826	2	0.1	0.0	0.4	597	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
Swelling (mm)	All	1729	155	9.0	7.7	10.4	1826	163	8.9	7.7	10.3	597	62	10.4	8.1	13.1	645	71	11.0	8.7	13.7
	>5	1729	18	1.0	0.6	1.6	1826	36	2.0	1.4	2.7	597	13	2.2	1.2	3.7	645	12	1.9	1.0	3.2
	>20	1729	4	0.2	0.1	0.6	1826	8	0.4	0.2	0.9	597	5	0.8	0.3	1.9	645	0	0.0	0.0	0.6
	Medical advice	1729	0	0.0	0.0	0.2	1826	1	0.1	0.0	0.3	597	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.28 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	2714	704	25.9	24.3	27.6	351	88	25.1	20.6	29.9	148	42	28.4	21.3	36.4	945	278	29.4	26.5	32.4	119	26	21.8	14.8	30.4
	Grade 2 or 3	2714	165	6.1	5.2	7.0	351	26	7.4	4.9	10.7	148	13	8.8	4.8	14.6	945	68	7.2	5.6	9.0	119	5	4.2	1.4	9.5
	Grade 3	2714	15	0.6	0.3	0.9	351	7	2.0	0.8	4.1	148	1	0.7	0.0	3.7	945	9	1.0	0.4	1.8	119	1	0.8	0.0	4.6
	Medical advice	2714	2	0.1	0.0	0.3	351	0	0.0	0.0	1.0	148	0	0.0	0.0	2.5	945	0	0.0	0.0	0.4	119	1	0.8	0.0	4.6
Redness (mm)	All	2714	713	26.3	24.6	28.0	351	75	21.4	17.2	26.0	148	17	11.5	6.8	17.8	945	253	26.8	24.0	29.7	119	27	22.7	15.5	31.3
	>5	2714	118	4.3	3.6	5.2	351	6	1.7	0.6	3.7	148	4	2.7	0.7	6.8	945	35	3.7	2.6	5.1	119	3	2.5	0.5	7.2
	>20	2714	12	0.4	0.2	0.8	351	0	0.0	0.0	1.0	148	1	0.7	0.0	3.7	945	8	0.8	0.4	1.7	119	0	0.0	0.0	3.1
	Medical advice	2714	3	0.1	0.0	0.3	351	0	0.0	0.0	1.0	148	0	0.0	0.0	2.5	945	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
Swelling (mm)	All	2714	249	9.2	8.1	10.3	351	32	9.1	6.3	12.6	148	13	8.8	4.8	14.6	945	94	9.9	8.1	12.0	119	20	16.8	10.6	24.8
	>5	2714	42	1.5	1.1	2.1	351	3	0.9	0.2	2.5	148	4	2.7	0.7	6.8	945	17	1.8	1.1	2.9	119	5	4.2	1.4	9.5
	>20	2714	10	0.4	0.2	0.7	351	0	0.0	0.0	1.0	148	2	1.4	0.2	4.8	945	4	0.4	0.1	1.1	119	1	0.8	0.0	4.6
	Medical advice	2714	1	0.0	0.0	0.2	351	0	0.0	0.0	1.0	148	0	0.0	0.0	2.5	945	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	65	18	27.7	17.3	40.2
	Grade 2 or 3	65	9	13.8	6.5	24.7
	Grade 3	65	2	3.1	0.4	10.7
	Medical advice	65	1	1.5	0.0	8.3
Redness (mm)	All	65	9	13.8	6.5	24.7
	>5	65	0	0.0	0.0	5.5
	>20	65	0	0.0	0.0	5.5
	Medical advice	65	0	0.0	0.0	5.5
Swelling (mm)	All	65	5	7.7	2.5	17.0
	>5	65	0	0.0	0.0	5.5
	>20	65	0	0.0	0.0	5.5
	Medical advice	65	0	0.0	0.0	5.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.29 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	123	45	36.6	28.1	45.7	125	49	39.2	30.6	48.3	125	38	30.4	22.5	39.3	373	132	35.4	30.5	40.5	127	47	37.0	28.6	46.0
	Grade 2 or 3	123	9	7.3	3.4	13.4	125	12	9.6	5.1	16.2	125	7	5.6	2.3	11.2	373	28	7.5	5.0	10.7	127	11	8.7	4.4	15.0
	Grade 3	123	0	0.0	0.0	3.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	2	1.6	0.2	5.6
	Medical advice	123	0	0.0	0.0	3.0	125	3	2.4	0.5	6.9	125	3	2.4	0.5	6.9	373	6	1.6	0.6	3.5	127	3	2.4	0.5	6.7
Irritability / fussiness	All	123	69	56.1	46.9	65.0	125	72	57.6	48.4	66.4	125	67	53.6	44.5	62.6	373	208	55.8	50.6	60.9	127	82	64.6	55.6	72.8
	Grade 2 or 3	123	21	17.1	10.9	24.9	125	27	21.6	14.7	29.8	125	22	17.6	11.4	25.4	373	70	18.8	14.9	23.1	127	31	24.4	17.2	32.8
	Grade 3	123	1	0.8	0.0	4.4	125	4	3.2	0.9	8.0	125	4	3.2	0.9	8.0	373	9	2.4	1.1	4.5	127	5	3.9	1.3	8.9
	Medical advice	123	0	0.0	0.0	3.0	125	5	4.0	1.3	9.1	125	4	3.2	0.9	8.0	373	9	2.4	1.1	4.5	127	7	5.5	2.2	11.0
Loss of appetite	All	123	60	48.8	39.7	58.0	125	62	49.6	40.5	58.7	125	48	38.4	29.8	47.5	373	170	45.6	40.4	50.8	127	61	48.0	39.1	57.1
	Grade 2 or 3	123	13	10.6	5.7	17.4	125	19	15.2	9.4	22.7	125	8	6.4	2.8	12.2	373	40	10.7	7.8	14.3	127	10	7.9	3.8	14.0
	Grade 3	123	3	2.4	0.5	7.0	125	4	3.2	0.9	8.0	125	0	0.0	0.0	2.9	373	7	1.9	0.8	3.8	127	0	0.0	0.0	2.9
	Medical advice	123	1	0.8	0.0	4.4	125	3	2.4	0.5	6.9	125	4	3.2	0.9	8.0	373	8	2.1	0.9	4.2	127	4	3.1	0.9	7.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.30 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	61	15	24.6	14.5	37.3	62	15	24.2	14.2	36.7	63	17	27.0	16.6	39.7	186	47	25.3	19.2	32.1	68	18	26.5	16.5	38.6
	Grade 2 or 3	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	3	4.8	1.0	13.3	186	11	5.9	3.0	10.3	68	7	10.3	4.2	20.1
	Grade 3	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	2	2.9	0.4	10.2
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	2	2.9	0.4	10.2
Irritability / fussiness	All	61	33	54.1	40.8	66.9	62	18	29.0	18.2	41.9	63	23	36.5	24.7	49.6	186	74	39.8	32.7	47.2	68	35	51.5	39.0	63.8
	Grade 2 or 3	61	11	18.0	9.4	30.0	62	5	8.1	2.7	17.8	63	10	15.9	7.9	27.3	186	26	14.0	9.3	19.8	68	13	19.1	10.6	30.5
	Grade 3	61	2	3.3	0.4	11.3	62	0	0.0	0.0	5.8	63	2	3.2	0.4	11.0	186	4	2.2	0.6	5.4	68	4	5.9	1.6	14.4
	Medical advice	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	2	2.9	0.4	10.2
Loss of appetite	All	61	23	37.7	25.6	51.0	62	23	37.1	25.2	50.3	63	21	33.3	22.0	46.3	186	67	36.0	29.1	43.4	68	34	50.0	37.6	62.4
	Grade 2 or 3	61	11	18.0	9.4	30.0	62	3	4.8	1.0	13.5	63	8	12.7	5.6	23.5	186	22	11.8	7.6	17.4	68	10	14.7	7.3	25.4
	Grade 3	61	5	8.2	2.7	18.1	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5	186	8	4.3	1.9	8.3	68	3	4.4	0.9	12.4
	Medical advice	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	2	2.9	0.4	10.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.31 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	336	155	46.1	40.7	51.6	332	160	48.2	42.7	53.7	337	166	49.3	43.8	54.7	1005	481	47.9	44.7	51.0	340	163	47.9	42.5	53.4
	Grade 2 or 3	336	37	11.0	7.9	14.9	332	46	13.9	10.3	18.0	337	47	13.9	10.4	18.1	1005	130	12.9	10.9	15.2	340	35	10.3	7.3	14.0
	Grade 3	336	3	0.9	0.2	2.6	332	7	2.1	0.9	4.3	337	6	1.8	0.7	3.8	1005	16	1.6	0.9	2.6	340	3	0.9	0.2	2.6
	Medical advice	336	1	0.3	0.0	1.6	332	0	0.0	0.0	1.1	337	1	0.3	0.0	1.6	1005	2	0.2	0.0	0.7	340	1	0.3	0.0	1.6
Irritability / fussiness	All	336	249	74.1	69.1	78.7	332	248	74.7	69.7	79.3	337	250	74.2	69.2	78.8	1005	747	74.3	71.5	77.0	340	252	74.1	69.1	78.7
	Grade 2 or 3	336	115	34.2	29.2	39.6	332	116	34.9	29.8	40.3	337	123	36.5	31.3	41.9	1005	354	35.2	32.3	38.3	340	116	34.1	29.1	39.4
	Grade 3	336	13	3.9	2.1	6.5	332	20	6.0	3.7	9.2	337	11	3.3	1.6	5.8	1005	44	4.4	3.2	5.8	340	14	4.1	2.3	6.8
	Medical advice	336	9	2.7	1.2	5.0	332	5	1.5	0.5	3.5	337	4	1.2	0.3	3.0	1005	18	1.8	1.1	2.8	340	8	2.4	1.0	4.6
Loss of appetite	All	336	159	47.3	41.9	52.8	332	178	53.6	48.1	59.1	337	182	54.0	48.5	59.4	1005	519	51.6	48.5	54.8	340	158	46.5	41.1	51.9
	Grade 2 or 3	336	48	14.3	10.7	18.5	332	50	15.1	11.4	19.4	337	48	14.2	10.7	18.4	1005	146	14.5	12.4	16.9	340	41	12.1	8.8	16.0
	Grade 3	336	6	1.8	0.7	3.8	332	7	2.1	0.9	4.3	337	4	1.2	0.3	3.0	1005	17	1.7	1.0	2.7	340	2	0.6	0.1	2.1
	Medical advice	336	2	0.6	0.1	2.1	332	1	0.3	0.0	1.7	337	3	0.9	0.2	2.6	1005	6	0.6	0.2	1.3	340	2	0.6	0.1	2.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.32 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	93	37	39.8	29.8	50.5	97	39	40.2	30.4	50.7	98	37	37.8	28.2	48.1	288	113	39.2	33.6	45.1	96	37	38.5	28.8	49.0
	Grade 2 or 3	93	11	11.8	6.1	20.2	97	15	15.5	8.9	24.2	98	12	12.2	6.5	20.4	288	38	13.2	9.5	17.7	96	11	11.5	5.9	19.6
	Grade 3	93	3	3.2	0.7	9.1	97	7	7.2	3.0	14.3	98	1	1.0	0.0	5.6	288	11	3.8	1.9	6.7	96	0	0.0	0.0	3.8
	Medical advice	93	6	6.5	2.4	13.5	97	4	4.1	1.1	10.2	98	9	9.2	4.3	16.7	288	19	6.6	4.0	10.1	96	3	3.1	0.6	8.9
Irritability / fussiness	All	93	50	53.8	43.1	64.2	97	46	47.4	37.2	57.8	98	48	49.0	38.7	59.3	288	144	50.0	44.1	55.9	96	41	42.7	32.7	53.2
	Grade 2 or 3	93	18	19.4	11.9	28.9	97	20	20.6	13.1	30.0	98	16	16.3	9.6	25.2	288	54	18.8	14.4	23.7	96	14	14.6	8.2	23.3
	Grade 3	93	2	2.2	0.3	7.6	97	7	7.2	3.0	14.3	98	4	4.1	1.1	10.1	288	13	4.5	2.4	7.6	96	0	0.0	0.0	3.8
	Medical advice	93	7	7.5	3.1	14.9	97	7	7.2	3.0	14.3	98	12	12.2	6.5	20.4	288	26	9.0	6.0	12.9	96	6	6.3	2.3	13.1
Loss of appetite	All	93	53	57.0	46.3	67.2	97	48	49.5	39.2	59.8	98	47	48.0	37.8	58.3	288	148	51.4	45.5	57.3	96	39	40.6	30.7	51.1
	Grade 2 or 3	93	14	15.1	8.5	24.0	97	20	20.6	13.1	30.0	98	18	18.4	11.3	27.5	288	52	18.1	13.8	23.0	96	11	11.5	5.9	19.6
	Grade 3	93	2	2.2	0.3	7.6	97	6	6.2	2.3	13.0	98	6	6.1	2.3	12.9	288	14	4.9	2.7	8.0	96	4	4.2	1.1	10.3
	Medical advice	93	7	7.5	3.1	14.9	97	8	8.2	3.6	15.6	98	9	9.2	4.3	16.7	288	24	8.3	5.4	12.1	96	6	6.3	2.3	13.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.33 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	577	281	48.7	44.6	52.9	560	272	48.6	44.4	52.8	577	275	47.7	43.5	51.8	1714	828	48.3	45.9	50.7	612	321	52.5	48.4	56.5
	Grade 2 or 3	577	99	17.2	14.2	20.5	560	105	18.8	15.6	22.2	577	100	17.3	14.3	20.7	1714	304	17.7	16.0	19.6	612	111	18.1	15.2	21.4
	Grade 3	577	16	2.8	1.6	4.5	560	22	3.9	2.5	5.9	577	15	2.6	1.5	4.3	1714	53	3.1	2.3	4.0	612	15	2.5	1.4	4.0
	Medical advice	577	12	2.1	1.1	3.6	560	8	1.4	0.6	2.8	577	10	1.7	0.8	3.2	1714	30	1.8	1.2	2.5	612	8	1.3	0.6	2.6
Irritability / fussiness	All	577	363	62.9	58.8	66.9	560	345	61.6	57.4	65.7	577	377	65.3	61.3	69.2	1714	1085	63.3	61.0	65.6	612	409	66.8	62.9	70.6
	Grade 2 or 3	577	161	27.9	24.3	31.8	560	156	27.9	24.2	31.8	577	167	28.9	25.3	32.8	1714	484	28.2	26.1	30.4	612	197	32.2	28.5	36.1
	Grade 3	577	38	6.6	4.7	8.9	560	32	5.7	3.9	8.0	577	36	6.2	4.4	8.5	1714	106	6.2	5.1	7.4	612	35	5.7	4.0	7.9
	Medical advice	577	18	3.1	1.9	4.9	560	15	2.7	1.5	4.4	577	20	3.5	2.1	5.3	1714	53	3.1	2.3	4.0	612	19	3.1	1.9	4.8
Loss of appetite	All	577	251	43.5	39.4	47.7	560	225	40.2	36.1	44.4	577	228	39.5	35.5	43.6	1714	704	41.1	38.7	43.4	612	256	41.8	37.9	45.9
	Grade 2 or 3	577	78	13.5	10.8	16.6	560	76	13.6	10.8	16.7	577	64	11.1	8.6	13.9	1714	218	12.7	11.2	14.4	612	92	15.0	12.3	18.1
	Grade 3	577	8	1.4	0.6	2.7	560	10	1.8	0.9	3.3	577	8	1.4	0.6	2.7	1714	26	1.5	1.0	2.2	612	22	3.6	2.3	5.4
	Medical advice	577	16	2.8	1.6	4.5	560	10	1.8	0.9	3.3	577	16	2.8	1.6	4.5	1714	42	2.5	1.8	3.3	612	10	1.6	0.8	3.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.34 Incidence of solicited local symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	1734	756	43.6	41.2	46.0	1832	845	46.1	43.8	48.4	598	272	45.5	41.4	49.6	645	314	48.7	44.8	52.6
	Grade 2 or 3	1734	240	13.8	12.2	15.6	1832	271	14.8	13.2	16.5	598	78	13.0	10.4	16.0	645	97	15.0	12.4	18.0
	Grade 3	1734	48	2.8	2.0	3.7	1832	37	2.0	1.4	2.8	598	11	1.8	0.9	3.3	645	11	1.7	0.9	3.0
	Medical advice	1734	28	1.6	1.1	2.3	1832	29	1.6	1.1	2.3	598	5	0.8	0.3	1.9	645	12	1.9	1.0	3.2
Irritability / fussiness	All	1734	1100	63.4	61.1	65.7	1832	1158	63.2	61.0	65.4	598	381	63.7	59.7	67.6	645	438	67.9	64.2	71.5
	Grade 2 or 3	1734	448	25.8	23.8	28.0	1832	540	29.5	27.4	31.6	598	173	28.9	25.3	32.7	645	198	30.7	27.2	34.4
	Grade 3	1734	82	4.7	3.8	5.8	1832	94	5.1	4.2	6.2	598	26	4.3	2.9	6.3	645	32	5.0	3.4	6.9
	Medical advice	1734	51	2.9	2.2	3.8	1832	56	3.1	2.3	4.0	598	19	3.2	1.9	4.9	645	23	3.6	2.3	5.3
Loss of appetite	All	1734	782	45.1	42.7	47.5	1832	826	45.1	42.8	47.4	598	264	44.1	40.1	48.2	645	284	44.0	40.2	48.0
	Grade 2 or 3	1734	208	12.0	10.5	13.6	1832	270	14.7	13.1	16.4	598	75	12.5	10.0	15.5	645	89	13.8	11.2	16.7
	Grade 3	1734	30	1.7	1.2	2.5	1832	42	2.3	1.7	3.1	598	15	2.5	1.4	4.1	645	16	2.5	1.4	4.0
	Medical advice	1734	36	2.1	1.5	2.9	1832	46	2.5	1.8	3.3	598	10	1.7	0.8	3.1	645	14	2.2	1.2	3.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.35 Incidence of solicited local symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	2720	1272	46.8	44.9	48.7	352	137	38.9	33.8	44.2	151	61	40.4	32.5	48.7	947	462	48.8	45.6	52.0	119	49	41.2	32.2	50.6
	Grade 2 or 3	2720	389	14.3	13.0	15.7	352	48	13.6	10.2	17.7	151	25	16.6	11.0	23.5	947	134	14.1	12.0	16.5	119	14	11.8	6.6	19.0
	Grade 3	2720	57	2.1	1.6	2.7	352	12	3.4	1.8	5.9	151	6	4.0	1.5	8.4	947	17	1.8	1.0	2.9	119	2	1.7	0.2	5.9
	Medical advice	2720	31	1.1	0.8	1.6	352	20	5.7	3.5	8.6	151	1	0.7	0.0	3.6	947	13	1.4	0.7	2.3	119	2	1.7	0.2	5.9
Irritability / fussiness	All	2720	1807	66.4	64.6	68.2	352	183	52.0	46.6	57.3	151	69	45.7	37.6	54.0	947	663	70.0	67.0	72.9	119	56	47.1	37.8	56.4
	Grade 2 or 3	2720	806	29.6	27.9	31.4	352	65	18.5	14.6	22.9	151	36	23.8	17.3	31.4	947	306	32.3	29.3	35.4	119	21	17.6	11.3	25.7
	Grade 3	2720	132	4.9	4.1	5.7	352	15	4.3	2.4	6.9	151	6	4.0	1.5	8.4	947	48	5.1	3.8	6.7	119	2	1.7	0.2	5.9
	Medical advice	2720	69	2.5	2.0	3.2	352	28	8.0	5.4	11.3	151	2	1.3	0.2	4.7	947	32	3.4	2.3	4.7	119	6	5.0	1.9	10.7
Loss of appetite	All	2720	1250	46.0	44.1	47.9	352	169	48.0	42.7	53.4	151	48	31.8	24.5	39.9	947	432	45.6	42.4	48.9	119	48	40.3	31.4	49.7
	Grade 2 or 3	2720	360	13.2	12.0	14.6	352	57	16.2	12.5	20.5	151	21	13.9	8.8	20.5	947	123	13.0	10.9	15.3	119	14	11.8	6.6	19.0
	Grade 3	2720	51	1.9	1.4	2.5	352	14	4.0	2.2	6.6	151	4	2.6	0.7	6.6	947	20	2.1	1.3	3.2	119	6	5.0	1.9	10.7
	Medical advice	2720	48	1.8	1.3	2.3	352	25	7.1	4.6	10.3	151	2	1.3	0.2	4.7	947	15	1.6	0.9	2.6	119	6	5.0	1.9	10.7

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	64	28	43.8	31.4	56.7
	Grade 2 or 3	64	11	17.2	8.9	28.7
	Grade 3	64	1	1.6	0.0	8.4
	Medical advice	64	0	0.0	0.0	5.6
Irritability / fussiness	All	64	35	54.7	41.7	67.2
	Grade 2 or 3	64	15	23.4	13.8	35.7
	Grade 3	64	3	4.7	1.0	13.1
	Medical advice	64	1	1.6	0.0	8.4
Loss of appetite	All	64	22	34.4	22.9	47.3
	Grade 2 or 3	64	10	15.6	7.8	26.9
	Grade 3	64	0	0.0	0.0	5.6
	Medical advice	64	1	1.6	0.0	8.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.36 Primary temperature recording route (Total vaccinated cohort)

		INV_MMR_1 N = 1239		INV_MMR_2 N = 1232		INV_MMR_3 N = 1243		INV_MMR N = 3714		COM_MMR N = 1289		Total N = 5003	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	1105	93.2	1106	94.1	1114	93.1	3325	93.5	1161	93.7	4486	93.5
	Oral	4	0.3	6	0.5	10	0.8	20	0.6	10	0.8	30	0.6
	Rectal	29	2.4	30	2.6	26	2.2	85	2.4	17	1.4	102	2.1
	Tympanic	24	2.0	21	1.8	27	2.3	72	2.0	27	2.2	99	2.1
	Temporal	24	2.0	12	1.0	20	1.7	56	1.6	24	1.9	80	1.7
	Missing confirmed*	4	0.3	1	0.1	3	0.3	8	0.2	4	0.3	12	0.3
	Missing**	49	4.1	56	4.8	43	3.6	148	4.2	46	3.7	194	4.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.37 Primary temperature recording route (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124		INV_MMR_2 N = 125		INV_MMR_3 N = 125		INV_MMR N = 374		COM_MMR N = 127		Total N = 501	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	118	95.9	121	96.8	119	95.2	358	96.0	118	92.9	476	95.2
	Oral	0	0.0	1	0.8	1	0.8	2	0.5	3	2.4	5	1.0
	Rectal	3	2.4	1	0.8	2	1.6	6	1.6	0	0.0	6	1.2
	Tympanic	0	0.0	1	0.8	1	0.8	2	0.5	2	1.6	4	0.8
	Temporal	2	1.6	1	0.8	2	1.6	5	1.3	4	3.1	9	1.8
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	1	0.8	0	0.0	0	0.0	1	0.3	0	0.0	1	0.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.38 Primary temperature recording route (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61		INV_MMR_2 N = 62		INV_MMR_3 N = 64		INV_MMR N = 187		COM_MMR N = 69		Total N = 256	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	61	100	59	95.2	61	96.8	181	97.3	67	98.5	248	97.6
	Oral	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Rectal	0	0.0	3	4.8	0	0.0	3	1.6	0	0.0	3	1.2
	Tympanic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Temporal	0	0.0	0	0.0	2	3.2	2	1.1	1	1.5	3	1.2
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	0	0.0	0	0.0	1	1.6	1	0.5	1	1.5	2	0.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.39 Primary temperature recording route (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338		INV_MMR_2 N = 335		INV_MMR_3 N = 337		INV_MMR N = 1010		COM_MMR N = 340		Total N = 1350	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	300	89.3	299	90.1	293	86.9	892	88.8	310	91.2	1202	89.4
	Oral	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Rectal	20	6.0	22	6.6	17	5.0	59	5.9	14	4.1	73	5.4
	Tympanic	15	4.5	10	3.0	24	7.1	49	4.9	13	3.8	62	4.6
	Temporal	1	0.3	1	0.3	3	0.9	5	0.5	3	0.9	8	0.6
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	2	0.6	3	0.9	0	0.0	5	0.5	0	0.0	5	0.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.40 Primary temperature recording route (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98		INV_MMR_2 N = 98		INV_MMR_3 N = 99		INV_MMR N = 295		COM_MMR N = 99		Total N = 394	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	92	98.9	97	100	98	100	287	99.7	96	100	383	99.7
	Oral	1	1.1	0	0.0	0	0.0	1	0.3	0	0.0	1	0.3
	Rectal	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Tympanic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Temporal	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	5	5.4	1	1.0	1	1.0	7	2.4	3	3.1	10	2.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.41 Primary temperature recording route (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618		INV_MMR_2 N = 612		INV_MMR_3 N = 618		INV_MMR N = 1848		COM_MMR N = 654		Total N = 2502	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	534	93.2	530	94.8	543	94.6	1607	94.2	570	93.8	2177	94.1
	Oral	3	0.5	5	0.9	9	1.6	17	1.0	7	1.2	24	1.0
	Rectal	6	1.0	4	0.7	7	1.2	17	1.0	3	0.5	20	0.9
	Tympanic	9	1.6	10	1.8	2	0.3	21	1.2	12	2.0	33	1.4
	Temporal	21	3.7	10	1.8	13	2.3	44	2.6	16	2.6	60	2.6
	Missing confirmed*	4	0.7	1	0.2	3	0.5	8	0.5	4	0.7	12	0.5
	Missing**	41	7.2	52	9.3	41	7.1	134	7.9	42	6.9	176	7.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.42 Primary temperature recording route (Total vaccinated cohort, by gender)

		INV_MMR				COM_MMR				Total			
		F N = 1816		M N = 1898		F N = 618		M N = 671		F N = 2434		M N = 2569	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	1615	93.4	1710	93.5	553	93.1	608	94.3	2168	93.3	2318	93.7
	Oral	10	0.6	10	0.5	5	0.8	5	0.8	15	0.6	15	0.6
	Rectal	40	2.3	45	2.5	8	1.3	9	1.4	48	2.1	54	2.2
	Tympanic	40	2.3	32	1.7	19	3.2	8	1.2	59	2.5	40	1.6
	Temporal	24	1.4	32	1.7	9	1.5	15	2.3	33	1.4	47	1.9
	Missing confirmed*	5	0.3	3	0.2	4	0.7	0	0.0	9	0.4	3	0.1
	Missing**	82	4.7	66	3.6	20	3.4	26	4.0	102	4.4	92	3.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.43 Primary temperature recording route (Total vaccinated cohort, by geographic ancestry)

		INV_MMR						COM_MMR					
		WH N = 2814		OT N = 364		AF N = 169		WH N = 970		OT N = 124		AF N = 70	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	2522	92.9	343	97.7	145	96.0	882	93.3	115	96.6	61	96.8
	Oral	13	0.5	2	0.6	1	0.7	8	0.8	0	0.0	2	3.2
	Rectal	80	2.9	0	0.0	1	0.7	17	1.8	0	0.0	0	0.0
	Tympanic	62	2.3	3	0.9	0	0.0	20	2.1	3	2.5	0	0.0
	Temporal	38	1.4	3	0.9	4	2.6	18	1.9	1	0.8	0	0.0
	Missing confirmed*	5	0.2	1	0.3	0	0.0	2	0.2	0	0.0	1	1.6
	Missing**	94	3.5	12	3.4	18	11.9	23	2.4	5	4.2	6	9.5

		Total					
		WH N = 3784		OT N = 488		AF N = 239	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	3404	93.0	458	97.4	206	96.3
	Oral	21	0.6	2	0.4	3	1.4
	Rectal	97	2.7	0	0.0	1	0.5
	Tympanic	82	2.2	6	1.3	0	0.0
	Temporal	56	1.5	4	0.9	4	1.9
	Missing confirmed*	7	0.2	1	0.2	1	0.5
	Missing**	117	3.2	17	3.6	24	11.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.44 Incidence of fever reported during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1190	404	33.9	31.3	36.7	1176	422	35.9	33.1	38.7	1200	418	34.8	32.1	37.6	3566	1244	34.9	33.3	36.5	1243	412	33.1	30.5	35.8
	≥38	1190	402	33.8	31.1	36.5	1176	422	35.9	33.1	38.7	1200	415	34.6	31.9	37.4	3566	1239	34.7	33.2	36.3	1243	411	33.1	30.5	35.8
	>38.5	1190	226	19.0	16.8	21.3	1176	242	20.6	18.3	23.0	1200	217	18.1	15.9	20.4	3566	685	19.2	17.9	20.5	1243	216	17.4	15.3	19.6
	>39.0	1190	108	9.1	7.5	10.9	1176	95	8.1	6.6	9.8	1200	95	7.9	6.5	9.6	3566	298	8.4	7.5	9.3	1243	95	7.6	6.2	9.3
	>39.5	1190	36	3.0	2.1	4.2	1176	37	3.1	2.2	4.3	1200	32	2.7	1.8	3.7	3566	105	2.9	2.4	3.6	1243	32	2.6	1.8	3.6
	>40.0	1190	4	0.3	0.1	0.9	1176	13	1.1	0.6	1.9	1200	11	0.9	0.5	1.6	3566	28	0.8	0.5	1.1	1243	8	0.6	0.3	1.3
	≥38 Related	1190	224	18.8	16.6	21.2	1176	225	19.1	16.9	21.5	1200	225	18.8	16.6	21.1	3566	674	18.9	17.6	20.2	1243	219	17.6	15.5	19.9
	>38.5 Related	1190	109	9.2	7.6	10.9	1176	114	9.7	8.1	11.5	1200	118	9.8	8.2	11.7	3566	341	9.6	8.6	10.6	1243	111	8.9	7.4	10.7
	>39.0 Related	1190	45	3.8	2.8	5.0	1176	37	3.1	2.2	4.3	1200	51	4.3	3.2	5.6	3566	133	3.7	3.1	4.4	1243	42	3.4	2.4	4.5
	>39.5 Related	1190	16	1.3	0.8	2.2	1176	13	1.1	0.6	1.9	1200	17	1.4	0.8	2.3	3566	46	1.3	0.9	1.7	1243	14	1.1	0.6	1.9
	>40.0 Related	1190	1	0.1	0.0	0.5	1176	5	0.4	0.1	1.0	1200	4	0.3	0.1	0.9	3566	10	0.3	0.1	0.5	1243	6	0.5	0.2	1.0
	Medical advice	1190	126	10.6	8.9	12.5	1176	120	10.2	8.5	12.1	1200	130	10.8	9.1	12.7	3566	376	10.5	9.6	11.6	1243	130	10.5	8.8	12.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.45 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	123	44	35.8	27.3	44.9	125	53	42.4	33.6	51.6	125	57	45.6	36.7	54.7	373	154	41.3	36.2	46.5	127	41	32.3	24.3	41.2
	≥38	123	44	35.8	27.3	44.9	125	53	42.4	33.6	51.6	125	57	45.6	36.7	54.7	373	154	41.3	36.2	46.5	127	41	32.3	24.3	41.2
	>38.5	123	23	18.7	12.2	26.7	125	27	21.6	14.7	29.8	125	29	23.2	16.1	31.6	373	79	21.2	17.1	25.7	127	19	15.0	9.3	22.4
	>39.0	123	7	5.7	2.3	11.4	125	16	12.8	7.5	20.0	125	10	8.0	3.9	14.2	373	33	8.8	6.2	12.2	127	4	3.1	0.9	7.9
	>39.5	123	2	1.6	0.2	5.8	125	7	5.6	2.3	11.2	125	4	3.2	0.9	8.0	373	13	3.5	1.9	5.9	127	1	0.8	0.0	4.3
	>40.0	123	0	0.0	0.0	3.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	≥38 Related	123	18	14.6	8.9	22.1	125	13	10.4	5.7	17.1	125	15	12.0	6.9	19.0	373	46	12.3	9.2	16.1	127	13	10.2	5.6	16.9
	>38.5 Related	123	11	8.9	4.5	15.4	125	8	6.4	2.8	12.2	125	8	6.4	2.8	12.2	373	27	7.2	4.8	10.4	127	5	3.9	1.3	8.9
	>39.0 Related	123	3	2.4	0.5	7.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	7	1.9	0.8	3.8	127	0	0.0	0.0	2.9
	>39.5 Related	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	>40.0 Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	11	8.9	4.5	15.4	125	12	9.6	5.1	16.2	125	13	10.4	5.7	17.1	373	36	9.7	6.9	13.1	127	13	10.2	5.6	16.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.46 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	61	26	42.6	30.0	55.9	62	27	43.5	31.0	56.7	63	34	54.0	40.9	66.6	186	87	46.8	39.4	54.2	68	30	44.1	32.1	56.7
	≥38	61	26	42.6	30.0	55.9	62	27	43.5	31.0	56.7	63	34	54.0	40.9	66.6	186	87	46.8	39.4	54.2	68	30	44.1	32.1	56.7
	>38.5	61	17	27.9	17.1	40.8	62	13	21.0	11.7	33.2	63	14	22.2	12.7	34.5	186	44	23.7	17.7	30.4	68	15	22.1	12.9	33.8
	>39.0	61	9	14.8	7.0	26.2	62	3	4.8	1.0	13.5	63	5	7.9	2.6	17.6	186	17	9.1	5.4	14.2	68	9	13.2	6.2	23.6
	>39.5	61	1	1.6	0.0	8.8	62	2	3.2	0.4	11.2	63	0	0.0	0.0	5.7	186	3	1.6	0.3	4.6	68	2	2.9	0.4	10.2
	>40.0	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	≥38 Related	61	8	13.1	5.8	24.2	62	11	17.7	9.2	29.5	63	10	15.9	7.9	27.3	186	29	15.6	10.7	21.6	68	14	20.6	11.7	32.1
	>38.5 Related	61	4	6.6	1.8	15.9	62	4	6.5	1.8	15.7	63	4	6.3	1.8	15.5	186	12	6.5	3.4	11.0	68	4	5.9	1.6	14.4
	>39.0 Related	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>39.5 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	>40.0 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	13	21.3	11.9	33.7	62	15	24.2	14.2	36.7	63	13	20.6	11.5	32.7	186	41	22.0	16.3	28.7	68	19	27.9	17.7	40.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.47 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	336	123	36.6	31.4	42.0	332	134	40.4	35.0	45.9	337	131	38.9	33.6	44.3	1005	388	38.6	35.6	41.7	340	109	32.1	27.1	37.3
	≥38	336	123	36.6	31.4	42.0	332	134	40.4	35.0	45.9	337	131	38.9	33.6	44.3	1005	388	38.6	35.6	41.7	340	109	32.1	27.1	37.3
	>38.5	336	60	17.9	13.9	22.4	332	74	22.3	17.9	27.2	337	65	19.3	15.2	23.9	1005	199	19.8	17.4	22.4	340	53	15.6	11.9	19.9
	>39.0	336	30	8.9	6.1	12.5	332	28	8.4	5.7	12.0	337	26	7.7	5.1	11.1	1005	84	8.4	6.7	10.2	340	23	6.8	4.3	10.0
	>39.5	336	12	3.6	1.9	6.2	332	7	2.1	0.9	4.3	337	5	1.5	0.5	3.4	1005	24	2.4	1.5	3.5	340	6	1.8	0.7	3.8
	>40.0	336	0	0.0	0.0	1.1	332	1	0.3	0.0	1.7	337	1	0.3	0.0	1.6	1005	2	0.2	0.0	0.7	340	2	0.6	0.1	2.1
	≥38 Related	336	83	24.7	20.2	29.7	332	93	28.0	23.2	33.2	337	92	27.3	22.6	32.4	1005	268	26.7	24.0	29.5	340	74	21.8	17.5	26.5
	>38.5 Related	336	34	10.1	7.1	13.9	332	42	12.7	9.3	16.7	337	43	12.8	9.4	16.8	1005	119	11.8	9.9	14.0	340	35	10.3	7.3	14.0
	>39.0 Related	336	16	4.8	2.7	7.6	332	16	4.8	2.8	7.7	337	18	5.3	3.2	8.3	1005	50	5.0	3.7	6.5	340	11	3.2	1.6	5.7
	>39.5 Related	336	5	1.5	0.5	3.4	332	4	1.2	0.3	3.1	337	3	0.9	0.2	2.6	1005	12	1.2	0.6	2.1	340	2	0.6	0.1	2.1
	>40.0 Related	336	0	0.0	0.0	1.1	332	1	0.3	0.0	1.7	337	0	0.0	0.0	1.1	1005	1	0.1	0.0	0.6	340	1	0.3	0.0	1.6
	Medical advice	336	24	7.1	4.6	10.4	332	24	7.2	4.7	10.6	337	20	5.9	3.7	9.0	1005	68	6.8	5.3	8.5	340	24	7.1	4.6	10.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.48 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	93	33	35.5	25.8	46.1	97	32	33.0	23.8	43.3	98	28	28.6	19.9	38.6	288	93	32.3	26.9	38.0	96	31	32.3	23.1	42.6
	≥38	93	33	35.5	25.8	46.1	97	32	33.0	23.8	43.3	98	28	28.6	19.9	38.6	288	93	32.3	26.9	38.0	96	31	32.3	23.1	42.6
	>38.5	93	15	16.1	9.3	25.2	97	19	19.6	12.2	28.9	98	14	14.3	8.0	22.8	288	48	16.7	12.6	21.5	96	9	9.4	4.4	17.1
	>39.0	93	4	4.3	1.2	10.6	97	4	4.1	1.1	10.2	98	6	6.1	2.3	12.9	288	14	4.9	2.7	8.0	96	3	3.1	0.6	8.9
	>39.5	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	3	3.1	0.6	8.7	288	4	1.4	0.4	3.5	96	2	2.1	0.3	7.3
	>40.0	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	≥38 Related	93	10	10.8	5.3	18.9	97	7	7.2	3.0	14.3	98	8	8.2	3.6	15.5	288	25	8.7	5.7	12.5	96	3	3.1	0.6	8.9
	>38.5 Related	93	4	4.3	1.2	10.6	97	2	2.1	0.3	7.3	98	5	5.1	1.7	11.5	288	11	3.8	1.9	6.7	96	1	1.0	0.0	5.7
	>39.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	2	2.0	0.2	7.2	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>39.5 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	>40.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	23	24.7	16.4	34.8	97	23	23.7	15.7	33.4	98	19	19.4	12.1	28.6	288	65	22.6	17.9	27.8	96	21	21.9	14.1	31.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.49 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	577	178	30.8	27.1	34.8	560	176	31.4	27.6	35.5	577	168	29.1	25.4	33.0	1714	522	30.5	28.3	32.7	612	201	32.8	29.1	36.7
	≥38	577	176	30.5	26.8	34.4	560	176	31.4	27.6	35.5	577	165	28.6	24.9	32.5	1714	517	30.2	28.0	32.4	612	200	32.7	29.0	36.6
	>38.5	577	111	19.2	16.1	22.7	560	109	19.5	16.3	23.0	577	95	16.5	13.5	19.7	1714	315	18.4	16.6	20.3	612	120	19.6	16.5	23.0
	>39.0	577	58	10.1	7.7	12.8	560	44	7.9	5.8	10.4	577	48	8.3	6.2	10.9	1714	150	8.8	7.5	10.2	612	56	9.2	7.0	11.7
	>39.5	577	21	3.6	2.3	5.5	560	20	3.6	2.2	5.5	577	20	3.5	2.1	5.3	1714	61	3.6	2.7	4.5	612	21	3.4	2.1	5.2
	>40.0	577	3	0.5	0.1	1.5	560	8	1.4	0.6	2.8	577	9	1.6	0.7	2.9	1714	20	1.2	0.7	1.8	612	6	1.0	0.4	2.1
	≥38 Related	577	105	18.2	15.1	21.6	560	101	18.0	14.9	21.5	577	100	17.3	14.3	20.7	1714	306	17.9	16.1	19.7	612	115	18.8	15.8	22.1
	>38.5 Related	577	56	9.7	7.4	12.4	560	58	10.4	8.0	13.2	577	58	10.1	7.7	12.8	1714	172	10.0	8.7	11.6	612	66	10.8	8.4	13.5
	>39.0 Related	577	25	4.3	2.8	6.3	560	18	3.2	1.9	5.0	577	29	5.0	3.4	7.1	1714	72	4.2	3.3	5.3	612	30	4.9	3.3	6.9
	>39.5 Related	577	9	1.6	0.7	2.9	560	8	1.4	0.6	2.8	577	12	2.1	1.1	3.6	1714	29	1.7	1.1	2.4	612	11	1.8	0.9	3.2
	>40.0 Related	577	1	0.2	0.0	1.0	560	4	0.7	0.2	1.8	577	4	0.7	0.2	1.8	1714	9	0.5	0.2	1.0	612	5	0.8	0.3	1.9
	Medical advice	577	55	9.5	7.3	12.2	560	46	8.2	6.1	10.8	577	65	11.3	8.8	14.1	1714	166	9.7	8.3	11.2	612	53	8.7	6.6	11.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.50 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1734	599	34.5	32.3	36.8	1832	645	35.2	33.0	37.4	598	201	33.6	29.8	37.6	645	211	32.7	29.1	36.5
	≥38	1734	597	34.4	32.2	36.7	1832	642	35.0	32.9	37.3	598	200	33.4	29.7	37.4	645	211	32.7	29.1	36.5
	>38.5	1734	340	19.6	17.8	21.6	1832	345	18.8	17.1	20.7	598	110	18.4	15.4	21.7	645	106	16.4	13.7	19.5
	>39.0	1734	133	7.7	6.5	9.0	1832	165	9.0	7.7	10.4	598	42	7.0	5.1	9.4	645	53	8.2	6.2	10.6
	>39.5	1734	46	2.7	1.9	3.5	1832	59	3.2	2.5	4.1	598	16	2.7	1.5	4.3	645	16	2.5	1.4	4.0
	>40.0	1734	15	0.9	0.5	1.4	1832	13	0.7	0.4	1.2	598	4	0.7	0.2	1.7	645	4	0.6	0.2	1.6
	≥38 Related	1734	337	19.4	17.6	21.4	1832	337	18.4	16.6	20.2	598	109	18.2	15.2	21.6	645	110	17.1	14.2	20.2
	>38.5 Related	1734	179	10.3	8.9	11.9	1832	162	8.8	7.6	10.2	598	59	9.9	7.6	12.5	645	52	8.1	6.1	10.4
	>39.0 Related	1734	58	3.3	2.5	4.3	1832	75	4.1	3.2	5.1	598	19	3.2	1.9	4.9	645	23	3.6	2.3	5.3
	>39.5 Related	1734	20	1.2	0.7	1.8	1832	26	1.4	0.9	2.1	598	7	1.2	0.5	2.4	645	7	1.1	0.4	2.2
	>40.0 Related	1734	6	0.3	0.1	0.8	1832	4	0.2	0.1	0.6	598	3	0.5	0.1	1.5	645	3	0.5	0.1	1.4
	Medical advice	1734	179	10.3	8.9	11.9	1832	197	10.8	9.4	12.3	598	58	9.7	7.4	12.4	645	72	11.2	8.8	13.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.51 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	2720	979	36.0	34.2	37.8	352	117	33.2	28.3	38.4	151	46	30.5	23.2	38.5	947	314	33.2	30.2	36.3	119	41	34.5	26.0	43.7
	≥38	2720	976	35.9	34.1	37.7	352	116	33.0	28.1	38.1	151	46	30.5	23.2	38.5	947	313	33.1	30.1	36.1	119	41	34.5	26.0	43.7
	>38.5	2720	530	19.5	18.0	21.0	352	61	17.3	13.5	21.7	151	27	17.9	12.1	24.9	947	170	18.0	15.6	20.5	119	16	13.4	7.9	20.9
	>39.0	2720	239	8.8	7.7	9.9	352	22	6.3	4.0	9.3	151	14	9.3	5.2	15.1	947	71	7.5	5.9	9.4	119	6	5.0	1.9	10.7
	>39.5	2720	83	3.1	2.4	3.8	352	7	2.0	0.8	4.1	151	4	2.6	0.7	6.6	947	24	2.5	1.6	3.7	119	2	1.7	0.2	5.9
	>40.0	2720	20	0.7	0.4	1.1	352	1	0.3	0.0	1.6	151	3	2.0	0.4	5.7	947	6	0.6	0.2	1.4	119	0	0.0	0.0	3.1
	≥38 Related	2720	537	19.7	18.3	21.3	352	38	10.8	7.8	14.5	151	24	15.9	10.5	22.7	947	173	18.3	15.9	20.9	119	11	9.2	4.7	15.9
	>38.5 Related	2720	259	9.5	8.4	10.7	352	19	5.4	3.3	8.3	151	15	9.9	5.7	15.9	947	87	9.2	7.4	11.2	119	5	4.2	1.4	9.5
	>39.0 Related	2720	103	3.8	3.1	4.6	352	7	2.0	0.8	4.1	151	8	5.3	2.3	10.2	947	31	3.3	2.2	4.6	119	1	0.8	0.0	4.6
	>39.5 Related	2720	34	1.3	0.9	1.7	352	3	0.9	0.2	2.5	151	3	2.0	0.4	5.7	947	11	1.2	0.6	2.1	119	0	0.0	0.0	3.1
	>40.0 Related	2720	5	0.2	0.1	0.4	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7	947	4	0.4	0.1	1.1	119	0	0.0	0.0	3.1
	Medical advice	2720	272	10.0	8.9	11.2	352	71	20.2	16.1	24.7	151	16	10.6	6.2	16.6	947	98	10.3	8.5	12.5	119	23	19.3	12.7	27.6

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	64	20	31.3	20.2	44.1
	≥38	64	20	31.3	20.2	44.1
	>38.5	64	12	18.8	10.1	30.5
	>39.0	64	8	12.5	5.6	23.2
	>39.5	64	2	3.1	0.4	10.8
	>40.0	64	0	0.0	0.0	5.6
	≥38 Related	64	12	18.8	10.1	30.5
	>38.5 Related	64	6	9.4	3.5	19.3
	>39.0 Related	64	2	3.1	0.4	10.8
	>39.5 Related	64	0	0.0	0.0	5.6
	>40.0 Related	64	0	0.0	0.0	5.6
	Medical advice	64	5	7.8	2.6	17.3

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.52 Incidence of fever reported during the 15-day (Days 0-14) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1190	326	27.4	24.9	30.0	1176	342	29.1	26.5	31.8	1200	339	28.3	25.7	30.9	3566	1007	28.2	26.8	29.7	1243	332	26.7	24.3	29.3
	≥38	1190	270	22.7	20.3	25.2	1176	289	24.6	22.1	27.1	1200	286	23.8	21.4	26.3	3566	845	23.7	22.3	25.1	1243	271	21.8	19.5	24.2
	>38.5	1190	133	11.2	9.4	13.1	1176	139	11.8	10.0	13.8	1200	138	11.5	9.7	13.4	3566	410	11.5	10.5	12.6	1243	128	10.3	8.7	12.1
	>39.0	1190	58	4.9	3.7	6.3	1176	53	4.5	3.4	5.9	1200	55	4.6	3.5	5.9	3566	166	4.7	4.0	5.4	1243	49	3.9	2.9	5.2
	>39.5	1190	19	1.6	1.0	2.5	1176	18	1.5	0.9	2.4	1200	19	1.6	1.0	2.5	3566	56	1.6	1.2	2.0	1243	18	1.4	0.9	2.3
	>40.0	1190	2	0.2	0.0	0.6	1176	6	0.5	0.2	1.1	1200	4	0.3	0.1	0.9	3566	12	0.3	0.2	0.6	1243	6	0.5	0.2	1.0
	≥38 Related	1190	202	17.0	14.9	19.2	1176	203	17.3	15.1	19.5	1200	200	16.7	14.6	18.9	3566	605	17.0	15.7	18.2	1243	194	15.6	13.6	17.7
	>38.5 Related	1190	94	7.9	6.4	9.6	1176	94	8.0	6.5	9.7	1200	103	8.6	7.1	10.3	3566	291	8.2	7.3	9.1	1243	93	7.5	6.1	9.1
	>39.0 Related	1190	38	3.2	2.3	4.4	1176	32	2.7	1.9	3.8	1200	43	3.6	2.6	4.8	3566	113	3.2	2.6	3.8	1243	32	2.6	1.8	3.6
	>39.5 Related	1190	13	1.1	0.6	1.9	1176	10	0.9	0.4	1.6	1200	16	1.3	0.8	2.2	3566	39	1.1	0.8	1.5	1243	12	1.0	0.5	1.7
	>40.0 Related	1190	1	0.1	0.0	0.5	1176	3	0.3	0.1	0.7	1200	4	0.3	0.1	0.9	3566	8	0.2	0.1	0.4	1243	5	0.4	0.1	0.9
	Medical advice	1190	60	5.0	3.9	6.4	1176	59	5.0	3.8	6.4	1200	72	6.0	4.7	7.5	3566	191	5.4	4.6	6.1	1243	68	5.5	4.3	6.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.53 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	123	35	28.5	20.7	37.3	125	42	33.6	25.4	42.6	125	46	36.8	28.4	45.9	373	123	33.0	28.2	38.0	127	32	25.2	17.9	33.7
	≥38	123	32	26.0	18.5	34.7	125	38	30.4	22.5	39.3	125	45	36.0	27.6	45.1	373	115	30.8	26.2	35.8	127	29	22.8	15.9	31.1
	>38.5	123	15	12.2	7.0	19.3	125	17	13.6	8.1	20.9	125	20	16.0	10.1	23.6	373	52	13.9	10.6	17.9	127	15	11.8	6.8	18.7
	>39.0	123	5	4.1	1.3	9.2	125	7	5.6	2.3	11.2	125	6	4.8	1.8	10.2	373	18	4.8	2.9	7.5	127	4	3.1	0.9	7.9
	>39.5	123	2	1.6	0.2	5.8	125	3	2.4	0.5	6.9	125	3	2.4	0.5	6.9	373	8	2.1	0.9	4.2	127	1	0.8	0.0	4.3
	>40.0	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	≥38 Related	123	18	14.6	8.9	22.1	125	13	10.4	5.7	17.1	125	15	12.0	6.9	19.0	373	46	12.3	9.2	16.1	127	13	10.2	5.6	16.9
	>38.5 Related	123	11	8.9	4.5	15.4	125	8	6.4	2.8	12.2	125	8	6.4	2.8	12.2	373	27	7.2	4.8	10.4	127	5	3.9	1.3	8.9
	>39.0 Related	123	3	2.4	0.5	7.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	7	1.9	0.8	3.8	127	0	0.0	0.0	2.9
	>39.5 Related	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	>40.0 Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	6	4.9	1.8	10.3	125	8	6.4	2.8	12.2	125	10	8.0	3.9	14.2	373	24	6.4	4.2	9.4	127	8	6.3	2.8	12.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.54 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	61	22	36.1	24.2	49.4	62	20	32.3	20.9	45.3	63	25	39.7	27.6	52.8	186	67	36.0	29.1	43.4	68	26	38.2	26.7	50.8
	≥38	61	19	31.1	19.9	44.3	62	20	32.3	20.9	45.3	63	20	31.7	20.6	44.7	186	59	31.7	25.1	38.9	68	25	36.8	25.4	49.3
	>38.5	61	10	16.4	8.2	28.1	62	9	14.5	6.9	25.8	63	6	9.5	3.6	19.6	186	25	13.4	8.9	19.2	68	10	14.7	7.3	25.4
	>39.0	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5	186	9	4.8	2.2	9.0	68	5	7.4	2.4	16.3
	>39.5	61	1	1.6	0.0	8.8	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>40.0	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	≥38 Related	61	8	13.1	5.8	24.2	62	10	16.1	8.0	27.7	63	10	15.9	7.9	27.3	186	28	15.1	10.2	21.0	68	13	19.1	10.6	30.5
	>38.5 Related	61	4	6.6	1.8	15.9	62	3	4.8	1.0	13.5	63	4	6.3	1.8	15.5	186	11	5.9	3.0	10.3	68	4	5.9	1.6	14.4
	>39.0 Related	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>39.5 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	>40.0 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	8	13.1	5.8	24.2	62	10	16.1	8.0	27.7	63	6	9.5	3.6	19.6	186	24	12.9	8.4	18.6	68	14	20.6	11.7	32.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.55 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	336	107	31.8	26.9	37.1	332	116	34.9	29.8	40.3	337	114	33.8	28.8	39.2	1005	337	33.5	30.6	36.5	340	97	28.5	23.8	33.6
	≥38	336	89	26.5	21.8	31.5	332	97	29.2	24.4	34.4	337	98	29.1	24.3	34.2	1005	284	28.3	25.5	31.2	340	81	23.8	19.4	28.7
	>38.5	336	38	11.3	8.1	15.2	332	47	14.2	10.6	18.4	337	47	13.9	10.4	18.1	1005	132	13.1	11.1	15.4	340	38	11.2	8.0	15.0
	>39.0	336	19	5.7	3.4	8.7	332	20	6.0	3.7	9.2	337	17	5.0	3.0	8.0	1005	56	5.6	4.2	7.2	340	15	4.4	2.5	7.2
	>39.5	336	6	1.8	0.7	3.8	332	6	1.8	0.7	3.9	337	3	0.9	0.2	2.6	1005	15	1.5	0.8	2.4	340	4	1.2	0.3	3.0
	>40.0	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	2	0.6	0.1	2.1
	≥38 Related	336	83	24.7	20.2	29.7	332	91	27.4	22.7	32.5	337	90	26.7	22.1	31.8	1005	264	26.3	23.6	29.1	340	73	21.5	17.2	26.2
	>38.5 Related	336	34	10.1	7.1	13.9	332	41	12.3	9.0	16.4	337	42	12.5	9.1	16.5	1005	117	11.6	9.7	13.8	340	34	10.0	7.0	13.7
	>39.0 Related	336	16	4.8	2.7	7.6	332	16	4.8	2.8	7.7	337	17	5.0	3.0	8.0	1005	49	4.9	3.6	6.4	340	11	3.2	1.6	5.7
	>39.5 Related	336	5	1.5	0.5	3.4	332	4	1.2	0.3	3.1	337	3	0.9	0.2	2.6	1005	12	1.2	0.6	2.1	340	2	0.6	0.1	2.1
	>40.0 Related	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	1	0.3	0.0	1.6
	Medical advice	336	9	2.7	1.2	5.0	332	5	1.5	0.5	3.5	337	12	3.6	1.9	6.1	1005	26	2.6	1.7	3.8	340	12	3.5	1.8	6.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.56 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	93	17	18.3	11.0	27.6	97	25	25.8	17.4	35.7	98	18	18.4	11.3	27.5	288	60	20.8	16.3	26.0	96	18	18.8	11.5	28.0
	≥38	93	16	17.2	10.2	26.4	97	22	22.7	14.8	32.3	98	18	18.4	11.3	27.5	288	56	19.4	15.0	24.5	96	17	17.7	10.7	26.8
	>38.5	93	4	4.3	1.2	10.6	97	10	10.3	5.1	18.1	98	8	8.2	3.6	15.5	288	22	7.6	4.8	11.3	96	2	2.1	0.3	7.3
	>39.0	93	0	0.0	0.0	3.9	97	4	4.1	1.1	10.2	98	3	3.1	0.6	8.7	288	7	2.4	1.0	4.9	96	0	0.0	0.0	3.8
	>39.5	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	1	1.0	0.0	5.6	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>40.0	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	≥38 Related	93	9	9.7	4.5	17.6	97	5	5.2	1.7	11.6	98	6	6.1	2.3	12.9	288	20	6.9	4.3	10.5	96	3	3.1	0.6	8.9
	>38.5 Related	93	3	3.2	0.7	9.1	97	0	0.0	0.0	3.7	98	4	4.1	1.1	10.1	288	7	2.4	1.0	4.9	96	1	1.0	0.0	5.7
	>39.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	2	2.0	0.2	7.2	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>39.5 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	>40.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	11	11.8	6.1	20.2	97	16	16.5	9.7	25.4	98	13	13.3	7.3	21.6	288	40	13.9	10.1	18.4	96	9	9.4	4.4	17.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.57 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	577	145	25.1	21.6	28.9	560	139	24.8	21.3	28.6	577	136	23.6	20.2	27.3	1714	420	24.5	22.5	26.6	612	159	26.0	22.5	29.6
	≥38	577	114	19.8	16.6	23.2	560	112	20.0	16.8	23.6	577	105	18.2	15.1	21.6	1714	331	19.3	17.5	21.3	612	119	19.4	16.4	22.8
	>38.5	577	66	11.4	9.0	14.3	560	56	10.0	7.6	12.8	577	57	9.9	7.6	12.6	1714	179	10.4	9.0	12.0	612	63	10.3	8.0	13.0
	>39.0	577	29	5.0	3.4	7.1	560	19	3.4	2.1	5.2	577	28	4.9	3.2	6.9	1714	76	4.4	3.5	5.5	612	25	4.1	2.7	6.0
	>39.5	577	10	1.7	0.8	3.2	560	7	1.3	0.5	2.6	577	12	2.1	1.1	3.6	1714	29	1.7	1.1	2.4	612	12	2.0	1.0	3.4
	>40.0	577	1	0.2	0.0	1.0	560	4	0.7	0.2	1.8	577	4	0.7	0.2	1.8	1714	9	0.5	0.2	1.0	612	4	0.7	0.2	1.7
	≥38 Related	577	84	14.6	11.8	17.7	560	84	15.0	12.1	18.2	577	79	13.7	11.0	16.8	1714	247	14.4	12.8	16.2	612	92	15.0	12.3	18.1
	>38.5 Related	577	42	7.3	5.3	9.7	560	42	7.5	5.5	10.0	577	45	7.8	5.7	10.3	1714	129	7.5	6.3	8.9	612	49	8.0	6.0	10.4
	>39.0 Related	577	18	3.1	1.9	4.9	560	13	2.3	1.2	3.9	577	22	3.8	2.4	5.7	1714	53	3.1	2.3	4.0	612	20	3.3	2.0	5.0
	>39.5 Related	577	6	1.0	0.4	2.2	560	5	0.9	0.3	2.1	577	11	1.9	1.0	3.4	1714	22	1.3	0.8	1.9	612	9	1.5	0.7	2.8
	>40.0 Related	577	1	0.2	0.0	1.0	560	3	0.5	0.1	1.6	577	4	0.7	0.2	1.8	1714	8	0.5	0.2	0.9	612	4	0.7	0.2	1.7
	Medical advice	577	26	4.5	3.0	6.5	560	20	3.6	2.2	5.5	577	31	5.4	3.7	7.5	1714	77	4.5	3.6	5.6	612	25	4.1	2.7	6.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.58 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1734	482	27.8	25.7	30.0	1832	525	28.7	26.6	30.8	598	166	27.8	24.2	31.5	645	166	25.7	22.4	29.3
	≥38	1734	407	23.5	21.5	25.5	1832	438	23.9	22.0	25.9	598	137	22.9	19.6	26.5	645	134	20.8	17.7	24.1
	>38.5	1734	208	12.0	10.5	13.6	1832	202	11.0	9.6	12.6	598	64	10.7	8.3	13.5	645	64	9.9	7.7	12.5
	>39.0	1734	69	4.0	3.1	5.0	1832	97	5.3	4.3	6.4	598	20	3.3	2.1	5.1	645	29	4.5	3.0	6.4
	>39.5	1734	24	1.4	0.9	2.1	1832	32	1.7	1.2	2.5	598	8	1.3	0.6	2.6	645	10	1.6	0.7	2.8
	>40.0	1734	7	0.4	0.2	0.8	1832	5	0.3	0.1	0.6	598	2	0.3	0.0	1.2	645	4	0.6	0.2	1.6
	≥38 Related	1734	301	17.4	15.6	19.2	1832	304	16.6	14.9	18.4	598	101	16.9	14.0	20.1	645	93	14.4	11.8	17.4
	>38.5 Related	1734	153	8.8	7.5	10.3	1832	138	7.5	6.4	8.8	598	50	8.4	6.3	10.9	645	43	6.7	4.9	8.9
	>39.0 Related	1734	48	2.8	2.0	3.7	1832	65	3.5	2.7	4.5	598	14	2.3	1.3	3.9	645	18	2.8	1.7	4.4
	>39.5 Related	1734	17	1.0	0.6	1.6	1832	22	1.2	0.8	1.8	598	6	1.0	0.4	2.2	645	6	0.9	0.3	2.0
	>40.0 Related	1734	5	0.3	0.1	0.7	1832	3	0.2	0.0	0.5	598	2	0.3	0.0	1.2	645	3	0.5	0.1	1.4
	Medical advice	1734	87	5.0	4.0	6.2	1832	104	5.7	4.7	6.8	598	30	5.0	3.4	7.1	645	38	5.9	4.2	8.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.59 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI				95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	2720	810	29.8	28.1	31.5	352	79	22.4	18.2	27.2	151	35	23.2	16.7	30.7	947	258	27.2	24.4	30.2	119	26	21.8	14.8	30.4
	≥38	2720	682	25.1	23.5	26.7	352	68	19.3	15.3	23.8	151	24	15.9	10.5	22.7	947	212	22.4	19.8	25.2	119	24	20.2	13.4	28.5
	>38.5	2720	324	11.9	10.7	13.2	352	31	8.8	6.1	12.3	151	12	7.9	4.2	13.5	947	104	11.0	9.1	13.1	119	6	5.0	1.9	10.7
	>39.0	2720	133	4.9	4.1	5.8	352	14	4.0	2.2	6.6	151	7	4.6	1.9	9.3	947	36	3.8	2.7	5.2	119	2	1.7	0.2	5.9
	>39.5	2720	43	1.6	1.1	2.1	352	4	1.1	0.3	2.9	151	3	2.0	0.4	5.7	947	13	1.4	0.7	2.3	119	0	0.0	0.0	3.1
	>40.0	2720	6	0.2	0.1	0.5	352	1	0.3	0.0	1.6	151	2	1.3	0.2	4.7	947	4	0.4	0.1	1.1	119	0	0.0	0.0	3.1
	≥38 Related	2720	494	18.2	16.7	19.7	352	28	8.0	5.4	11.3	151	20	13.2	8.3	19.7	947	156	16.5	14.2	19.0	119	8	6.7	2.9	12.8
	>38.5 Related	2720	229	8.4	7.4	9.5	352	12	3.4	1.8	5.9	151	12	7.9	4.2	13.5	947	75	7.9	6.3	9.8	119	3	2.5	0.5	7.2
	>39.0 Related	2720	90	3.3	2.7	4.1	352	6	1.7	0.6	3.7	151	7	4.6	1.9	9.3	947	24	2.5	1.6	3.7	119	0	0.0	0.0	3.1
	>39.5 Related	2720	29	1.1	0.7	1.5	352	2	0.6	0.1	2.0	151	3	2.0	0.4	5.7	947	9	1.0	0.4	1.8	119	0	0.0	0.0	3.1
	>40.0 Related	2720	3	0.1	0.0	0.3	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7	947	3	0.3	0.1	0.9	119	0	0.0	0.0	3.1
	Medical advice	2720	129	4.7	4.0	5.6	352	45	12.8	9.5	16.7	151	4	2.6	0.7	6.6	947	53	5.6	4.2	7.3	119	10	8.4	4.1	14.9

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	64	18	28.1	17.6	40.8
	≥38	64	14	21.9	12.5	34.0
	>38.5	64	8	12.5	5.6	23.2
	>39.0	64	4	6.3	1.7	15.2
	>39.5	64	2	3.1	0.4	10.8
	>40.0	64	0	0.0	0.0	5.6
	≥38 Related	64	11	17.2	8.9	28.7
	>38.5 Related	64	5	7.8	2.6	17.3
	>39.0 Related	64	1	1.6	0.0	8.4
	>39.5 Related	64	0	0.0	0.0	5.6
	>40.0 Related	64	0	0.0	0.0	5.6
	Medical advice	64	3	4.7	1.0	13.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.60 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	123	33	26.8	19.2	35.6	125	37	29.6	21.8	38.4	125	41	32.8	24.7	41.8	373	111	29.8	25.2	34.7	127	29	22.8	15.9	31.1
	≥38	123	30	24.4	17.1	33.0	125	34	27.2	19.6	35.9	125	39	31.2	23.2	40.1	373	103	27.6	23.1	32.5	127	25	19.7	13.2	27.7
	>38.5	123	13	10.6	5.7	17.4	125	15	12.0	6.9	19.0	125	17	13.6	8.1	20.9	373	45	12.1	8.9	15.8	127	12	9.4	5.0	15.9
	>39.0	123	4	3.3	0.9	8.1	125	5	4.0	1.3	9.1	125	6	4.8	1.8	10.2	373	15	4.0	2.3	6.5	127	4	3.1	0.9	7.9
	>39.5	123	1	0.8	0.0	4.4	125	3	2.4	0.5	6.9	125	3	2.4	0.5	6.9	373	7	1.9	0.8	3.8	127	1	0.8	0.0	4.3
	>40.0	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	≥38 Related	123	17	13.8	8.3	21.2	125	11	8.8	4.5	15.2	125	13	10.4	5.7	17.1	373	41	11.0	8.0	14.6	127	12	9.4	5.0	15.9
	>38.5 Related	123	9	7.3	3.4	13.4	125	6	4.8	1.8	10.2	125	8	6.4	2.8	12.2	373	23	6.2	3.9	9.1	127	4	3.1	0.9	7.9
	>39.0 Related	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	>39.5 Related	123	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	3	0.8	0.2	2.3	127	0	0.0	0.0	2.9
	>40.0 Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	6	4.9	1.8	10.3	125	8	6.4	2.8	12.2	125	9	7.2	3.3	13.2	373	23	6.2	3.9	9.1	127	5	3.9	1.3	8.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.61 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	61	21	34.4	22.7	47.7	62	17	27.4	16.9	40.2	63	20	31.7	20.6	44.7	186	58	31.2	24.6	38.4	68	25	36.8	25.4	49.3
	≥38	61	18	29.5	18.5	42.6	62	16	25.8	15.5	38.5	63	16	25.4	15.3	37.9	186	50	26.9	20.7	33.9	68	24	35.3	24.1	47.8
	>38.5	61	8	13.1	5.8	24.2	62	5	8.1	2.7	17.8	63	6	9.5	3.6	19.6	186	19	10.2	6.3	15.5	68	9	13.2	6.2	23.6
	>39.0	61	4	6.6	1.8	15.9	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5	186	7	3.8	1.5	7.6	68	5	7.4	2.4	16.3
	>39.5	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	1	1.5	0.0	7.9
	>40.0	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	≥38 Related	61	7	11.5	4.7	22.2	62	8	12.9	5.7	23.9	63	8	12.7	5.6	23.5	186	23	12.4	8.0	18.0	68	11	16.2	8.4	27.1
	>38.5 Related	61	3	4.9	1.0	13.7	62	1	1.6	0.0	8.7	63	4	6.3	1.8	15.5	186	8	4.3	1.9	8.3	68	3	4.4	0.9	12.4
	>39.0 Related	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>39.5 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	>40.0 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	7	11.5	4.7	22.2	62	8	12.9	5.7	23.9	63	5	7.9	2.6	17.6	186	20	10.8	6.7	16.1	68	13	19.1	10.6	30.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.62 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	336	96	28.6	23.8	33.7	332	103	31.0	26.1	36.3	337	109	32.3	27.4	37.6	1005	308	30.6	27.8	33.6	340	88	25.9	21.3	30.9
	≥38	336	79	23.5	19.1	28.4	332	93	28.0	23.2	33.2	337	89	26.4	21.8	31.5	1005	261	26.0	23.3	28.8	340	75	22.1	17.8	26.8
	>38.5	336	33	9.8	6.9	13.5	332	45	13.6	10.1	17.7	337	42	12.5	9.1	16.5	1005	120	11.9	10.0	14.1	340	37	10.9	7.8	14.7
	>39.0	336	15	4.5	2.5	7.3	332	20	6.0	3.7	9.2	337	15	4.5	2.5	7.2	1005	50	5.0	3.7	6.5	340	15	4.4	2.5	7.2
	>39.5	336	6	1.8	0.7	3.8	332	5	1.5	0.5	3.5	337	3	0.9	0.2	2.6	1005	14	1.4	0.8	2.3	340	4	1.2	0.3	3.0
	>40.0	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	2	0.6	0.1	2.1
	≥38 Related	336	77	22.9	18.5	27.8	332	88	26.5	21.8	31.6	337	83	24.6	20.1	29.6	1005	248	24.7	22.0	27.5	340	70	20.6	16.4	25.3
	>38.5 Related	336	31	9.2	6.4	12.8	332	40	12.0	8.7	16.0	337	39	11.6	8.4	15.5	1005	110	10.9	9.1	13.0	340	33	9.7	6.8	13.4
	>39.0 Related	336	14	4.2	2.3	6.9	332	16	4.8	2.8	7.7	337	15	4.5	2.5	7.2	1005	45	4.5	3.3	5.9	340	11	3.2	1.6	5.7
	>39.5 Related	336	5	1.5	0.5	3.4	332	3	0.9	0.2	2.6	337	3	0.9	0.2	2.6	1005	11	1.1	0.5	1.9	340	2	0.6	0.1	2.1
	>40.0 Related	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	1	0.3	0.0	1.6
	Medical advice	336	6	1.8	0.7	3.8	332	5	1.5	0.5	3.5	337	12	3.6	1.9	6.1	1005	23	2.3	1.5	3.4	340	12	3.5	1.8	6.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.63 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	93	13	14.0	7.7	22.7	97	17	17.5	10.6	26.6	98	16	16.3	9.6	25.2	288	46	16.0	11.9	20.7	96	17	17.7	10.7	26.8
	≥38	93	13	14.0	7.7	22.7	97	16	16.5	9.7	25.4	98	16	16.3	9.6	25.2	288	45	15.6	11.6	20.3	96	16	16.7	9.8	25.6
	>38.5	93	3	3.2	0.7	9.1	97	7	7.2	3.0	14.3	98	8	8.2	3.6	15.5	288	18	6.3	3.7	9.7	96	2	2.1	0.3	7.3
	>39.0	93	0	0.0	0.0	3.9	97	3	3.1	0.6	8.8	98	3	3.1	0.6	8.7	288	6	2.1	0.8	4.5	96	0	0.0	0.0	3.8
	>39.5	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	1	1.0	0.0	5.6	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>40.0	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	≥38 Related	93	5	5.4	1.8	12.1	97	3	3.1	0.6	8.8	98	6	6.1	2.3	12.9	288	14	4.9	2.7	8.0	96	3	3.1	0.6	8.9
	>38.5 Related	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	4	4.1	1.1	10.1	288	5	1.7	0.6	4.0	96	1	1.0	0.0	5.7
	>39.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	2	2.0	0.2	7.2	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>39.5 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	>40.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	9	9.7	4.5	17.6	97	13	13.4	7.3	21.8	98	12	12.2	6.5	20.4	288	34	11.8	8.3	16.1	96	8	8.3	3.7	15.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.64 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	577	118	20.5	17.2	24.0	560	113	20.2	16.9	23.7	577	111	19.2	16.1	22.7	1714	342	20.0	18.1	21.9	612	125	20.4	17.3	23.8
	≥38	577	86	14.9	12.1	18.1	560	83	14.8	12.0	18.0	577	76	13.2	10.5	16.2	1714	245	14.3	12.7	16.0	612	86	14.1	11.4	17.1
	>38.5	577	46	8.0	5.9	10.5	560	44	7.9	5.8	10.4	577	41	7.1	5.1	9.5	1714	131	7.6	6.4	9.0	612	43	7.0	5.1	9.3
	>39.0	577	21	3.6	2.3	5.5	560	17	3.0	1.8	4.8	577	23	4.0	2.5	5.9	1714	61	3.6	2.7	4.5	612	15	2.5	1.4	4.0
	>39.5	577	8	1.4	0.6	2.7	560	7	1.3	0.5	2.6	577	10	1.7	0.8	3.2	1714	25	1.5	0.9	2.1	612	8	1.3	0.6	2.6
	>40.0	577	1	0.2	0.0	1.0	560	4	0.7	0.2	1.8	577	4	0.7	0.2	1.8	1714	9	0.5	0.2	1.0	612	3	0.5	0.1	1.4
	≥38 Related	577	58	10.1	7.7	12.8	560	57	10.2	7.8	13.0	577	55	9.5	7.3	12.2	1714	170	9.9	8.5	11.4	612	63	10.3	8.0	13.0
	>38.5 Related	577	27	4.7	3.1	6.7	560	31	5.5	3.8	7.8	577	32	5.5	3.8	7.7	1714	90	5.3	4.2	6.4	612	32	5.2	3.6	7.3
	>39.0 Related	577	12	2.1	1.1	3.6	560	11	2.0	1.0	3.5	577	18	3.1	1.9	4.9	1714	41	2.4	1.7	3.2	612	11	1.8	0.9	3.2
	>39.5 Related	577	5	0.9	0.3	2.0	560	5	0.9	0.3	2.1	577	9	1.6	0.7	2.9	1714	19	1.1	0.7	1.7	612	6	1.0	0.4	2.1
	>40.0 Related	577	1	0.2	0.0	1.0	560	3	0.5	0.1	1.6	577	4	0.7	0.2	1.8	1714	8	0.5	0.2	0.9	612	3	0.5	0.1	1.4
	Medical advice	577	21	3.6	2.3	5.5	560	19	3.4	2.1	5.2	577	24	4.2	2.7	6.1	1714	64	3.7	2.9	4.7	612	17	2.8	1.6	4.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.65 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1734	411	23.7	21.7	25.8	1832	454	24.8	22.8	26.8	598	142	23.7	20.4	27.4	645	142	22.0	18.9	25.4
	≥38	1734	339	19.6	17.7	21.5	1832	365	19.9	18.1	21.8	598	112	18.7	15.7	22.1	645	114	17.7	14.8	20.8
	>38.5	1734	169	9.7	8.4	11.2	1832	164	9.0	7.7	10.4	598	49	8.2	6.1	10.7	645	54	8.4	6.4	10.8
	>39.0	1734	59	3.4	2.6	4.4	1832	80	4.4	3.5	5.4	598	14	2.3	1.3	3.9	645	25	3.9	2.5	5.7
	>39.5	1734	21	1.2	0.8	1.8	1832	28	1.5	1.0	2.2	598	5	0.8	0.3	1.9	645	9	1.4	0.6	2.6
	>40.0	1734	7	0.4	0.2	0.8	1832	5	0.3	0.1	0.6	598	1	0.2	0.0	0.9	645	4	0.6	0.2	1.6
	≥38 Related	1734	246	14.2	12.6	15.9	1832	250	13.6	12.1	15.3	598	82	13.7	11.1	16.7	645	77	11.9	9.5	14.7
	>38.5 Related	1734	127	7.3	6.1	8.7	1832	109	5.9	4.9	7.1	598	37	6.2	4.4	8.4	645	36	5.6	3.9	7.6
	>39.0 Related	1734	42	2.4	1.8	3.3	1832	52	2.8	2.1	3.7	598	8	1.3	0.6	2.6	645	15	2.3	1.3	3.8
	>39.5 Related	1734	15	0.9	0.5	1.4	1832	19	1.0	0.6	1.6	598	3	0.5	0.1	1.5	645	6	0.9	0.3	2.0
	>40.0 Related	1734	5	0.3	0.1	0.7	1832	3	0.2	0.0	0.5	598	1	0.2	0.0	0.9	645	3	0.5	0.1	1.4
	Medical advice	1734	78	4.5	3.6	5.6	1832	86	4.7	3.8	5.8	598	23	3.8	2.5	5.7	645	32	5.0	3.4	6.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

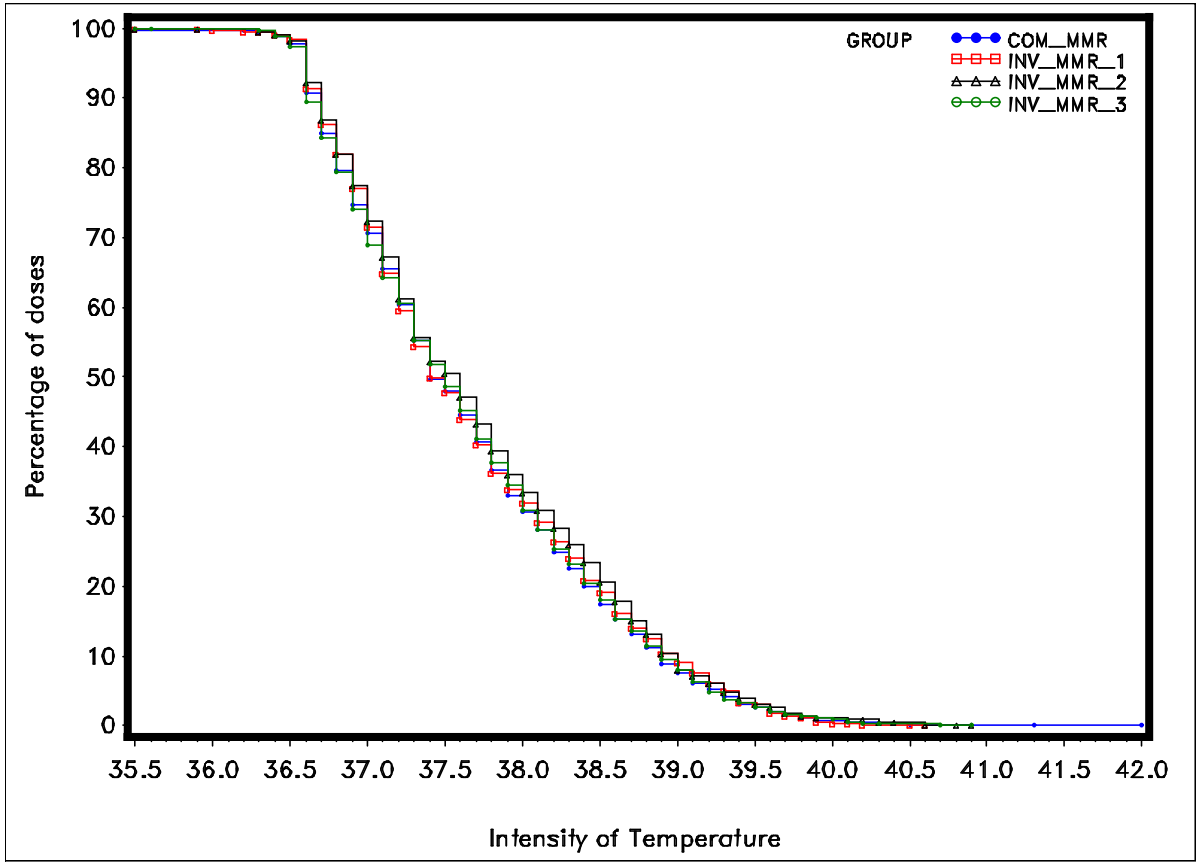
Table 8.66 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	2720	712	26.2	24.5	27.9	352	62	17.6	13.8	22.0	151	23	15.2	9.9	22.0	947	225	23.8	21.1	26.6	119	24	20.2	13.4	28.5
	≥38	2720	590	21.7	20.2	23.3	352	53	15.1	11.5	19.2	151	10	6.6	3.2	11.8	947	183	19.3	16.9	22.0	119	21	17.6	11.3	25.7
	>38.5	2720	273	10.0	8.9	11.2	352	25	7.1	4.6	10.3	151	5	3.3	1.1	7.6	947	86	9.1	7.3	11.1	119	6	5.0	1.9	10.7
	>39.0	2720	116	4.3	3.5	5.1	352	12	3.4	1.8	5.9	151	4	2.6	0.7	6.6	947	31	3.3	2.2	4.6	119	2	1.7	0.2	5.9
	>39.5	2720	39	1.4	1.0	2.0	352	4	1.1	0.3	2.9	151	3	2.0	0.4	5.7	947	10	1.1	0.5	1.9	119	0	0.0	0.0	3.1
	>40.0	2720	6	0.2	0.1	0.5	352	1	0.3	0.0	1.6	151	2	1.3	0.2	4.7	947	3	0.3	0.1	0.9	119	0	0.0	0.0	3.1
	≥38 Related	2720	427	15.7	14.4	17.1	352	18	5.1	3.1	8.0	151	6	4.0	1.5	8.4	947	134	14.1	12.0	16.5	119	6	5.0	1.9	10.7
	>38.5 Related	2720	197	7.2	6.3	8.3	352	8	2.3	1.0	4.4	151	5	3.3	1.1	7.6	947	62	6.5	5.1	8.3	119	3	2.5	0.5	7.2
	>39.0 Related	2720	79	2.9	2.3	3.6	352	5	1.4	0.5	3.3	151	4	2.6	0.7	6.6	947	20	2.1	1.3	3.2	119	0	0.0	0.0	3.1
	>39.5 Related	2720	26	1.0	0.6	1.4	352	2	0.6	0.1	2.0	151	3	2.0	0.4	5.7	947	7	0.7	0.3	1.5	119	0	0.0	0.0	3.1
	>40.0 Related	2720	3	0.1	0.0	0.3	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7	947	2	0.2	0.0	0.8	119	0	0.0	0.0	3.1
	Medical advice	2720	113	4.2	3.4	5.0	352	39	11.1	8.0	14.8	151	2	1.3	0.2	4.7	947	44	4.6	3.4	6.2	119	9	7.6	3.5	13.9

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	64	12	18.8	10.1	30.5
	≥38	64	10	15.6	7.8	26.9
	>38.5	64	5	7.8	2.6	17.3
	>39.0	64	3	4.7	1.0	13.1
	>39.5	64	2	3.1	0.4	10.8
	>40.0	64	0	0.0	0.0	5.6
	≥38 Related	64	7	10.9	4.5	21.2
	>38.5 Related	64	2	3.1	0.4	10.8
	>39.0 Related	64	0	0.0	0.0	5.6
	>39.5 Related	64	0	0.0	0.0	5.6
	>40.0 Related	64	0	0.0	0.0	5.6
	Medical advice	64	1	1.6	0.0	8.4

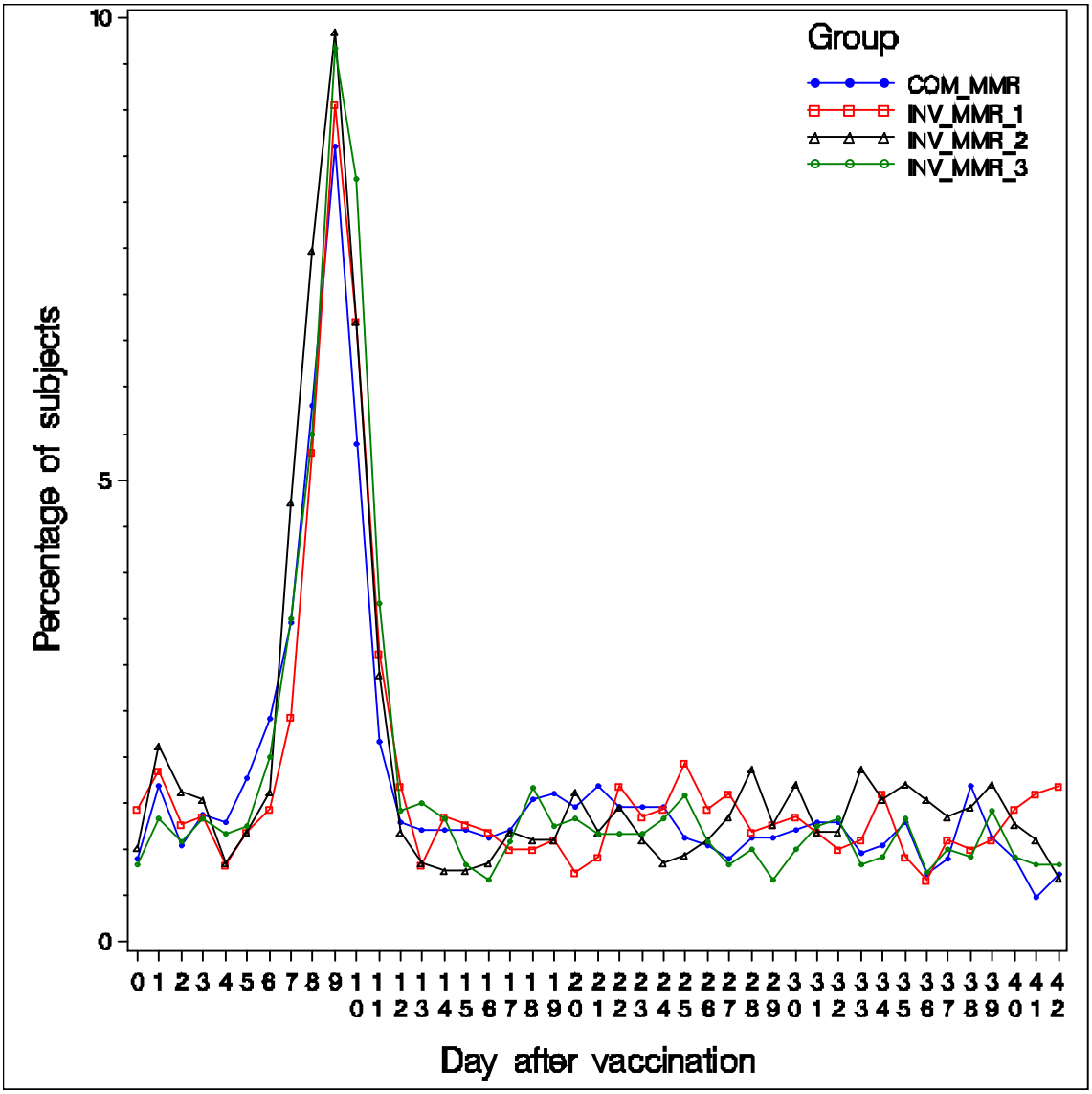
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Figure 8.1 Reverse cumulative distribution curve for Temperature (Total vaccinated cohort) (Dose : (1), during the whole follow-up period)



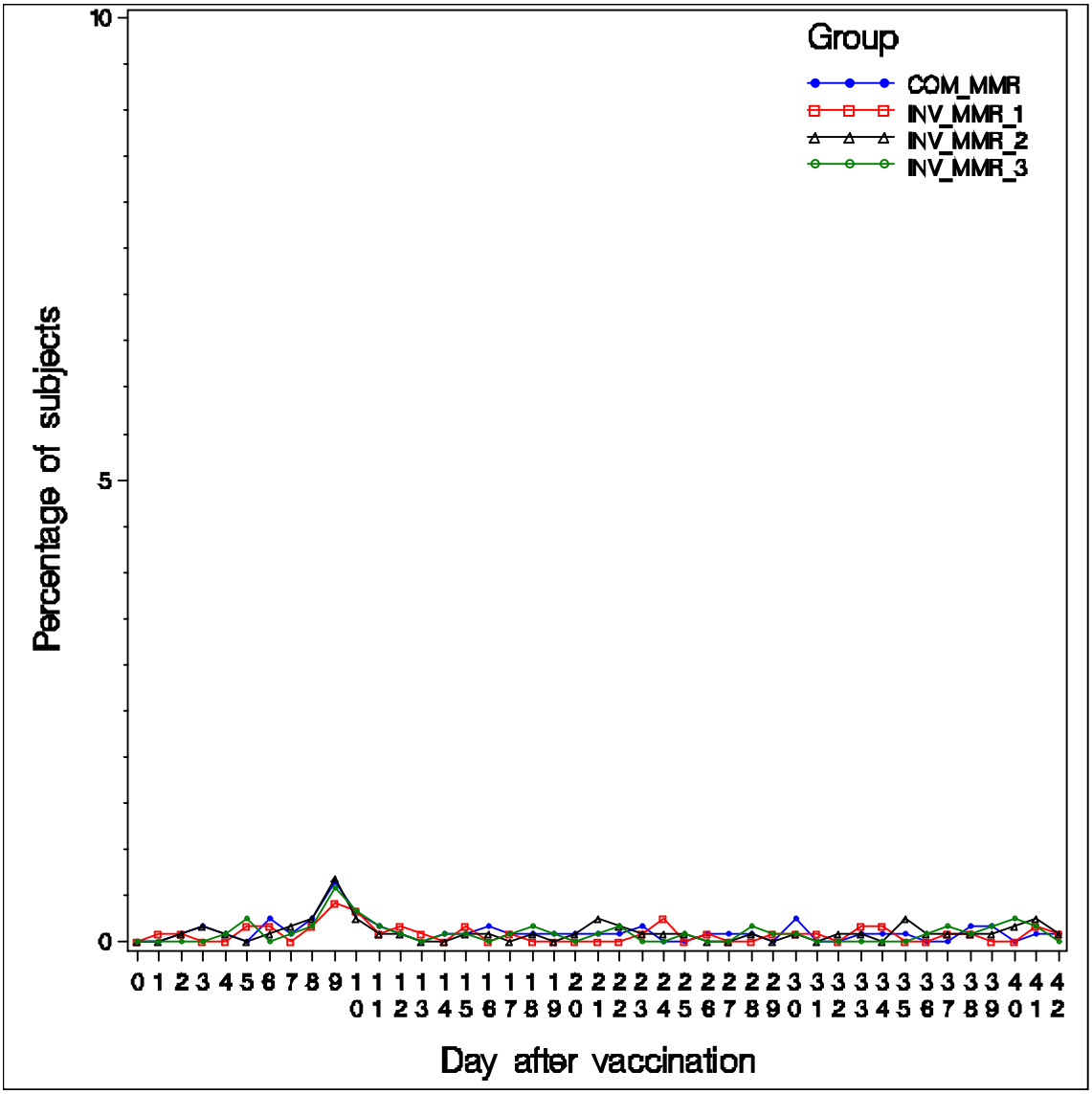
INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Percentage computed on documented dose

Figure 8.2 Daily prevalence of fever between Day 0 and Day 42 after vaccination (Total vaccinated cohort)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Percentage computed on documented dose

Figure 8.3 Daily prevalence of fever >39.5C between Day 0 and Day 42 after vaccination (Total vaccinated cohort)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Percentage computed on documented dose

Table 8.67 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 2 or 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
Parotid gland	All	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 2 or 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.68 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 2 or 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
Parotid gland	All	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 2 or 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.69 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	336	3	0.9	0.2	2.6	332	1	0.3	0.0	1.7	337	2	0.6	0.1	2.1	1005	6	0.6	0.2	1.3	340	2	0.6	0.1	2.1
	Grade 2 or 3	336	2	0.6	0.1	2.1	332	1	0.3	0.0	1.7	337	2	0.6	0.1	2.1	1005	5	0.5	0.2	1.2	340	1	0.3	0.0	1.6
	Grade 3	336	1	0.3	0.0	1.6	332	0	0.0	0.0	1.1	337	1	0.3	0.0	1.6	1005	2	0.2	0.0	0.7	340	0	0.0	0.0	1.1
	Related	336	1	0.3	0.0	1.6	332	1	0.3	0.0	1.7	337	0	0.0	0.0	1.1	1005	2	0.2	0.0	0.7	340	2	0.6	0.1	2.1
	Medical advice	336	3	0.9	0.2	2.6	332	1	0.3	0.0	1.7	337	2	0.6	0.1	2.1	1005	6	0.6	0.2	1.3	340	1	0.3	0.0	1.6
Parotid gland	All	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Grade 2 or 3	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Grade 3	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Related	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.70 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Grade 2 or 3	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Grade 3	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
Parotid gland	All	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Grade 2 or 3	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Grade 3	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.71 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	3	0.5	0.1	1.5	1714	3	0.2	0.0	0.5	612	1	0.2	0.0	0.9
	Grade 2 or 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	1	0.2	0.0	1.0	1714	1	0.1	0.0	0.3	612	0	0.0	0.0	0.6
	Grade 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	1	0.2	0.0	1.0	1714	1	0.1	0.0	0.3	612	0	0.0	0.0	0.6
	Related	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	2	0.3	0.0	1.2	1714	2	0.1	0.0	0.4	612	0	0.0	0.0	0.6
	Medical advice	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	2	0.3	0.0	1.2	1714	2	0.1	0.0	0.4	612	0	0.0	0.0	0.6
Parotid gland	All	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Grade 2 or 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Grade 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Related	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Medical advice	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.72 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	1734	5	0.3	0.1	0.7	1832	5	0.3	0.1	0.6	598	0	0.0	0.0	0.6	645	3	0.5	0.1	1.4
	Grade 2 or 3	1734	3	0.2	0.0	0.5	1832	4	0.2	0.1	0.6	598	0	0.0	0.0	0.6	645	1	0.2	0.0	0.9
	Grade 3	1734	2	0.1	0.0	0.4	1832	2	0.1	0.0	0.4	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Related	1734	2	0.1	0.0	0.4	1832	2	0.1	0.0	0.4	598	0	0.0	0.0	0.6	645	2	0.3	0.0	1.1
	Medical advice	1734	4	0.2	0.1	0.6	1832	5	0.3	0.1	0.6	598	0	0.0	0.0	0.6	645	1	0.2	0.0	0.9
Parotid gland	All	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Grade 2 or 3	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Grade 3	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Related	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Medical advice	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.73 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	2720	8	0.3	0.1	0.6	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	3	0.3	0.1	0.9	119	0	0.0	0.0	3.1
	Grade 2 or 3	2720	5	0.2	0.1	0.4	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	1	0.1	0.0	0.6	119	0	0.0	0.0	3.1
	Grade 3	2720	2	0.1	0.0	0.3	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Related	2720	3	0.1	0.0	0.3	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	2	0.2	0.0	0.8	119	0	0.0	0.0	3.1
	Medical advice	2720	8	0.3	0.1	0.6	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	1	0.1	0.0	0.6	119	0	0.0	0.0	3.1
Parotid gland	All	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Grade 2 or 3	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Grade 3	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Related	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Medical advice	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	64	0	0.0	0.0	5.6
	Grade 2 or 3	64	0	0.0	0.0	5.6
	Grade 3	64	0	0.0	0.0	5.6
	Related	64	0	0.0	0.0	5.6
	Medical advice	64	0	0.0	0.0	5.6
Parotid gland	All	64	0	0.0	0.0	5.6
	Grade 2 or 3	64	0	0.0	0.0	5.6
	Grade 3	64	0	0.0	0.0	5.6
	Related	64	0	0.0	0.0	5.6
	Medical advice	64	0	0.0	0.0	5.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.74 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	123	39	31.7	23.6	40.7	125	31	24.8	17.5	33.3	125	38	30.4	22.5	39.3
	With fever	123	11	8.9	4.6	15.4	125	14	11.2	6.3	18.1	125	19	15.2	9.4	22.7
	Varicella like	123	7	5.7	2.3	11.4	125	6	4.8	1.8	10.2	125	8	6.4	2.8	12.2
	Measles/Rubella like	123	6	4.9	1.8	10.3	125	2	1.6	0.2	5.7	125	4	3.2	0.9	8.0
	Grade 3	123	2	1.6	0.2	5.8	125	5	4.0	1.3	9.1	125	0	0.0	0.0	2.9
	Related	123	12	9.8	5.1	16.4	125	6	4.8	1.8	10.2	125	13	10.4	5.7	17.1
	Med adv	123	30	24.4	17.1	33.0	125	23	18.4	12.0	26.3	125	22	17.6	11.4	25.4
Localized	Any	123	26	21.1	14.3	29.4	125	21	16.8	10.7	24.5	125	29	23.2	16.1	31.6
	Administration site	123	1	0.8	0.0	4.5	125	0	0.0	0.0	2.9	125	1	0.8	0.0	4.4
	Other site	123	26	21.1	14.3	29.4	125	21	16.8	10.7	24.5	125	28	22.4	15.4	30.7
	With fever	123	3	2.4	0.5	7.0	125	6	4.8	1.8	10.2	125	13	10.4	5.7	17.1
	Varicella like	123	5	4.1	1.3	9.2	125	4	3.2	0.9	8.0	125	6	4.8	1.8	10.2
	Measles/Rubella like	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	2	1.6	0.2	5.7
	Grade 3	123	0	0.0	0.0	3.0	125	2	1.6	0.2	5.7	125	0	0.0	0.0	2.9
	Related	123	6	4.9	1.8	10.3	125	4	3.2	0.9	8.0	125	8	6.4	2.8	12.2
	Med adv	123	17	13.8	8.3	21.2	125	15	12.0	6.9	19.0	125	15	12.0	6.9	19.0
Generalized	Any	123	13	10.6	5.8	17.4	125	11	8.8	4.5	15.2	125	10	8.0	3.9	14.2
	With fever	123	8	6.5	2.9	12.4	125	9	7.2	3.4	13.2	125	6	4.8	1.8	10.2
	Varicella like	123	2	1.6	0.2	5.8	125	2	1.6	0.2	5.7	125	2	1.6	0.2	5.7
	Measles/Rubella like	123	4	3.3	0.9	8.1	125	1	0.8	0.0	4.4	125	2	1.6	0.2	5.7
	Grade 3	123	2	1.6	0.2	5.8	125	3	2.4	0.5	6.9	125	0	0.0	0.0	2.9
	Related	123	6	4.9	1.8	10.3	125	2	1.6	0.2	5.7	125	5	4.0	1.3	9.1
	Med adv	123	13	10.6	5.8	17.4	125	9	7.2	3.4	13.2	125	8	6.4	2.8	12.2

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	373	108	29.0	24.4	33.9	127	43	33.9	25.7	42.8
	With fever	373	44	11.8	8.7	15.5	127	15	11.8	6.8	18.7
	Varicella like	373	21	5.6	3.5	8.5	127	12	9.4	5.0	15.9
	Measles/Rubella like	373	12	3.2	1.7	5.6	127	5	3.9	1.3	9.0
	Grade 3	373	7	1.9	0.8	3.8	127	3	2.4	0.5	6.8
	Related	373	31	8.3	5.7	11.6	127	13	10.2	5.6	16.9
	Med adv	373	75	20.1	16.2	24.5	127	35	27.6	20.0	36.2
Localized	Any	373	76	20.4	16.4	24.8	127	25	19.7	13.2	27.7
	Administration site	373	2	0.5	0.1	1.9	127	2	1.6	0.2	5.6
	Other site	373	75	20.1	16.2	24.5	127	23	18.1	11.8	25.9
	With fever	373	22	5.9	3.7	8.8	127	4	3.1	0.9	7.9
	Varicella like	373	15	4.0	2.3	6.6	127	5	3.9	1.3	9.0
	Measles/Rubella like	373	5	1.3	0.4	3.1	127	0	0.0	0.0	2.9
	Grade 3	373	2	0.5	0.1	1.9	127	0	0.0	0.0	2.9
	Related	373	18	4.8	2.9	7.5	127	5	3.9	1.3	9.0
	Med adv	373	47	12.6	9.4	16.4	127	19	15.0	9.3	22.4
Generalized	Any	373	34	9.1	6.4	12.5	127	22	17.3	11.2	25.0
	With fever	373	23	6.2	4.0	9.1	127	11	8.7	4.4	15.0
	Varicella like	373	6	1.6	0.6	3.5	127	7	5.5	2.2	11.0
	Measles/Rubella like	373	7	1.9	0.8	3.8	127	5	3.9	1.3	9.0
	Grade 3	373	5	1.3	0.4	3.1	127	3	2.4	0.5	6.8
	Related	373	13	3.5	1.9	5.9	127	8	6.3	2.8	12.0
	Med adv	373	30	8.0	5.5	11.3	127	19	15.0	9.3	22.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.75 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	61	8	13.1	5.8	24.2	62	6	9.7	3.6	19.9	63	10	15.9	7.9	27.3
	With fever	61	2	3.3	0.4	11.4	62	3	4.8	1.0	13.5	63	6	9.5	3.6	19.6
	Varicella like	61	4	6.6	1.8	16.0	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5
	Measles/Rubella like	61	1	1.6	0.0	8.8	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5
	Grade 3	61	0	0.0	0.0	5.9	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7
	Related	61	0	0.0	0.0	5.9	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5
	Med adv	61	4	6.6	1.8	16.0	62	6	9.7	3.6	19.9	63	6	9.5	3.6	19.6
Localized	Any	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	9	14.3	6.8	25.4
	Administration site	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5
	Other site	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	9	14.3	6.8	25.4
	With fever	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	5	7.9	2.6	17.6
	Varicella like	61	3	4.9	1.0	13.7	62	1	1.6	0.0	8.7	63	1	1.6	0.0	8.5
	Measles/Rubella like	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7
	Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5
	Med adv	61	2	3.3	0.4	11.4	62	3	4.8	1.0	13.5	63	5	7.9	2.6	17.6
Generalized	Any	61	3	4.9	1.0	13.7	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5
	With fever	61	1	1.6	0.0	8.8	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5
	Varicella like	61	1	1.6	0.0	8.8	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7
	Measles/Rubella like	61	0	0.0	0.0	5.9	62	2	3.2	0.4	11.2	63	0	0.0	0.0	5.7
	Grade 3	61	0	0.0	0.0	5.9	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7
	Related	61	0	0.0	0.0	5.9	62	3	4.8	1.0	13.5	63	0	0.0	0.0	5.7
	Med adv	61	2	3.3	0.4	11.4	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	186	24	12.9	8.5	18.6	68	7	10.3	4.2	20.1
	With fever	186	11	5.9	3.0	10.3	68	3	4.4	0.9	12.4
	Varicella like	186	7	3.8	1.5	7.6	68	1	1.5	0.0	7.9
	Measles/Rubella like	186	4	2.2	0.6	5.4	68	1	1.5	0.0	7.9
	Grade 3	186	1	0.5	0.0	3.0	68	1	1.5	0.0	7.9
	Related	186	4	2.2	0.6	5.4	68	3	4.4	0.9	12.4
	Med adv	186	16	8.6	5.0	13.6	68	5	7.4	2.4	16.3
Localized	Any	186	17	9.1	5.4	14.2	68	4	5.9	1.6	14.4
	Administration site	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	Other site	186	17	9.1	5.4	14.2	68	4	5.9	1.6	14.4
	With fever	186	6	3.2	1.2	6.9	68	1	1.5	0.0	7.9
	Varicella like	186	5	2.7	0.9	6.2	68	1	1.5	0.0	7.9
	Measles/Rubella like	186	2	1.1	0.1	3.8	68	0	0.0	0.0	5.3
	Grade 3	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Related	186	1	0.5	0.0	3.0	68	2	2.9	0.4	10.2
	Med adv	186	10	5.4	2.6	9.7	68	2	2.9	0.4	10.2
Generalized	Any	186	7	3.8	1.5	7.6	68	3	4.4	0.9	12.4
	With fever	186	5	2.7	0.9	6.2	68	2	2.9	0.4	10.2
	Varicella like	186	2	1.1	0.1	3.8	68	0	0.0	0.0	5.3
	Measles/Rubella like	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	Grade 3	186	1	0.5	0.0	3.0	68	1	1.5	0.0	7.9
	Related	186	3	1.6	0.3	4.6	68	1	1.5	0.0	7.9
	Med adv	186	6	3.2	1.2	6.9	68	3	4.4	0.9	12.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.76 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	336	151	44.9	39.5	50.4	332	141	42.5	37.1	48.0	337	163	48.4	42.9	53.9
	With fever	336	46	13.7	10.2	17.8	332	53	16.0	12.2	20.4	337	59	17.5	13.6	22.0
	Varicella like	336	60	17.9	13.9	22.4	332	54	16.3	12.5	20.7	337	65	19.3	15.2	23.9
	Measles/Rubella like	336	38	11.3	8.1	15.2	332	45	13.6	10.1	17.7	337	34	10.1	7.1	13.8
	Grade 3	336	22	6.5	4.2	9.8	332	19	5.7	3.5	8.8	337	16	4.7	2.7	7.6
	Related	336	93	27.7	23.0	32.8	332	94	28.3	23.5	33.5	337	101	30.0	25.1	35.2
	Med adv	336	53	15.8	12.0	20.1	332	39	11.7	8.5	15.7	337	51	15.1	11.5	19.4
Localized	Any	336	98	29.2	24.4	34.3	332	101	30.4	25.5	35.7	337	111	32.9	27.9	38.2
	Administration site	336	4	1.2	0.3	3.0	332	9	2.7	1.3	5.1	337	5	1.5	0.5	3.4
	Other site	336	96	28.6	23.8	33.7	332	96	28.9	24.1	34.1	337	108	32.0	27.1	37.3
	With fever	336	21	6.3	3.9	9.4	332	31	9.3	6.4	13.0	337	29	8.6	5.8	12.1
	Varicella like	336	45	13.4	9.9	17.5	332	44	13.3	9.8	17.4	337	44	13.1	9.7	17.1
	Measles/Rubella like	336	10	3.0	1.4	5.4	332	14	4.2	2.3	7.0	337	14	4.2	2.3	6.9
	Grade 3	336	2	0.6	0.1	2.1	332	3	0.9	0.2	2.6	337	2	0.6	0.1	2.1
	Related	336	55	16.4	12.6	20.8	332	62	18.7	14.6	23.3	337	65	19.3	15.2	23.9
	Med adv	336	22	6.5	4.2	9.8	332	22	6.6	4.2	9.9	337	20	5.9	3.7	9.0
Generalized	Any	336	65	19.3	15.3	24.0	332	58	17.5	13.5	22.0	337	64	19.0	14.9	23.6
	With fever	336	30	8.9	6.1	12.5	332	27	8.1	5.4	11.6	337	32	9.5	6.6	13.1
	Varicella like	336	16	4.8	2.8	7.6	332	12	3.6	1.9	6.2	337	22	6.5	4.1	9.7
	Measles/Rubella like	336	28	8.3	5.6	11.8	332	31	9.3	6.4	13.0	337	20	5.9	3.7	9.0
	Grade 3	336	21	6.3	3.9	9.4	332	16	4.8	2.8	7.7	337	14	4.2	2.3	6.9
	Related	336	44	13.1	9.7	17.2	332	40	12.0	8.8	16.0	337	40	11.9	8.6	15.8
	Med adv	336	35	10.4	7.4	14.2	332	21	6.3	4.0	9.5	337	34	10.1	7.1	13.8

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	1005	455	45.3	42.2	48.4	340	160	47.1	41.7	52.5
	With fever	1005	158	15.7	13.5	18.1	340	40	11.8	8.5	15.7
	Varicella like	1005	179	17.8	15.5	20.3	340	58	17.1	13.2	21.5
	Measles/Rubella like	1005	117	11.6	9.7	13.8	340	38	11.2	8.0	15.0
	Grade 3	1005	57	5.7	4.3	7.3	340	10	2.9	1.4	5.3
	Related	1005	288	28.7	25.9	31.6	340	90	26.5	21.9	31.5
	Med adv	1005	143	14.2	12.1	16.5	340	48	14.1	10.6	18.3
Localized	Any	1005	310	30.8	28.0	33.8	340	116	34.1	29.1	39.4
	Administration site	1005	18	1.8	1.1	2.8	340	8	2.4	1.0	4.6
	Other site	1005	300	29.9	27.0	32.8	340	109	32.1	27.1	37.3
	With fever	1005	81	8.1	6.5	9.9	340	25	7.4	4.8	10.7
	Varicella like	1005	133	13.2	11.2	15.5	340	47	13.8	10.3	18.0
	Measles/Rubella like	1005	38	3.8	2.7	5.2	340	14	4.1	2.3	6.8
	Grade 3	1005	7	0.7	0.3	1.4	340	1	0.3	0.0	1.6
	Related	1005	182	18.1	15.8	20.6	340	62	18.2	14.3	22.8
	Med adv	1005	64	6.4	4.9	8.1	340	28	8.2	5.5	11.7
Generalized	Any	1005	187	18.6	16.3	21.2	340	62	18.2	14.3	22.8
	With fever	1005	89	8.9	7.2	10.8	340	19	5.6	3.4	8.6
	Varicella like	1005	50	5.0	3.7	6.5	340	12	3.5	1.8	6.1
	Measles/Rubella like	1005	79	7.9	6.3	9.7	340	24	7.1	4.6	10.3
	Grade 3	1005	51	5.1	3.8	6.6	340	9	2.6	1.2	5.0
	Related	1005	124	12.3	10.4	14.5	340	37	10.9	7.8	14.7
	Med adv	1005	90	9.0	7.3	10.9	340	25	7.4	4.8	10.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.77 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	93	23	24.7	16.4	34.8	97	18	18.6	11.4	27.7	98	10	10.2	5.0	18.0
	With fever	93	9	9.7	4.5	17.6	97	6	6.2	2.3	13.0	98	0	0.0	0.0	3.7
	Varicella like	93	4	4.3	1.2	10.7	97	3	3.1	0.6	8.8	98	1	1.0	0.0	5.6
	Measles/Rubella like	93	2	2.2	0.3	7.6	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Grade 3	93	1	1.1	0.0	5.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Related	93	12	12.9	6.9	21.5	97	6	6.2	2.3	13.0	98	4	4.1	1.1	10.1
	Med adv	93	15	16.1	9.3	25.2	97	17	17.5	10.6	26.6	98	7	7.1	2.9	14.2
Localized	Any	93	16	17.2	10.2	26.4	97	11	11.3	5.8	19.4	98	8	8.2	3.6	15.5
	Administration site	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6
	Other site	93	16	17.2	10.2	26.4	97	11	11.3	5.8	19.4	98	7	7.1	2.9	14.2
	With fever	93	6	6.5	2.4	13.5	97	2	2.1	0.3	7.3	98	0	0.0	0.0	3.7
	Varicella like	93	4	4.3	1.2	10.7	97	2	2.1	0.3	7.3	98	1	1.0	0.0	5.6
	Measles/Rubella like	93	2	2.2	0.3	7.6	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Grade 3	93	1	1.1	0.0	5.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Related	93	8	8.6	3.8	16.3	97	3	3.1	0.6	8.8	98	3	3.1	0.6	8.7
	Med adv	93	10	10.8	5.3	18.9	97	11	11.3	5.8	19.4	98	5	5.1	1.7	11.5
Generalized	Any	93	7	7.5	3.1	14.9	97	8	8.2	3.6	15.6	98	3	3.1	0.6	8.7
	With fever	93	3	3.2	0.7	9.1	97	5	5.2	1.7	11.6	98	0	0.0	0.0	3.7
	Varicella like	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7
	Measles/Rubella like	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Grade 3	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Related	93	4	4.3	1.2	10.7	97	3	3.1	0.6	8.8	98	1	1.0	0.0	5.6
	Med adv	93	5	5.4	1.8	12.1	97	7	7.2	3.0	14.3	98	2	2.0	0.3	7.2

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	288	51	17.7	13.5	22.6	96	21	21.9	14.1	31.5
	With fever	288	15	5.2	2.9	8.4	96	4	4.2	1.2	10.3
	Varicella like	288	8	2.8	1.2	5.4	96	3	3.1	0.7	8.9
	Measles/Rubella like	288	2	0.7	0.1	2.5	96	1	1.0	0.0	5.7
	Grade 3	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Related	288	22	7.6	4.9	11.3	96	5	5.2	1.7	11.7
	Med adv	288	39	13.5	9.8	18.0	96	16	16.7	9.8	25.7
Localized	Any	288	35	12.2	8.6	16.5	96	16	16.7	9.8	25.7
	Administration site	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Other site	288	34	11.8	8.3	16.1	96	16	16.7	9.8	25.7
	With fever	288	8	2.8	1.2	5.4	96	2	2.1	0.3	7.3
	Varicella like	288	7	2.4	1.0	4.9	96	1	1.0	0.0	5.7
	Measles/Rubella like	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	Grade 3	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Related	288	14	4.9	2.7	8.0	96	4	4.2	1.2	10.3
	Med adv	288	26	9.0	6.0	13.0	96	12	12.5	6.6	20.8
Generalized	Any	288	18	6.3	3.8	9.7	96	6	6.3	2.3	13.1
	With fever	288	8	2.8	1.2	5.4	96	2	2.1	0.3	7.3
	Varicella like	288	1	0.3	0.0	1.9	96	2	2.1	0.3	7.3
	Measles/Rubella like	288	0	0.0	0.0	1.3	96	1	1.0	0.0	5.7
	Grade 3	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Related	288	8	2.8	1.2	5.4	96	2	2.1	0.3	7.3
	Med adv	288	14	4.9	2.7	8.0	96	4	4.2	1.2	10.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.78 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	577	131	22.7	19.4	26.3	560	135	24.1	20.6	27.9	577	139	24.1	20.7	27.8
	With fever	577	38	6.6	4.7	8.9	560	47	8.4	6.2	11.0	577	34	5.9	4.1	8.1
	Varicella like	577	12	2.1	1.1	3.6	560	13	2.3	1.2	3.9	577	10	1.7	0.8	3.2
	Measles/Rubella like	577	24	4.2	2.7	6.1	560	39	7.0	5.0	9.4	577	37	6.4	4.6	8.7
	Grade 3	577	8	1.4	0.6	2.7	560	12	2.1	1.1	3.7	577	20	3.5	2.1	5.3
	Related	577	36	6.2	4.4	8.5	560	56	10.0	7.6	12.8	577	52	9.0	6.8	11.7
	Med adv	577	58	10.1	7.7	12.8	560	51	9.1	6.9	11.8	577	64	11.1	8.7	13.9
Localized	Any	577	85	14.7	11.9	17.9	560	88	15.7	12.8	19.0	577	94	16.3	13.4	19.6
	Administration site	577	5	0.9	0.3	2.0	560	7	1.3	0.5	2.6	577	4	0.7	0.2	1.8
	Other site	577	82	14.2	11.5	17.3	560	82	14.6	11.8	17.9	577	90	15.6	12.7	18.8
	With fever	577	17	2.9	1.7	4.7	560	28	5.0	3.4	7.2	577	20	3.5	2.1	5.3
	Varicella like	577	11	1.9	1.0	3.4	560	6	1.1	0.4	2.3	577	3	0.5	0.1	1.5
	Measles/Rubella like	577	10	1.7	0.8	3.2	560	19	3.4	2.1	5.3	577	17	2.9	1.7	4.7
	Grade 3	577	3	0.5	0.1	1.5	560	5	0.9	0.3	2.1	577	7	1.2	0.5	2.5
	Related	577	18	3.1	1.9	4.9	560	32	5.7	3.9	8.0	577	24	4.2	2.7	6.1
	Med adv	577	33	5.7	4.0	7.9	560	26	4.6	3.1	6.7	577	35	6.1	4.3	8.3
Generalized	Any	577	55	9.5	7.3	12.2	560	58	10.4	8.0	13.2	577	55	9.5	7.3	12.2
	With fever	577	24	4.2	2.7	6.1	560	21	3.8	2.3	5.7	577	16	2.8	1.6	4.5
	Varicella like	577	1	0.2	0.0	1.0	560	7	1.3	0.5	2.6	577	7	1.2	0.5	2.5
	Measles/Rubella like	577	15	2.6	1.5	4.3	560	21	3.8	2.3	5.7	577	22	3.8	2.4	5.7
	Grade 3	577	6	1.0	0.4	2.3	560	7	1.3	0.5	2.6	577	13	2.3	1.2	3.8
	Related	577	20	3.5	2.1	5.3	560	26	4.6	3.1	6.7	577	29	5.0	3.4	7.1
	Med adv	577	28	4.9	3.3	6.9	560	28	5.0	3.4	7.2	577	31	5.4	3.7	7.5

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	1714	405	23.6	21.6	25.7	612	147	24.0	20.7	27.6
	With fever	1714	119	6.9	5.8	8.3	612	42	6.9	5.0	9.2
	Varicella like	1714	35	2.0	1.4	2.8	612	11	1.8	0.9	3.2
	Measles/Rubella like	1714	100	5.8	4.8	7.1	612	32	5.2	3.6	7.3
	Grade 3	1714	40	2.3	1.7	3.2	612	11	1.8	0.9	3.2
	Related	1714	144	8.4	7.1	9.8	612	51	8.3	6.3	10.8
	Med adv	1714	173	10.1	8.7	11.6	612	60	9.8	7.6	12.4
Localized	Any	1714	267	15.6	13.9	17.4	612	105	17.2	14.3	20.4
	Administration site	1714	16	0.9	0.5	1.5	612	6	1.0	0.4	2.1
	Other site	1714	254	14.8	13.2	16.6	612	100	16.3	13.5	19.5
	With fever	1714	65	3.8	2.9	4.8	612	22	3.6	2.3	5.4
	Varicella like	1714	20	1.2	0.7	1.8	612	7	1.1	0.5	2.3
	Measles/Rubella like	1714	46	2.7	2.0	3.6	612	21	3.4	2.1	5.2
	Grade 3	1714	15	0.9	0.5	1.4	612	4	0.7	0.2	1.7
	Related	1714	74	4.3	3.4	5.4	612	30	4.9	3.3	6.9
	Med adv	1714	94	5.5	4.5	6.7	612	34	5.6	3.9	7.7
Generalized	Any	1714	168	9.8	8.4	11.3	612	50	8.2	6.1	10.6
	With fever	1714	61	3.6	2.7	4.6	612	21	3.4	2.1	5.2
	Varicella like	1714	15	0.9	0.5	1.4	612	4	0.7	0.2	1.7
	Measles/Rubella like	1714	58	3.4	2.6	4.4	612	11	1.8	0.9	3.2
	Grade 3	1714	26	1.5	1.0	2.2	612	7	1.1	0.5	2.3
	Related	1714	75	4.4	3.5	5.5	612	21	3.4	2.1	5.2
	Med adv	1714	87	5.1	4.1	6.2	612	29	4.7	3.2	6.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.79 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR									
		F					M				
					95% CI					95% CI	
Symptom	rash type	N	n	%	LL	UL	N	n	%	LL	UL
Any	Localized or generalized	1734	517	29.8	27.7	32.0	1832	526	28.7	26.7	30.8
	With fever	1734	173	10.0	8.6	11.5	1832	174	9.5	8.2	10.9
	Varicella like	1734	127	7.3	6.1	8.7	1832	123	6.7	5.6	8.0
	Measles/Rubella like	1734	111	6.4	5.3	7.7	1832	124	6.8	5.7	8.0
	Grade 3	1734	54	3.1	2.4	4.0	1832	52	2.8	2.1	3.7
	Related	1734	239	13.8	12.2	15.5	1832	250	13.6	12.1	15.3
	Med adv	1734	235	13.6	12.0	15.3	1832	211	11.5	10.1	13.1
Localized	Any	1734	350	20.2	18.3	22.2	1832	355	19.4	17.6	21.3
	Administration site	1734	20	1.2	0.7	1.8	1832	18	1.0	0.6	1.6
	Other site	1734	338	19.5	17.7	21.4	1832	342	18.7	16.9	20.5
	With fever	1734	87	5.0	4.0	6.2	1832	95	5.2	4.2	6.3
	Varicella like	1734	85	4.9	3.9	6.0	1832	95	5.2	4.2	6.3
	Measles/Rubella like	1734	43	2.5	1.8	3.3	1832	50	2.7	2.0	3.6
	Grade 3	1734	11	0.6	0.3	1.1	1832	14	0.8	0.4	1.3
	Related	1734	136	7.8	6.6	9.2	1832	153	8.4	7.1	9.7
	Med adv	1734	123	7.1	5.9	8.4	1832	118	6.4	5.4	7.7
Generalized	Any	1734	209	12.1	10.6	13.7	1832	205	11.2	9.8	12.7
	With fever	1734	96	5.5	4.5	6.7	1832	90	4.9	4.0	6.0
	Varicella like	1734	45	2.6	1.9	3.5	1832	29	1.6	1.1	2.3
	Measles/Rubella like	1734	70	4.0	3.2	5.1	1832	76	4.1	3.3	5.2
	Grade 3	1734	45	2.6	1.9	3.5	1832	38	2.1	1.5	2.8
	Related	1734	117	6.7	5.6	8.0	1832	106	5.8	4.8	7.0
	Med adv	1734	127	7.3	6.1	8.7	1832	100	5.5	4.5	6.6

		COM_MMR									
		F					M				
					95% CI					95% CI	
Symptom	rash type	N	n	%	LL	UL	N	n	%	LL	UL
Any	Localized or generalized	598	179	29.9	26.3	33.8	645	199	30.9	27.3	34.6
	With fever	598	54	9.0	6.9	11.6	645	50	7.8	5.8	10.1
	Varicella like	598	35	5.9	4.1	8.1	645	50	7.8	5.8	10.1
	Measles/Rubella like	598	35	5.9	4.1	8.1	645	42	6.5	4.7	8.7
	Grade 3	598	13	2.2	1.2	3.7	645	12	1.9	1.0	3.2
	Related	598	76	12.7	10.2	15.7	645	86	13.3	10.8	16.2
	Med adv	598	77	12.9	10.3	15.8	645	87	13.5	11.0	16.4
Localized	Any	598	125	20.9	17.7	24.4	645	141	21.9	18.7	25.3
	Administration site	598	11	1.8	0.9	3.3	645	5	0.8	0.3	1.8
	Other site	598	116	19.4	16.3	22.8	645	136	21.1	18.0	24.4
	With fever	598	27	4.5	3.0	6.5	645	27	4.2	2.8	6.0
	Varicella like	598	26	4.3	2.9	6.3	645	35	5.4	3.8	7.5
	Measles/Rubella like	598	15	2.5	1.4	4.1	645	20	3.1	1.9	4.8
	Grade 3	598	2	0.3	0.0	1.2	645	3	0.5	0.1	1.4
	Related	598	44	7.4	5.4	9.8	645	59	9.1	7.0	11.6
	Med adv	598	46	7.7	5.7	10.1	645	49	7.6	5.7	9.9
Generalized	Any	598	65	10.9	8.5	13.6	645	78	12.1	9.7	14.9
	With fever	598	29	4.8	3.3	6.9	645	26	4.0	2.7	5.9
	Varicella like	598	9	1.5	0.7	2.8	645	16	2.5	1.4	4.0
	Measles/Rubella like	598	20	3.3	2.1	5.1	645	22	3.4	2.2	5.1
	Grade 3	598	11	1.8	0.9	3.3	645	9	1.4	0.6	2.6

		COM_MMR									
		F					M				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Related	598	33	5.5	3.8	7.7	645	36	5.6	3.9	7.6
	Med adv	598	34	5.7	4.0	7.9	645	46	7.1	5.3	9.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.80 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR														
		WH					OT					AF				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	2720	846	31.1	29.4	32.9	352	70	19.9	15.8	24.4	151	34	22.5	16.1	30.0
	With fever	2720	287	10.6	9.4	11.8	352	22	6.3	4.0	9.3	151	10	6.6	3.2	11.8
	Varicella like	2720	232	8.5	7.5	9.6	352	9	2.6	1.2	4.8	151	2	1.3	0.2	4.7
	Measles/Rubella like	2720	193	7.1	6.2	8.1	352	9	2.6	1.2	4.8	151	4	2.6	0.7	6.6
	Grade 3	2720	94	3.5	2.8	4.2	352	1	0.3	0.0	1.6	151	2	1.3	0.2	4.7
	Related	2720	402	14.8	13.5	16.2	352	32	9.1	6.3	12.6	151	7	4.6	1.9	9.3
	Med adv	2720	363	13.3	12.1	14.7	352	43	12.2	9.0	16.1	151	15	9.9	5.7	15.9
Localized	Any	2720	567	20.8	19.3	22.4	352	49	13.9	10.5	18.0	151	20	13.2	8.3	19.7
	Administration site	2720	29	1.1	0.7	1.5	352	3	0.9	0.2	2.5	151	3	2.0	0.4	5.7
	Other site	2720	549	20.2	18.7	21.7	352	46	13.1	9.7	17.0	151	17	11.3	6.7	17.4
	With fever	2720	144	5.3	4.5	6.2	352	13	3.7	2.0	6.2	151	5	3.3	1.1	7.6
	Varicella like	2720	169	6.2	5.3	7.2	352	7	2.0	0.8	4.1	151	2	1.3	0.2	4.7
	Measles/Rubella like	2720	67	2.5	1.9	3.1	352	7	2.0	0.8	4.1	151	2	1.3	0.2	4.7
	Grade 3	2720	19	0.7	0.4	1.1	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4
	Related	2720	234	8.6	7.6	9.7	352	20	5.7	3.5	8.6	151	5	3.3	1.1	7.6
	Med adv	2720	189	6.9	6.0	8.0	352	28	8.0	5.4	11.3	151	6	4.0	1.5	8.5
Generalized	Any	2720	344	12.6	11.4	14.0	352	25	7.1	4.7	10.3	151	15	9.9	5.7	15.9
	With fever	2720	160	5.9	5.0	6.8	352	11	3.1	1.6	5.5	151	6	4.0	1.5	8.5
	Varicella like	2720	67	2.5	1.9	3.1	352	2	0.6	0.1	2.0	151	0	0.0	0.0	2.4
	Measles/Rubella like	2720	128	4.7	3.9	5.6	352	2	0.6	0.1	2.0	151	2	1.3	0.2	4.7
	Grade 3	2720	77	2.8	2.2	3.5	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7
	Related	2720	189	6.9	6.0	8.0	352	12	3.4	1.8	5.9	151	2	1.3	0.2	4.7
	Med adv	2720	192	7.1	6.1	8.1	352	17	4.8	2.8	7.6	151	9	6.0	2.8	11.0

		COM_MMR														
		WH					OT					AF				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	947	303	32.0	29.0	35.1	119	28	23.5	16.2	32.2	64	16	25.0	15.0	37.4
	With fever	947	85	9.0	7.2	11.0	119	6	5.0	1.9	10.7	64	5	7.8	2.6	17.3
	Varicella like	947	78	8.2	6.6	10.2	119	3	2.5	0.5	7.2	64	1	1.6	0.0	8.4
	Measles/Rubella like	947	63	6.7	5.2	8.4	119	1	0.8	0.0	4.6	64	2	3.1	0.4	10.8
	Grade 3	947	23	2.4	1.6	3.6	119	0	0.0	0.0	3.1	64	0	0.0	0.0	5.6
	Related	947	136	14.4	12.2	16.8	119	5	4.2	1.4	9.5	64	6	9.4	3.5	19.3
	Med adv	947	133	14.0	11.9	16.4	119	17	14.3	8.6	21.9	64	6	9.4	3.5	19.3
Localized	Any	947	210	22.2	19.6	25.0	119	22	18.5	12.0	26.6	64	12	18.8	10.1	30.5
	Administration site	947	14	1.5	0.8	2.5	119	1	0.8	0.0	4.6	64	0	0.0	0.0	5.6
	Other site	947	198	20.9	18.4	23.6	119	21	17.6	11.3	25.7	64	12	18.8	10.1	30.5
	With fever	947	43	4.5	3.3	6.1	119	3	2.5	0.5	7.2	64	3	4.7	1.0	13.1
	Varicella like	947	57	6.0	4.6	7.7	119	1	0.8	0.0	4.6	64	1	1.6	0.0	8.4
	Measles/Rubella like	947	25	2.6	1.7	3.9	119	0	0.0	0.0	3.1	64	2	3.1	0.4	10.8
	Grade 3	947	5	0.5	0.2	1.2	119	0	0.0	0.0	3.1	64	0	0.0	0.0	5.6
	Related	947	84	8.9	7.1	10.9	119	4	3.4	0.9	8.4	64	5	7.8	2.6	17.3
	Med adv	947	76	8.0	6.4	9.9	119	12	10.1	5.3	17.0	64	3	4.7	1.0	13.1
Generalized	Any	947	121	12.8	10.7	15.1	119	7	5.9	2.4	11.7	64	4	6.3	1.7	15.2
	With fever	947	46	4.9	3.6	6.4	119	3	2.5	0.5	7.2	64	2	3.1	0.4	10.8
	Varicella like	947	22	2.3	1.5	3.5	119	2	1.7	0.2	5.9	64	0	0.0	0.0	5.6
	Measles/Rubella like	947	38	4.0	2.9	5.5	119	1	0.8	0.0	4.6	64	0	0.0	0.0	5.6
	Grade 3	947	18	1.9	1.1	3.0	119	0	0.0	0.0	3.1	64	0	0.0	0.0	5.6

		COM_MMR														
		WH					OT					AF				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Related	947	61	6.4	5.0	8.2	119	2	1.7	0.2	5.9	64	1	1.6	0.0	8.4
	Med adv	947	67	7.1	5.5	8.9	119	5	4.2	1.4	9.5	64	3	4.7	1.0	13.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.81 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		615	49.6	46.8	52.5	633	51.4	48.5	54.2	609	49.0	46.2	51.8	1857	50.0	48.4	51.6	618	47.9	45.2	50.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	4	0.3	0.1	0.8	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Leukocytosis (10024378)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Leukopenia (10024384)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lymphadenopathy (10025197)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	2	0.2	0.0	0.6	12	0.3	0.2	0.6	4	0.3	0.1	0.8
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Deafness (10011878)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear pain (10014020)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	4	0.3	0.1	0.8	10	0.3	0.1	0.5	4	0.3	0.1	0.8
	Ear swelling (10014025)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Excessive cerumen production (10076897)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otorrhoea (10033101)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Dacryostenosis acquired (10053990)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye discharge (10015915)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye irritation (10015946)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye swelling (10015967)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eyelid oedema (10015993)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hypermetropia (10020675)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lacrimation increased (10023644)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lid sulcus deepened (10072716)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Strabismus (10042159)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain upper (10000087)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.8
	Anal fissure (10002153)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Aphthous ulcer (10002959)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Chapped lips (10049047)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Constipation (10010774)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	9	0.7	0.3	1.4	16	0.4	0.2	0.7	8	0.6	0.3	1.2
	Diarrhoea (10012735)	64	5.2	4.0	6.5	58	4.7	3.6	6.0	49	3.9	2.9	5.2	171	4.6	4.0	5.3	64	5.0	3.8	6.3
	Dyspepsia (10013946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Dysphagia (10013950)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Enterocolitis (10014893)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Faeces soft (10074859)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Flatulence (10016766)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Gastrooesophageal reflux disease (10017885)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Gingival hypertrophy (10018284)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival pain (10018286)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Haematochezia (10018836)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lip swelling (10024570)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Oral mucosal eruption (10030997)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Post-tussive vomiting (10066220)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Ranula (10037838)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Regurgitation (10067171)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Salivary gland enlargement (10039408)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Salivary gland pain (10039421)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salivary hypersecretion (10039424)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Stomatitis (10042128)	0	0.0	0.0	0.3	4	0.3	0.1	0.8	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Teething (10043183)	91	7.3	6.0	8.9	92	7.5	6.1	9.1	77	6.2	4.9	7.7	260	7.0	6.2	7.9	95	7.4	6.0	8.9
	Toothache (10044055)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	6	0.5	0.2	1.0
	Vomiting (10047700)	38	3.1	2.2	4.2	35	2.8	2.0	3.9	34	2.7	1.9	3.8	107	2.9	2.4	3.5	43	3.3	2.4	4.5
General disorders and administration site conditions (10018065)	Crying (10011469)	4	0.3	0.1	0.8	5	0.4	0.1	0.9	2	0.2	0.0	0.6	11	0.3	0.1	0.5	4	0.3	0.1	0.8
	Cyst (10011732)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Discomfort (10013082)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Feeling hot (10016334)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Influenza like illness (10022004)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site bruising (10022052)	4	0.3	0.1	0.8	5	0.4	0.1	0.9	1	0.1	0.0	0.4	10	0.3	0.1	0.5	2	0.2	0.0	0.6
	Injection site erosion (10022059)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site erythema (10022061)	31	2.5	1.7	3.5	29	2.4	1.6	3.4	32	2.6	1.8	3.6	92	2.5	2.0	3.0	26	2.0	1.3	2.9
	Injection site haematoma (10022066)	5	0.4	0.1	0.9	1	0.1	0.0	0.5	3	0.2	0.0	0.7	9	0.2	0.1	0.5	0	0.0	0.0	0.3
	Injection site haemorrhage (10022067)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Injection site induration (10022075)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	2	0.2	0.0	0.6	8	0.2	0.1	0.4	3	0.2	0.0	0.7
	Injection site mass (10022081)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Injection site nodule (10057880)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site pain (10022086)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Injection site papule (10066044)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	5	0.4	0.1	0.9
	Injection site swelling (10053425)	12	1.0	0.5	1.7	8	0.6	0.3	1.3	11	0.9	0.4	1.6	31	0.8	0.6	1.2	9	0.7	0.3	1.3
	Injection site vesicles (10022111)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oedema peripheral (10030124)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain (10033371)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Pyrexia (10037660)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Secretion discharge (10053459)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Swelling (10042674)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vessel puncture site haematoma (10065902)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Food allergy (10016946)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.4	0.1	0.9	9	0.2	0.1	0.5	4	0.3	0.1	0.8
	Hypersensitivity (10020751)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Immunisation reaction (10021432)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Milk allergy (10027633)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seasonal allergy (10048908)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acute sinusitis (10001076)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Adenovirus infection (10060931)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body tinea (10005913)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchiolitis (10006448)	2	0.2	0.0	0.6	9	0.7	0.3	1.4	7	0.6	0.2	1.2	18	0.5	0.3	0.8	7	0.5	0.2	1.1
	Bronchitis (10006451)	10	0.8	0.4	1.5	13	1.1	0.6	1.8	10	0.8	0.4	1.5	33	0.9	0.6	1.2	12	0.9	0.5	1.6
	Bullous impetigo (10006563)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Candida nappy rash (10007135)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cellulitis (10007882)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Clostridium difficile infection (10054236)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	27	2.2	1.4	3.2	21	1.7	1.1	2.6	39	3.1	2.2	4.3	87	2.3	1.9	2.9	32	2.5	1.7	3.5
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Croup infectious (10011416)	4	0.3	0.1	0.8	11	0.9	0.4	1.6	8	0.6	0.3	1.3	23	0.6	0.4	0.9	6	0.5	0.2	1.0
	Ear infection (10014011)	9	0.7	0.3	1.4	14	1.1	0.6	1.9	4	0.3	0.1	0.8	27	0.7	0.5	1.1	13	1.0	0.5	1.7

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Enterovirus infection (10014909)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Epstein-barr virus infection (10015108)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exanthema subitum (10015586)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Eye infection (10015929)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Folliculitis (10016936)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Fungal infection (10017533)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis (10017888)	27	2.2	1.4	3.2	22	1.8	1.1	2.7	36	2.9	2.0	4.0	85	2.3	1.8	2.8	31	2.4	1.6	3.4
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastroenteritis viral (10017918)	3	0.2	0.0	0.7	6	0.5	0.2	1.1	6	0.5	0.2	1.0	15	0.4	0.2	0.7	6	0.5	0.2	1.0
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gingivitis (10018292)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand-foot-and-mouth disease (10019113)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	9	0.7	0.3	1.4	14	0.4	0.2	0.6	5	0.4	0.1	0.9
	Herpangina (10019936)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hordeolum (10020377)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Impetigo (10021531)	4	0.3	0.1	0.8	1	0.1	0.0	0.5	1	0.1	0.0	0.4	6	0.2	0.1	0.4	2	0.2	0.0	0.6
	Infected bite (10076911)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza (10022000)	2	0.2	0.0	0.6	5	0.4	0.1	0.9	1	0.1	0.0	0.4	8	0.2	0.1	0.4	10	0.8	0.4	1.4
	Injection site abscess (10022044)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Laryngitis (10023874)	1	0.1	0.0	0.4	8	0.6	0.3	1.3	2	0.2	0.0	0.6	11	0.3	0.1	0.5	6	0.5	0.2	1.0
	Lice infestation (10024424)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Localised infection (10024774)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lower respiratory tract infection (10024968)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	74	6.0	4.7	7.4	75	6.1	4.8	7.6	74	6.0	4.7	7.4	223	6.0	5.3	6.8	65	5.0	3.9	6.4
	Oral candidiasis (10030963)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oral herpes (10067152)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Oral infection (10048685)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis externa (10033072)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	80	6.5	5.2	8.0	75	6.1	4.8	7.6	63	5.1	3.9	6.4	218	5.9	5.1	6.7	87	6.7	5.4	8.3
	Otitis media acute (10033079)	8	0.6	0.3	1.3	7	0.6	0.2	1.2	13	1.0	0.6	1.8	28	0.8	0.5	1.1	9	0.7	0.3	1.3
	Otitis media chronic (10033081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Paronychia (10034016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Periorbital cellulitis (10057182)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pharyngitis (10034835)	20	1.6	1.0	2.5	31	2.5	1.7	3.6	14	1.1	0.6	1.9	65	1.8	1.4	2.2	23	1.8	1.1	2.7
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pharyngotonsillitis (10049140)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	6	0.5	0.2	1.0	8	0.2	0.1	0.4	1	0.1	0.0	0.4
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia viral (10035737)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract infection (10062352)	8	0.6	0.3	1.3	11	0.9	0.4	1.6	9	0.7	0.3	1.4	28	0.8	0.5	1.1	7	0.5	0.2	1.1
	Respiratory tract infection viral (10062106)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	4	0.3	0.1	0.8
	Rhinitis (10039083)	46	3.7	2.7	4.9	49	4.0	3.0	5.2	38	3.1	2.2	4.2	133	3.6	3.0	4.2	41	3.2	2.3	4.3
	Roseola (10039222)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sinusitis (10040753)	9	0.7	0.3	1.4	3	0.2	0.1	0.7	4	0.3	0.1	0.8	16	0.4	0.2	0.7	3	0.2	0.0	0.7
	Skin bacterial infection (10052891)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin candida (10054152)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Staphylococcal infection (10058080)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Streptococcal infection (10061372)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.2	0.0	0.7	5	0.1	0.0	0.3	3	0.2	0.0	0.7
	Subcutaneous abscess (10042343)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tonsillitis (10044008)	21	1.7	1.1	2.6	9	0.7	0.3	1.4	9	0.7	0.3	1.4	39	1.1	0.7	1.4	15	1.2	0.7	1.9
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract infection (10046306)	106	8.6	7.1	10.3	124	10.1	8.4	11.9	122	9.8	8.2	11.6	352	9.5	8.6	10.5	122	9.5	7.9	11.2
	Urinary tract infection (10046571)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Viral infection (10047461)	15	1.2	0.7	2.0	21	1.7	1.1	2.6	24	1.9	1.2	2.9	60	1.6	1.2	2.1	15	1.2	0.7	1.9
	Viral pharyngitis (10047473)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Viral rash (10047476)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral tonsillitis (10047480)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Animal bite (10002515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Arthropod bite (10003399)	7	0.6	0.2	1.2	7	0.6	0.2	1.2	5	0.4	0.1	0.9	19	0.5	0.3	0.8	4	0.3	0.1	0.8
	Arthropod sting (10003402)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Bite (10004966)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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	Concussion (10010254)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Contusion (10050584)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Craniocerebral injury (10070976)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Ear canal injury (10056319)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear injury (10057446)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye contusion (10073354)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Face injury (10050392)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Fall (10016173)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gingival injury (10049300)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Head injury (10019196)	5	0.4	0.1	0.9	6	0.5	0.2	1.1	6	0.5	0.2	1.0	17	0.5	0.3	0.7	2	0.2	0.0	0.6
	Heat stroke (10019345)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Laceration (10023572)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	2	0.2	0.0	0.6	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Limb injury (10061225)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Lip injury (10055082)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Nail avulsion (10028686)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Upper limb fracture (10061394)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wound (10052428)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cold agglutinins positive (10009854)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight decreased (10047895)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Dehydration (10012174)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Lactose intolerance (10023681)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Knee deformity (10062061)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Synovial cyst (10042858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Drooling (10013642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Epilepsy (10015037)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exaggerated startle response (10066482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Febrile convulsion (10016284)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gross motor delay (10069118)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Headache (10019211)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Lethargy (10024264)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nystagmus (10029864)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Post-traumatic headache (10036313)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Somnolence (10041349)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Speech disorder developmental (10041467)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tremor (10044565)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Depressed mood (10012374)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Insomnia (10022437)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Irritability (10022998)	11	0.9	0.4	1.6	12	1.0	0.5	1.7	9	0.7	0.3	1.4	32	0.9	0.6	1.2	17	1.3	0.8	2.1
	Middle insomnia (10027590)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Restlessness (10038743)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Sleep disorder (10040984)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sleep terror (10041010)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tearfulness (10043169)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Terminal insomnia (10068932)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary tract disorder (10046566)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Balanoposthitis (10004078)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Bilateral breast buds (10004557)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Genital labial adhesions (10064162)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	5	0.4	0.1	0.9
	Bronchial hyperreactivity (10066091)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Bronchospasm (10006482)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Catarrh (10007774)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cough (10011224)	33	2.7	1.8	3.7	42	3.4	2.5	4.6	38	3.1	2.2	4.2	113	3.0	2.5	3.6	36	2.8	2.0	3.8
	Dyspnoea (10013968)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Epistaxis (10015090)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	1	0.1	0.0	0.4	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	10	0.8	0.4	1.5	11	0.9	0.4	1.6	5	0.4	0.1	0.9	26	0.7	0.5	1.0	11	0.9	0.4	1.5
	Nasal discomfort (10052437)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oropharyngeal pain (10068319)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory disorder (10038683)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.3	0.1	0.8	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract congestion (10052251)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rhinitis allergic (10039085)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	3	0.2	0.0	0.7	8	0.2	0.1	0.4	1	0.1	0.0	0.4
	Rhinorrhoea (10039101)	22	1.8	1.1	2.7	23	1.9	1.2	2.8	20	1.6	1.0	2.5	65	1.8	1.4	2.2	21	1.6	1.0	2.5
	Sinus congestion (10040742)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sneezing (10041232)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract congestion (10052252)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	6	0.5	0.2	1.0	14	0.4	0.2	0.6	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Blister (10005191)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis (10012431)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Dermatitis allergic (10012434)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis atopic (10012438)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	4	0.3	0.1	0.8	9	0.2	0.1	0.5	3	0.2	0.0	0.7
	Dermatitis contact (10012442)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	3	0.2	0.0	0.7	4	0.3	0.1	0.8	3	0.2	0.0	0.7	10	0.3	0.1	0.5	5	0.4	0.1	0.9
	Drug eruption (10013687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dry skin (10013786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eczema (10014184)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.1	0.0	0.3	5	0.4	0.1	0.9
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Erythema (10015150)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Hyperhidrosis (10020642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hyperkeratosis (10020649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ingrowing nail (10022013)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Keratosis pilaris (10066295)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Macule (10025421)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Miliaria (10027627)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Papule (10033733)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prurigo (10037083)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pruritus (10037087)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seborrhoea (10039792)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin irritation (10040880)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Skin mass (10067868)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin warm (10040952)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Solar dermatitis (10041303)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Swelling face (10042682)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Urticaria (10046735)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pallor (10033546)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.82 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		59	47.6	38.5	56.7	65	52.0	42.9	61.0	60	48.0	39.0	57.1	184	49.2	44.0	54.4	56	44.1	35.3	53.2
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Lymphadenopathy (10025197)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Eyelid oedema (10015993)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	7	5.6	2.3	11.3	4	3.2	0.9	8.0	4	3.2	0.9	8.0	15	4.0	2.3	6.5	7	5.5	2.2	11.0
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Flatulence (10016766)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival swelling (10018291)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Salivary hypersecretion (10039424)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Teething (10043183)	9	7.3	3.4	13.3	12	9.6	5.1	16.2	7	5.6	2.3	11.2	28	7.5	5.0	10.6	7	5.5	2.2	11.0
	Toothache (10044055)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Vomiting (10047700)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	3	2.4	0.5	6.9	8	2.1	0.9	4.2	3	2.4	0.5	6.7
General disorders and administration site conditions (10018065)	Injection site erosion (10022059)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site erythema (10022061)	9	7.3	3.4	13.3	5	4.0	1.3	9.1	7	5.6	2.3	11.2	21	5.6	3.5	8.5	9	7.1	3.3	13.0
	Injection site haematoma (10022066)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site pain (10022086)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Injection site papule (10066044)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site swelling (10053425)	4	3.2	0.9	8.1	1	0.8	0.0	4.4	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pyrexia (10037660)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Food allergy (10016946)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Infections and infestations (10021881)	Adenovirus infection (10060931)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Bronchitis (10006451)	1	0.8	0.0	4.4	4	3.2	0.9	8.0	1	0.8	0.0	4.4	6	1.6	0.6	3.5	2	1.6	0.2	5.6
	Conjunctivitis (10010741)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear infection (10014011)	3	2.4	0.5	6.9	5	4.0	1.3	9.1	1	0.8	0.0	4.4	9	2.4	1.1	4.5	6	4.7	1.8	10.0
	Enterovirus infection (10014909)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	0	0.0	0.0	2.9	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	1	0.8	0.0	4.4	4	1.1	0.3	2.7	3	2.4	0.5	6.7
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	1.6	0.2	5.7	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Influenza (10022000)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Nasopharyngitis (10028810)	4	3.2	0.9	8.1	7	5.6	2.3	11.2	3	2.4	0.5	6.9	14	3.7	2.1	6.2	2	1.6	0.2	5.6
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pneumonia (10035664)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Respiratory tract infection (10062352)	1	0.8	0.0	4.4	2	1.6	0.2	5.7	0	0.0	0.0	2.9	3	0.8	0.2	2.3	0	0.0	0.0	2.9
	Respiratory tract infection viral (10062106)	3	2.4	0.5	6.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	4	1.1	0.3	2.7	3	2.4	0.5	6.7
	Rhinitis (10039083)	13	10.5	5.7	17.3	17	13.6	8.1	20.9	15	12.0	6.9	19.0	45	12.0	8.9	15.8	12	9.4	5.0	15.9
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	7	1.9	0.8	3.8	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Viral infection (10047461)	3	2.4	0.5	6.9	9	7.2	3.3	13.2	8	6.4	2.8	12.2	20	5.3	3.3	8.1	5	3.9	1.3	8.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Nervous system disorders (10029205)	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Psychiatric disorders (10037175)	Sleep disorder (10040984)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Cough (10011224)	11	8.9	4.5	15.3	13	10.4	5.7	17.1	8	6.4	2.8	12.2	32	8.6	5.9	11.9	8	6.3	2.8	12.0
	Epistaxis (10015090)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rhinorrhoea (10039101)	2	1.6	0.2	5.7	2	1.6	0.2	5.7	2	1.6	0.2	5.7	6	1.6	0.6	3.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Eczema (10014184)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Erythema (10015150)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Hyperhidrosis (10020642)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.83 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		39	63.9	50.6	75.8	40	64.5	51.3	76.3	41	64.1	51.1	75.7	120	64.2	56.8	71.0	44	63.8	51.3	75.0
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	8	13.1	5.8	24.2	1	1.6	0.0	8.7	2	3.1	0.4	10.8	11	5.9	3.0	10.3	7	10.1	4.2	19.8
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Faeces soft (10074859)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Teething (10043183)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	3	4.3	0.9	12.2
	Toothache (10044055)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Vomiting (10047700)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	3	4.7	1.0	13.1	7	3.7	1.5	7.6	3	4.3	0.9	12.2
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oedema peripheral (10030124)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchitis (10006451)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	2	2.9	0.4	10.1
	Candida infection (10074170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Conjunctivitis (10010741)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	5	7.8	2.6	17.3	8	4.3	1.9	8.3	5	7.2	2.4	16.1
	Ear infection (10014011)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	3	4.7	1.0	13.1	7	3.7	1.5	7.6	3	4.3	0.9	12.2
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Impetigo (10021531)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Laryngitis (10023874)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Nasopharyngitis (10028810)	11	18.0	9.4	30.0	7	11.3	4.7	21.9	11	17.2	8.9	28.7	29	15.5	10.6	21.5	10	14.5	7.2	25.0
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Otitis media (10033078)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Otitis media acute (10033079)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	5	7.8	2.6	17.3	8	4.3	1.9	8.3	2	2.9	0.4	10.1
	Pharyngitis (10034835)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	1	1.4	0.0	7.8
	Pharyngotonsillitis (10049140)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Pneumonia (10035664)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Respiratory tract infection (10062352)	4	6.6	1.8	15.9	5	8.1	2.7	17.8	3	4.7	1.0	13.1	12	6.4	3.4	10.9	5	7.2	2.4	16.1
	Rhinitis (10039083)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Tonsillitis (10044008)	7	11.5	4.7	22.2	4	6.5	1.8	15.7	3	4.7	1.0	13.1	14	7.5	4.2	12.2	8	11.6	5.1	21.6
	Upper respiratory tract infection (10046306)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	2	3.1	0.4	10.8	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Viral infection (10047461)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	2	2.9	0.4	10.1
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	3	4.7	1.0	13.1	5	2.7	0.9	6.1	0	0.0	0.0	5.2
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	2	2.9	0.4	10.1
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Balanoposthitis (10004078)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchospasm (10006482)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	3	4.7	1.0	13.1	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Catarrh (10007774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Cough (10011224)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	2	2.9	0.4	10.1
	Epistaxis (10015090)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Nasal congestion (10028735)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Dermatitis atopic (10012438)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	3	4.7	1.0	13.1	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.84 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		201	59.5	54.0	64.7	197	58.8	53.3	64.1	206	61.1	55.7	66.4	604	59.8	56.7	62.8	184	54.1	48.7	59.5
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	2	0.6	0.1	2.1	8	0.8	0.3	1.6	1	0.3	0.0	1.6
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Ear swelling (10014025)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye irritation (10015946)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye swelling (10015967)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Aphthous ulcer (10002959)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Chapped lips (10049047)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	3	0.9	0.2	2.6
	Diarrhoea (10012735)	7	2.1	0.8	4.2	22	6.6	4.2	9.8	22	6.5	4.1	9.7	51	5.0	3.8	6.6	8	2.4	1.0	4.6
	Flatulence (10016766)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Haematochezia (10018836)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Regurgitation (10067171)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Salivary gland enlargement (10039408)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Salivary gland pain (10039421)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Salivary hypersecretion (10039424)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Teething (10043183)	56	16.6	12.8	21.0	38	11.3	8.2	15.2	46	13.6	10.2	17.8	140	13.9	11.8	16.1	47	13.8	10.3	18.0
	Toothache (10044055)	3	0.9	0.2	2.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	3	0.9	0.2	2.6
	Vomiting (10047700)	4	1.2	0.3	3.0	12	3.6	1.9	6.2	4	1.2	0.3	3.0	20	2.0	1.2	3.0	8	2.4	1.0	4.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
General disorders and administration site conditions (10018065)	Crying (10011469)	4	1.2	0.3	3.0	5	1.5	0.5	3.4	2	0.6	0.1	2.1	11	1.1	0.5	1.9	4	1.2	0.3	3.0
	Injection site bruising (10022052)	2	0.6	0.1	2.1	3	0.9	0.2	2.6	1	0.3	0.0	1.6	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Injection site erythema (10022061)	16	4.7	2.7	7.6	17	5.1	3.0	8.0	21	6.2	3.9	9.4	54	5.3	4.0	6.9	13	3.8	2.1	6.4
	Injection site haematoma (10022066)	4	1.2	0.3	3.0	1	0.3	0.0	1.7	3	0.9	0.2	2.6	8	0.8	0.3	1.6	0	0.0	0.0	1.1
	Injection site haemorrhage (10022067)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1
	Injection site induration (10022075)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Injection site nodule (10057880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Injection site pain (10022086)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	3	0.9	0.2	2.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
	Injection site papule (10066044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Injection site swelling (10053425)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	6	1.8	0.7	3.8	13	1.3	0.7	2.2	4	1.2	0.3	3.0
	Injection site vesicles (10022111)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pain (10033371)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Secretion discharge (10053459)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Swelling (10042674)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Infections and infestations (10021881)	Adenovirus infection (10060931)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchiolitis (10006448)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	2	0.6	0.1	2.1	7	0.7	0.3	1.4	6	1.8	0.7	3.8
	Conjunctivitis (10010741)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	12	3.6	1.9	6.1	19	1.9	1.1	2.9	5	1.5	0.5	3.4
	Ear infection (10014011)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	2	0.6	0.1	2.1
	Enterovirus infection (10014909)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Exanthema subitum (10015586)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gastroenteritis (10017888)	8	2.4	1.0	4.6	8	2.4	1.0	4.7	10	3.0	1.4	5.4	26	2.6	1.7	3.7	10	2.9	1.4	5.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	3	0.9	0.2	2.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Impetigo (10021531)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Influenza (10022000)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	4	1.2	0.3	3.0
	Injection site abscess (10022044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laryngitis (10023874)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	0	0.0	0.0	1.1	4	0.4	0.1	1.0	2	0.6	0.1	2.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Molluscum contagiosum (10027807)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nasopharyngitis (10028810)	9	2.7	1.2	5.0	5	1.5	0.5	3.4	7	2.1	0.8	4.2	21	2.1	1.3	3.2	8	2.4	1.0	4.6
	Oral candidiasis (10030963)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Oral herpes (10067152)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	35	10.4	7.3	14.1	45	13.4	10.0	17.6	32	9.5	6.6	13.1	112	11.1	9.2	13.2	37	10.9	7.8	14.7
	Pharyngitis (10034835)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	3	0.9	0.2	2.6	4	1.2	0.3	3.0	6	1.8	0.7	3.8	13	1.3	0.7	2.2	2	0.6	0.1	2.1
	Rhinitis (10039083)	28	8.3	5.6	11.8	24	7.2	4.6	10.5	20	5.9	3.7	9.0	72	7.1	5.6	8.9	21	6.2	3.9	9.3
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tonsillitis (10044008)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Upper respiratory tract infection (10046306)	65	19.2	15.2	23.8	72	21.5	17.2	26.3	74	22.0	17.7	26.8	211	20.9	18.4	23.5	58	17.1	13.2	21.5
	Urinary tract infection (10046571)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	1	0.3	0.0	1.6	7	0.7	0.3	1.4	1	0.3	0.0	1.6
	Arthropod sting (10003402)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Wound (10052428)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Nervous system disorders (10029205)	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Poor quality sleep (10062519)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Post-traumatic headache (10036313)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Somnolence (10041349)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Irritability (10022998)	5	1.5	0.5	3.4	7	2.1	0.8	4.3	7	2.1	0.8	4.2	19	1.9	1.1	2.9	10	2.9	1.4	5.3
	Restlessness (10038743)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Sleep disorder (10040984)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tearfulness (10043169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Terminal insomnia (10068932)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Cough (10011224)	4	1.2	0.3	3.0	10	3.0	1.4	5.4	6	1.8	0.7	3.8	20	2.0	1.2	3.0	8	2.4	1.0	4.6
	Dyspnoea (10013968)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Epistaxis (10015090)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nasal congestion (10028735)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Oropharyngeal pain (10068319)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rhinitis allergic (10039085)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Skin irritation (10040880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Swelling face (10042682)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.85 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		67	68.4	58.2	77.4	63	64.3	54.0	73.7	58	58.6	48.2	68.4	188	63.7	58.0	69.2	62	62.6	52.3	72.1
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Constipation (10010774)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Diarrhoea (10012735)	9	9.2	4.3	16.7	5	5.1	1.7	11.5	3	3.0	0.6	8.6	17	5.8	3.4	9.1	4	4.0	1.1	10.0
	Dyspepsia (10013946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	2	2.0	0.2	7.1
	Faeces soft (10074859)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Teething (10043183)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	3.7	4	4.1	1.1	10.1	3	3.0	0.6	8.6	7	2.4	1.0	4.8	2	2.0	0.2	7.1
	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Conjunctivitis (10010741)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	2	2.0	0.2	7.1	5	1.7	0.6	3.9	4	4.0	1.1	10.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	8	8.2	3.6	15.5	5	5.1	1.7	11.5	13	13.1	7.2	21.4	26	8.8	5.8	12.6	10	10.1	5.0	17.8
	Gastroenteritis viral (10017918)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Gingivitis (10018292)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Nasopharyngitis (10028810)	37	37.8	28.2	48.1	34	34.7	25.4	45.0	34	34.3	25.1	44.6	105	35.6	30.1	41.3	29	29.3	20.6	39.3
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media (10033078)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media acute (10033079)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	2	2.0	0.2	7.1	4	1.4	0.4	3.4	1	1.0	0.0	5.5
	Pharyngitis (10034835)	6	6.1	2.3	12.9	12	12.2	6.5	20.4	4	4.0	1.1	10.0	22	7.5	4.7	11.1	13	13.1	7.2	21.4

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngotonsillitis (10049140)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Pneumonia viral (10035737)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis (10039083)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	1	1.0	0.0	5.5	3	1.0	0.2	2.9	5	5.1	1.7	11.4
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	11	11.2	5.7	19.2	4	4.1	1.1	10.1	4	4.0	1.1	10.0	19	6.4	3.9	9.9	6	6.1	2.3	12.7
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	2	2.0	0.2	7.1	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	4	4.0	1.1	10.0	7	2.4	1.0	4.8	1	1.0	0.0	5.5
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Headache (10019211)	3	3.1	0.6	8.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Bronchospasm (10006482)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cough (10011224)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinorrhoea (10039101)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	2	2.0	0.2	7.1	4	1.4	0.4	3.4	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Miliaria (10027627)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Prurigo (10037083)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Solar dermatitis (10041303)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.86 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		249	40.3	36.4	44.3	268	43.8	39.8	47.8	244	39.5	35.6	43.5	761	41.2	38.9	43.5	272	41.6	37.8	45.5
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Leukocytosis (10024378)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Leukopenia (10024384)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphadenitis (10025188)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lymphadenopathy (10025197)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Deafness (10011878)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ear pain (10014020)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.5	0.1	1.4	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lid sulcus deepened (10072716)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abdominal pain upper (10000087)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Aphthous ulcer (10002959)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Constipation (10010774)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	7	1.1	0.5	2.3	14	0.8	0.4	1.3	4	0.6	0.2	1.6
	Diarrhoea (10012735)	33	5.3	3.7	7.4	26	4.2	2.8	6.2	18	2.9	1.7	4.6	77	4.2	3.3	5.2	38	5.8	4.1	7.9
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival pain (10018286)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival swelling (10018291)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Lip swelling (10024570)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Oral mucosal eruption (10030997)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Post-tussive vomiting (10066220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Teething (10043183)	22	3.6	2.2	5.3	39	6.4	4.6	8.6	21	3.4	2.1	5.1	82	4.4	3.5	5.5	38	5.8	4.1	7.9
	Toothache (10044055)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Vomiting (10047700)	26	4.2	2.8	6.1	20	3.3	2.0	5.0	24	3.9	2.5	5.7	70	3.8	3.0	4.8	29	4.4	3.0	6.3
General disorders and administration site conditions (10018065)	Cyst (10011732)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Discomfort (10013082)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Feeling hot (10016334)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Influenza like illness (10022004)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site bruising (10022052)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site erosion (10022059)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Injection site erythema (10022061)	6	1.0	0.4	2.1	6	1.0	0.4	2.1	4	0.6	0.2	1.6	16	0.9	0.5	1.4	4	0.6	0.2	1.6
	Injection site induration (10022075)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site mass (10022081)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site pain (10022086)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site papule (10066044)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Injection site swelling (10053425)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	4	0.6	0.2	1.6	12	0.6	0.3	1.1	4	0.6	0.2	1.6
	Injection site vesicles (10022111)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pain (10033371)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pyrexia (10037660)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Vessel puncture site haematoma (10065902)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Food allergy (10016946)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.6	0.2	1.6	7	0.4	0.2	0.8	2	0.3	0.0	1.1
	Hypersensitivity (10020751)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seasonal allergy (10048908)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acute sinusitis (10001076)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Adenovirus infection (10060931)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	2	0.3	0.0	1.2	4	0.7	0.2	1.7	3	0.5	0.1	1.4	9	0.5	0.2	0.9	5	0.8	0.2	1.8
	Bronchitis (10006451)	5	0.8	0.3	1.9	1	0.2	0.0	0.9	4	0.6	0.2	1.6	10	0.5	0.3	1.0	2	0.3	0.0	1.1
	Candida infection (10074170)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Cellulitis (10007882)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	20	3.2	2.0	5.0	15	2.5	1.4	4.0	19	3.1	1.9	4.8	54	2.9	2.2	3.8	18	2.8	1.6	4.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Croup infectious (10011416)	4	0.6	0.2	1.6	11	1.8	0.9	3.2	8	1.3	0.6	2.5	23	1.2	0.8	1.9	6	0.9	0.3	2.0
	Ear infection (10014011)	4	0.6	0.2	1.6	6	1.0	0.4	2.1	2	0.3	0.0	1.2	12	0.6	0.3	1.1	3	0.5	0.1	1.3
	Eye infection (10015929)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Folliculitis (10016936)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Fungal infection (10017533)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Gastroenteritis (10017888)	7	1.1	0.5	2.3	8	1.3	0.6	2.6	9	1.5	0.7	2.7	24	1.3	0.8	1.9	7	1.1	0.4	2.2

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	4	0.6	0.2	1.6	10	0.5	0.3	1.0	5	0.8	0.2	1.8
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand-foot-and-mouth disease (10019113)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.8	0.3	1.9	10	0.5	0.3	1.0	5	0.8	0.2	1.8
	Herpangina (10019936)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hordeolum (10020377)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Impetigo (10021531)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Influenza (10022000)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.3	0.1	0.6	5	0.8	0.2	1.8
	Lice infestation (10024424)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Nasopharyngitis (10028810)	13	2.1	1.1	3.6	22	3.6	2.3	5.4	19	3.1	1.9	4.8	54	2.9	2.2	3.8	16	2.4	1.4	3.9
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral herpes (10067152)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Otitis externa (10033072)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	43	7.0	5.1	9.3	29	4.7	3.2	6.7	31	5.0	3.4	7.0	103	5.6	4.6	6.7	48	7.3	5.5	9.6
	Otitis media acute (10033079)	6	1.0	0.4	2.1	4	0.7	0.2	1.7	6	1.0	0.4	2.1	16	0.9	0.5	1.4	6	0.9	0.3	2.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pharyngitis (10034835)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	7	1.1	0.5	2.3	26	1.4	0.9	2.1	7	1.1	0.4	2.2
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pneumonia (10035664)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.5	0.1	1.4	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis (10039083)	3	0.5	0.1	1.4	7	1.1	0.5	2.3	1	0.2	0.0	0.9	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Roseola (10039222)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Sinusitis (10040753)	8	1.3	0.6	2.5	3	0.5	0.1	1.4	4	0.6	0.2	1.6	15	0.8	0.5	1.3	3	0.5	0.1	1.3
	Skin candida (10054152)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Subcutaneous abscess (10042343)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tonsillitis (10044008)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	36	5.8	4.1	8.0	48	7.8	5.8	10.3	43	7.0	5.1	9.3	127	6.9	5.8	8.1	60	9.2	7.1	11.7
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	10	1.6	0.8	3.0	8	1.3	0.6	2.6	14	2.3	1.2	3.8	32	1.7	1.2	2.4	8	1.2	0.5	2.4
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral rash (10047476)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral upper respiratory tract infection (10047482)	4	0.6	0.2	1.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	6	0.3	0.1	0.7	2	0.3	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Animal bite (10002515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Contusion (10050584)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	0	0.0	0.0	0.6	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Craniocerebral injury (10070976)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gingival injury (10049300)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	3	0.5	0.1	1.4	4	0.7	0.2	1.7	2	0.3	0.0	1.2	9	0.5	0.2	0.9	1	0.2	0.0	0.8
	Laceration (10023572)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	7	0.4	0.2	0.8	1	0.2	0.0	0.8
	Limb injury (10061225)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Lip injury (10055082)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Nail avulsion (10028686)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Skin abrasion (10064990)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Thermal burn (10053615)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Upper limb fracture (10061394)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cold agglutinins positive (10009854)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Dehydration (10012174)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Lactose intolerance (10023681)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Nervous system disorders (10029205)	Drooling (10013642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gross motor delay (10069118)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Headache (10019211)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lethargy (10024264)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Poor quality sleep (10062519)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Speech disorder developmental (10041467)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tremor (10044565)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Depressed mood (10012374)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Insomnia (10022437)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Irritability (10022998)	6	1.0	0.4	2.1	5	0.8	0.3	1.9	2	0.3	0.0	1.2	13	0.7	0.4	1.2	7	1.1	0.4	2.2
	Middle insomnia (10027590)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Sleep disorder (10040984)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep terror (10041010)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Bronchial hyperreactivity (10066091)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Cough (10011224)	16	2.6	1.5	4.2	19	3.1	1.9	4.8	23	3.7	2.4	5.5	58	3.1	2.4	4.0	18	2.8	1.6	4.3
	Dyspnoea (10013968)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Epistaxis (10015090)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Nasal congestion (10028735)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	4	0.6	0.2	1.6	22	1.2	0.7	1.8	11	1.7	0.8	3.0
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory disorder (10038683)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.6	0.2	1.6	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Rhinorrhoea (10039101)	20	3.2	2.0	5.0	19	3.1	1.9	4.8	16	2.6	1.5	4.2	55	3.0	2.2	3.9	20	3.1	1.9	4.7
	Sinus congestion (10040742)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Sneezing (10041232)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	6	1.0	0.4	2.1	14	0.8	0.4	1.3	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Blister (10005191)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dermatitis (10012431)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dermatitis atopic (10012438)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Dermatitis contact (10012442)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	2	0.3	0.0	1.2	8	0.4	0.2	0.9	4	0.6	0.2	1.6
	Dry skin (10013786)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Eczema (10014184)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Erythema (10015150)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Keratosis pilaris (10066295)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Macule (10025421)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Papule (10033733)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Seborrhoea (10039792)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Skin mass (10067868)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin warm (10040952)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Swelling face (10042682)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Urticaria (10046735)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pallor (10033546)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.87 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		70	5.6	4.4	7.1	77	6.3	5.0	7.7	78	6.3	5.0	7.8	225	6.1	5.3	6.9	85	6.6	5.3	8.1
Ear and labyrinth disorders (10013993)	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otorrhoea (10033101)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Constipation (10010774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Diarrhoea (10012735)	5	0.4	0.1	0.9	8	0.6	0.3	1.3	4	0.3	0.1	0.8	17	0.5	0.3	0.7	9	0.7	0.3	1.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Stomatitis (10042128)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Teething (10043183)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	6	0.5	0.2	1.0
	Vomiting (10047700)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	2	0.2	0.0	0.6	8	0.2	0.1	0.4	10	0.8	0.4	1.4
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Influenza like illness (10022004)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site erosion (10022059)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site erythema (10022061)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site pain (10022086)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site swelling (10053425)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Food allergy (10016946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Adenovirus infection (10060931)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchiolitis (10006448)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchitis (10006451)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Candida infection (10074170)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Conjunctivitis (10010741)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	3	0.2	0.0	0.7	10	0.3	0.1	0.5	4	0.3	0.1	0.8
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Croup infectious (10011416)	1	0.1	0.0	0.4	5	0.4	0.1	0.9	2	0.2	0.0	0.6	8	0.2	0.1	0.4	0	0.0	0.0	0.3
	Ear infection (10014011)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Exanthema subitum (10015586)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye infection (10015929)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Gastroenteritis (10017888)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis viral (10017918)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Herpangina (10019936)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Impetigo (10021531)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza (10022000)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.8
	Laryngitis (10023874)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	2	0.2	0.0	0.6	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Nasopharyngitis (10028810)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Otitis externa (10033072)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otitis media (10033078)	22	1.8	1.1	2.7	22	1.8	1.1	2.7	20	1.6	1.0	2.5	64	1.7	1.3	2.2	27	2.1	1.4	3.0
	Otitis media acute (10033079)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Pharyngitis (10034835)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	2	0.2	0.0	0.6	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Respiratory tract infection (10062352)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rhinitis (10039083)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Roseola (10039222)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillitis (10044008)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract infection (10046306)	15	1.2	0.7	2.0	14	1.1	0.6	1.9	18	1.4	0.9	2.3	47	1.3	0.9	1.7	6	0.5	0.2	1.0
	Urinary tract infection (10046571)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Viral infection (10047461)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	6	0.5	0.2	1.0	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
Injury, poisoning and procedural complications (10022117)	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Craniocerebral injury (10070976)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Head injury (10019196)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Laceration (10023572)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Limb injury (10061225)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Thermal burn (10053615)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper limb fracture (10061394)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dehydration (10012174)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Lethargy (10024264)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cough (10011224)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	4	0.3	0.1	0.8	7	0.2	0.1	0.4	5	0.4	0.1	0.9

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dyspnoea (10013968)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory disorder (10038683)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinorrhoea (10039101)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	3	0.2	0.0	0.7	6	0.2	0.1	0.4	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis contact (10012442)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Urticaria (10046735)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.88 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		3	2.4	0.5	6.9	2	1.6	0.2	5.7	4	3.2	0.9	8.0	9	2.4	1.1	4.5	4	3.1	0.9	7.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
General disorders and administration site conditions (10018065)	Injection site erosion (10022059)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site swelling (10053425)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Infections and infestations (10021881)	Eye infection (10015929)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pharyngitis (10034835)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Rhinitis (10039083)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral infection (10047461)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	2	1.6	0.2	5.7	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications (10022117)	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	0	0.0	0.0	2.9	2	0.5	0.1	1.9	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.89 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	3	4.3	0.9	12.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Laryngitis (10023874)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Nasopharyngitis (10028810)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Otitis media (10033078)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.90 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		32	9.5	6.6	13.1	35	10.4	7.4	14.2	32	9.5	6.6	13.1	99	9.8	8.0	11.8	36	10.6	7.5	14.4
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	2	0.6	0.1	2.1	6	0.6	0.2	1.3	2	0.6	0.1	2.1
	Teething (10043183)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	4	1.2	0.3	3.0
	Vomiting (10047700)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Injection site erythema (10022061)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Injection site swelling (10053425)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Infections and infestations (10021881)	Adenovirus infection (10060931)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1
	Conjunctivitis (10010741)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Ear infection (10014011)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Exanthema subitum (10015586)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Gastroenteritis (10017888)	3	0.9	0.2	2.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Impetigo (10021531)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Laryngitis (10023874)	0	0.0	0.0	1.1	3	0.9	0.2	2.6	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Nasopharyngitis (10028810)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Otitis media (10033078)	12	3.6	1.8	6.1	18	5.4	3.2	8.4	13	3.9	2.1	6.5	43	4.3	3.1	5.7	18	5.3	3.2	8.2
	Pharyngitis (10034835)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Pneumonia (10035664)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Rhinitis (10039083)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tonsillitis (10044008)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Upper respiratory tract infection (10046306)	12	3.6	1.8	6.1	6	1.8	0.7	3.9	14	4.2	2.3	6.9	32	3.2	2.2	4.4	4	1.2	0.3	3.0
	Urinary tract infection (10046571)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Cough (10011224)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Dyspnoea (10013968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.91 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		2	2.0	0.2	7.2	4	4.1	1.1	10.1	3	3.0	0.6	8.6	9	3.1	1.4	5.7	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Conjunctivitis (10010741)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastroenteritis (10017888)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastroenteritis viral (10017918)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Nasopharyngitis (10028810)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngitis (10034835)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.92 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		32	5.2	3.6	7.2	36	5.9	4.2	8.1	38	6.1	4.4	8.3	106	5.7	4.7	6.9	42	6.4	4.7	8.6
Ear and labyrinth disorders (10013993)	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Otorrhoea (10033101)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Diarrhoea (10012735)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	2	0.3	0.0	1.2	10	0.5	0.3	1.0	7	1.1	0.4	2.2
	Gingival swelling (10018291)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Teething (10043183)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Vomiting (10047700)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	2	0.3	0.0	1.2	7	0.4	0.2	0.8	9	1.4	0.6	2.6
General disorders and administration site conditions (10018065)	Influenza like illness (10022004)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site pain (10022086)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site swelling (10053425)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Food allergy (10016946)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Adenovirus infection (10060931)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchitis (10006451)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Candida infection (10074170)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Conjunctivitis (10010741)	4	0.6	0.2	1.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Croup infectious (10011416)	1	0.2	0.0	0.9	5	0.8	0.3	1.9	2	0.3	0.0	1.2	8	0.4	0.2	0.9	0	0.0	0.0	0.6
	Ear infection (10014011)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Eye infection (10015929)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Gastroenteritis (10017888)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Herpangina (10019936)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Influenza (10022000)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	3	0.5	0.1	1.3
	Nasopharyngitis (10028810)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Otitis externa (10033072)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	7	1.1	0.5	2.3	20	1.1	0.7	1.7	9	1.4	0.6	2.6
	Otitis media acute (10033079)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Pharyngitis (10034835)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis (10039083)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Roseola (10039222)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillitis (10044008)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	3	0.5	0.1	1.4	8	1.3	0.6	2.6	4	0.6	0.2	1.6	15	0.8	0.5	1.3	2	0.3	0.0	1.1
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral infection (10047461)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.5	0.1	1.4	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Injury, poisoning and procedural complications (10022117)	Craniocerebral injury (10070976)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Hand fracture (10019114)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Head injury (10019196)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Laceration (10023572)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Limb injury (10061225)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Thermal burn (10053615)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper limb fracture (10061394)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dehydration (10012174)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
Nervous system disorders (10029205)	Lethargy (10024264)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory disorder (10038683)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinorrhoea (10039101)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis contact (10012442)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Urticaria (10046735)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.93 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		48	3.9	2.9	5.1	49	4.0	3.0	5.2	47	3.8	2.8	5.0	144	3.9	3.3	4.5	63	4.9	3.8	6.2
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Eye disorders (10015919)	Lacrimation increased (10023644)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Diarrhoea (10012735)	6	0.5	0.2	1.1	7	0.6	0.2	1.2	15	1.2	0.7	2.0	28	0.8	0.5	1.1	15	1.2	0.7	1.9
	Flatulence (10016766)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Salivary gland enlargement (10039408)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Salivary gland pain (10039421)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vomiting (10047700)	8	0.6	0.3	1.3	10	0.8	0.4	1.5	7	0.6	0.2	1.2	25	0.7	0.4	1.0	11	0.9	0.4	1.5
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Feeling hot (10016334)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site bruising (10022052)	4	0.3	0.1	0.8	4	0.3	0.1	0.8	0	0.0	0.0	0.3	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Injection site erythema (10022061)	4	0.3	0.1	0.8	2	0.2	0.0	0.6	2	0.2	0.0	0.6	8	0.2	0.1	0.4	6	0.5	0.2	1.0
	Injection site haematoma (10022066)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Injection site haemorrhage (10022067)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Injection site induration (10022075)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site pain (10022086)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site papule (10066044)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site swelling (10053425)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oedema peripheral (10030124)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain (10033371)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pyrexia (10037660)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Immune system disorders (10021428)	Hypersensitivity (10020751)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchitis (10006451)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastroenteritis (10017888)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Laryngitis (10023874)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Oral herpes (10067152)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pharyngitis (10034835)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Pneumonia (10035664)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinitis (10039083)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	2	0.2	0.0	0.6	6	0.2	0.1	0.4	3	0.2	0.0	0.7
	Upper respiratory tract infection (10046306)	4	0.3	0.1	0.8	7	0.6	0.2	1.2	6	0.5	0.2	1.0	17	0.5	0.3	0.7	9	0.7	0.3	1.3
	Viral infection (10047461)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Viral rash (10047476)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Irritability (10022998)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Restlessness (10038743)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Sleep disorder (10040984)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sleep terror (10041010)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Nasal congestion (10028735)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rhinorrhoea (10039101)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Wheezing (10047924)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Erythema (10015150)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hyperhidrosis (10020642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin warm (10040952)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Swelling face (10042682)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.94 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		3	2.4	0.5	6.9	2	1.6	0.2	5.7	1	0.8	0.0	4.4	6	1.6	0.6	3.5	5	3.9	1.3	8.9
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Vomiting (10047700)	2	1.6	0.2	5.7	0	0.0	0.0	2.9	0	0.0	0.0	2.9	2	0.5	0.1	1.9	1	0.8	0.0	4.3
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	3	2.4	0.5	6.7
	Injection site swelling (10053425)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Infections and infestations (10021881)	Pharyngitis (10034835)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Hyperhidrosis (10020642)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.95 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oedema peripheral (10030124)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.96 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		18	5.3	3.2	8.3	23	6.9	4.4	10.1	24	7.1	4.6	10.4	65	6.4	5.0	8.1	31	9.1	6.3	12.7
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Diarrhoea (10012735)	2	0.6	0.1	2.1	5	1.5	0.5	3.4	9	2.7	1.2	5.0	16	1.6	0.9	2.6	4	1.2	0.3	3.0
	Flatulence (10016766)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Salivary gland enlargement (10039408)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Salivary gland pain (10039421)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Vomiting (10047700)	1	0.3	0.0	1.6	6	1.8	0.7	3.9	2	0.6	0.1	2.1	9	0.9	0.4	1.7	3	0.9	0.2	2.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Injection site bruising (10022052)	2	0.6	0.1	2.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Injection site erythema (10022061)	3	0.9	0.2	2.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Injection site haematoma (10022066)	3	0.9	0.2	2.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Injection site haemorrhage (10022067)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Injection site induration (10022075)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Injection site swelling (10053425)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	2	0.6	0.1	2.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Pain (10033371)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Gastroenteritis (10017888)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Oral herpes (10067152)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Rhinitis (10039083)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Upper respiratory tract infection (10046306)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	1	0.3	0.0	1.6	8	0.8	0.3	1.6	6	1.8	0.7	3.8
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Restlessness (10038743)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Sleep disorder (10040984)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Swelling face (10042682)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.97 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		4	4.1	1.1	10.1	3	3.1	0.6	8.7	0	0.0	0.0	3.7	7	2.4	1.0	4.8	1	1.0	0.0	5.5
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Laryngitis (10023874)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Nasopharyngitis (10028810)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	4	1.4	0.4	3.4	1	1.0	0.0	5.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.98 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		23	3.7	2.4	5.5	19	3.1	1.9	4.8	22	3.6	2.2	5.3	64	3.5	2.7	4.4	26	4.0	2.6	5.8
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
Eye disorders (10015919)	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	6	1.0	0.4	2.1	11	0.6	0.3	1.1	10	1.5	0.7	2.8
	Vomiting (10047700)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	5	0.8	0.3	1.9	13	0.7	0.4	1.2	7	1.1	0.4	2.2
General disorders and administration site conditions (10018065)	Feeling hot (10016334)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site bruising (10022052)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site erythema (10022061)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site pain (10022086)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Injection site papule (10066044)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pain (10033371)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pyrexia (10037660)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Immune system disorders (10021428)	Hypersensitivity (10020751)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis (10017888)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Nasopharyngitis (10028810)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Oral herpes (10067152)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Pharyngitis (10034835)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Pneumonia (10035664)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	0	0.0	0.0	0.6	4	0.7	0.2	1.7	5	0.8	0.3	1.9	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Viral infection (10047461)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral rash (10047476)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Viral upper respiratory tract infection (10047482)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Nervous system disorders (10029205)	Poor quality sleep (10062519)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Irritability (10022998)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep disorder (10040984)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep terror (10041010)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Nasal congestion (10028735)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Rhinorrhoea (10039101)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	1	0.2	0.0	0.9	6	0.3	0.1	0.7	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Skin warm (10040952)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.99 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		350	28.2	25.8	30.8	357	29.0	26.5	31.6	339	27.3	24.8	29.8	1046	28.2	26.7	29.6	356	27.6	25.2	30.1
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Leukocytosis (10024378)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Leukopenia (10024384)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	3	0.2	0.0	0.7
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Deafness (10011878)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear pain (10014020)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.3	0.1	0.8	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Excessive cerumen production (10076897)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otorrhoea (10033101)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dacryostenosis acquired (10053990)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye discharge (10015915)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eyelid oedema (10015993)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hypermetropia (10020675)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lacrimation increased (10023644)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Strabismus (10042159)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain upper (10000087)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Anal fissure (10002153)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Constipation (10010774)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	5	0.4	0.1	0.9	8	0.2	0.1	0.4	3	0.2	0.0	0.7
	Diarrhoea (10012735)	24	1.9	1.2	2.9	14	1.1	0.6	1.9	12	1.0	0.5	1.7	50	1.3	1.0	1.8	27	2.1	1.4	3.0
	Dyspepsia (10013946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Dysphagia (10013950)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Enterocolitis (10014893)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastrooesophageal reflux disease (10017885)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Gingival hypertrophy (10018284)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival pain (10018286)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Ranula (10037838)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Stomatitis (10042128)	0	0.0	0.0	0.3	4	0.3	0.1	0.8	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Teething (10043183)	4	0.3	0.1	0.8	6	0.5	0.2	1.1	5	0.4	0.1	0.9	15	0.4	0.2	0.7	8	0.6	0.3	1.2
	Toothache (10044055)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vomiting (10047700)	8	0.6	0.3	1.3	4	0.3	0.1	0.8	6	0.5	0.2	1.0	18	0.5	0.3	0.8	12	0.9	0.5	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Influenza like illness (10022004)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site erythema (10022061)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	0	0.0	0.0	0.3	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Injection site swelling (10053425)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyrexia (10037660)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Food allergy (10016946)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	3	0.2	0.0	0.7	6	0.2	0.1	0.4	4	0.3	0.1	0.8
	Hypersensitivity (10020751)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Immunisation reaction (10021432)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Milk allergy (10027633)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Seasonal allergy (10048908)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acute sinusitis (10001076)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Adenovirus infection (10060931)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body tinea (10005913)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchiolitis (10006448)	2	0.2	0.0	0.6	8	0.6	0.3	1.3	7	0.6	0.2	1.2	17	0.5	0.3	0.7	7	0.5	0.2	1.1
	Bronchitis (10006451)	10	0.8	0.4	1.5	13	1.1	0.6	1.8	10	0.8	0.4	1.5	33	0.9	0.6	1.2	12	0.9	0.5	1.6
	Bullous impetigo (10006563)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Candida nappy rash (10007135)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cellulitis (10007882)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Clostridium difficile infection (10054236)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	20	1.6	1.0	2.5	17	1.4	0.8	2.2	28	2.3	1.5	3.2	65	1.8	1.4	2.2	28	2.2	1.4	3.1
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Croup infectious (10011416)	4	0.3	0.1	0.8	11	0.9	0.4	1.6	6	0.5	0.2	1.0	21	0.6	0.4	0.9	6	0.5	0.2	1.0
	Ear infection (10014011)	8	0.6	0.3	1.3	14	1.1	0.6	1.9	4	0.3	0.1	0.8	26	0.7	0.5	1.0	13	1.0	0.5	1.7
	Enterovirus infection (10014909)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Epstein-barr virus infection (10015108)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exanthema subitum (10015586)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye infection (10015929)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Folliculitis (10016936)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Fungal infection (10017533)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis (10017888)	19	1.5	0.9	2.4	13	1.1	0.6	1.8	23	1.9	1.2	2.8	55	1.5	1.1	1.9	18	1.4	0.8	2.2
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastroenteritis viral (10017918)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	3	0.2	0.0	0.7	8	0.2	0.1	0.4	3	0.2	0.0	0.7
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gingivitis (10018292)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand-foot-and-mouth disease (10019113)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	6	0.5	0.2	1.0	10	0.3	0.1	0.5	5	0.4	0.1	0.9
	Herpangina (10019936)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hordeolum (10020377)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Impetigo (10021531)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	1	0.1	0.0	0.4	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Infected bite (10076911)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza (10022000)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	0	0.0	0.0	0.3	6	0.2	0.1	0.4	6	0.5	0.2	1.0
	Laryngitis (10023874)	1	0.1	0.0	0.4	7	0.6	0.2	1.2	2	0.2	0.0	0.6	10	0.3	0.1	0.5	5	0.4	0.1	0.9
	Localised infection (10024774)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	50	4.0	3.0	5.3	45	3.7	2.7	4.9	50	4.0	3.0	5.3	145	3.9	3.3	4.6	37	2.9	2.0	3.9
	Oral candidiasis (10030963)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oral herpes (10067152)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Oral infection (10048685)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis externa (10033072)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	80	6.5	5.2	8.0	75	6.1	4.8	7.6	63	5.1	3.9	6.4	218	5.9	5.1	6.7	86	6.7	5.4	8.2
	Otitis media acute (10033079)	6	0.5	0.2	1.1	7	0.6	0.2	1.2	13	1.0	0.6	1.8	26	0.7	0.5	1.0	9	0.7	0.3	1.3
	Otitis media chronic (10033081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Paronychia (10034016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Periorbital cellulitis (10057182)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngitis (10034835)	20	1.6	1.0	2.5	31	2.5	1.7	3.6	14	1.1	0.6	1.9	65	1.8	1.4	2.2	23	1.8	1.1	2.7
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pharyngotonsillitis (10049140)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	6	0.5	0.2	1.0	8	0.2	0.1	0.4	1	0.1	0.0	0.4
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia viral (10035737)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract infection (10062352)	4	0.3	0.1	0.8	6	0.5	0.2	1.1	7	0.6	0.2	1.2	17	0.5	0.3	0.7	5	0.4	0.1	0.9
	Respiratory tract infection viral (10062106)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Rhinitis (10039083)	9	0.7	0.3	1.4	14	1.1	0.6	1.9	6	0.5	0.2	1.0	29	0.8	0.5	1.1	13	1.0	0.5	1.7
	Roseola (10039222)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sinusitis (10040753)	9	0.7	0.3	1.4	3	0.2	0.1	0.7	4	0.3	0.1	0.8	16	0.4	0.2	0.7	3	0.2	0.0	0.7
	Skin bacterial infection (10052891)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin candida (10054152)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Staphylococcal infection (10058080)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Streptococcal infection (10061372)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.2	0.0	0.7	5	0.1	0.0	0.3	3	0.2	0.0	0.7
	Subcutaneous abscess (10042343)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tonsillitis (10044008)	21	1.7	1.1	2.6	9	0.7	0.3	1.4	9	0.7	0.3	1.4	39	1.1	0.7	1.4	15	1.2	0.7	1.9
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract infection (10046306)	48	3.9	2.9	5.1	65	5.3	4.1	6.7	57	4.6	3.5	5.9	170	4.6	3.9	5.3	63	4.9	3.8	6.2
	Urinary tract infection (10046571)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Viral infection (10047461)	12	1.0	0.5	1.7	17	1.4	0.8	2.2	17	1.4	0.8	2.2	46	1.2	0.9	1.6	13	1.0	0.5	1.7
	Viral pharyngitis (10047473)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Viral rash (10047476)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral tonsillitis (10047480)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	4	0.3	0.1	0.8	10	0.3	0.1	0.5	3	0.2	0.0	0.7
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Animal bite (10002515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Arthropod bite (10003399)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Arthropod sting (10003402)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bite (10004966)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Concussion (10010254)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Contusion (10050584)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	1	0.1	0.0	0.4	4	0.1	0.0	0.3	4	0.3	0.1	0.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Craniocerebral injury (10070976)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Ear canal injury (10056319)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear injury (10057446)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye contusion (10073354)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Face injury (10050392)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Head injury (10019196)	3	0.2	0.0	0.7	4	0.3	0.1	0.8	3	0.2	0.0	0.7	10	0.3	0.1	0.5	2	0.2	0.0	0.6
	Heat stroke (10019345)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Laceration (10023572)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	1	0.1	0.0	0.4	6	0.2	0.1	0.4	2	0.2	0.0	0.6
	Limb injury (10061225)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Lip injury (10055082)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Upper limb fracture (10061394)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wound (10052428)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight decreased (10047895)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Lactose intolerance (10023681)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Knee deformity (10062061)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Synovial cyst (10042858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Epilepsy (10015037)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Exaggerated startle response (10066482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Febrile convulsion (10016284)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gross motor delay (10069118)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Headache (10019211)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nystagmus (10029864)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Speech disorder developmental (10041467)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tremor (10044565)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Insomnia (10022437)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Irritability (10022998)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary tract disorder (10046566)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Balanoposthitis (10004078)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Bilateral breast buds (10004557)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Genital labial adhesions (10064162)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	5	0.4	0.1	0.9
	Bronchial hyperreactivity (10066091)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Bronchospasm (10006482)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Catarrh (10007774)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cough (10011224)	13	1.0	0.6	1.8	16	1.3	0.7	2.1	12	1.0	0.5	1.7	41	1.1	0.8	1.5	16	1.2	0.7	2.0
	Dyspnoea (10013968)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Nasal discomfort (10052437)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory disorder (10038683)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinitis allergic (10039085)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Rhinorrhoea (10039101)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract congestion (10052252)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	6	0.5	0.2	1.0	14	0.4	0.2	0.6	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Dermatitis atopic (10012438)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Dermatitis contact (10012442)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	3	0.2	0.0	0.7	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Drug eruption (10013687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eczema (10014184)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	5	0.4	0.1	0.9
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Erythema (10015150)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hyperkeratosis (10020649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ingrowing nail (10022013)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Keratosis pilaris (10066295)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Miliaria (10027627)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prurigo (10037083)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Seborrhoea (10039792)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Skin irritation (10040880)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urticaria (10046735)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.100 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		23	18.5	12.1	26.5	27	21.6	14.7	29.8	24	19.2	12.7	27.2	74	19.8	15.9	24.2	26	20.5	13.8	28.5
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	1	0.8	0.0	4.4	2	1.6	0.2	5.7	0	0.0	0.0	2.9	3	0.8	0.2	2.3	0	0.0	0.0	2.9
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Teething (10043183)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyrexia (10037660)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Immune system disorders (10021428)	Food allergy (10016946)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Infections and infestations (10021881)	Bronchitis (10006451)	1	0.8	0.0	4.4	4	3.2	0.9	8.0	1	0.8	0.0	4.4	6	1.6	0.6	3.5	2	1.6	0.2	5.6
	Ear infection (10014011)	3	2.4	0.5	6.9	5	4.0	1.3	9.1	1	0.8	0.0	4.4	9	2.4	1.1	4.5	6	4.7	1.8	10.0
	Enterovirus infection (10014909)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	0	0.0	0.0	2.9	3	0.8	0.2	2.3	2	1.6	0.2	5.6
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Laryngitis (10023874)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Nasopharyngitis (10028810)	0	0.0	0.0	2.9	2	1.6	0.2	5.7	0	0.0	0.0	2.9	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pneumonia (10035664)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Respiratory tract infection (10062352)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Respiratory tract infection viral (10062106)	3	2.4	0.5	6.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Rhinitis (10039083)	2	1.6	0.2	5.7	5	4.0	1.3	9.1	2	1.6	0.2	5.7	9	2.4	1.1	4.5	4	3.1	0.9	7.9
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	2	1.6	0.2	5.7	2	1.6	0.2	5.7	2	1.6	0.2	5.7	6	1.6	0.6	3.5	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Viral infection (10047461)	1	0.8	0.0	4.4	5	4.0	1.3	9.1	3	2.4	0.5	6.9	9	2.4	1.1	4.5	3	2.4	0.5	6.7
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Nervous system disorders (10029205)	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Cough (10011224)	5	4.0	1.3	9.2	4	3.2	0.9	8.0	1	0.8	0.0	4.4	10	2.7	1.3	4.9	1	0.8	0.0	4.3
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose

n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.101 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		38	62.3	49.0	74.4	36	58.1	44.8	70.5	37	57.8	44.8	70.1	111	59.4	51.9	66.5	43	62.3	49.8	73.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	7	11.5	4.7	22.2	1	1.6	0.0	8.7	2	3.1	0.4	10.8	10	5.3	2.6	9.6	5	7.2	2.4	16.1
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Teething (10043183)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Toothache (10044055)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Vomiting (10047700)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	2	3.1	0.4	10.8	5	2.7	0.9	6.1	2	2.9	0.4	10.1
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchitis (10006451)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	2	2.9	0.4	10.1
	Candida infection (10074170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Conjunctivitis (10010741)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	4	6.3	1.7	15.2	7	3.7	1.5	7.6	5	7.2	2.4	16.1
	Ear infection (10014011)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	2	3.1	0.4	10.8	6	3.2	1.2	6.9	3	4.3	0.9	12.2
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Impetigo (10021531)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Laryngitis (10023874)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Nasopharyngitis (10028810)	10	16.4	8.2	28.1	6	9.7	3.6	19.9	10	15.6	7.8	26.9	26	13.9	9.3	19.7	10	14.5	7.2	25.0
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Otitis media (10033078)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Otitis media acute (10033079)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	5	7.8	2.6	17.3	7	3.7	1.5	7.6	2	2.9	0.4	10.1
	Pharyngitis (10034835)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	1	1.4	0.0	7.8
	Pharyngotonsillitis (10049140)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Pneumonia (10035664)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Respiratory tract infection (10062352)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	3	4.7	1.0	13.1	11	5.9	3.0	10.3	5	7.2	2.4	16.1
	Rhinitis (10039083)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Tonsillitis (10044008)	7	11.5	4.7	22.2	4	6.5	1.8	15.7	3	4.7	1.0	13.1	14	7.5	4.2	12.2	8	11.6	5.1	21.6
	Upper respiratory tract infection (10046306)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	2	3.1	0.4	10.8	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Viral infection (10047461)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	2	2.9	0.4	10.1
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	3	4.7	1.0	13.1	5	2.7	0.9	6.1	0	0.0	0.0	5.2
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	2	2.9	0.4	10.1
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Balanoposthitis (10004078)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchospasm (10006482)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	3	4.7	1.0	13.1	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Catarrh (10007774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Cough (10011224)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	2	2.9	0.4	10.1
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Dermatitis atopic (10012438)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	3	4.7	1.0	13.1	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.102 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		75	22.2	17.9	27.0	78	23.3	18.9	28.2	70	20.8	16.6	25.5	223	22.1	19.6	24.8	71	20.9	16.7	25.6
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Diarrhoea (10012735)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Teething (10043183)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Vomiting (10047700)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Injection site erythema (10022061)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Infections and infestations (10021881)	Adenovirus infection (10060931)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchiolitis (10006448)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	2	0.6	0.1	2.1	7	0.7	0.3	1.4	6	1.8	0.7	3.8
	Conjunctivitis (10010741)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	6	1.8	0.7	3.8	12	1.2	0.6	2.1	4	1.2	0.3	3.0
	Ear infection (10014011)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	2	0.6	0.1	2.1
	Enterovirus infection (10014909)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gastroenteritis (10017888)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Impetigo (10021531)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Laryngitis (10023874)	0	0.0	0.0	1.1	3	0.9	0.2	2.6	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Nasopharyngitis (10028810)	3	0.9	0.2	2.6	0	0.0	0.0	1.1	3	0.9	0.2	2.6	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	35	10.4	7.3	14.1	45	13.4	10.0	17.6	32	9.5	6.6	13.1	112	11.1	9.2	13.2	37	10.9	7.8	14.7
	Pharyngitis (10034835)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	4	1.2	0.3	3.0	5	0.5	0.2	1.2	0	0.0	0.0	1.1
	Rhinitis (10039083)	3	0.9	0.2	2.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	7	0.7	0.3	1.4	2	0.6	0.1	2.1
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tonsillitis (10044008)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Upper respiratory tract infection (10046306)	18	5.3	3.2	8.3	17	5.1	3.0	8.0	20	5.9	3.7	9.0	55	5.4	4.1	7.0	14	4.1	2.3	6.8
	Urinary tract infection (10046571)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Wound (10052428)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Cough (10011224)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	5	0.5	0.2	1.2	5	1.5	0.5	3.4
	Dyspnoea (10013968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.103 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		62	63.3	52.9	72.8	61	62.2	51.9	71.8	55	55.6	45.2	65.5	178	60.3	54.5	66.0	58	58.6	48.2	68.4
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Constipation (10010774)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Diarrhoea (10012735)	4	4.1	1.1	10.1	4	4.1	1.1	10.1	3	3.0	0.6	8.6	11	3.7	1.9	6.6	3	3.0	0.6	8.6
	Dyspepsia (10013946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	2	2.0	0.2	7.1
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	3.7	4	4.1	1.1	10.1	3	3.0	0.6	8.6	7	2.4	1.0	4.8	2	2.0	0.2	7.1
	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Conjunctivitis (10010741)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	2	2.0	0.2	7.1	4	1.4	0.4	3.4	4	4.0	1.1	10.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	8	8.2	3.6	15.5	5	5.1	1.7	11.5	13	13.1	7.2	21.4	26	8.8	5.8	12.6	10	10.1	5.0	17.8
	Gastroenteritis viral (10017918)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Gingivitis (10018292)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Nasopharyngitis (10028810)	34	34.7	25.4	45.0	32	32.7	23.5	42.9	32	32.3	23.3	42.5	98	33.2	27.9	38.9	24	24.2	16.2	33.9
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media (10033078)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media acute (10033079)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	2	2.0	0.2	7.1	4	1.4	0.4	3.4	1	1.0	0.0	5.5
	Pharyngitis (10034835)	6	6.1	2.3	12.9	12	12.2	6.5	20.4	4	4.0	1.1	10.0	22	7.5	4.7	11.1	13	13.1	7.2	21.4
	Pharyngotonsillitis (10049140)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Pneumonia viral (10035737)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis (10039083)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	5	5.1	1.7	11.4

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	11	11.2	5.7	19.2	4	4.1	1.1	10.1	4	4.0	1.1	10.0	19	6.4	3.9	9.9	6	6.1	2.3	12.7
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	2	2.0	0.2	7.1	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	3	3.0	0.6	8.6	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Bronchospasm (10006482)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cough (10011224)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Miliaria (10027627)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Prurigo (10037083)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled

COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.104 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		152	24.6	21.2	28.2	155	25.3	21.9	29.0	153	24.8	21.4	28.4	460	24.9	22.9	26.9	158	24.2	20.9	27.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Leukocytosis (10024378)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Leukopenia (10024384)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphadenopathy (10025197)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Deafness (10011878)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ear pain (10014020)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.8	0.3	1.9	8	0.4	0.2	0.9	2	0.3	0.0	1.1
	Diarrhoea (10012735)	11	1.8	0.9	3.2	4	0.7	0.2	1.7	5	0.8	0.3	1.9	20	1.1	0.7	1.7	18	2.8	1.6	4.3
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival swelling (10018291)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Teething (10043183)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	2	0.3	0.0	1.2	10	0.5	0.3	1.0	4	0.6	0.2	1.6
	Vomiting (10047700)	6	1.0	0.4	2.1	3	0.5	0.1	1.4	4	0.6	0.2	1.6	13	0.7	0.4	1.2	9	1.4	0.6	2.6
General disorders and administration site conditions (10018065)	Influenza like illness (10022004)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site erythema (10022061)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site swelling (10053425)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyrexia (10037660)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Food allergy (10016946)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Hypersensitivity (10020751)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seasonal allergy (10048908)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acute sinusitis (10001076)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	3	0.5	0.1	1.4	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Bronchitis (10006451)	5	0.8	0.3	1.9	1	0.2	0.0	0.9	4	0.6	0.2	1.6	10	0.5	0.3	1.0	2	0.3	0.0	1.1
	Candida infection (10074170)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cellulitis (10007882)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	14	2.3	1.2	3.8	12	2.0	1.0	3.4	16	2.6	1.5	4.2	42	2.3	1.6	3.1	15	2.3	1.3	3.8
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Croup infectious (10011416)	4	0.6	0.2	1.6	11	1.8	0.9	3.2	6	1.0	0.4	2.1	21	1.1	0.7	1.7	6	0.9	0.3	2.0
	Ear infection (10014011)	3	0.5	0.1	1.4	6	1.0	0.4	2.1	2	0.3	0.0	1.2	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Folliculitis (10016936)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Fungal infection (10017533)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis (10017888)	6	1.0	0.4	2.1	6	1.0	0.4	2.1	6	1.0	0.4	2.1	18	1.0	0.6	1.5	5	0.8	0.2	1.8
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand-foot-and-mouth disease (10019113)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.6	0.2	1.6	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Herpangina (10019936)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hordeolum (10020377)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Impetigo (10021531)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Influenza (10022000)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.3	0.1	0.6	4	0.6	0.2	1.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Nasopharyngitis (10028810)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	5	0.8	0.3	1.9	13	0.7	0.4	1.2	1	0.2	0.0	0.8
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral herpes (10067152)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Otitis externa (10033072)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	43	7.0	5.1	9.3	29	4.7	3.2	6.7	31	5.0	3.4	7.0	103	5.6	4.6	6.7	47	7.2	5.3	9.4

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Otitis media acute (10033079)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	6	1.0	0.4	2.1	15	0.8	0.5	1.3	6	0.9	0.3	2.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pharyngitis (10034835)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	7	1.1	0.5	2.3	26	1.4	0.9	2.1	7	1.1	0.4	2.2
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pneumonia (10035664)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.5	0.1	1.4	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis (10039083)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	1	0.2	0.0	0.9	9	0.5	0.2	0.9	2	0.3	0.0	1.1
	Roseola (10039222)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Sinusitis (10040753)	8	1.3	0.6	2.5	3	0.5	0.1	1.4	4	0.6	0.2	1.6	15	0.8	0.5	1.3	3	0.5	0.1	1.3
	Skin candida (10054152)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Subcutaneous abscess (10042343)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tonsillitis (10044008)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	26	4.2	2.8	6.1	44	7.2	5.3	9.5	32	5.2	3.6	7.2	102	5.5	4.5	6.7	45	6.9	5.1	9.1
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	9	1.5	0.7	2.7	8	1.3	0.6	2.6	12	1.9	1.0	3.4	29	1.6	1.1	2.2	8	1.2	0.5	2.4

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral rash (10047476)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral upper respiratory tract infection (10047482)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	2	0.3	0.0	1.2	5	0.3	0.1	0.6	2	0.3	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Animal bite (10002515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Contusion (10050584)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Craniocerebral injury (10070976)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Laceration (10023572)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Limb injury (10061225)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Lip injury (10055082)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Skin abrasion (10064990)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Upper limb fracture (10061394)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Lactose intolerance (10023681)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Musculoskeletal and connective tissue disorders (10028395)	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Nervous system disorders (10029205)	Gross motor delay (10069118)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Speech disorder developmental (10041467)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tremor (10044565)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Insomnia (10022437)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Irritability (10022998)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Bronchial hyperreactivity (10066091)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Cough (10011224)	5	0.8	0.3	1.9	10	1.6	0.8	3.0	9	1.5	0.7	2.7	24	1.3	0.8	1.9	8	1.2	0.5	2.4
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory disorder (10038683)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinorrhoea (10039101)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	6	1.0	0.4	2.1	14	0.8	0.4	1.3	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dermatitis atopic (10012438)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Dermatitis contact (10012442)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Eczema (10014184)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Erythema (10015150)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Keratosis pilaris (10066295)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seborrhoea (10039792)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urticaria (10046735)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

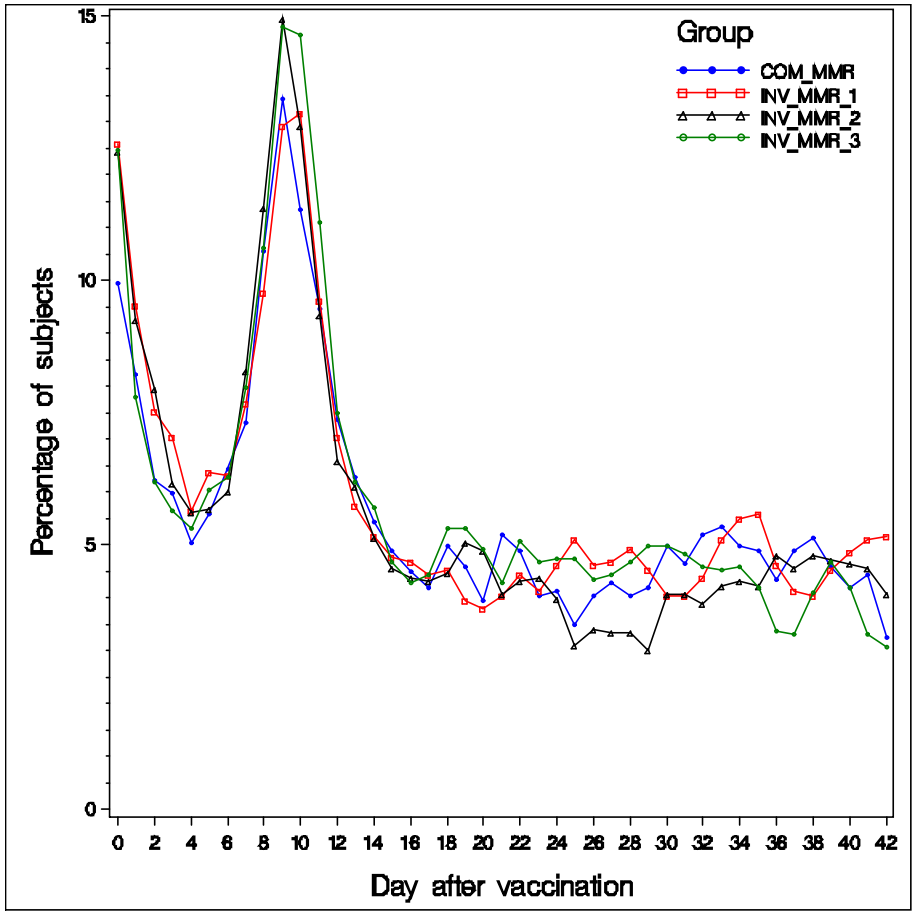
INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.105 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1239	845	68.2	65.5	70.8	1232	837	67.9	65.3	70.5	1243	833	67.0	64.3	69.6	3714	2515	67.7	66.2	69.2	1289	879	68.2	65.6	70.7
Any antipyretic	1239	632	51.0	48.2	53.8	1232	641	52.0	49.2	54.9	1243	610	49.1	46.3	51.9	3714	1883	50.7	49.1	52.3	1289	667	51.7	49.0	54.5
Prophylactic antipyretic	1239	40	3.2	2.3	4.4	1232	47	3.8	2.8	5.0	1243	38	3.1	2.2	4.2	3714	125	3.4	2.8	4.0	1289	36	2.8	2.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Figure 8.4 Percentage of subjects who took antipyretics by day (Day 0 to Day 42) (Total vaccinated cohort)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR

Table 8.106 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	124	72	58.1	48.9	66.9	125	69	55.2	46.0	64.1	125	64	51.2	42.1	60.2	374	205	54.8	49.6	59.9	127	68	53.5	44.5	62.4
Any antipyretic	124	44	35.5	27.1	44.6	125	46	36.8	28.4	45.9	125	37	29.6	21.8	38.4	374	127	34.0	29.2	39.0	127	41	32.3	24.3	41.2
Prophylactic antipyretic	124	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	125	1	0.8	0.0	4.4	374	1	0.3	0.0	1.5	127	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.107 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	61	37	60.7	47.3	72.9	62	41	66.1	53.0	77.7	64	42	65.6	52.7	77.1	187	120	64.2	56.8	71.0	69	39	56.5	44.0	68.4
Any antipyretic	61	29	47.5	34.6	60.7	62	28	45.2	32.5	58.3	64	24	37.5	25.7	50.5	187	81	43.3	36.1	50.7	69	31	44.9	32.9	57.4
Prophylactic antipyretic	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	64	0	0.0	0.0	5.6	187	0	0.0	0.0	2.0	69	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.108 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	338	313	92.6	89.3	95.2	335	300	89.6	85.8	92.6	337	305	90.5	86.9	93.4	1010	918	90.9	88.9	92.6	340	308	90.6	87.0	93.5
Any antipyretic	338	220	65.1	59.7	70.2	335	211	63.0	57.6	68.2	337	204	60.5	55.1	65.8	1010	635	62.9	59.8	65.9	340	206	60.6	55.2	65.8
Prophylactic antipyretic	338	4	1.2	0.3	3.0	335	3	0.9	0.2	2.6	337	4	1.2	0.3	3.0	1010	11	1.1	0.5	1.9	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.109 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	98	65	66.3	56.1	75.6	98	65	66.3	56.1	75.6	99	59	59.6	49.3	69.3	295	189	64.1	58.3	69.5	99	64	64.6	54.4	74.0
Any antipyretic	98	57	58.2	47.8	68.1	98	54	55.1	44.7	65.2	99	49	49.5	39.3	59.7	295	160	54.2	48.4	60.0	99	51	51.5	41.3	61.7
Prophylactic antipyretic	98	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	99	0	0.0	0.0	3.7	295	0	0.0	0.0	1.2	99	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.110 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	618	358	57.9	53.9	61.9	612	362	59.2	55.1	63.1	618	363	58.7	54.7	62.7	1848	1083	58.6	56.3	60.9	654	400	61.2	57.3	64.9
Any antipyretic	618	282	45.6	41.7	49.7	612	302	49.3	45.3	53.4	618	296	47.9	43.9	51.9	1848	880	47.6	45.3	49.9	654	338	51.7	47.8	55.6
Prophylactic antipyretic	618	36	5.8	4.1	8.0	612	44	7.2	5.3	9.5	618	33	5.3	3.7	7.4	1848	113	6.1	5.1	7.3	654	35	5.4	3.8	7.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.111 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

	INV_MMR										COM_MMR									
	F					M					F					M				
				95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1816	1194	65.7	63.5	67.9	1898	1321	69.6	67.5	71.7	618	422	68.3	64.5	71.9	671	457	68.1	64.4	71.6
Any antipyretic	1816	891	49.1	46.7	51.4	1898	992	52.3	50.0	54.5	618	306	49.5	45.5	53.5	671	361	53.8	49.9	57.6
Prophylactic antipyretic	1816	65	3.6	2.8	4.5	1898	60	3.2	2.4	4.1	618	11	1.8	0.9	3.2	671	25	3.7	2.4	5.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.112 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

	INV_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	2814	2004	71.2	69.5	72.9	364	229	62.9	57.7	67.9	169	84	49.7	41.9	57.5
Any antipyretic	2814	1480	52.6	50.7	54.5	364	191	52.5	47.2	57.7	169	57	33.7	26.6	41.4
Prophylactic antipyretic	2814	99	3.5	2.9	4.3	364	7	1.9	0.8	3.9	169	9	5.3	2.5	9.9

	COM_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	970	700	72.2	69.2	75.0	124	79	63.7	54.6	72.2	70	36	51.4	39.2	63.6
Any antipyretic	970	519	53.5	50.3	56.7	124	63	50.8	41.7	59.9	70	29	41.4	29.8	53.8
Prophylactic antipyretic	970	25	2.6	1.7	3.8	124	4	3.2	0.9	8.1	70	2	2.9	0.3	9.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.113 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1239	680	54.9	52.1	57.7	1232	676	54.9	52.0	57.7	1243	669	53.8	51.0	56.6	3714	2025	54.5	52.9	56.1	1289	697	54.1	51.3	56.8
Any antipyretic	1239	479	38.7	35.9	41.4	1232	473	38.4	35.7	41.2	1243	465	37.4	34.7	40.2	3714	1417	38.2	36.6	39.7	1289	493	38.2	35.6	41.0
Prophylactic antipyretic	1239	40	3.2	2.3	4.4	1232	47	3.8	2.8	5.0	1243	38	3.1	2.2	4.2	3714	125	3.4	2.8	4.0	1289	36	2.8	2.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.114 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Estonia)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	124	47	37.9	29.3	47.1	125	52	41.6	32.9	50.8	125	44	35.2	26.9	44.2	374	143	38.2	33.3	43.4	127	55	43.3	34.5	52.4
Any antipyretic	124	30	24.2	17.0	32.7	125	32	25.6	18.2	34.2	125	27	21.6	14.7	29.8	374	89	23.8	19.6	28.4	127	31	24.4	17.2	32.8
Prophylactic antipyretic	124	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	125	1	0.8	0.0	4.4	374	1	0.3	0.0	1.5	127	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.115 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Spain)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	61	25	41.0	28.6	54.3	62	23	37.1	25.2	50.3	64	23	35.9	24.3	48.9	187	71	38.0	31.0	45.3	69	22	31.9	21.2	44.2
Any antipyretic	61	20	32.8	21.3	46.0	62	16	25.8	15.5	38.5	64	14	21.9	12.5	34.0	187	50	26.7	20.5	33.7	69	16	23.2	13.9	34.9
Prophylactic antipyretic	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	64	0	0.0	0.0	5.6	187	0	0.0	0.0	2.0	69	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.116 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Finland)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	338	298	88.2	84.2	91.4	335	284	84.8	80.5	88.4	337	290	86.1	81.9	89.6	1010	872	86.3	84.1	88.4	340	284	83.5	79.2	87.3
Any antipyretic	338	177	52.4	46.9	57.8	335	161	48.1	42.6	53.6	337	161	47.8	42.3	53.3	1010	499	49.4	46.3	52.5	340	155	45.6	40.2	51.0
Prophylactic antipyretic	338	4	1.2	0.3	3.0	335	3	0.9	0.2	2.6	337	4	1.2	0.3	3.0	1010	11	1.1	0.5	1.9	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.117 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Mexico)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	98	36	36.7	27.2	47.1	98	45	45.9	35.8	56.3	99	39	39.4	29.7	49.7	295	120	40.7	35.0	46.5	99	38	38.4	28.8	48.7
Any antipyretic	98	26	26.5	18.1	36.4	98	32	32.7	23.5	42.9	99	30	30.3	21.5	40.4	295	88	29.8	24.7	35.4	99	31	31.3	22.4	41.4
Prophylactic antipyretic	98	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	99	0	0.0	0.0	3.7	295	0	0.0	0.0	1.2	99	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.118 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, United States)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	618	274	44.3	40.4	48.4	612	272	44.4	40.5	48.5	618	273	44.2	40.2	48.2	1848	819	44.3	42.0	46.6	654	298	45.6	41.7	49.5
Any antipyretic	618	226	36.6	32.8	40.5	612	232	37.9	34.0	41.9	618	233	37.7	33.9	41.7	1848	691	37.4	35.2	39.6	654	260	39.8	36.0	43.6
Prophylactic antipyretic	618	36	5.8	4.1	8.0	612	44	7.2	5.3	9.5	618	33	5.3	3.7	7.4	1848	113	6.1	5.1	7.3	654	35	5.4	3.8	7.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.119 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by gender)

	INV_MMR										COM_MMR									
	F					M					F					M				
				95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1816	959	52.8	50.5	55.1	1898	1066	56.2	53.9	58.4	618	328	53.1	49.1	57.1	671	369	55.0	51.1	58.8
Any antipyretic	1816	670	36.9	34.7	39.2	1898	747	39.4	37.2	41.6	618	217	35.1	31.3	39.0	671	276	41.1	37.4	45.0
Prophylactic antipyretic	1816	65	3.6	2.8	4.5	1898	60	3.2	2.4	4.1	618	11	1.8	0.9	3.2	671	25	3.7	2.4	5.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.120 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

	INV_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	2814	1665	59.2	57.3	61.0	364	152	41.8	36.6	47.0	169	58	34.3	27.2	42.0
Any antipyretic	2814	1137	40.4	38.6	42.2	364	116	31.9	27.1	36.9	169	45	26.6	20.1	34.0
Prophylactic antipyretic	2814	99	3.5	2.9	4.3	364	7	1.9	0.8	3.9	169	9	5.3	2.5	9.9

	COM_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	970	577	59.5	56.3	62.6	124	47	37.9	29.3	47.1	70	23	32.9	22.1	45.1
Any antipyretic	970	395	40.7	37.6	43.9	124	38	30.6	22.7	39.6	70	20	28.6	18.4	40.6
Prophylactic antipyretic	970	25	2.6	1.7	3.8	124	4	3.2	0.9	8.1	70	2	2.9	0.3	9.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.121 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		74	59.7	50.5	68.4	78	62.4	53.3	70.9	74	59.2	50.1	67.9	226	60.4	55.3	65.4	67	52.8	43.7	61.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Lymphadenopathy (10025197)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Auricular swelling (10003800)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear pain (10014020)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Eyelid oedema (10015993)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Diarrhoea (10012735)	8	6.5	2.8	12.3	6	4.8	1.8	10.2	6	4.8	1.8	10.2	20	5.3	3.3	8.1	7	5.5	2.2	11.0
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Flatulence (10016766)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival swelling (10018291)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Salivary hypersecretion (10039424)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Stomatitis (10042128)	0	0.0	0.0	2.9	4	3.2	0.9	8.0	1	0.8	0.0	4.4	5	1.3	0.4	3.1	0	0.0	0.0	2.9
	Teething (10043183)	9	7.3	3.4	13.3	13	10.4	5.7	17.1	7	5.6	2.3	11.2	29	7.8	5.3	10.9	7	5.5	2.2	11.0
	Toothache (10044055)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Vomiting (10047700)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	3	2.4	0.5	6.9	8	2.1	0.9	4.2	4	3.1	0.9	7.9
General disorders and administration site conditions (10018065)	Injection site erosion (10022059)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site erythema (10022061)	9	7.3	3.4	13.3	5	4.0	1.3	9.1	7	5.6	2.3	11.2	21	5.6	3.5	8.5	9	7.1	3.3	13.0
	Injection site haematoma (10022066)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site pain (10022086)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Injection site papule (10066044)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site swelling (10053425)	4	3.2	0.9	8.1	1	0.8	0.0	4.4	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pyrexia (10037660)	4	3.2	0.9	8.1	6	4.8	1.8	10.2	2	1.6	0.2	5.7	12	3.2	1.7	5.5	1	0.8	0.0	4.3
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Food allergy (10016946)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	1	0.8	0.0	4.4	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Infections and infestations (10021881)	Adenovirus infection (10060931)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Bronchitis (10006451)	4	3.2	0.9	8.1	4	3.2	0.9	8.0	4	3.2	0.9	8.0	12	3.2	1.7	5.5	5	3.9	1.3	8.9
	Conjunctivitis (10010741)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear infection (10014011)	6	4.8	1.8	10.2	12	9.6	5.1	16.2	8	6.4	2.8	12.2	26	7.0	4.6	10.0	11	8.7	4.4	15.0
	Enterovirus infection (10014909)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	0	0.0	0.0	2.9	2	0.5	0.1	1.9	2	1.6	0.2	5.6
	Exanthema subitum (10015586)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	2	1.6	0.2	5.7	5	1.3	0.4	3.1	4	3.1	0.9	7.9
	Fungal skin infection (10017543)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gastroenteritis rotavirus (10017913)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	4	1.1	0.3	2.7	1	0.8	0.0	4.3
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Impetigo (10021531)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Influenza (10022000)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	2	1.6	0.2	5.7	5	1.3	0.4	3.1	2	1.6	0.2	5.6
	Nasopharyngitis (10028810)	5	4.0	1.3	9.2	9	7.2	3.3	13.2	3	2.4	0.5	6.9	17	4.5	2.7	7.2	3	2.4	0.5	6.7
	Neutropenic infection (10059482)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	2	1.6	0.2	5.7	1	0.8	0.0	4.4	5	4.0	1.3	9.1	8	2.1	0.9	4.2	4	3.1	0.9	7.9
	Otitis media acute (10033079)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	7	1.9	0.8	3.8	2	1.6	0.2	5.6
	Pneumonia (10035664)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	1	0.8	0.0	4.4	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyelonephritis acute (10037597)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Respiratory tract infection (10062352)	1	0.8	0.0	4.4	2	1.6	0.2	5.7	0	0.0	0.0	2.9	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Respiratory tract infection viral (10062106)	4	3.2	0.9	8.1	1	0.8	0.0	4.4	0	0.0	0.0	2.9	5	1.3	0.4	3.1	6	4.7	1.8	10.0

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis (10039083)	16	12.9	7.6	20.1	18	14.4	8.8	21.8	16	12.8	7.5	20.0	50	13.4	10.1	17.2	15	11.8	6.8	18.7
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	2	1.6	0.2	5.6
	Tracheitis (10044302)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	7	5.6	2.3	11.3	4	3.2	0.9	8.0	4	3.2	0.9	8.0	15	4.0	2.3	6.5	0	0.0	0.0	2.9
	Urinary tract infection (10046571)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Varicella (10046980)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	2	1.6	0.2	5.6
	Viral infection (10047461)	8	6.5	2.8	12.3	11	8.8	4.5	15.2	11	8.8	4.5	15.2	30	8.0	5.5	11.3	8	6.3	2.8	12.0
	Viral pharyngitis (10047473)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral rash (10047476)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Burns second degree (10006802)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Concussion (10010254)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Head injury (10019196)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Psychiatric disorders (10037175)	Sleep disorder (10040984)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Cough (10011224)	17	13.7	8.2	21.0	17	13.6	8.1	20.9	14	11.2	6.3	18.1	48	12.8	9.6	16.7	10	7.9	3.8	14.0
	Epistaxis (10015090)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Rhinorrhoea (10039101)	2	1.6	0.2	5.7	2	1.6	0.2	5.7	2	1.6	0.2	5.7	6	1.6	0.6	3.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dermatitis allergic (10012434)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	4	3.2	0.9	8.0	5	1.3	0.4	3.1	1	0.8	0.0	4.3
	Dermatitis atopic (10012438)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Eczema (10014184)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Erythema (10015150)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Hyperhidrosis (10020642)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rash (10037844)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	1.6	0.2	5.7	3	0.8	0.2	2.3	2	1.6	0.2	5.6
	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.122 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		55	90.2	79.8	96.3	57	91.9	82.2	97.3	59	92.2	82.7	97.4	171	91.4	86.5	95.0	64	92.8	83.9	97.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	3	4.7	1.0	13.1	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Iron deficiency anaemia (10022972)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lymphadenitis (10025188)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Congenital, familial and genetic disorders (10010331)	Talipes (10043101)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eye discharge (10015915)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Eyelid oedema (10015993)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Lacrimation increased (10023644)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Anal fissure (10002153)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Aphthous ulcer (10002959)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Colitis (10009887)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Constipation (10010774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Diarrhoea (10012735)	15	24.6	14.5	37.3	9	14.5	6.9	25.8	11	17.2	8.9	28.7	35	18.7	13.4	25.1	21	30.4	19.9	42.7
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Faeces soft (10074859)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Inguinal hernia (10022016)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral contusion (10078170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral disorder (10067621)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Stomatitis (10042128)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Teething (10043183)	4	6.6	1.8	15.9	6	9.7	3.6	19.9	4	6.3	1.7	15.2	14	7.5	4.2	12.2	4	5.8	1.6	14.2
	Toothache (10044055)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	2	2.9	0.4	10.1
	Vomiting (10047700)	5	8.2	2.7	18.1	6	9.7	3.6	19.9	6	9.4	3.5	19.3	17	9.1	5.4	14.2	6	8.7	3.3	18.0

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
General disorders and administration site conditions (10018065)	Asthenia (10003549)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oedema peripheral (10030124)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pain (10033371)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pyrexia (10037660)	6	9.8	3.7	20.2	2	3.2	0.4	11.2	3	4.7	1.0	13.1	11	5.9	3.0	10.3	4	5.8	1.6	14.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Selective iga immunodeficiency (10039915)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Adenoiditis (10051223)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Bronchiolitis (10006448)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	1	1.6	0.0	8.4	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Bronchitis (10006451)	8	13.1	5.8	24.2	9	14.5	6.9	25.8	12	18.8	10.1	30.5	29	15.5	10.6	21.5	10	14.5	7.2	25.0
	Burn infection (10051548)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Candida infection (10074170)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	4	5.8	1.6	14.2
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cellulitis (10007882)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Cellulitis orbital (10007918)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Conjunctivitis (10010741)	8	13.1	5.8	24.2	11	17.7	9.2	29.5	15	23.4	13.8	35.7	34	18.2	12.9	24.5	14	20.3	11.6	31.7
	Coxsackie viral infection (10011261)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	3	4.7	1.0	13.1	7	3.7	1.5	7.6	0	0.0	0.0	5.2
	Cystitis (10011781)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Ear infection (10014011)	5	8.2	2.7	18.1	7	11.3	4.7	21.9	4	6.3	1.7	15.2	16	8.6	5.0	13.5	4	5.8	1.6	14.2
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Erythema infectiosum (10015214)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	15	24.6	14.5	37.3	11	17.7	9.2	29.5	12	18.8	10.1	30.5	38	20.3	14.8	26.8	14	20.3	11.6	31.7
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hand-foot-and-mouth disease (10019113)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Herpangina (10019936)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	3	4.7	1.0	13.1	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Herpes simplex (10019948)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Hordeolum (10020377)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Impetigo (10021531)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Laryngitis (10023874)	6	9.8	3.7	20.2	6	9.7	3.6	19.9	6	9.4	3.5	19.3	18	9.6	5.8	14.8	9	13.0	6.1	23.3
	Nasopharyngitis (10028810)	24	39.3	27.1	52.7	17	27.4	16.9	40.2	20	31.3	20.2	44.1	61	32.6	26.0	39.8	24	34.8	23.7	47.2
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Oral herpes (10067152)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Otitis externa (10033072)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Otitis media (10033078)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	4	6.3	1.7	15.2	9	4.8	2.2	8.9	5	7.2	2.4	16.1
	Otitis media acute (10033079)	7	11.5	4.7	22.2	3	4.8	1.0	13.5	11	17.2	8.9	28.7	21	11.2	7.1	16.7	8	11.6	5.1	21.6
	Pharyngitis (10034835)	12	19.7	10.6	31.8	15	24.2	14.2	36.7	11	17.2	8.9	28.7	38	20.3	14.8	26.8	14	20.3	11.6	31.7
	Pharyngotonsillitis (10049140)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Pneumonia (10035664)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Respiratory tract infection (10062352)	10	16.4	8.2	28.1	12	19.4	10.4	31.4	7	10.9	4.5	21.2	29	15.5	10.6	21.5	13	18.8	10.4	30.1
	Rhinitis (10039083)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	1	1.6	0.0	8.4	4	2.1	0.6	5.4	2	2.9	0.4	10.1
	Rotavirus infection (10067470)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Tonsillitis (10044008)	15	24.6	14.5	37.3	12	19.4	10.4	31.4	16	25.0	15.0	37.4	43	23.0	17.2	29.7	21	30.4	19.9	42.7
	Upper respiratory tract infection (10046306)	7	11.5	4.7	22.2	5	8.1	2.7	17.8	10	15.6	7.8	26.9	22	11.8	7.5	17.3	10	14.5	7.2	25.0
	Viral diarrhoea (10051511)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Viral infection (10047461)	4	6.6	1.8	15.9	9	14.5	6.9	25.8	5	7.8	2.6	17.3	18	9.6	5.8	14.8	9	13.0	6.1	23.3
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1
	Viral rash (10047476)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	1	1.6	0.0	8.4	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	6	9.4	3.5	19.3	14	7.5	4.2	12.2	4	5.8	1.6	14.2

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	4	6.6	1.8	15.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eyelid injury (10069200)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Fall (10016173)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Head injury (10019196)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Injury (10022116)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lip injury (10055082)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Poisoning (10061355)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Skull fracture (10061365)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Wound (10052428)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	1	1.6	0.0	8.4	4	2.1	0.6	5.4	0	0.0	0.0	5.2
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cardiac murmur functional (10007587)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Iron deficiency (10022970)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	0	0.0	0.0	5.6	4	2.1	0.6	5.4	1	1.4	0.0	7.8
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Synovitis (10042868)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Mycosis fungoides (10028483)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Balanoposthitis (10004078)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Oedema genital (10030104)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Perineal cyst (10066058)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchitis chronic (10006458)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchospasm (10006482)	3	4.9	1.0	13.7	6	9.7	3.6	19.9	6	9.4	3.5	19.3	15	8.0	4.6	12.9	6	8.7	3.3	18.0
	Catarrh (10007774)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	1	1.6	0.0	8.4	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Cough (10011224)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Epistaxis (10015090)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Increased bronchial secretion (10062530)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Nasal congestion (10028735)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	3	4.3	0.9	12.2
	Dermatitis atopic (10012438)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	5	7.8	2.6	17.3	9	4.8	2.2	8.9	4	5.8	1.6	14.2
	Dermatitis contact (10012442)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	3	4.7	1.0	13.1	11	5.9	3.0	10.3	6	8.7	3.3	18.0
	Dyshidrotic eczema (10013913)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	5	7.2	2.4	16.1
	Lichen striatus (10066945)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Miliaria (10027627)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	1	1.6	0.0	8.4	5	2.7	0.9	6.1	2	2.9	0.4	10.1
	Onychomalacia (10058673)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Rash (10037844)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	7	10.9	4.5	21.2	13	7.0	3.8	11.6	2	2.9	0.4	10.1
	Seborrhoeic dermatitis (10039793)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Urticaria (10046735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	3	4.7	1.0	13.1	4	2.1	0.6	5.4	4	5.8	1.6	14.2
Vascular disorders (10047065)	Haematoma (10018852)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.123 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		261	77.2	72.4	81.6	248	74.0	69.0	78.6	249	73.9	68.9	78.5	758	75.0	72.3	77.7	238	70.0	64.8	74.8
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenitis (10025188)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	2	0.6	0.1	2.1	8	0.8	0.3	1.6	1	0.3	0.0	1.6
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Ear swelling (10014025)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Endocrine disorders (10014698)	Hypothyroidism (10021114)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Blepharitis (10005148)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Conjunctivitis allergic (10010744)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye irritation (10015946)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye swelling (10015967)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Panophthalmitis (10033683)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Aphthous ulcer (10002959)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Chapped lips (10049047)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Coeliac disease (10009839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	4	1.2	0.3	3.0
	Diarrhoea (10012735)	9	2.7	1.2	5.0	22	6.6	4.2	9.8	24	7.1	4.6	10.4	55	5.4	4.1	7.0	10	2.9	1.4	5.3
	Flatulence (10016766)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Gastrooesophageal reflux disease (10017885)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Haematochezia (10018836)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Regurgitation (10067171)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salivary gland enlargement (10039408)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Salivary gland pain (10039421)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Salivary hypersecretion (10039424)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Stomatitis (10042128)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Teething (10043183)	56	16.6	12.8	21.0	38	11.3	8.2	15.2	48	14.2	10.7	18.4	142	14.1	12.0	16.4	49	14.4	10.9	18.6
	Tongue ulceration (10043991)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Toothache (10044055)	3	0.9	0.2	2.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	3	0.9	0.2	2.6
	Vomiting (10047700)	4	1.2	0.3	3.0	12	3.6	1.9	6.2	4	1.2	0.3	3.0	20	2.0	1.2	3.0	8	2.4	1.0	4.6
General disorders and administration site conditions (10018065)	Crying (10011469)	4	1.2	0.3	3.0	5	1.5	0.5	3.4	2	0.6	0.1	2.1	11	1.1	0.5	1.9	4	1.2	0.3	3.0
	Developmental delay (10012559)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fatigue (10016256)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Feeling hot (10016334)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gait disturbance (10017577)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Ill-defined disorder (10061520)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza like illness (10022004)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Injection site bruising (10022052)	2	0.6	0.1	2.1	3	0.9	0.2	2.6	1	0.3	0.0	1.6	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Injection site erythema (10022061)	16	4.7	2.7	7.6	17	5.1	3.0	8.0	21	6.2	3.9	9.4	54	5.3	4.0	6.9	13	3.8	2.1	6.4
	Injection site haematoma (10022066)	4	1.2	0.3	3.0	1	0.3	0.0	1.7	3	0.9	0.2	2.6	8	0.8	0.3	1.6	0	0.0	0.0	1.1
	Injection site haemorrhage (10022067)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1
	Injection site induration (10022075)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Injection site nodule (10057880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Injection site pain (10022086)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	3	0.9	0.2	2.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
	Injection site papule (10066044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Injection site swelling (10053425)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	6	1.8	0.7	3.8	13	1.3	0.7	2.2	4	1.2	0.3	3.0
	Injection site vesicles (10022111)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pain (10033371)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pyrexia (10037660)	6	1.8	0.7	3.8	8	2.4	1.0	4.7	3	0.9	0.2	2.6	17	1.7	1.0	2.7	9	2.6	1.2	5.0
	Secretion discharge (10053459)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Swelling (10042674)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Drug hypersensitivity (10013700)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Hypersensitivity (10020751)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Milk allergy (10027633)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Seasonal allergy (10048908)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Adenovirus infection (10060931)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Borrelia infection (10061591)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Bronchiolitis (10006448)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	1	0.3	0.0	1.6	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Bronchitis (10006451)	11	3.3	1.6	5.7	15	4.5	2.5	7.3	13	3.9	2.1	6.5	39	3.9	2.8	5.2	18	5.3	3.2	8.2
	Conjunctivitis (10010741)	21	6.2	3.9	9.3	26	7.8	5.1	11.2	24	7.1	4.6	10.4	71	7.0	5.5	8.8	23	6.8	4.3	10.0
	Ear infection (10014011)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	1	0.3	0.0	1.6	8	0.8	0.3	1.6	4	1.2	0.3	3.0
	Enterovirus infection (10014909)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	7	0.7	0.3	1.4	4	1.2	0.3	3.0
	Exanthema subitum (10015586)	5	1.5	0.5	3.4	6	1.8	0.7	3.9	3	0.9	0.2	2.6	14	1.4	0.8	2.3	6	1.8	0.7	3.8
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fungal skin infection (10017543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Gastroenteritis (10017888)	11	3.3	1.6	5.7	9	2.7	1.2	5.0	11	3.3	1.6	5.8	31	3.1	2.1	4.3	12	3.5	1.8	6.1
	Gastroenteritis norovirus (10068189)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Gingivitis (10018292)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	2	0.6	0.1	2.1	5	1.5	0.5	3.4	5	1.5	0.5	3.4	12	1.2	0.6	2.1	2	0.6	0.1	2.1
	Herpes zoster (10019974)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Impetigo (10021531)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	5	0.5	0.2	1.2	1	0.3	0.0	1.6
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	1	0.3	0.0	1.6	5	0.5	0.2	1.2	4	1.2	0.3	3.0
	Injection site abscess (10022044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laryngitis (10023874)	8	2.4	1.0	4.6	13	3.9	2.1	6.5	12	3.6	1.9	6.1	33	3.3	2.3	4.6	6	1.8	0.7	3.8

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Localised infection (10024774)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Lyme disease (10025169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Molluscum contagiosum (10027807)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	3	0.9	0.2	2.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Nasopharyngitis (10028810)	12	3.6	1.8	6.1	9	2.7	1.2	5.0	10	3.0	1.4	5.4	31	3.1	2.1	4.3	11	3.2	1.6	5.7
	Oral candidiasis (10030963)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Oral herpes (10067152)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	98	29.0	24.2	34.1	105	31.3	26.4	36.6	87	25.8	21.2	30.8	290	28.7	25.9	31.6	104	30.6	25.7	35.8
	Otitis media acute (10033079)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Pharyngitis (10034835)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	3	0.9	0.2	2.6	7	0.7	0.3	1.4	3	0.9	0.2	2.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	3	0.9	0.2	2.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	8	0.8	0.3	1.6	2	0.6	0.1	2.1
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pyelonephritis (10037596)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus infection (10061603)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	5	1.5	0.5	3.4	6	1.8	0.7	3.9	9	2.7	1.2	5.0	20	2.0	1.2	3.0	2	0.6	0.1	2.1
	Respiratory tract infection viral (10062106)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinitis (10039083)	29	8.6	5.8	12.1	24	7.2	4.6	10.5	22	6.5	4.1	9.7	75	7.4	5.9	9.2	22	6.5	4.1	9.6
	Roseola (10039222)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin infection (10040872)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Tonsillitis (10044008)	6	1.8	0.7	3.8	3	0.9	0.2	2.6	2	0.6	0.1	2.1	11	1.1	0.5	1.9	3	0.9	0.2	2.6
	Upper respiratory tract infection (10046306)	87	25.7	21.2	30.7	90	26.9	22.2	32.0	90	26.7	22.1	31.8	267	26.4	23.7	29.3	70	20.6	16.4	25.3
	Urinary tract infection (10046571)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	3	0.9	0.2	2.6
	Varicella (10046980)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	5	1.5	0.5	3.4	3	0.9	0.2	2.6	1	0.3	0.0	1.6	9	0.9	0.4	1.7	2	0.6	0.1	2.1
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye injury (10061128)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Ligament sprain (10024453)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Post vaccination syndrome (10036242)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Post-traumatic pain (10065016)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Radial head dislocation (10073749)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin wound (10072170)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Splinter (10041662)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Thermal burn (10053615)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Wound (10052428)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
Investigations (10022891)	Cardiac murmur (10007586)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hypoglycaemia (10020993)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Overweight (10033307)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Skin papilloma (10040907)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Poor quality sleep (10062519)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Post-traumatic headache (10036313)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Somnolence (10041349)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Irritability (10022998)	5	1.5	0.5	3.4	7	2.1	0.8	4.3	7	2.1	0.8	4.2	19	1.9	1.1	2.9	10	2.9	1.4	5.3
	Restlessness (10038743)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Sleep disorder (10040984)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tearfulness (10043169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Terminal insomnia (10068932)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

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	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Testicular retraction (10043348)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Apnoea (10002974)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Bronchitis chronic (10006458)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Cough (10011224)	9	2.7	1.2	5.0	11	3.3	1.7	5.8	9	2.7	1.2	5.0	29	2.9	1.9	4.1	16	4.7	2.7	7.5
	Dyspnoea (10013968)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Epistaxis (10015090)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nasal congestion (10028735)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Oropharyngeal pain (10068319)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rhinitis allergic (10039085)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Dermatitis atopic (10012438)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	3	0.9	0.2	2.6	9	0.9	0.4	1.7	4	1.2	0.3	3.0
	Dermatitis diaper (10012444)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	2	0.6	0.1	2.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Dry skin (10013786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eczema (10014184)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash (10037844)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash erythematous (10037855)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rash macular (10037867)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rash papular (10037876)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash vesicular (10037898)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin burning sensation (10054786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Skin irritation (10040880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Swelling face (10042682)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Urticaria (10046735)	5	1.5	0.5	3.4	1	0.3	0.0	1.7	0	0.0	0.0	1.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.124 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		87	88.8	80.8	94.3	89	90.8	83.3	95.7	93	93.9	87.3	97.7	269	91.2	87.4	94.2	88	88.9	81.0	94.3
Cardiac disorders (10007541)	Supraventricular extrasystoles (10042602)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Congenital, familial and genetic disorders (10010331)	Congenital cardiovascular anomaly (10061054)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Eye disorders (10015919)	Blepharitis (10005148)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	2.0	0.2	7.1	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Entropion (10061842)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Colitis (10009887)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Constipation (10010774)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Diarrhoea (10012735)	17	17.3	10.4	26.3	8	8.2	3.6	15.5	11	11.1	5.7	19.0	36	12.2	8.7	16.5	6	6.1	2.3	12.7
	Dyspepsia (10013946)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Faeces soft (10074859)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastritis (10017853)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Teething (10043183)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tongue ulceration (10043991)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	4	4.1	1.1	10.1	0	0.0	0.0	3.7	0	0.0	0.0	3.7	4	1.4	0.4	3.4	2	2.0	0.2	7.1
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	4	4.1	1.1	10.1	1	1.0	0.0	5.6	1	1.0	0.0	5.5	6	2.0	0.7	4.4	3	3.0	0.6	8.6
Immune system disorders (10021428)	Allergy to animal (10001742)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Drug hypersensitivity (10013700)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Milk allergy (10027633)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Infections and infestations (10021881)	Bronchiolitis (10006448)	4	4.1	1.1	10.1	9	9.2	4.3	16.7	6	6.1	2.3	12.7	19	6.4	3.9	9.9	5	5.1	1.7	11.4
	Bronchitis (10006451)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Candida nappy rash (10007135)	5	5.1	1.7	11.5	2	2.0	0.2	7.2	1	1.0	0.0	5.5	8	2.7	1.2	5.3	3	3.0	0.6	8.6

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Conjunctivitis (10010741)	6	6.1	2.3	12.9	6	6.1	2.3	12.9	4	4.0	1.1	10.0	16	5.4	3.1	8.7	8	8.1	3.6	15.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cutaneous larva migrans (10059547)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Ear infection (10014011)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	22	22.4	14.6	32.0	20	20.4	12.9	29.7	28	28.3	19.7	38.2	70	23.7	19.0	29.0	22	22.2	14.5	31.7
	Gastroenteritis viral (10017918)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Gingivitis (10018292)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Nasopharyngitis (10028810)	69	70.4	60.3	79.2	68	69.4	59.3	78.3	73	73.7	63.9	82.1	210	71.2	65.7	76.3	67	67.7	57.5	76.7
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Oral herpes (10067152)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Otitis externa (10033072)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Otitis media (10033078)	2	2.0	0.2	7.2	4	4.1	1.1	10.1	2	2.0	0.2	7.1	8	2.7	1.2	5.3	2	2.0	0.2	7.1
	Otitis media acute (10033079)	3	3.1	0.6	8.7	3	3.1	0.6	8.7	4	4.0	1.1	10.0	10	3.4	1.6	6.1	5	5.1	1.7	11.4
	Parasitic gastroenteritis (10067720)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngitis (10034835)	22	22.4	14.6	32.0	19	19.4	12.1	28.6	22	22.2	14.5	31.7	63	21.4	16.8	26.5	21	21.2	13.6	30.6
	Pharyngitis bacterial (10057869)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngotonsillitis (10049140)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	2	2.0	0.2	7.1	6	2.0	0.7	4.4	4	4.0	1.1	10.0
	Pneumonia (10035664)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia viral (10035737)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Rhinitis (10039083)	7	7.1	2.9	14.2	2	2.0	0.2	7.2	3	3.0	0.6	8.6	12	4.1	2.1	7.0	11	11.1	5.7	19.0
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	1	1.0	0.0	5.5	4	1.4	0.4	3.4	3	3.0	0.6	8.6
	Tonsillitis (10044008)	17	17.3	10.4	26.3	13	13.3	7.3	21.6	9	9.1	4.2	16.6	39	13.2	9.6	17.6	10	10.1	5.0	17.8
	Tracheitis (10044302)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Urinary tract infection (10046571)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Varicella (10046980)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	2	2.0	0.2	7.2	1	1.0	0.0	5.5	5	1.7	0.6	3.9	0	0.0	0.0	3.7
	Viral rash (10047476)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	3	3.0	0.6	8.6	6	2.0	0.7	4.4	1	1.0	0.0	5.5
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	1	1.0	0.0	5.6	5	5.1	1.7	11.5	2	2.0	0.2	7.1	8	2.7	1.2	5.3	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Burns second degree (10006802)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Eye burns (10015911)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	3	3.1	0.6	8.7	6	6.1	2.3	12.9	6	6.1	2.3	12.7	15	5.1	2.9	8.2	5	5.1	1.7	11.4
	Limb injury (10061225)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Lip injury (10055082)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Malnutrition (10061273)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Headache (10019211)	3	3.1	0.6	8.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Seizure (10039906)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	3	3.1	0.6	8.7	4	4.1	1.1	10.1	4	4.0	1.1	10.0	11	3.7	1.9	6.6	6	6.1	2.3	12.7
	Bronchospasm (10006482)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5
	Cough (10011224)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Productive cough (10036790)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Rhinorrhoea (10039101)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	2	2.0	0.2	7.1	5	1.7	0.6	3.9	0	0.0	0.0	3.7
	Vasomotor rhinitis (10047145)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Wheezing (10047924)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	2.0	0.2	7.2	3	3.1	0.6	8.7	1	1.0	0.0	5.5	6	2.0	0.7	4.4	2	2.0	0.2	7.1
	Dermatitis allergic (10012434)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Dermatitis atopic (10012438)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	4	4.0	1.1	10.0	7	2.4	1.0	4.8	4	4.0	1.1	10.0
	Dermatitis contact (10012442)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	2	2.0	0.2	7.1	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Dermatitis diaper (10012444)	4	4.1	1.1	10.1	2	2.0	0.2	7.2	6	6.1	2.3	12.7	12	4.1	2.1	7.0	1	1.0	0.0	5.5
	Miliaria (10027627)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Prurigo (10037083)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	2	2.0	0.2	7.1	5	1.7	0.6	3.9	2	2.0	0.2	7.1
	Rash (10037844)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Rash erythematous (10037855)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Skin disorder (10040831)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Solar dermatitis (10041303)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Urticaria (10046735)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Urticaria vesiculosa (10046755)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vitiligo (10047642)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	4	4.0	1.1	10.0	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.125 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		428	69.3	65.5	72.9	432	70.6	66.8	74.2	430	69.6	65.8	73.2	1290	69.8	67.7	71.9	475	72.6	69.0	76.0
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	6	0.3	0.1	0.7	4	0.6	0.2	1.6
	Iron deficiency anaemia (10022972)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Leukocytosis (10024378)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	5	0.8	0.2	1.8
	Leukopenia (10024384)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Lymphadenitis (10025188)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lymphadenopathy (10025197)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	4	0.6	0.2	1.6
	Thrombocytopenia (10043554)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Congenital, familial and genetic disorders (10010331)	Ankyloglossia congenital (10049244)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Atrial septal defect (10003664)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cerebral palsy (10008129)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cleft uvula (10053507)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cryptorchism (10011498)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Imperforate hymen (10021529)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Microcephaly (10027534)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Phimosis (10034878)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Supernumerary nipple (10042571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Talipes (10043101)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tibial torsion (10064515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Conductive deafness (10010280)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Deafness (10011878)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Ear pain (10014020)	11	1.8	0.9	3.2	4	0.7	0.2	1.7	11	1.8	0.9	3.2	26	1.4	0.9	2.1	10	1.5	0.7	2.8
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Middle ear effusion (10062545)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Eye disorders (10015919)	Astigmatism (10003569)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Conjunctivitis allergic (10010744)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Eye swelling (10015967)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Eyelid oedema (10015993)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lid sulcus deepened (10072716)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pseudostrabismus (10072123)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Scleral haemorrhage (10050508)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Strabismus (10042159)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Abdominal distension (10000060)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Abdominal pain upper (10000087)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Anal skin tags (10002172)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Aphthous ulcer (10002959)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Chapped lips (10049047)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chronic gastritis (10008882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Colitis (10009887)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	8	1.3	0.6	2.5	8	1.3	0.6	2.6	16	2.6	1.5	4.2	32	1.7	1.2	2.4	11	1.7	0.8	3.0
	Dental caries (10012318)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Diarrhoea (10012735)	53	8.6	6.5	11.1	43	7.0	5.1	9.3	37	6.0	4.3	8.2	133	7.2	6.1	8.5	56	8.6	6.5	11.0
	Dysphagia (10013950)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Faeces discoloured (10016100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastritis (10017853)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gingival pain (10018286)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival swelling (10018291)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Haematochezia (10018836)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Inguinal hernia (10022016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lip swelling (10024570)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Melaena (10027141)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mouth cyst (10028020)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mucous stools (10028140)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral mucosal eruption (10030997)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Post-tussive vomiting (10066220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Proctitis (10036774)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	1	0.2	0.0	0.9	6	1.0	0.4	2.1	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Teething (10043183)	29	4.7	3.2	6.7	48	7.8	5.8	10.3	31	5.0	3.4	7.0	108	5.8	4.8	7.0	45	6.9	5.1	9.1
	Tooth discolouration (10044032)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Toothache (10044055)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Umbilical hernia (10045458)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Vomiting (10047700)	43	7.0	5.1	9.3	28	4.6	3.1	6.5	40	6.5	4.7	8.7	111	6.0	5.0	7.2	43	6.6	4.8	8.8
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cyst (10011732)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Developmental delay (10012559)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Discomfort (10013082)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Fatigue (10016256)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Feeling hot (10016334)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Gait disturbance (10017577)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Gait inability (10017581)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Influenza like illness (10022004)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Injection site bruising (10022052)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site erosion (10022059)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Injection site erythema (10022061)	6	1.0	0.4	2.1	6	1.0	0.4	2.1	4	0.6	0.2	1.6	16	0.9	0.5	1.4	4	0.6	0.2	1.6
	Injection site induration (10022075)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site mass (10022081)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site pain (10022086)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site papule (10066044)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Injection site rash (10022094)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Injection site swelling (10053425)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	4	0.6	0.2	1.6	12	0.6	0.3	1.1	4	0.6	0.2	1.6
	Injection site vesicles (10022111)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Mucosal inflammation (10028116)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pain (10033371)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pyrexia (10037660)	44	7.1	5.2	9.4	49	8.0	6.0	10.4	37	6.0	4.3	8.2	130	7.0	5.9	8.3	45	6.9	5.1	9.1
	Vessel puncture site bruise (10063881)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vessel puncture site haematoma (10065902)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Immune system disorders (10021428)	Allergy to animal (10001742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Drug hypersensitivity (10013700)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.6	0.2	1.6	6	0.3	0.1	0.7	6	0.9	0.3	2.0
	Food allergy (10016946)	4	0.6	0.2	1.6	5	0.8	0.3	1.9	8	1.3	0.6	2.5	17	0.9	0.5	1.5	5	0.8	0.2	1.8
	Hypersensitivity (10020751)	2	0.3	0.0	1.2	4	0.7	0.2	1.7	3	0.5	0.1	1.4	9	0.5	0.2	0.9	2	0.3	0.0	1.1
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Multiple allergies (10028164)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Seasonal allergy (10048908)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	0	0.0	0.0	0.6	8	0.4	0.2	0.9	2	0.3	0.0	1.1
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Abscess limb (10050473)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Abscess neck (10053576)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acarodermatitis (10063409)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Acute sinusitis (10001076)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	6	1.0	0.4	2.1	16	0.9	0.5	1.4	2	0.3	0.0	1.1
	Adenovirus infection (10060931)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Bronchiolitis (10006448)	15	2.4	1.4	4.0	15	2.5	1.4	4.0	11	1.8	0.9	3.2	41	2.2	1.6	3.0	18	2.8	1.6	4.3
	Bronchitis (10006451)	7	1.1	0.5	2.3	7	1.1	0.5	2.3	14	2.3	1.2	3.8	28	1.5	1.0	2.2	9	1.4	0.6	2.6
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchitis viral (10053160)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Candida infection (10074170)	7	1.1	0.5	2.3	5	0.8	0.3	1.9	3	0.5	0.1	1.4	15	0.8	0.5	1.3	8	1.2	0.5	2.4
	Candida nappy rash (10007135)	6	1.0	0.4	2.1	5	0.8	0.3	1.9	3	0.5	0.1	1.4	14	0.8	0.4	1.3	6	0.9	0.3	2.0
	Cellulitis (10007882)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	7	1.1	0.5	2.3	16	0.9	0.5	1.4	3	0.5	0.1	1.3
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	44	7.1	5.2	9.4	49	8.0	6.0	10.4	54	8.7	6.6	11.2	147	8.0	6.8	9.3	53	8.1	6.1	10.5
	Conjunctivitis bacterial (10061784)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	3	0.5	0.1	1.4	13	0.7	0.4	1.2	4	0.6	0.2	1.6
	Croup infectious (10011416)	28	4.5	3.0	6.5	37	6.0	4.3	8.2	33	5.3	3.7	7.4	98	5.3	4.3	6.4	33	5.0	3.5	7.0
	Cutaneous larva migrans (10059547)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Diarrhoea infectious (10012742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Ear infection (10014011)	14	2.3	1.2	3.8	12	2.0	1.0	3.4	6	1.0	0.4	2.1	32	1.7	1.2	2.4	15	2.3	1.3	3.8
	Eczema herpeticum (10014197)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema infected (10014199)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Enteritis infectious (10058839)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Erythema infectiosum (10015214)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Escherichia urinary tract infection (10052238)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Exanthema subitum (10015586)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	External ear cellulitis (10015729)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye infection (10015929)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Folliculitis (10016936)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	1.0	0.4	2.1	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Fungal infection (10017533)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Fungal skin infection (10017543)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	4	0.6	0.2	1.6
	Gastroenteritis (10017888)	27	4.4	2.9	6.3	28	4.6	3.1	6.5	22	3.6	2.2	5.3	77	4.2	3.3	5.2	22	3.4	2.1	5.0
	Gastroenteritis enteroviral (10017901)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	6	1.0	0.4	2.1	19	1.0	0.6	1.6	7	1.1	0.4	2.2
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hand-foot-and-mouth disease (10019113)	16	2.6	1.5	4.2	19	3.1	1.9	4.8	17	2.8	1.6	4.4	52	2.8	2.1	3.7	21	3.2	2.0	4.9
	Herpangina (10019936)	5	0.8	0.3	1.9	5	0.8	0.3	1.9	4	0.6	0.2	1.6	14	0.8	0.4	1.3	2	0.3	0.0	1.1
	Herpes dermatitis (10062639)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hordeolum (10020377)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Impetigo (10021531)	11	1.8	0.9	3.2	5	0.8	0.3	1.9	3	0.5	0.1	1.4	19	1.0	0.6	1.6	7	1.1	0.4	2.2
	Infected bite (10076911)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Influenza (10022000)	5	0.8	0.3	1.9	8	1.3	0.6	2.6	4	0.6	0.2	1.6	17	0.9	0.5	1.5	8	1.2	0.5	2.4
	Lice infestation (10024424)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.5	0.1	1.4	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Mycoplasma infection (10061300)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Nasopharyngitis (10028810)	24	3.9	2.5	5.7	30	4.9	3.3	6.9	28	4.5	3.0	6.5	82	4.4	3.5	5.5	26	4.0	2.6	5.8
	Neonatal candida infection (10028924)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Onychomycosis (10030338)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Oral herpes (10067152)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Otitis externa (10033072)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Otitis media (10033078)	111	18.0	15.0	21.2	110	18.0	15.0	21.2	98	15.9	13.1	19.0	319	17.3	15.6	19.1	133	20.3	17.3	23.6
	Otitis media acute (10033079)	20	3.2	2.0	5.0	12	2.0	1.0	3.4	23	3.7	2.4	5.5	55	3.0	2.2	3.9	26	4.0	2.6	5.8
	Otitis media chronic (10033081)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Otosalpingitis (10033102)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Parotitis (10034038)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pertussis (10034738)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pharyngitis (10034835)	29	4.7	3.2	6.7	32	5.2	3.6	7.3	28	4.5	3.0	6.5	89	4.8	3.9	5.9	28	4.3	2.9	6.1
	Pharyngitis streptococcal (10034839)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	7	1.1	0.5	2.3	15	0.8	0.5	1.3	6	0.9	0.3	2.0
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Pneumonia (10035664)	8	1.3	0.6	2.5	14	2.3	1.3	3.8	6	1.0	0.4	2.1	28	1.5	1.0	2.2	5	0.8	0.2	1.8
	Pyoderma (10037632)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Respiratory tract infection (10062352)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Rhinitis (10039083)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	8	1.3	0.6	2.5	27	1.5	1.0	2.1	11	1.7	0.8	3.0
	Roseola (10039222)	5	0.8	0.3	1.9	6	1.0	0.4	2.1	7	1.1	0.5	2.3	18	1.0	0.6	1.5	1	0.2	0.0	0.8
	Salmonellosis (10039447)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Scarlet fever (10039587)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Sinusitis (10040753)	22	3.6	2.2	5.3	10	1.6	0.8	3.0	12	1.9	1.0	3.4	44	2.4	1.7	3.2	15	2.3	1.3	3.8
	Skin candida (10054152)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	3	0.5	0.1	1.4	9	0.5	0.2	0.9	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	2	0.3	0.0	1.2	8	1.3	0.6	2.6	4	0.6	0.2	1.6	14	0.8	0.4	1.3	8	1.2	0.5	2.4
	Subcutaneous abscess (10042343)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	0	0.0	0.0	0.6	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Tinea capitis (10043866)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea cruris (10043868)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea infection (10060889)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tinea nigra (10043871)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillitis (10044008)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	10	0.5	0.3	1.0	6	0.9	0.3	2.0
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	114	18.4	15.5	21.7	131	21.4	18.2	24.9	125	20.2	17.1	23.6	370	20.0	18.2	21.9	145	22.2	19.0	25.6
	Urethritis (10046480)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Vaginal infection (10046914)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	44	7.1	5.2	9.4	32	5.2	3.6	7.3	43	7.0	5.1	9.3	119	6.4	5.4	7.7	33	5.0	3.5	7.0
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral rash (10047476)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	11	1.8	0.9	3.2	29	1.6	1.1	2.2	9	1.4	0.6	2.6
	Viral upper respiratory tract infection (10047482)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	7	1.1	0.5	2.3	17	0.9	0.5	1.5	7	1.1	0.4	2.2
	Vulvovaginitis (10047794)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Animal bite (10002515)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Animal scratch (10002519)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	5	0.8	0.3	1.9	6	1.0	0.4	2.1	10	1.6	0.8	3.0	21	1.1	0.7	1.7	7	1.1	0.4	2.2
	Burns first degree (10006797)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Burns second degree (10006802)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chemical eye injury (10055116)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Clavicle fracture (10009245)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Concussion (10010254)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Contusion (10050584)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	4	0.6	0.2	1.6	13	0.7	0.4	1.2	10	1.5	0.7	2.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Craniocerebral injury (10070976)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye contusion (10073354)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Eyelid injury (10069200)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Face injury (10050392)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Foot fracture (10016970)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in eye (10017012)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Gingival injury (10049300)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	7	1.1	0.5	2.3	26	1.4	0.9	2.1	5	0.8	0.2	1.8
	Humerus fracture (10020462)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Joint dislocation (10023204)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Joint injury (10060820)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Laceration (10023572)	8	1.3	0.6	2.5	2	0.3	0.0	1.2	10	1.6	0.8	3.0	20	1.1	0.7	1.7	9	1.4	0.6	2.6
	Ligament sprain (10024453)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Limb crushing injury (10064031)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Limb injury (10061225)	5	0.8	0.3	1.9	3	0.5	0.1	1.4	3	0.5	0.1	1.4	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Lip injury (10055082)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.8	0.3	1.9	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Mouth injury (10049294)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Nail avulsion (10028686)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Procedural pain (10064882)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	2	0.3	0.0	1.2	7	0.4	0.2	0.8	5	0.8	0.2	1.8
	Radius fracture (10037802)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Scar (10039580)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin abrasion (10064990)	0	0.0	0.0	0.6	6	1.0	0.4	2.1	1	0.2	0.0	0.9	7	0.4	0.2	0.8	3	0.5	0.1	1.3
	Splinter (10041662)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sunburn (10042496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Thermal burn (10053615)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	3	0.5	0.1	1.4	7	0.4	0.2	0.8	3	0.5	0.1	1.3
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Upper limb fracture (10061394)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Wrist fracture (10048049)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Investigations (10022891)	Blood lead increased (10005642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Blood urine present (10018870)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body height below normal (10056811)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cardiac murmur (10007586)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Cold agglutinins positive (10009854)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Dehydration (10012174)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	3	0.5	0.1	1.4	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Failure to thrive (10016165)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hypoglycaemia (10020993)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Iron deficiency (10022970)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lactose intolerance (10023681)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Overweight (10033307)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight gain poor (10047897)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foot deformity (10061159)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Limb asymmetry (10070670)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Muscular weakness (10028372)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pain in extremity (10033425)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	4	0.6	0.2	1.6	11	0.6	0.3	1.1	1	0.2	0.0	0.8
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Toe walking (10068872)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Trigger finger (10044654)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma of skin (10018823)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphangioma (10025219)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Skin papilloma (10040907)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Drooling (10013642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Febrile convulsion (10016284)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	9	0.5	0.2	0.9	4	0.6	0.2	1.6
	Gross motor delay (10069118)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Headache (10019211)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lethargy (10024264)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Loss of consciousness (10024855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Motor developmental delay (10070302)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Poor quality sleep (10062519)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Seizure (10039906)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder (10041466)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder developmental (10041467)	4	0.6	0.2	1.6	3	0.5	0.1	1.4	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Tremor (10044565)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Breath holding (10006322)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Depressed mood (10012374)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Insomnia (10022437)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Irritability (10022998)	11	1.8	0.9	3.2	9	1.5	0.7	2.8	4	0.6	0.2	1.6	24	1.3	0.8	1.9	9	1.4	0.6	2.6
	Middle insomnia (10027590)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pica (10035001)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep disorder (10040984)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Sleep terror (10041010)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	2	0.3	0.0	1.1
Renal and urinary disorders (10038359)	Dysuria (10013990)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Haematuria (10018867)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pollakiuria (10036018)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Genital labial adhesions (10064162)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Penile adhesion (10059636)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Prepuce redundant (10036624)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulval disorder (10047754)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulvovaginal discomfort (10047786)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Respiratory, thoracic and mediastinal disorders (10038738)	Adenoidal hypertrophy (10001229)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Aspiration (10003504)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Asthma (10003553)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	11	1.8	0.9	3.2	19	1.0	0.6	1.6	10	1.5	0.7	2.8
	Bronchial hyperreactivity (10066091)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	5	0.8	0.3	1.9	14	0.8	0.4	1.3	5	0.8	0.2	1.8
	Bronchospasm (10006482)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cough (10011224)	36	5.8	4.1	8.0	37	6.0	4.3	8.2	38	6.1	4.4	8.3	111	6.0	5.0	7.2	42	6.4	4.7	8.6
	Dyspnoea (10013968)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Epistaxis (10015090)	1	0.2	0.0	0.9	6	1.0	0.4	2.1	1	0.2	0.0	0.9	8	0.4	0.2	0.9	2	0.3	0.0	1.1
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	11	1.8	0.9	3.2	11	1.8	0.9	3.2	11	1.8	0.9	3.2	33	1.8	1.2	2.5	15	2.3	1.3	3.8
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Nasal obstruction (10028748)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Oropharyngeal pain (10068319)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Respiratory disorder (10038683)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	1.0	0.4	2.1	11	0.6	0.3	1.1	2	0.3	0.0	1.1
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	14	2.3	1.2	3.8	9	1.5	0.7	2.8	8	1.3	0.6	2.5	31	1.7	1.1	2.4	13	2.0	1.1	3.4
	Rhinorrhoea (10039101)	23	3.7	2.4	5.5	22	3.6	2.3	5.4	21	3.4	2.1	5.1	66	3.6	2.8	4.5	23	3.5	2.2	5.2
	Sinus congestion (10040742)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Sneezing (10041232)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Stridor (10042241)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tachypnoea (10043089)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	5	0.8	0.3	1.9	18	2.9	1.8	4.6	9	1.5	0.7	2.7	32	1.7	1.2	2.4	6	0.9	0.3	2.0
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Blister (10005191)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Dermatitis (10012431)	10	1.6	0.8	3.0	3	0.5	0.1	1.4	5	0.8	0.3	1.9	18	1.0	0.6	1.5	5	0.8	0.2	1.8
	Dermatitis allergic (10012434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Dermatitis atopic (10012438)	5	0.8	0.3	1.9	13	2.1	1.1	3.6	17	2.8	1.6	4.4	35	1.9	1.3	2.6	5	0.8	0.2	1.8
	Dermatitis contact (10012442)	3	0.5	0.1	1.4	7	1.1	0.5	2.3	4	0.6	0.2	1.6	14	0.8	0.4	1.3	3	0.5	0.1	1.3
	Dermatitis diaper (10012444)	25	4.0	2.6	5.9	23	3.8	2.4	5.6	26	4.2	2.8	6.1	74	4.0	3.2	5.0	40	6.1	4.4	8.2
	Drug eruption (10013687)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dry skin (10013786)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ecchymosis (10014080)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema (10014184)	9	1.5	0.7	2.7	5	0.8	0.3	1.9	8	1.3	0.6	2.5	22	1.2	0.7	1.8	15	2.3	1.3	3.8
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Erythema (10015150)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Erythema multiforme (10015218)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Granuloma annulare (10018692)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hair disorder (10019037)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Henoch-schonlein purpura (10019617)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Keratosis pilaris (10066295)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Lichen sclerosus (10024434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Macule (10025421)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Miliaria (10027627)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Nail disorder (10028694)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Papule (10033733)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pityriasis (10035110)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pityriasis rosea (10035114)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Rash (10037844)	18	2.9	1.7	4.6	12	2.0	1.0	3.4	12	1.9	1.0	3.4	42	2.3	1.6	3.1	11	1.7	0.8	3.0
	Rash erythematous (10037855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash generalised (10037858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash macular (10037867)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash maculo-papular (10037868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash papular (10037876)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash scarlatiniform (10037890)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seborrhoea (10039792)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Seborrhoeic dermatitis (10039793)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Skin fissures (10040849)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Skin hypopigmentation (10040868)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Skin lesion (10040882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin mass (10067868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Skin warm (10040952)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Swelling face (10042682)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Urticaria (10046735)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	3	0.5	0.1	1.4	16	0.9	0.5	1.4	4	0.6	0.2	1.6
Surgical and medical procedures (10042613)	Myringotomy (10028662)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pallor (10033546)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.126 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	0.8	0.0	4.4	2	1.6	0.2	5.7	1	0.8	0.0	4.4	4	1.1	0.3	2.7	5	3.9	1.3	8.9
Gastrointestinal disorders (10017947)	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Enterovirus infection (10014909)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pneumonia (10035664)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral infection (10047461)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Injury, poisoning and procedural complications (10022117)	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Concussion (10010254)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.127 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		25	41.0	28.6	54.3	21	33.9	22.3	47.0	29	45.3	32.8	58.3	75	40.1	33.0	47.5	25	36.2	25.0	48.7
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Colitis (10009887)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Constipation (10010774)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Diarrhoea (10012735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	3	4.3	0.9	12.2
	Oral contusion (10078170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Teething (10043183)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Vomiting (10047700)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	0	0.0	0.0	5.2
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchiolitis (10006448)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Bronchitis (10006451)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	2	3.1	0.4	10.8	7	3.7	1.5	7.6	1	1.4	0.0	7.8
	Burn infection (10051548)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Cellulitis orbital (10007918)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Conjunctivitis (10010741)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	2	3.1	0.4	10.8	6	3.2	1.2	6.9	1	1.4	0.0	7.8
	Coxsackie viral infection (10011261)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Ear infection (10014011)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Gastroenteritis (10017888)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	4	6.3	1.7	15.2	8	4.3	1.9	8.3	4	5.8	1.6	14.2
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Hand-foot-and-mouth disease (10019113)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Herpangina (10019936)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Impetigo (10021531)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Laryngitis (10023874)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	2	3.1	0.4	10.8	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Nasopharyngitis (10028810)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	2	2.9	0.4	10.1
	Oral herpes (10067152)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Otitis media (10033078)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Otitis media acute (10033079)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	2	3.1	0.4	10.8	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Pharyngitis (10034835)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	0	0.0	0.0	5.6	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Pharyngotonsillitis (10049140)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Pneumonia (10035664)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Respiratory tract infection (10062352)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Tonsillitis (10044008)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	3	4.7	1.0	13.1	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Upper respiratory tract infection (10046306)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	1	1.6	0.0	8.4	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Viral diarrhoea (10051511)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Viral infection (10047461)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	2	3.1	0.4	10.8	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Contusion (10050584)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	3	4.3	0.9	12.2
	Head injury (10019196)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Lip injury (10055082)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Poisoning (10061355)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Wound (10052428)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Reproductive system and breast disorders (10038604)	Perineal cyst (10066058)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchospasm (10006482)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	3	4.7	1.0	13.1	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Catarrh (10007774)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cough (10011224)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Miliaria (10027627)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rash (10037844)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	3	4.7	1.0	13.1	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Urticaria (10046735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	2	2.9	0.4	10.1
Vascular disorders (10047065)	Haematoma (10018852)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.128 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		27	8.0	5.3	11.4	23	6.9	4.4	10.1	23	6.8	4.4	10.1	73	7.2	5.7	9.0	26	7.6	5.1	11.0
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Teething (10043183)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Pyrexia (10037660)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	3	0.9	0.2	2.6
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Hypersensitivity (10020751)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	3	0.9	0.2	2.6	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Conjunctivitis (10010741)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Ear infection (10014011)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Exanthema subitum (10015586)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Gastroenteritis (10017888)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Influenza (10022000)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laryngitis (10023874)	2	0.6	0.1	2.1	3	0.9	0.2	2.6	2	0.6	0.1	2.1	7	0.7	0.3	1.4	1	0.3	0.0	1.6
	Otitis media (10033078)	6	1.8	0.7	3.8	13	3.9	2.1	6.5	9	2.7	1.2	5.0	28	2.8	1.8	4.0	5	1.5	0.5	3.4
	Pneumonia (10035664)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pyelonephritis (10037596)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinitis (10039083)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Tonsillitis (10044008)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Upper respiratory tract infection (10046306)	7	2.1	0.8	4.2	5	1.5	0.5	3.4	4	1.2	0.3	3.0	16	1.6	0.9	2.6	7	2.1	0.8	4.2
	Urinary tract infection (10046571)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Eye injury (10061128)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Radial head dislocation (10073749)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Skin and subcutaneous tissue disorders (10040785)	Skin burning sensation (10054786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.129 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	1.0	0.0	5.6	5	5.1	1.7	11.5	5	5.1	1.7	11.4	11	3.7	1.9	6.6	0	0.0	0.0	3.7
Infections and infestations (10021881)	Gastroenteritis (10017888)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Nasopharyngitis (10028810)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Otitis media acute (10033079)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Injury, poisoning and procedural complications (10022117)	Head injury (10019196)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	2.0	0.2	7.1	2	0.7	0.1	2.4	0	0.0	0.0	3.7
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Urticaria vesiculosa (10046755)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.130 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		69	11.2	8.8	13.9	65	10.6	8.3	13.3	78	12.6	10.1	15.5	212	11.5	10.1	13.0	78	11.9	9.5	14.7
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Diarrhoea (10012735)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	8	0.4	0.2	0.9	7	1.1	0.4	2.2
	Gastritis (10017853)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Stomatitis (10042128)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Teething (10043183)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Vomiting (10047700)	6	1.0	0.4	2.1	2	0.3	0.0	1.2	4	0.6	0.2	1.6	12	0.6	0.3	1.1	9	1.4	0.6	2.6
General disorders and administration site conditions (10018065)	Gait disturbance (10017577)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyrexia (10037660)	11	1.8	0.9	3.2	5	0.8	0.3	1.9	6	1.0	0.4	2.1	22	1.2	0.7	1.8	12	1.8	1.0	3.2
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Food allergy (10016946)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Hypersensitivity (10020751)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Seasonal allergy (10048908)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abscess neck (10053576)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Bronchitis (10006451)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Candida infection (10074170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Candida nappy rash (10007135)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cellulitis (10007882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Conjunctivitis (10010741)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Croup infectious (10011416)	3	0.5	0.1	1.4	12	2.0	1.0	3.4	5	0.8	0.3	1.9	20	1.1	0.7	1.7	8	1.2	0.5	2.4
	Ear infection (10014011)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Fungal skin infection (10017543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis (10017888)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	5	0.8	0.2	1.8
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand-foot-and-mouth disease (10019113)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Herpangina (10019936)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Impetigo (10021531)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Influenza (10022000)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasopharyngitis (10028810)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Otitis externa (10033072)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Otitis media (10033078)	11	1.8	0.9	3.2	8	1.3	0.6	2.6	12	1.9	1.0	3.4	31	1.7	1.1	2.4	13	2.0	1.1	3.4
	Otitis media acute (10033079)	2	0.3	0.0	1.2	4	0.7	0.2	1.7	1	0.2	0.0	0.9	7	0.4	0.2	0.8	3	0.5	0.1	1.3
	Pharyngitis (10034835)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.6	0.2	1.6	8	0.4	0.2	0.9	2	0.3	0.0	1.1
	Pharyngitis streptococcal (10034839)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pneumonia (10035664)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	3	0.5	0.1	1.4	7	0.4	0.2	0.8	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinitis (10039083)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Scarlet fever (10039587)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Sinusitis (10040753)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Skin candida (10054152)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Streptococcal infection (10061372)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Upper respiratory tract infection (10046306)	5	0.8	0.3	1.9	8	1.3	0.6	2.6	8	1.3	0.6	2.5	21	1.1	0.7	1.7	8	1.2	0.5	2.4
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral infection (10047461)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.6	0.2	1.6	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Viral rash (10047476)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	2	0.3	0.0	1.2	6	0.3	0.1	0.7	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral upper respiratory tract infection (10047482)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	3	0.5	0.1	1.4	7	0.4	0.2	0.8	2	0.3	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Animal bite (10002515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Chemical eye injury (10055116)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Clavicle fracture (10009245)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Concussion (10010254)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Contusion (10050584)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Craniocerebral injury (10070976)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Eyelid injury (10069200)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Foreign body in eye (10017012)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	2	0.3	0.0	1.2	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Humerus fracture (10020462)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Joint dislocation (10023204)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Laceration (10023572)	7	1.1	0.5	2.3	2	0.3	0.0	1.2	7	1.1	0.5	2.3	16	0.9	0.5	1.4	3	0.5	0.1	1.3
	Limb injury (10061225)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Lip injury (10055082)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Mouth injury (10049294)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Skin abrasion (10064990)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Thermal burn (10053615)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	3	0.5	0.1	1.3
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Pyogenic granuloma (10037649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Nervous system disorders (10029205)	Febrile convulsion (10016284)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	7	0.4	0.2	0.8	0	0.0	0.0	0.6
	Seizure (10039906)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tremor (10044565)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Breath holding (10006322)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Irritability (10022998)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Renal and urinary disorders (10038359)	Pollakiuria (10036018)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Aspiration (10003504)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Asthma (10003553)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchospasm (10006482)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cough (10011224)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Dyspnoea (10013968)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis allergic (10039085)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinorrhoea (10039101)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stridor (10042241)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dermatitis contact (10012442)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pityriasis (10035110)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rash (10037844)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Rash generalised (10037858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash scarlatiniform (10037890)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urticaria (10046735)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.131 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		46	37.1	28.6	46.2	47	37.6	29.1	46.7	44	35.2	26.9	44.2	137	36.6	31.7	41.7	46	36.2	27.9	45.2
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Auricular swelling (10003800)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear pain (10014020)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Diarrhoea (10012735)	2	1.6	0.2	5.7	5	4.0	1.3	9.1	2	1.6	0.2	5.7	9	2.4	1.1	4.5	0	0.0	0.0	2.9
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Stomatitis (10042128)	0	0.0	0.0	2.9	4	3.2	0.9	8.0	1	0.8	0.0	4.4	5	1.3	0.4	3.1	0	0.0	0.0	2.9
	Teething (10043183)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyrexia (10037660)	4	3.2	0.9	8.1	6	4.8	1.8	10.2	2	1.6	0.2	5.7	12	3.2	1.7	5.5	1	0.8	0.0	4.3
Immune system disorders (10021428)	Food allergy (10016946)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	1	0.8	0.0	4.4	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Infections and infestations (10021881)	Bronchitis (10006451)	4	3.2	0.9	8.1	4	3.2	0.9	8.0	4	3.2	0.9	8.0	12	3.2	1.7	5.5	5	3.9	1.3	8.9
	Ear infection (10014011)	6	4.8	1.8	10.2	12	9.6	5.1	16.2	8	6.4	2.8	12.2	26	7.0	4.6	10.0	11	8.7	4.4	15.0
	Enterovirus infection (10014909)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6
	Exanthema subitum (10015586)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	1	0.8	0.0	4.4	4	1.1	0.3	2.7	3	2.4	0.5	6.7
	Fungal skin infection (10017543)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gastroenteritis rotavirus (10017913)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Impetigo (10021531)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	2	1.6	0.2	5.7	5	1.3	0.4	3.1	2	1.6	0.2	5.6
	Nasopharyngitis (10028810)	1	0.8	0.0	4.4	4	3.2	0.9	8.0	0	0.0	0.0	2.9	5	1.3	0.4	3.1	2	1.6	0.2	5.6
	Neutropenic infection (10059482)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	2	1.6	0.2	5.7	1	0.8	0.0	4.4	4	3.2	0.9	8.0	7	1.9	0.8	3.8	4	3.1	0.9	7.9
	Otitis media acute (10033079)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	7	1.9	0.8	3.8	2	1.6	0.2	5.6
	Pneumonia (10035664)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyelonephritis acute (10037597)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Respiratory tract infection (10062352)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Respiratory tract infection viral (10062106)	4	3.2	0.9	8.1	0	0.0	0.0	2.9	0	0.0	0.0	2.9	4	1.1	0.3	2.7	4	3.1	0.9	7.9
	Rhinitis (10039083)	5	4.0	1.3	9.2	6	4.8	1.8	10.2	4	3.2	0.9	8.0	15	4.0	2.3	6.5	7	5.5	2.2	11.0
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	2	1.6	0.2	5.6
	Tracheitis (10044302)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	5	4.0	1.3	9.2	4	3.2	0.9	8.0	4	3.2	0.9	8.0	13	3.5	1.9	5.9	0	0.0	0.0	2.9
	Urinary tract infection (10046571)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Varicella (10046980)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	2	1.6	0.2	5.6
	Viral infection (10047461)	6	4.8	1.8	10.2	7	5.6	2.3	11.2	6	4.8	1.8	10.2	19	5.1	3.1	7.8	6	4.7	1.8	10.0
	Viral pharyngitis (10047473)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral rash (10047476)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Burns second degree (10006802)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Concussion (10010254)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Head injury (10019196)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Cough (10011224)	11	8.9	4.5	15.3	9	7.2	3.3	13.2	7	5.6	2.3	11.2	27	7.2	4.8	10.3	4	3.1	0.9	7.9
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Dermatitis allergic (10012434)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	3	2.4	0.5	6.9	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Dermatitis atopic (10012438)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rash (10037844)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	1.6	0.2	5.7	3	0.8	0.2	2.3	2	1.6	0.2	5.6
	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.132 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		55	90.2	79.8	96.3	56	90.3	80.1	96.4	59	92.2	82.7	97.4	170	90.9	85.8	94.6	64	92.8	83.9	97.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	3	4.7	1.0	13.1	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Iron deficiency anaemia (10022972)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lymphadenitis (10025188)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Congenital, familial and genetic disorders (10010331)	Talipes (10043101)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eye discharge (10015915)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Eyelid oedema (10015993)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Lacrimation increased (10023644)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Anal fissure (10002153)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Aphthous ulcer (10002959)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Colitis (10009887)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Constipation (10010774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Diarrhoea (10012735)	14	23.0	13.2	35.5	9	14.5	6.9	25.8	11	17.2	8.9	28.7	34	18.2	12.9	24.5	19	27.5	17.5	39.6
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Inguinal hernia (10022016)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral contusion (10078170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral disorder (10067621)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Stomatitis (10042128)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Teething (10043183)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	3	4.7	1.0	13.1	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Toothache (10044055)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Vomiting (10047700)	4	6.6	1.8	15.9	6	9.7	3.6	19.9	5	7.8	2.6	17.3	15	8.0	4.6	12.9	5	7.2	2.4	16.1
General disorders and administration site conditions (10018065)	Asthenia (10003549)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pain (10033371)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pyrexia (10037660)	6	9.8	3.7	20.2	1	1.6	0.0	8.7	2	3.1	0.4	10.8	9	4.8	2.2	8.9	4	5.8	1.6	14.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Selective iga immunodeficiency (10039915)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Adenoiditis (10051223)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Bronchiolitis (10006448)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	1	1.6	0.0	8.4	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Bronchitis (10006451)	8	13.1	5.8	24.2	9	14.5	6.9	25.8	12	18.8	10.1	30.5	29	15.5	10.6	21.5	10	14.5	7.2	25.0
	Burn infection (10051548)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Candida infection (10074170)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	4	5.8	1.6	14.2
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cellulitis (10007882)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Cellulitis orbital (10007918)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Conjunctivitis (10010741)	8	13.1	5.8	24.2	11	17.7	9.2	29.5	14	21.9	12.5	34.0	33	17.6	12.5	23.9	14	20.3	11.6	31.7
	Coxsackie viral infection (10011261)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	3	4.7	1.0	13.1	7	3.7	1.5	7.6	0	0.0	0.0	5.2
	Cystitis (10011781)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Ear infection (10014011)	5	8.2	2.7	18.1	7	11.3	4.7	21.9	3	4.7	1.0	13.1	15	8.0	4.6	12.9	4	5.8	1.6	14.2
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Erythema infectiosum (10015214)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	15	24.6	14.5	37.3	11	17.7	9.2	29.5	11	17.2	8.9	28.7	37	19.8	14.3	26.2	13	18.8	10.4	30.1
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Hand-foot-and-mouth disease (10019113)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Herpangina (10019936)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	3	4.7	1.0	13.1	8	4.3	1.9	8.3	3	4.3	0.9	12.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Herpes simplex (10019948)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Hordeolum (10020377)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Impetigo (10021531)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Laryngitis (10023874)	6	9.8	3.7	20.2	6	9.7	3.6	19.9	6	9.4	3.5	19.3	18	9.6	5.8	14.8	9	13.0	6.1	23.3
	Nasopharyngitis (10028810)	24	39.3	27.1	52.7	17	27.4	16.9	40.2	20	31.3	20.2	44.1	61	32.6	26.0	39.8	24	34.8	23.7	47.2
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Oral herpes (10067152)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Otitis externa (10033072)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Otitis media (10033078)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	4	6.3	1.7	15.2	9	4.8	2.2	8.9	5	7.2	2.4	16.1
	Otitis media acute (10033079)	6	9.8	3.7	20.2	3	4.8	1.0	13.5	11	17.2	8.9	28.7	20	10.7	6.7	16.0	8	11.6	5.1	21.6
	Pharyngitis (10034835)	12	19.7	10.6	31.8	15	24.2	14.2	36.7	10	15.6	7.8	26.9	37	19.8	14.3	26.2	14	20.3	11.6	31.7
	Pharyngotonsillitis (10049140)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Pneumonia (10035664)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Respiratory tract infection (10062352)	9	14.8	7.0	26.2	12	19.4	10.4	31.4	7	10.9	4.5	21.2	28	15.0	10.2	20.9	13	18.8	10.4	30.1
	Rhinitis (10039083)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	1	1.6	0.0	8.4	4	2.1	0.6	5.4	2	2.9	0.4	10.1
	Rotavirus infection (10067470)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Tonsillitis (10044008)	15	24.6	14.5	37.3	12	19.4	10.4	31.4	16	25.0	15.0	37.4	43	23.0	17.2	29.7	21	30.4	19.9	42.7
	Upper respiratory tract infection (10046306)	7	11.5	4.7	22.2	5	8.1	2.7	17.8	10	15.6	7.8	26.9	22	11.8	7.5	17.3	10	14.5	7.2	25.0
	Viral diarrhoea (10051511)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Viral infection (10047461)	4	6.6	1.8	15.9	9	14.5	6.9	25.8	5	7.8	2.6	17.3	18	9.6	5.8	14.8	8	11.6	5.1	21.6
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1
	Viral rash (10047476)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	1	1.6	0.0	8.4	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	6	9.4	3.5	19.3	14	7.5	4.2	12.2	4	5.8	1.6	14.2
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	4	6.6	1.8	15.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Eyelid injury (10069200)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Fall (10016173)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Head injury (10019196)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Injury (10022116)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lip injury (10055082)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Poisoning (10061355)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Skull fracture (10061365)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Wound (10052428)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	1	1.6	0.0	8.4	4	2.1	0.6	5.4	0	0.0	0.0	5.2
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cardiac murmur functional (10007587)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Iron deficiency (10022970)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	0	0.0	0.0	5.6	4	2.1	0.6	5.4	1	1.4	0.0	7.8
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Synovitis (10042868)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Mycosis fungoides (10028483)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Balanoposthitis (10004078)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Oedema genital (10030104)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Perineal cyst (10066058)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchitis chronic (10006458)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchospasm (10006482)	3	4.9	1.0	13.7	6	9.7	3.6	19.9	6	9.4	3.5	19.3	15	8.0	4.6	12.9	6	8.7	3.3	18.0

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Catarrh (10007774)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	1	1.6	0.0	8.4	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Cough (10011224)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Epistaxis (10015090)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Increased bronchial secretion (10062530)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Nasal congestion (10028735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	3	4.3	0.9	12.2
	Dermatitis atopic (10012438)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	5	7.8	2.6	17.3	9	4.8	2.2	8.9	4	5.8	1.6	14.2
	Dermatitis contact (10012442)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	3	4.7	1.0	13.1	11	5.9	3.0	10.3	6	8.7	3.3	18.0
	Dyshidrotic eczema (10013913)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	5	7.2	2.4	16.1
	Lichen striatus (10066945)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Miliaria (10027627)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	1	1.6	0.0	8.4	5	2.7	0.9	6.1	2	2.9	0.4	10.1
	Onychomalacia (10058673)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Rash (10037844)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	7	10.9	4.5	21.2	13	7.0	3.8	11.6	2	2.9	0.4	10.1
	Seborrhoeic dermatitis (10039793)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Urticaria (10046735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	3	4.7	1.0	13.1	4	2.1	0.6	5.4	4	5.8	1.6	14.2
Vascular disorders (10047065)	Haematoma (10018852)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.133 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		187	55.3	49.9	60.7	177	52.8	47.3	58.3	159	47.2	41.7	52.7	523	51.8	48.6	54.9	170	50.0	44.6	55.4
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Endocrine disorders (10014698)	Hypothyroidism (10021114)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Blepharitis (10005148)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye swelling (10015967)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Panophthalmitis (10033683)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Coeliac disease (10009839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Diarrhoea (10012735)	2	0.6	0.1	2.1	4	1.2	0.3	3.0	4	1.2	0.3	3.0	10	1.0	0.5	1.8	3	0.9	0.2	2.6
	Gastrooesophageal reflux disease (10017885)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Stomatitis (10042128)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Teething (10043183)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Tongue ulceration (10043991)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Vomiting (10047700)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Developmental delay (10012559)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fatigue (10016256)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gait disturbance (10017577)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ill-defined disorder (10061520)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza like illness (10022004)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Injection site erythema (10022061)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Pyrexia (10037660)	6	1.8	0.7	3.8	8	2.4	1.0	4.7	3	0.9	0.2	2.6	17	1.7	1.0	2.7	8	2.4	1.0	4.6
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Drug hypersensitivity (10013700)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Hypersensitivity (10020751)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Milk allergy (10027633)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Seasonal allergy (10048908)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Adenovirus infection (10060931)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Borrelia infection (10061591)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Bronchiolitis (10006448)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	1	0.3	0.0	1.6	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Bronchitis (10006451)	11	3.3	1.6	5.7	15	4.5	2.5	7.3	13	3.9	2.1	6.5	39	3.9	2.8	5.2	18	5.3	3.2	8.2
	Conjunctivitis (10010741)	21	6.2	3.9	9.3	25	7.5	4.9	10.8	19	5.6	3.4	8.7	65	6.4	5.0	8.1	22	6.5	4.1	9.6
	Ear infection (10014011)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	1	0.3	0.0	1.6	8	0.8	0.3	1.6	4	1.2	0.3	3.0
	Enterovirus infection (10014909)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	7	0.7	0.3	1.4	3	0.9	0.2	2.6
	Exanthema subitum (10015586)	5	1.5	0.5	3.4	6	1.8	0.7	3.9	3	0.9	0.2	2.6	14	1.4	0.8	2.3	5	1.5	0.5	3.4
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fungal skin infection (10017543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Gastroenteritis (10017888)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	2	0.6	0.1	2.1	8	0.8	0.3	1.6	2	0.6	0.1	2.1
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gingivitis (10018292)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	2	0.6	0.1	2.1	5	1.5	0.5	3.4	3	0.9	0.2	2.6	10	1.0	0.5	1.8	2	0.6	0.1	2.1
	Herpes zoster (10019974)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Impetigo (10021531)	2	0.6	0.1	2.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	0	0.0	0.0	1.1	4	0.4	0.1	1.0	2	0.6	0.1	2.1
	Laryngitis (10023874)	8	2.4	1.0	4.6	12	3.6	1.9	6.2	12	3.6	1.9	6.1	32	3.2	2.2	4.4	5	1.5	0.5	3.4

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Localised infection (10024774)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Lyme disease (10025169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Molluscum contagiosum (10027807)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nasopharyngitis (10028810)	6	1.8	0.7	3.8	4	1.2	0.3	3.0	7	2.1	0.8	4.2	17	1.7	1.0	2.7	4	1.2	0.3	3.0
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	98	29.0	24.2	34.1	105	31.3	26.4	36.6	87	25.8	21.2	30.8	290	28.7	25.9	31.6	104	30.6	25.7	35.8
	Otitis media acute (10033079)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Pharyngitis (10034835)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	3	0.9	0.2	2.6	7	0.7	0.3	1.4	3	0.9	0.2	2.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	3	0.9	0.2	2.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	8	0.8	0.3	1.6	2	0.6	0.1	2.1
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pyelonephritis (10037596)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus infection (10061603)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	7	2.1	0.8	4.2	13	1.3	0.7	2.2	1	0.3	0.0	1.6
	Respiratory tract infection viral (10062106)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinitis (10039083)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	3	0.9	0.2	2.6	10	1.0	0.5	1.8	3	0.9	0.2	2.6
	Roseola (10039222)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin infection (10040872)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tonsillitis (10044008)	6	1.8	0.7	3.8	3	0.9	0.2	2.6	2	0.6	0.1	2.1	11	1.1	0.5	1.9	3	0.9	0.2	2.6
	Upper respiratory tract infection (10046306)	46	13.6	10.1	17.7	40	11.9	8.7	15.9	44	13.1	9.6	17.1	130	12.9	10.9	15.1	32	9.4	6.5	13.0
	Urinary tract infection (10046571)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	3	0.9	0.2	2.6
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	5	0.5	0.2	1.2	2	0.6	0.1	2.1
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye injury (10061128)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Ligament sprain (10024453)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Post vaccination syndrome (10036242)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Radial head dislocation (10073749)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin wound (10072170)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Splinter (10041662)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Wound (10052428)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Investigations (10022891)	Cardiac murmur (10007586)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Metabolism and nutrition disorders (10027433)	Hypoglycaemia (10020993)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Overweight (10033307)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Skin papilloma (10040907)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Irritability (10022998)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Testicular retraction (10043348)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Apnoea (10002974)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Bronchitis chronic (10006458)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Cough (10011224)	6	1.8	0.7	3.8	4	1.2	0.3	3.0	5	1.5	0.5	3.4	15	1.5	0.8	2.4	14	4.1	2.3	6.8
	Dyspnoea (10013968)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	3	0.9	0.2	2.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Dermatitis atopic (10012438)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	7	0.7	0.3	1.4	4	1.2	0.3	3.0
	Dermatitis diaper (10012444)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dry skin (10013786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eczema (10014184)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash (10037844)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash macular (10037867)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rash papular (10037876)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash vesicular (10037898)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin burning sensation (10054786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Urticaria (10046735)	5	1.5	0.5	3.4	1	0.3	0.0	1.7	0	0.0	0.0	1.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.134 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		83	84.7	76.0	91.2	89	90.8	83.3	95.7	91	91.9	84.7	96.4	263	89.2	85.0	92.5	86	86.9	78.6	92.8
Cardiac disorders (10007541)	Supraventricular extrasystoles (10042602)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Congenital, familial and genetic disorders (10010331)	Congenital cardiovascular anomaly (10061054)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Eye disorders (10015919)	Blepharitis (10005148)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	2.0	0.2	7.1	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Entropion (10061842)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Colitis (10009887)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Constipation (10010774)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Diarrhoea (10012735)	12	12.2	6.5	20.4	7	7.1	2.9	14.2	11	11.1	5.7	19.0	30	10.2	7.0	14.2	5	5.1	1.7	11.4
	Dyspepsia (10013946)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Gastritis (10017853)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Tongue ulceration (10043991)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	2	2.0	0.2	7.1
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	4	4.1	1.1	10.1	1	1.0	0.0	5.6	1	1.0	0.0	5.5	6	2.0	0.7	4.4	3	3.0	0.6	8.6
Immune system disorders (10021428)	Allergy to animal (10001742)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Drug hypersensitivity (10013700)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Milk allergy (10027633)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Infections and infestations (10021881)	Bronchiolitis (10006448)	4	4.1	1.1	10.1	9	9.2	4.3	16.7	6	6.1	2.3	12.7	19	6.4	3.9	9.9	5	5.1	1.7	11.4
	Bronchitis (10006451)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Candida nappy rash (10007135)	5	5.1	1.7	11.5	2	2.0	0.2	7.2	1	1.0	0.0	5.5	8	2.7	1.2	5.3	3	3.0	0.6	8.6

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Conjunctivitis (10010741)	5	5.1	1.7	11.5	6	6.1	2.3	12.9	4	4.0	1.1	10.0	15	5.1	2.9	8.2	8	8.1	3.6	15.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cutaneous larva migrans (10059547)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Ear infection (10014011)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	22	22.4	14.6	32.0	20	20.4	12.9	29.7	28	28.3	19.7	38.2	70	23.7	19.0	29.0	22	22.2	14.5	31.7
	Gastroenteritis viral (10017918)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Gingivitis (10018292)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Nasopharyngitis (10028810)	65	66.3	56.1	75.6	67	68.4	58.2	77.4	72	72.7	62.9	81.2	204	69.2	63.5	74.4	64	64.6	54.4	74.0
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Oral herpes (10067152)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Otitis externa (10033072)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Otitis media (10033078)	2	2.0	0.2	7.2	4	4.1	1.1	10.1	2	2.0	0.2	7.1	8	2.7	1.2	5.3	2	2.0	0.2	7.1
	Otitis media acute (10033079)	3	3.1	0.6	8.7	3	3.1	0.6	8.7	4	4.0	1.1	10.0	10	3.4	1.6	6.1	5	5.1	1.7	11.4
	Parasitic gastroenteritis (10067720)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngitis (10034835)	22	22.4	14.6	32.0	19	19.4	12.1	28.6	22	22.2	14.5	31.7	63	21.4	16.8	26.5	21	21.2	13.6	30.6
	Pharyngitis bacterial (10057869)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngotonsillitis (10049140)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	2	2.0	0.2	7.1	6	2.0	0.7	4.4	4	4.0	1.1	10.0
	Pneumonia (10035664)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia viral (10035737)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Rhinitis (10039083)	7	7.1	2.9	14.2	1	1.0	0.0	5.6	3	3.0	0.6	8.6	11	3.7	1.9	6.6	11	11.1	5.7	19.0
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	1	1.0	0.0	5.5	4	1.4	0.4	3.4	3	3.0	0.6	8.6
	Tonsillitis (10044008)	17	17.3	10.4	26.3	13	13.3	7.3	21.6	9	9.1	4.2	16.6	39	13.2	9.6	17.6	10	10.1	5.0	17.8
	Tracheitis (10044302)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Urinary tract infection (10046571)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Varicella (10046980)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	2	2.0	0.2	7.2	1	1.0	0.0	5.5	5	1.7	0.6	3.9	0	0.0	0.0	3.7
	Viral rash (10047476)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	3	3.0	0.6	8.6	6	2.0	0.7	4.4	1	1.0	0.0	5.5
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	1	1.0	0.0	5.6	5	5.1	1.7	11.5	2	2.0	0.2	7.1	8	2.7	1.2	5.3	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Burns second degree (10006802)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Eye burns (10015911)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	2	2.0	0.2	7.2	6	6.1	2.3	12.9	5	5.1	1.7	11.4	13	4.4	2.4	7.4	5	5.1	1.7	11.4
	Limb injury (10061225)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Lip injury (10055082)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Malnutrition (10061273)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Seizure (10039906)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	3	3.1	0.6	8.7	4	4.1	1.1	10.1	4	4.0	1.1	10.0	11	3.7	1.9	6.6	6	6.1	2.3	12.7
	Bronchospasm (10006482)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5
	Cough (10011224)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5
	Productive cough (10036790)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Rhinorrhoea (10039101)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vasomotor rhinitis (10047145)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Wheezing (10047924)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	2.0	0.2	7.2	3	3.1	0.6	8.7	1	1.0	0.0	5.5	6	2.0	0.7	4.4	2	2.0	0.2	7.1
	Dermatitis allergic (10012434)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Dermatitis atopic (10012438)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	4	4.0	1.1	10.0	7	2.4	1.0	4.8	4	4.0	1.1	10.0
	Dermatitis contact (10012442)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	2	2.0	0.2	7.1	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Dermatitis diaper (10012444)	4	4.1	1.1	10.1	2	2.0	0.2	7.2	6	6.1	2.3	12.7	12	4.1	2.1	7.0	1	1.0	0.0	5.5
	Miliaria (10027627)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Prurigo (10037083)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	2	2.0	0.2	7.1	5	1.7	0.6	3.9	2	2.0	0.2	7.1
	Rash (10037844)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Rash erythematous (10037855)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Skin disorder (10040831)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Urticaria (10046735)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Urticaria vesiculosa (10046755)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vitiligo (10047642)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	4	4.0	1.1	10.0	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.135 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		372	60.2	56.2	64.1	367	60.0	56.0	63.9	374	60.5	56.5	64.4	1113	60.2	58.0	62.5	413	63.1	59.3	66.9
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	4	0.6	0.2	1.6	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Iron deficiency anaemia (10022972)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Leukocytosis (10024378)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	5	0.8	0.2	1.8
	Leukopenia (10024384)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Lymphadenopathy (10025197)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Thrombocytopenia (10043554)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Congenital, familial and genetic disorders (10010331)	Ankyloglossia congenital (10049244)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Atrial septal defect (10003664)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cerebral palsy (10008129)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cleft uvula (10053507)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cryptorchism (10011498)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Imperforate hymen (10021529)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Microcephaly (10027534)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Phimosis (10034878)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Supernumerary nipple (10042571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Talipes (10043101)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tibial torsion (10064515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Conductive deafness (10010280)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Deafness (10011878)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Ear pain (10014020)	10	1.6	0.8	3.0	3	0.5	0.1	1.4	11	1.8	0.9	3.2	24	1.3	0.8	1.9	9	1.4	0.6	2.6
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Middle ear effusion (10062545)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Eye disorders (10015919)	Astigmatism (10003569)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Conjunctivitis allergic (10010744)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Eye swelling (10015967)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eyelid oedema (10015993)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pseudostrabismus (10072123)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Scleral haemorrhage (10050508)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Strabismus (10042159)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abdominal distension (10000060)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Anal skin tags (10002172)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Aphthous ulcer (10002959)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Chapped lips (10049047)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chronic gastritis (10008882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Colitis (10009887)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	7	1.1	0.5	2.3	6	1.0	0.4	2.1	14	2.3	1.2	3.8	27	1.5	1.0	2.1	9	1.4	0.6	2.6
	Dental caries (10012318)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Diarrhoea (10012735)	29	4.7	3.2	6.7	20	3.3	2.0	5.0	23	3.7	2.4	5.5	72	3.9	3.1	4.9	35	5.4	3.8	7.4
	Dysphagia (10013950)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Gastritis (10017853)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gingival swelling (10018291)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Haematochezia (10018836)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Inguinal hernia (10022016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Melaena (10027141)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mouth cyst (10028020)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mucous stools (10028140)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Proctitis (10036774)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	1	0.2	0.0	0.9	6	1.0	0.4	2.1	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Teething (10043183)	8	1.3	0.6	2.5	14	2.3	1.3	3.8	10	1.6	0.8	3.0	32	1.7	1.2	2.4	8	1.2	0.5	2.4
	Tooth discolouration (10044032)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Umbilical hernia (10045458)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Vomiting (10047700)	23	3.7	2.4	5.5	11	1.8	0.9	3.2	15	2.4	1.4	4.0	49	2.7	2.0	3.5	21	3.2	2.0	4.9
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Developmental delay (10012559)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Feeling hot (10016334)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gait disturbance (10017577)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Gait inability (10017581)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Influenza like illness (10022004)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Injection site erythema (10022061)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site rash (10022094)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site swelling (10053425)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mucosal inflammation (10028116)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pain (10033371)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyrexia (10037660)	35	5.7	4.0	7.8	38	6.2	4.4	8.4	33	5.3	3.7	7.4	106	5.7	4.7	6.9	36	5.5	3.9	7.5
Immune system disorders (10021428)	Allergy to animal (10001742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Drug hypersensitivity (10013700)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.6	0.2	1.6	6	0.3	0.1	0.7	6	0.9	0.3	2.0

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Food allergy (10016946)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	6	1.0	0.4	2.1	14	0.8	0.4	1.3	5	0.8	0.2	1.8
	Hypersensitivity (10020751)	1	0.2	0.0	0.9	4	0.7	0.2	1.7	3	0.5	0.1	1.4	8	0.4	0.2	0.9	1	0.2	0.0	0.8
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Multiple allergies (10028164)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Seasonal allergy (10048908)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Abscess limb (10050473)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Abscess neck (10053576)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acarodermatitis (10063409)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Acute sinusitis (10001076)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	6	1.0	0.4	2.1	16	0.9	0.5	1.4	2	0.3	0.0	1.1
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Bronchiolitis (10006448)	15	2.4	1.4	4.0	14	2.3	1.3	3.8	11	1.8	0.9	3.2	40	2.2	1.6	2.9	17	2.6	1.5	4.1
	Bronchitis (10006451)	7	1.1	0.5	2.3	7	1.1	0.5	2.3	14	2.3	1.2	3.8	28	1.5	1.0	2.2	9	1.4	0.6	2.6
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchitis viral (10053160)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Candida infection (10074170)	7	1.1	0.5	2.3	5	0.8	0.3	1.9	3	0.5	0.1	1.4	15	0.8	0.5	1.3	8	1.2	0.5	2.4
	Candida nappy rash (10007135)	6	1.0	0.4	2.1	5	0.8	0.3	1.9	3	0.5	0.1	1.4	14	0.8	0.4	1.3	6	0.9	0.3	2.0
	Cellulitis (10007882)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	7	1.1	0.5	2.3	16	0.9	0.5	1.4	3	0.5	0.1	1.3
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	37	6.0	4.3	8.2	46	7.5	5.6	9.9	49	7.9	5.9	10.3	132	7.1	6.0	8.4	49	7.5	5.6	9.8
	Conjunctivitis bacterial (10061784)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	2	0.3	0.0	1.2	12	0.6	0.3	1.1	4	0.6	0.2	1.6
	Croup infectious (10011416)	28	4.5	3.0	6.5	37	6.0	4.3	8.2	31	5.0	3.4	7.0	96	5.2	4.2	6.3	33	5.0	3.5	7.0
	Cutaneous larva migrans (10059547)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Diarrhoea infectious (10012742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Ear infection (10014011)	13	2.1	1.1	3.6	12	2.0	1.0	3.4	6	1.0	0.4	2.1	31	1.7	1.1	2.4	15	2.3	1.3	3.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Eczema herpeticum (10014197)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema infected (10014199)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Enteritis infectious (10058839)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Erythema infectiosum (10015214)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Escherichia urinary tract infection (10052238)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Exanthema subitum (10015586)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	External ear cellulitis (10015729)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye infection (10015929)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Folliculitis (10016936)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.8	0.3	1.9	10	0.5	0.3	1.0	3	0.5	0.1	1.3
	Fungal infection (10017533)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Fungal skin infection (10017543)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	4	0.6	0.2	1.6
	Gastroenteritis (10017888)	26	4.2	2.8	6.1	24	3.9	2.5	5.8	19	3.1	1.9	4.8	69	3.7	2.9	4.7	21	3.2	2.0	4.9
	Gastroenteritis enteroviral (10017901)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	7	1.1	0.5	2.3	2	0.3	0.0	1.2	3	0.5	0.1	1.4	12	0.6	0.3	1.1	5	0.8	0.2	1.8
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hand-foot-and-mouth disease (10019113)	16	2.6	1.5	4.2	18	2.9	1.8	4.6	15	2.4	1.4	4.0	49	2.7	2.0	3.5	21	3.2	2.0	4.9
	Herpangina (10019936)	5	0.8	0.3	1.9	5	0.8	0.3	1.9	4	0.6	0.2	1.6	14	0.8	0.4	1.3	2	0.3	0.0	1.1
	Herpes dermatitis (10062639)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hordeolum (10020377)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Impetigo (10021531)	11	1.8	0.9	3.2	5	0.8	0.3	1.9	3	0.5	0.1	1.4	19	1.0	0.6	1.6	6	0.9	0.3	2.0
	Infected bite (10076911)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Influenza (10022000)	5	0.8	0.3	1.9	8	1.3	0.6	2.6	4	0.6	0.2	1.6	17	0.9	0.5	1.5	6	0.9	0.3	2.0
	Lice infestation (10024424)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Mycoplasma infection (10061300)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Nasopharyngitis (10028810)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	7	1.1	0.5	2.3	25	1.4	0.9	2.0	4	0.6	0.2	1.6
	Neonatal candida infection (10028924)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Onychomycosis (10030338)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Oral herpes (10067152)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Otitis externa (10033072)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Otitis media (10033078)	111	18.0	15.0	21.2	108	17.6	14.7	20.9	98	15.9	13.1	19.0	317	17.2	15.5	19.0	132	20.2	17.2	23.5
	Otitis media acute (10033079)	19	3.1	1.9	4.8	12	2.0	1.0	3.4	23	3.7	2.4	5.5	54	2.9	2.2	3.8	26	4.0	2.6	5.8
	Otitis media chronic (10033081)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Otosalpingitis (10033102)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Parotitis (10034038)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pertussis (10034738)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pharyngitis (10034835)	28	4.5	3.0	6.5	32	5.2	3.6	7.3	28	4.5	3.0	6.5	88	4.8	3.8	5.8	28	4.3	2.9	6.1
	Pharyngitis streptococcal (10034839)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	7	1.1	0.5	2.3	15	0.8	0.5	1.3	6	0.9	0.3	2.0
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Pneumonia (10035664)	8	1.3	0.6	2.5	14	2.3	1.3	3.8	6	1.0	0.4	2.1	28	1.5	1.0	2.2	5	0.8	0.2	1.8
	Pyoderma (10037632)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Respiratory tract infection (10062352)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis (10039083)	7	1.1	0.5	2.3	10	1.6	0.8	3.0	8	1.3	0.6	2.5	25	1.4	0.9	2.0	10	1.5	0.7	2.8
	Roseola (10039222)	4	0.6	0.2	1.6	5	0.8	0.3	1.9	4	0.6	0.2	1.6	13	0.7	0.4	1.2	1	0.2	0.0	0.8
	Salmonellosis (10039447)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Scarlet fever (10039587)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Sinusitis (10040753)	21	3.4	2.1	5.1	10	1.6	0.8	3.0	11	1.8	0.9	3.2	42	2.3	1.6	3.1	14	2.1	1.2	3.6
	Skin candida (10054152)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	3	0.5	0.1	1.4	9	0.5	0.2	0.9	1	0.2	0.0	0.8
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	2	0.3	0.0	1.2	8	1.3	0.6	2.6	4	0.6	0.2	1.6	14	0.8	0.4	1.3	8	1.2	0.5	2.4
	Subcutaneous abscess (10042343)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Tinea capitis (10043866)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea cruris (10043868)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea infection (10060889)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tinea nigra (10043871)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillitis (10044008)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	10	0.5	0.3	1.0	6	0.9	0.3	2.0
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	97	15.7	12.9	18.8	125	20.4	17.3	23.8	110	17.8	14.9	21.0	332	18.0	16.2	19.8	132	20.2	17.2	23.5
	Urethritis (10046480)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Vaginal infection (10046914)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	43	7.0	5.1	9.3	32	5.2	3.6	7.3	42	6.8	4.9	9.1	117	6.3	5.3	7.5	32	4.9	3.4	6.8
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral rash (10047476)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	11	1.8	0.9	3.2	29	1.6	1.1	2.2	9	1.4	0.6	2.6
	Viral upper respiratory tract infection (10047482)	6	1.0	0.4	2.1	3	0.5	0.1	1.4	7	1.1	0.5	2.3	16	0.9	0.5	1.4	7	1.1	0.4	2.2
	Vulvovaginitis (10047794)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Animal bite (10002515)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Arthropod bite (10003399)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	10	1.6	0.8	3.0	16	0.9	0.5	1.4	5	0.8	0.2	1.8
	Burns first degree (10006797)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Burns second degree (10006802)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chemical eye injury (10055116)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Clavicle fracture (10009245)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Concussion (10010254)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Contusion (10050584)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	4	0.6	0.2	1.6	12	0.6	0.3	1.1	10	1.5	0.7	2.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Craniocerebral injury (10070976)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye contusion (10073354)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Eyelid injury (10069200)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Face injury (10050392)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Foot fracture (10016970)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in eye (10017012)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Gingival injury (10049300)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	6	1.0	0.4	2.1	8	1.3	0.6	2.6	5	0.8	0.3	1.9	19	1.0	0.6	1.6	5	0.8	0.2	1.8
	Humerus fracture (10020462)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Joint dislocation (10023204)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Joint injury (10060820)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Laceration (10023572)	8	1.3	0.6	2.5	2	0.3	0.0	1.2	9	1.5	0.7	2.7	19	1.0	0.6	1.6	9	1.4	0.6	2.6
	Ligament sprain (10024453)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Limb crushing injury (10064031)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Limb injury (10061225)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	3	0.5	0.1	1.4	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Lip injury (10055082)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	5	0.8	0.3	1.9	8	0.4	0.2	0.9	3	0.5	0.1	1.3
	Mouth injury (10049294)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Nail avulsion (10028686)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Procedural pain (10064882)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	2	0.3	0.0	1.2	7	0.4	0.2	0.8	5	0.8	0.2	1.8
	Radius fracture (10037802)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Skin abrasion (10064990)	0	0.0	0.0	0.6	5	0.8	0.3	1.9	1	0.2	0.0	0.9	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Splinter (10041662)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sunburn (10042496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Thermal burn (10053615)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Upper limb fracture (10061394)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Wrist fracture (10048049)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Investigations (10022891)	Blood lead increased (10005642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body height below normal (10056811)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cardiac murmur (10007586)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Dehydration (10012174)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	3	0.5	0.1	1.4	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Failure to thrive (10016165)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hypoglycaemia (10020993)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Iron deficiency (10022970)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lactose intolerance (10023681)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight gain poor (10047897)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foot deformity (10061159)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Limb asymmetry (10070670)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pain in extremity (10033425)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	4	0.6	0.2	1.6	11	0.6	0.3	1.1	1	0.2	0.0	0.8
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Toe walking (10068872)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Trigger finger (10044654)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma of skin (10018823)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphangioma (10025219)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Skin papilloma (10040907)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Febrile convulsion (10016284)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	9	0.5	0.2	0.9	4	0.6	0.2	1.6
	Gross motor delay (10069118)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Lethargy (10024264)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Loss of consciousness (10024855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Motor developmental delay (10070302)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Seizure (10039906)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder (10041466)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder developmental (10041467)	4	0.6	0.2	1.6	3	0.5	0.1	1.4	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Tremor (10044565)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Breath holding (10006322)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Insomnia (10022437)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Irritability (10022998)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	3	0.5	0.1	1.4	13	0.7	0.4	1.2	2	0.3	0.0	1.1
	Pica (10035001)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Sleep disorder (10040984)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep terror (10041010)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
Renal and urinary disorders (10038359)	Dysuria (10013990)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Haematuria (10018867)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pollakiuria (10036018)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Genital labial adhesions (10064162)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Penile adhesion (10059636)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Prepuce redundant (10036624)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulval disorder (10047754)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulvovaginal discomfort (10047786)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Respiratory, thoracic and mediastinal disorders (10038738)	Adenoidal hypertrophy (10001229)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Aspiration (10003504)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Asthma (10003553)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	11	1.8	0.9	3.2	19	1.0	0.6	1.6	10	1.5	0.7	2.8
	Bronchial hyperreactivity (10066091)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	5	0.8	0.3	1.9	14	0.8	0.4	1.3	5	0.8	0.2	1.8
	Bronchospasm (10006482)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cough (10011224)	24	3.9	2.5	5.7	24	3.9	2.5	5.8	22	3.6	2.2	5.3	70	3.8	3.0	4.8	32	4.9	3.4	6.8
	Dyspnoea (10013968)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Epistaxis (10015090)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	3	0.5	0.1	1.4	4	0.7	0.2	1.7	6	1.0	0.4	2.1	13	0.7	0.4	1.2	4	0.6	0.2	1.6
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Nasal obstruction (10028748)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Oropharyngeal pain (10068319)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Respiratory disorder (10038683)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	14	2.3	1.2	3.8	8	1.3	0.6	2.6	8	1.3	0.6	2.5	30	1.6	1.1	2.3	12	1.8	1.0	3.2
	Rhinorrhoea (10039101)	2	0.3	0.0	1.2	5	0.8	0.3	1.9	3	0.5	0.1	1.4	10	0.5	0.3	1.0	2	0.3	0.0	1.1
	Stridor (10042241)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tachypnoea (10043089)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	5	0.8	0.3	1.9	18	2.9	1.8	4.6	9	1.5	0.7	2.7	32	1.7	1.2	2.4	5	0.8	0.2	1.8
Skin and subcutaneous tissue disorders (10040785)	Blister (10005191)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Dermatitis (10012431)	10	1.6	0.8	3.0	3	0.5	0.1	1.4	5	0.8	0.3	1.9	18	1.0	0.6	1.5	5	0.8	0.2	1.8
	Dermatitis allergic (10012434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Dermatitis atopic (10012438)	5	0.8	0.3	1.9	13	2.1	1.1	3.6	17	2.8	1.6	4.4	35	1.9	1.3	2.6	4	0.6	0.2	1.6
	Dermatitis contact (10012442)	3	0.5	0.1	1.4	7	1.1	0.5	2.3	4	0.6	0.2	1.6	14	0.8	0.4	1.3	3	0.5	0.1	1.3
	Dermatitis diaper (10012444)	21	3.4	2.1	5.1	21	3.4	2.1	5.2	25	4.0	2.6	5.9	67	3.6	2.8	4.6	36	5.5	3.9	7.5
	Drug eruption (10013687)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ecchymosis (10014080)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema (10014184)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	8	1.3	0.6	2.5	21	1.1	0.7	1.7	14	2.1	1.2	3.6
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Erythema (10015150)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Erythema multiforme (10015218)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Granuloma annulare (10018692)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hair disorder (10019037)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Henoch-schonlein purpura (10019617)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Keratosis pilaris (10066295)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Lichen sclerosus (10024434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Miliaria (10027627)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nail disorder (10028694)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pityriasis (10035110)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pityriasis rosea (10035114)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash (10037844)	14	2.3	1.2	3.8	10	1.6	0.8	3.0	10	1.6	0.8	3.0	34	1.8	1.3	2.6	8	1.2	0.5	2.4
	Rash erythematous (10037855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash generalised (10037858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash macular (10037867)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash maculo-papular (10037868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash papular (10037876)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash scarlatiniform (10037890)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seborrhoea (10039792)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Seborrhoeic dermatitis (10039793)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Skin fissures (10040849)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin hypopigmentation (10040868)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Skin lesion (10040882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin mass (10067868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urticaria (10046735)	6	1.0	0.4	2.1	4	0.7	0.2	1.7	3	0.5	0.1	1.4	13	0.7	0.4	1.2	3	0.5	0.1	1.3
Surgical and medical procedures (10042613)	Myringotomy (10028662)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.136 Listings of SAEs (Total vaccinated cohort)

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
INV_MMR_1	PPD	M	United States	Ot	62	Wheezing with upper respiratory infection	Upper respiratory tract infection	Infections and infestations	HO	1	62	28	2	N	Recovered/resolved
		F	United States	Wh	59	Escherichia coli urinary tract infection	Escherichia urinary tract infection	Infections and infestations	HO	1	48	32	3	N	Recovered/resolved
		F	United States	Wh	74	Pneumonia	Pneumonia	Infections and infestations	HO	1	121	5	3	N	Recovered/resolved
		F	United States	As	72	Respiratory syncytial virus bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	125	11	3	N	Recovered/resolved
		F	United States	Wh	57	Viral upper respiratory infection	Viral upper respiratory tract infection	Infections and infestations	HO	1	34	10	2	N	Recovered/resolved
					58	Hypoxia	Hypoxia	Respiratory, thoracic and mediastinal disorders	HO	1	38	2	3	N	Recovered/resolved
		M	United States	Af	69	Pneumonia	Pneumonia	Infections and infestations	HO	1	98	8	3	N	Recovered/resolved
		F	United States	Af	58	Cellulitis	Cellulitis	Infections and infestations	HO	1	3	25	2	N	Recovered/resolved
					58	Conjunctivitis	Conjunctivitis	Infections and infestations	HO	1	3	25	2	N	Recovered/resolved
		M	United States	Wh	70	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	ER	1	122	8	3	N	Recovered/resolved
					71	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	129	5	3	N	Recovered/resolved
		M	United States	Ot	56	Scalp abscess	Subcutaneous abscess	Infections and infestations	HO	1	18	5	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	F	Estonia	Wh	66	Pyelonephritis acute	Pyelonephritis acute	Infections and infestations	HO	1	96	9	2	N	Recovered/resolved
		M	Estonia	Wh	81	Superficial injury of head	Head injury	Injury, poisoning and procedural complications	HO	1	176	3	2	N	Recovered/resolved
		M	Estonia	Wh	61	Rotavirus infection	Rotavirus infection	Infections and infestations	HO	1	3	8	3	N	Recovered/resolved
		M	Finland	Wh	67	Concussion of the brain	Concussion	Injury, poisoning and procedural complications	HO	1	91	4	2	N	Recovered/resolved
		F	Finland	Wh	86	Acute obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	184	14	2	N	Recovered/resolved
		F	Finland	Wh	66	Acute obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	94	42	2	N	Recovered/resolved
		M	Finland	Wh	61	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	33	19	3	N	Recovered/resolved
		F	Finland	Wh	80	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	172	5	2	N	Recovered/resolved
		F	Finland	Wh	66	Gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	78	8	3	N	Recovered/resolved
		F	Spain	Wh	64	Pharyngitis	Pharyngitis	Infections and infestations	HO	1	74	10	3	N	Recovered/resolved
		F	Mexico	Ot	61	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	58	6	2	N	Recovered/resolved
		M	Mexico	Ot	61	Epilepsy	Epilepsy	Nervous system disorders	MD	1	10	.	2	N	Not recovered/not resolved
					84	Gastritis per medication	Gastritis	Gastrointestinal disorders	HO	1	173	2	2	N	Recovered/resolved
					84	Head trauma	Head injury	Injury, poisoning and procedural complications	HO	1	172	3	1	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
INV_MMR_2	PPD	F	United States	As	72	Croup	Croup infectious	Infections and infestations	HO	1	120	8	3	N	Recovered/resolved
		M	United States	Wh	56	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	21	2	2	N	Recovered/resolved
					56	Leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	19	4	2	N	Recovered/resolved
		F	United States	Wh	75	Mycoplasma pneumoniae	Mycoplasma infection	Infections and infestations	HO	1	147	16	2	N	Recovered/resolved
		M	United States	Af	78	Concussion	Concussion	Injury, poisoning and procedural complications	HO	1	176	14	2	N	Recovered/resolved
					78	Fractured right foot	Foot fracture	Injury, poisoning and procedural complications	HO	1	176	14	2	N	Recovered/resolved
		F	United States	Wh	79	Reactive airways disease exacerbation	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	190	8	3	N	Recovered/resolved
		F	United States	Wh	71	Bronchiolitis due to respiratory syncytial virus	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	128	11	3	N	Recovered/resolved
		M	United States	Wh	55	Reactive airway disease	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	22	5	2	N	Recovered/resolved
					65	Asthma exacerbation	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	92	9	2	N	Recovered/resolved
		M	United States	Ot	54	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	8	6	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD				54	Rotavirus gastroenteritis	Gastroenteritis rotavirus	Infections and infestations	HO	1	8	6	2	N	Recovered/resolved
		M	Estonia	Wh	72	Viral intestinal infection, unspecified	Gastroenteritis viral	Infections and infestations	HO	1	47	7	2	N	Recovered/resolved
		F	Estonia	Wh	88	Acute upper respiratory infection of multiple and unspecified sites	Upper respiratory tract infection	Infections and infestations	HO	1	157	15	2	N	Recovered/resolved
		F	Estonia	Wh	57	Pharyngitis acute	Pharyngitis	Infections and infestations	HO	1	7	5	2	N	Recovered/resolved
		M	Estonia	Wh	61	Laryngitis	Laryngitis	Infections and infestations	HO	1	18	10	2	N	Recovered/resolved
		M	Estonia	Wh	75	Body burns level ii	Burns second degree	Injury, poisoning and procedural complications	HO	1	143	40	2	N	Recovered/resolved
		M	Estonia	Wh	76	Viral pharyngitis	Viral pharyngitis	Infections and infestations	HO	1	144	15	2	N	Recovered/resolved
		M	Estonia	Wh	64	Rhinopharyngitis acute	Nasopharyngitis	Infections and infestations	HO	1	73	3	2	N	Recovered/resolved
		M	Finland	Wh	70	Acute asthma exacerbation	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	27	6	3	N	Recovered/resolved
		F	Finland	Wh	55	Gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	0	14	2	Y	Recovered/resolved
		F	Finland	Wh	62	Fracture of femur	Femur fracture	Injury, poisoning and procedural complications	HO	1	39	26	3	N	Recovered/resolved
		M	Finland	Wh	58	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	37	12	3	N	Recovered/resolved
		F	Finland	Wh	65	Streptococcus pneumoniae septicemia	Pneumococcal sepsis	Infections and infestations	HO	1	40	23	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	M	Finland	Wh	76	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	171	7	2	N	Recovered/resolved
		M	Finland	Wh	58	Type 1 diabetes	Type 1 diabetes mellitus	Metabolism and nutrition disorders	HO	1	44	.	3	N	Not recovered/not resolved
		F	Finland	Wh	73	Respiratory syncytial virus (rsv) pneumonia	Pneumonia respiratory syncytial viral	Infections and infestations	HO	1	139	6	3	N	Recovered/resolved
					73	Respiratory tract infection (rhino virus)	Respiratory tract infection viral	Infections and infestations	HO	1	139	6	3	N	Recovered/resolved
		F	Mexico	Ot	60	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	29	12	2	N	Recovered/resolved
		M	Mexico	Ot	58	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	33	11	2	N	Recovered/resolved
		M	Mexico	Ot	69	Bronchial hyperreactivity	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	114	14	2	N	Recovered/resolved
					69	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	114	14	2	N	Recovered/resolved
		F	Mexico	Ot	62	Community acquired pneumonia	Pneumonia	Infections and infestations	HO	1	69	16	2	N	Recovered/resolved
		F	United States	Wh	80	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	115	11	3	N	Recovered/resolved
INV_MMR_3		F	United States	Af	60	Pneumonia	Pneumonia	Infections and infestations	HO	1	53	23	3	N	Recovered/resolved
		F	United States	Af	55	Pneumonia	Pneumonia	Infections and infestations	HO	1	26	25	1	N	Recovered/resolved
		M	United States	Wh	75	Loss of consciousness	Loss of consciousness	Nervous system disorders	HO	1	162	2	3	N	Recovered/resolved
					75	Seizure	Seizure	Nervous system disorders	HO	1	162	2	3	N	Recovered/resolved
		F	United States	Af	56	herpangina	Herpangina	Infections and infestations	HO	1	24	27	3	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	F	United States	Wh	68	Respiratory syncitail virus bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	111	9	2	N	Recovered/resolved
		F	United States	Wh	60	Cellulitis	Cellulitis	Infections and infestations	HO	1	57	10	2	N	Recovered/resolved
					60	Left conjunctivitis	Conjunctivitis	Infections and infestations	ER	1	57	5	2	N	Recovered/resolved
					61	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	60	2	2	N	Recovered/resolved
					61	Left otitis media	Otitis media	Infections and infestations	HO	1	59	9	2	N	Recovered/resolved
		M	United States	Ot	77	Abscess	Abscess	Infections and infestations	HO	1	97	9	3	N	Recovered/resolved
		F	Estonia	Wh	84	Pyelonephritis acute	Pyelonephritis acute	Infections and infestations	HO	1	150	12	2	N	Recovered/resolved
		M	Estonia	Wh	52	Enterocolitis acutae	Enterocolitis	Gastrointestinal disorders	HO	1	4	9	2	N	Recovered/resolved
		M	Estonia	Wh	73	Bronchitis	Bronchitis	Infections and infestations	HO	1	143	14	1	N	Recovered/resolved
		M	Estonia	Wh	77	Second-degree burns	Burns second degree	Injury, poisoning and procedural complications	HO	1	130	24	2	N	Recovered/resolved
		F	Estonia	Wh	57	Adenoviral enteritis	Gastroenteritis adenovirus	Infections and infestations	HO	1	25	6	2	N	Recovered/resolved
		M	Finland	Wh	76	Pneumonia	Pneumonia	Infections and infestations	HO	1	152	13	2	N	Recovered/resolved
		F	Finland	Wh	75	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	144	9	2	N	Recovered/resolved
		F	Finland	Wh	57	febrile seizure	Febrile convulsion	Nervous system disorders	ER	1	9	1	2	Y	Recovered/resolved
		M	Finland	Wh	80	Otitis media	Otitis media	Infections and infestations	HO	1	183	3	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	M	Finland	Wh	76	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	159	18	2	N	Recovered/resolved
		F	Finland	Wh	56	Viral infection	Viral infection	Infections and infestations	HO	1	24	19	3	N	Recovered/resolved
					57	Otitis media	Otitis media	Infections and infestations	HO	1	31	12	3	N	Recovered/resolved
					57	Cerebral convulsions	Seizure	Nervous system disorders	HO	1	34	1	3	N	Recovered/resolved
		F	Spain	Wh	66	Fever	Pyrexia	General disorders and administration site conditions	HO	1	93	17	2	N	Recovered/resolved
					66	Acute tonsillitis	Tonsillitis	Infections and infestations	MD	1	93	6	2	N	Recovered/resolved
					67	Diarrhea	Diarrhoea	Gastrointestinal disorders	HO	1	102	11	2	N	Recovered/resolved
					67	Otitis media	Otitis media	Infections and infestations	MD	1	98	5	2	N	Recovered/resolved
		M	Spain	Wh	67	Cellulitis	Cellulitis	Infections and infestations	HO	1	90	35	3	N	Recovered/resolved
		F	Mexico	Ot	68	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	112	12	2	N	Recovered/resolved
		F	Mexico	Ot	73	Phalanx amputation	Finger amputation	Surgical and medical procedures	HO	1	151	47	3	N	Recovered/resolved with sequelae
		F	Mexico	Ot	75	Community acquired bacterial pneumonia	Pneumonia bacterial	Infections and infestations	HO	1	151	51	2	N	Recovered/resolved
		M	Mexico	Ot	67	Gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	90	3	2	N	Recovered/resolved
		M	United States	Wh	78	Unspecified viral infection	Viral infection	Infections and infestations	HO	1	167	3	2	N	Recovered/resolved
		F	United States	Wh	57	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	31	4	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD				57	Acute gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	31	4	2	N	Recovered/resolved
		F	United States	Wh	70	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	57	17	2	N	Recovered/resolved
		F	United States	Af	77	Acute bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	169	12	1	N	Recovered/resolved
COM_MMR		F	United States	As	71	Febrile seizure	Febrile convulsion	Nervous system disorders	HO	1	128	2	3	N	Recovered/resolved
		F	United States	Wh	79	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	183	13	3	N	Recovered/resolved
					79	Conjunctivitis	Conjunctivitis	Infections and infestations	MD	1	182	7	3	N	Recovered/resolved
					80	Leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	188	8	3	N	Recovered/resolved
		F	United States	Wh	59	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	17	12	3	N	Recovered/resolved
					59	Rsv bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	16	13	3	N	Recovered/resolved
		F	United States	Wh	59	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	51	5	3	N	Recovered/resolved
					59	Leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	51	5	2	N	Recovered/resolved
					59	Acute otits media	Otitis media acute	Infections and infestations	MD	1	50	6	3	N	Recovered/resolved
		F	United States	Wh	82	Febrile seizure	Febrile convulsion	Nervous system disorders	HO	1	171	1	2	N	Recovered/resolved
		F	Estonia	Wh	69	Respiratory syncytial virus pneumonia	Pneumonia respiratory syncytial viral	Infections and infestations	HO	1	19	20	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD				70	Otitis media bilateral ears	Otitis media	Infections and infestations	HO	1	30	9	1	N	Recovered/resolved
		F	Estonia	Wh	61	Urticaria	Urticaria	Skin and subcutaneous tissue disorders	HO	1	4	16	2	N	Recovered/resolved
		F	Estonia	Wh	62	Acute rotavirus gastroenteritis	Gastroenteritis rotavirus	Infections and infestations	HO	1	72	6	2	N	Recovered/resolved
		F	Estonia	Wh	62	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	57	4	2	N	Recovered/resolved
					62	Adenovirus gastroenteritis	Gastroenteritis adenovirus	Infections and infestations	HO	1	57	4	2	N	Recovered/resolved
					74	Tonsillitis acuta	Tonsillitis	Infections and infestations	HO	1	142	14	2	N	Recovered/resolved
					75	Otitis media bilateralis	Otitis media	Infections and infestations	HO	1	145	9	2	N	Recovered/resolved
					80	Neutropenia parainfection	Neutropenic infection	Infections and infestations	HO	1	181	8	2	N	Recovered/resolved
					80	Infection viral	Viral infection	Infections and infestations	HO	1	179	7	2	N	Recovered/resolved
		F	Estonia	Wh	66	Febrile convulsions	Febrile convulsion	Nervous system disorders	HO	1	87	1	2	N	Recovered/resolved
					66	Unspecified viral infection	Viral infection	Infections and infestations	HO	1	87	2	2	N	Recovered/resolved
		M	Finland	Wh	65	Urticaria	Urticaria	Skin and subcutaneous tissue disorders	HO	1	52	16	3	N	Recovered/resolved
		M	Finland	Wh	57	Asthma infectious	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	37	15	2	N	Recovered/resolved
		M	Finland	Wh	59	Obtructive bronchitis	Bronchitis	Infections and infestations	HO	1	44	44	3	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	M	Finland	Wh	60	Febrile convulsions	Febrile convulsion	Nervous system disorders	HO	1	51	2	2	N	Recovered/resolved
		M	Finland	Wh	81	Diarrhea	Diarrhoea	Gastrointestinal disorders	HO	1	192	3	1	N	Recovered/resolved
					81	Hypoglycemia	Hypoglycaemia	Metabolism and nutrition disorders	HO	1	193	5	3	N	Recovered/resolved
		F	Finland	Wh	64	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	80	6	2	N	Recovered/resolved
					79	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	189	15	2	N	Recovered/resolved
		F	Finland	Wh	75	Infection viral	Viral infection	Infections and infestations	HO	1	152	20	3	N	Recovered/resolved
		M	Spain	Wh	73	Acute gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	136	4	2	N	Recovered/resolved
		F	Mexico	Ot	61	Bronchial hyperreactor	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	58	7	2	N	Recovered/resolved
					63	Milk allergy	Milk allergy	Immune system disorders	HO	1	71	8	1	N	Recovered/resolved
		F	Mexico	Ot	70	Bronchial hyperreactivity	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	104	26	2	N	Recovered/resolved
		F	Mexico	Ot	70	Acute gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	113	12	2	N	Recovered/resolved
		F	United States	Wh	52	Bronchiolitis exacerbation	Bronchiolitis	Infections and infestations	HO	1	1	18	2	N	Recovered/resolved
		M	United States	Af	80	Reactive airway disease	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	173	7	3	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	F	United States	Wh	74	Complex febrile seizure	Febrile convulsion	Nervous system disorders	HO	1	98	2	3	N	Recovered/resolved
		M	United States	Ot	88	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	192	10	3	N	Recovered/resolved

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR

MODULAR APPENDICES

List of modular appendices available for the study report and ICH-specific appendices - Study Information equivalent numbering

Modular appendices	ICH numbering
Protocol and protocol amendments.	16.1.1
Sample Case Report form	16.1.2
List of IECs or IRBs & List of Investigators and other important participants in the study	16.1.3 & 16.1.4
Representative written information for patient and sample consent forms.	16.1.3
Investigator CVs or equivalent summaries of training and experience relevant to the performance of the clinical study	16.1.4
Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement	16.1.5
Listings of patients receiving test drug(s) /investigational product(s) from specific batches, where more than one batch was used	16.1.6
Randomization list	16.1.7
Audit certificates	16.1.8
Documentation of statistical methods	16.1.9
Documentation of inter-laboratory standardization methods and quality assurance procedures	16.1.10
Publications based on the study.	16.1.11
Important publications referenced in the report	16.1.12
Individual listings	16.2
Case report forms (CRFs /eCRFs) CRFs /eCRFs for deaths, other SAEs and withdrawals due to adverse events	16.3 16.3.1

Protocol and Protocol Amendments

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115648 (MMR-160)
Protocol Amendment 2 Final

Clinical Study Protocol
Sponsor:
GlaxoSmithKline Biologicals
89, Rue de l'Institut, 1330 Rixensart, Belgium

Primary Study vaccine and number	GlaxoSmithKline (GSK) Biologicals' live attenuated measles, mumps, rubella vaccine (MMR) Vaccine number 209762
Other Study vaccines	• Measles, mumps and rubella virus vaccine live (M-M-R®II, Merck & Co., Inc., or M-M-RVaxPro®, Sanofi Pasteur/Merck Sharp and Dohme [SPMSD]) • Varicella virus vaccine live (Varivax®, Merck & Co., Inc.) • Hepatitis A vaccine, inactivated (Havrix®, GSK Biologicals) • Pneumococcal 13-valent conjugate vaccine (diphtheria CRM_{197} protein) (Prevnar 13®, *Pfizer* Inc.)
eTrack study number and Abbreviated Title	115648 (MMR-160)
Investigational New Drug (IND) number	BB-IND 7229
EudraCT number	2011-004891-12
Date of protocol	Final: 13 July 2012
Date of protocol amendment	Amendment 1 Final: 14 May 2014 Amendment 2 Final: 26 February 2015
Title	Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.
Detailed Title	A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.
Co-ordinating author (Amended: 26-FEB-2015)	PPD Scientific writer

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eTrack study number and Abbreviated Title	115648 (MMR-160)
Investigational New Drug (IND) number	BB-IND 7229
EudraCT number	2011-004891-12
Detailed Title	A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.
Contributing authors ***(Amended: 26-FEB-2015)***	• PPD Director, Clinical Research and Development Lead, Vaccines for MMR and Varicella • PPD Director, Clinical Research and Development Lead • PPD Project Statistician • PPD Director, Statistical Manager • PPD Study Delivery Lead • PPD Study Manager • PPD Study Data Manager • PPD ***Director, Safety Evaluation and Risk Management*** • PPD Clinical Immunology • PPD Global Regulatory Affairs • PPD Vice President and Director, Global Vaccine Development, GSK Biological

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115648 (MMR-160)
Protocol Amendment 2 Final

Protocol Amendment 2 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	115648 (MMR-160)
IND number	BB-IND 7229
EudraCT number	2011-004891-12
Date of protocol amendment	Amendment 2 Final: 26 February 2015
Detailed Title	A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.
Sponsor signatory	Ouzama Henry, Director, Clinical Research and Development Lead, Vaccines for MMR and Varicella
Signature	_____
Date	_____

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Protocol Amendment 2 Rationale

Amendment number:	Amendment 2
Rationale/background for changes:	
• Following comments from CBER, the *Streptococcus pneumoniae* testing will not be the 22F ELISA currently listed but a validated assay accepted by CBER. The assessment of this assay is ongoing. As such, the secondary endpoint related to assessment of the percentage of subjects with Streptococcus pneumoniae antibody concentrations ≥0.05, 0.2, 0.5, and 1.0 µg/mL with the 22F ELISA has been removed. The need for any additional endpoints related to *Streptococcus pneumoniae* antibody testing will be reassessed once a CBER validated assay is selected. • Serological assays for the determination of antibodies against measles, rubella and varicella viruses now will be performed by GSK Biologicals' laboratory in Laval, Canada. Note : In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party CRO • Serological testing for the co-administered vaccines (i.e. VV, HAV and PCV-13) will be completed much later than the antibody determination for measles, mumps and rubella. Therefore the immunogenicity data analysis for the co-administered vaccines will be included in the final analysis performed at the end of the study. • Other minor corrections were implemented.	

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Protocol Amendment 2 Investigator Agreement

I agree:

- **To conduct the study in compliance with this protocol, any mutually agreed future protocol amendments or protocol administrative changes, and with any other study conduct procedures and/or study conduct documents provided by GlaxoSmithKline Biologicals (GSK Biologicals).**
- **To assume responsibility for the proper conduct of the study at this site.**
- **That I am aware of, and will comply with, 'Good Clinical Practice' (GCP) and all applicable regulatory requirements.**
- **To ensure that all persons assisting me with the study are adequately informed about the GSK Biologicals' investigational product(s) and other study-related duties and functions as described in the protocol.**
- **To acquire the reference ranges for laboratory tests performed locally and, if required by local regulations, obtain the laboratory's current certification or Quality Assurance procedure manual.**
- **To ensure that no clinical samples (including serum samples) are retained onsite or elsewhere without the approval of GSK Biologicals and the express written informed consent of the child's parent(s)/legally authorized representative (LAR(s)).**
- **To perform no other biological assays on the clinical samples except those described in the protocol or its amendment(s).**
- **To cooperate with a representative of GSK Biologicals in the monitoring process of the study and in resolution of queries about the data.**
- **That I have been informed that certain regulatory authorities require the sponsor to obtain and supply, as necessary, details about the investigator's ownership interest in the sponsor or the investigational product, and more generally about his/her financial ties with the sponsor. GSK Biologicals will use and disclose the information solely for the purpose of complying with regulatory requirements.**

Hence I:

- **Agree to supply GSK Biologicals with any necessary information regarding ownership interest and financial ties (including those of my spouse and dependent children).**
- **Agree to promptly update this information if any relevant changes occur during the course of the study and for one year following completion of the study.**
- **Agree that GSK Biologicals may disclose any information it has about such ownership interests and financial ties to regulatory authorities.**
- **Agree to provide GSK Biologicals with an updated Curriculum Vitae and other documents required by regulatory agencies for this study.**

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115648 (MMR-160)
Protocol Amendment 2 Final

eTrack study number and Abbreviated Title	115648 (MMR-160)
IND number	BB-IND 7229
EudraCT number	2011-004891-12
Date of protocol amendment	Amendment 2 Final: 26 February 2015
Detailed Title	A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.
Investigator name	_____
Signature	_____
Date	_____

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Sponsor Information

1. Sponsor

GlaxoSmithKline Biologicals
89, Rue de l'Institut, 1330 Rixensart, Belgium

2. Sponsor Medical Expert for the Study

Refer to the local study contact information document.

3. Sponsor Study Monitor

Refer to the local study contact information document.

4. Sponsor Study Contact for Reporting of a Serious Adverse Event

GSK Biologicals Central Back-up Study Contact for Reporting SAEs: refer to protocol Section 8.3.2.

5. GSK Biologicals' Central Safety Physician On-Call Contact information for Emergency Unblinding

GSK Biologicals Central Safety Physician and Back-up Phone contact: refer to protocol Section 8.7.

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SYNOPSIS

Detailed Title

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.

Indication

GSK's candidate combined measles, mumps and rubella investigational vaccine (referred to as Inv_MMR vaccine throughout this document) will be used for active immunization against measles, mumps and rubella diseases in healthy children, 12 to 15 months of age.

Rationale for the study and study design

- **Rationale for the study:**

Measles, mumps and rubella are common viral illnesses of childhood. These highly infectious diseases and their complications are responsible for considerable morbidity and mortality throughout the world. Measles can cause pneumonia and encephalitis. Mumps is associated with complications including aseptic meningitis, deafness and orchitis. Rubella symptoms in children include fever, swollen lymph nodes and rash; while rubella infection in pregnant women can cause congenital rubella syndrome. When immunization against these diseases is routinely practiced, significant reduction in disease incidence and associated complications has been reported. GSK Biologicals' trivalent combined measles, mumps and rubella vaccine (referred to as Inv_MMR vaccine in this document) is licensed outside the United States (US) under the trade name of *Priorix* in over 100 countries, including Canada, Australia, and all countries in the European Union.

This study is intended to support licensure of GSK's Inv_MMR vaccine in the US by generating immunogenicity and safety data in children 12 to 15 months of age. The US Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommends routine 2-dose vaccination with MMR vaccine at 12 to15 months and at 4 to 6 years of age.

- **Rationale for the study design:**

This study is designed to evaluate consistency of the immune response to three different lots of Inv_MMR vaccine manufactured to target potencies. In addition, the study is designed to evaluate the immunogenicity of Inv_MMR vaccine in contrast to the US standard of care (*MMR II* vaccine referred to as Com_MMR throughout this document) when both are used as a first (primary)

dose. In order to obtain more representative data on the comparator vaccine, the Com_MMR used in this study will consist of two lots designated Com_MMR_L1 and Com_MMR_L2. Throughout the study Com_MMR_L1 and Com_MMR_L2 will be analyzed as pooled lots.

In the US, the primary dose of measles, mumps and rubella-containing vaccine is routinely co-administered with *Varivax* (VV), *Havrix* (HAV) and *Prevnar 13* (PCV-13) at 12 to 15 months of age. Hence, in the US, the study will also evaluate the safety and immunogenicity of both Inv_MMR and Com_MMR vaccines when both are co-administered with these vaccines. In other countries the study will evaluate safety and immunogenicity of Inv_MMR and Com_MMR vaccines when co-administered with *Varivax* and *Havrix*. Note: Given the heterogeneity in the use of pediatric pneumococcal vaccines globally, and administration of these vaccines generally begins in infancy, *Prevnar 13* will be administered only to children enrolled in the US who previously received a 3-dose series of *Prevnar 13* only (i.e., no doses given as *Prevnar/Prevenar*), at least 60 days prior to study entry.

Objectives

Primary

The co-primary objectives will be assessed in a hierarchical manner according to the order presented below. A co-primary objective can only be met if the statistical criteria for that objective are met as well as the statistical criteria for all previous co-primary objectives.

All primary and secondary immunogenicity endpoints will be tested with an Enzyme-Linked Immunosorbent Assay (ELISA).

Note: all criteria will be assessed for each assay separately. With the exception of anti-pneumococcal antibodies, the criteria will be specific to children seronegative for the assay at pre-vaccination.

1. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

   Criteria:
   - For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for antibodies to measles, mumps, and rubella viruses.

2. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.

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Criteria:

- For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses.

3. To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

   Criteria:

   - The lower limit of the two-sided 95% CI on the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses.

4. To demonstrate non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.

   Criteria:

   - The lower limit of the two-sided 95% CI on GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.

5. To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

   Criteria:

   - The lower limit of the two-sided 95% CI for the seroresponse rate for the pooled Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.

Secondary

1. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of seroresponse rate and GMC for antibodies to varicella zoster virus (VZV) at Day 42 (in a subset of children enrolled in the US).

   Criteria:

   - The lower limit of the two-sided 95% CI for the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rates for antibodies to VZV is ≥-10%.
   - The lower limit of the two-sided 95% CI on the GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to VZV.

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2. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of GMC for antibodies to hepatitis A virus (HAV) at Day 42 (in a subset of children enrolled in the US).

   Criteria:
   - The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to HAV (post-dose 1) is ≥0.5.

3. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of antibodies to S. pneumoniae (PS) (13 serotypes), at Day 42 (in a subset of children administered Prevnar 13 in the US).

   Criteria:
   - The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.

4. To assess the immunogenicity of Havrix with respect to the seroresponse rates for antibodies to HAV in the pooled Inv_MMR groups in contrast to the pooled Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).

5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with Varivax, Havrix (to all children) and Prevnar 13 (only to children enrolled in the US).

Study design

Experimental design: Phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with five parallel groups.

Duration of the study:

- Primary Epoch: The study period is approximately 6 months starting at Visit 1 (Day 0) and ending with Visit 3 (Day 180).

Synopsis Table 1 Study groups and epochs foreseen in the study

Study groups	Number of subjects	Age (Min/Max)	Primary Epoch
Inv_MMR_L1	1250	12 – 15 months	●
Inv_MMR_L2	1250	12 – 15 months	●
Inv_MMR_L3	1250	12 – 15 months	●
Com_MMR_L1	625	12 – 15 months	●
Com_MMR_L2	625	12 – 15 months	●

L = Lot

Control: active control

- Com_MMR_L1 and Com_MMR_L2 vaccine.

Co-Administered vaccines:

- All children will receive Havrix and Varivax as study vaccines, concomitantly with MMR vaccine at 12 to 15 months of age at Visit 1.
- *Prevnar 13* will be administered only to children recruited in the US.
- At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of Havrix and/or varicella vaccine to selected non-US countries if local health departments do not routinely provide hepatitis A and varicella vaccination. Note that the second dose of Havrix and varicella vaccine is not part of the study procedures.

Vaccination schedule:

- A single vaccination, with either one of the three Inv_MMR lots or one of two Com_MMR active control lots, along with the three co-administered vaccines Varivax, Havrix (to all children) and Prevnar 13 (only to children enrolled in the US), will be administered at Visit 1 (12-15 months of age).

Treatment groups:

Synopsis Table 2 Treatment groups

Treatment name	Vaccine / Product name	Treatment Groups				
		Inv_MMR_L1 (active)	Inv_MMR_L2 (active)	Inv_MMR_L3 (active)	Com_MMR_L1 (control)	Com_MMR_L2 (control)
Inv_MMR_L1	Inv_MMR_L1	X				
	Inv_MMR Diluent	X				
Inv_MMR_L2	Inv_MMR_L2		X			
	Inv_MMR Diluent		X			
Inv_MMR_L3	Inv_MMR_L3			X		
	Inv_MMR Diluent			X		
Com_MMR_L1	Com_MMR_L1				X	
	Com_MMR_L1 Diluent†				X	
Com_MMR_L2	Com_MMR_L2					X
	Com_MMR_L2 Diluent†					X
Varivax	*Varivax*	X	X	X	X	X
	Varivax Diluent	X	X	X	X	X
Havrix	*Havrix*	X	X	X	X	X
*Prevnar 13**	*Prevnar 13*	X	X	X	X	X

L= Lot
†The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
* *Prevnar-13* will only be given to children enrolled in the US

Treatment allocation: 5000 healthy children 12 to15 months of age will be randomized in a 2:2:2:1:1 ratio.

- Children will be given either one dose of Inv_MMR_L1 (1250 children), one dose of Inv_MMR_L2 (1250 children), one dose of Inv_MMR_L3 (1250 children), or one dose of either Com_MMR_L1 (625 children) or Com_MMR_L2 (625 children).
- Overall, the randomization is 3:1 (Inv_MMR:Com_MMR) and the treatment allocation at the investigator site will be performed using a central randomization system on the Internet (SBIR).

Blinding: observer-blind.

The study will be conducted in a double-blind fashion, with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots and in an observer-blind fashion for the comparison of the pooled lots of Inv_MMR vaccine versus the pooled Com_MMR vaccine lots.

Synopsis Table 3 Blinding of study epochs

Study Epoch	Blinding
Primary Epoch	observer-blind

Visits: Children from each treatment group will participate in three study visits (Day 0, Day 42 and Day 180)

Sampling:

- Blood samples will be collected from each child at Day 0 and Day 42.

Type of study: self-contained.

Data collection: Electronic Case Report Form eCRF using remote data entry (RDE).

Number of subjects

5000 Children

Endpoints

Primary

- Immunogenicity of the MMR vaccines at Day 42.
  - Seroresponse to measles, mumps and rubella viruses.
  - Measles, mumps and rubella virus antibody concentrations.

Secondary

- Immunogenicity of the *Varivax*, *Havrix* and *Prevnar 13* vaccines in a subset of children at Day 42.
  - Seroresponse to VZV.

    - VZV antibody concentrations.
    - HAV antibody concentrations.
    - Seroresponse to HAV.
    - Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.
- Complementary read-out for immunogenicity of the MMR vaccines at Day 42.
    - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
    - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms.
    - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
    - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
    - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.
- Unsolicited adverse events.
    - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest.
    - Occurrence of new onset chronic disease (NOCD) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting emergency room (ER) visits from Day 0 through the end of study.
- Serious adverse events.
    - Occurrence of serious adverse events from Day 0 through the end of study.

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LIST OF ABBREVIATIONS

Ab	Antibody
ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
ANOVA	Analysis of Variance
Anti-HAV	Antibody to hepatitis A virus
Anti-measles	Antibody to measles virus
Anti-mumps	Antibody to mumps virus
Anti-PS	Antibody to *S. pneumoniae* serotypes
Anti-rubella	Antibody to rubella virus
Anti-VZV	Antibody to varicella zoster virus
ATP	According-To-Protocol
BB IND	Biological Investigational New Drug
°C	Degree Celsius
CBER	***Center for Biologics Evaluation and Research***
CCID	Cell Culture Infectious Dose
CDC	Centers for Disease Control
CD-ROM	Compact Disc Read-Only Memory
CI	Confidence Interval
Cm	Centimeter
Com_MMR_L1	Comparator MMR Vaccine Lot 1
Com_MMR_L2	Comparator MMR Vaccine Lot 2
CRM_{197}	Cross-Reactive Material (mutant diphtheria toxin)
CRO	***Contract Research Organization (Amended: 26-FEB-2015)***
DC	Diary Card
DNA	Deoxyribonucleic Acid
eCRF	electronic Case Report Form
EDTA	Ethylenediamine-Tetraacetic Acid
ELISA	Enzyme-Linked Immunosorbent Assay
ER	Emergency Room
EU	ELISA Unit
°F	Degree Fahrenheit
Flu	Influenza
GCP	Good Clinical Practice
GMC	Geometric Mean Concentration
GMT	Geometric Mean Titer
GSK	GlaxoSmithKline
HAV	Hepatitis A Vaccine *Havrix*

Hib	Haemophilus influenzae type b conjugate vaccine
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
IgG	Immunoglobulin class G
IM	Intramuscular
IND	Investigational New Drug
Inv_MMR_L1	Investigational MMR Vaccine Lot 1
Inv_MMR_L2	Investigational MMR Vaccine Lot 2
Inv_MMR_L3	Investigational MMR Vaccine Lot 3
IRB	Institutional Review Board
IU	International Unit
L	Lot
LAR(s)	Legally Acceptable Representative(s)
LOD	Limit of Detection
LOQ	Limit of Quantitation
mcg / µg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
mIU	Milli International Unit
mL	Milliliter
mm	Millimeter
MMR	Measles, Mumps and Rubella vaccine
MMWR	Morbidity and Mortality Weekly Report
MRC	Medical Research Council
NB	Nota Bene
NOCD	New Onset Chronic Disease
PASS	Power Analysis and Sample Size (software)
PCV-7	Pneumococcal Conjugate Vaccine *Prevnar*
PCV-13	Pneumococcal Conjugate Vaccine *Prevnar 13*
PFU	Plaque Forming Units
PPD	Pharmaceutical Product Development, Inc.
PPM	Parts Per Million
PS	*S. pneumoniae*
RDE	Remote Data Entry
SAE	Serious Adverse Event
SAS®	Statistical Analysis System

SBIR	Randomization System on Internet
SC	Subcutaneous
SD	Standard Deviation
SDV	Source Document Verification
SOP	Standard Operating Procedures
SPM	Study Procedures Manual
SPMSD	Sanofi Pasteur/Merck Sharp and Dohme
TCID	Tissue Culture Infectious Dose
US	United States (of America)
Vacc	Vaccination
vs.	Versus
VV	Varicella Vaccine *Varivax*
VZV	Varicella Zoster Virus
WHO	World Health Organization

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GLOSSARY OF TERMS

Adverse event: Any untoward medical occurrence in a patient or clinical investigation child, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also includes failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse.

Blinding: A procedure in which one or more parties to the trial are kept unaware of the treatment assignment in order to reduce the risk of biased study outcomes. The level of blinding is maintained throughout the conduct of the trial, and only when the data are cleaned to an acceptable level of quality will appropriate personnel be unblinded or when required in case of a serious adverse event. In an observer-blind study, the child/parent(s)/Legally Acceptable Representative(s) (LAR(s)) and the site and sponsor personnel involved in the clinical evaluation of the children are blinded while other study personnel may be aware of the treatment assignment. In a double blind study, the child/parent(s)/LAR(s), the investigator and sponsor staff who are involved in the treatment or clinical evaluation of the children and the review or analysis of data are all unaware of the treatment assignments. Partially-blind is to be used for study designs with different blinding levels between different groups, e.g., double-blinded consistency lots which are open with respect to the control group.

Child: Term used throughout the protocol to denote an individual who has been contacted in order to participate or participates in the clinical study, either as a recipient of the investigational product(s) or as a control.

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Child in care: A child who has been placed under the control or protection of an agency, organization, institution or entity by the courts, the government or a government body, acting in accordance with powers conferred on them by law or regulation. The definition of a child in care can include a child cared for by foster parents or living in a care home or institution, provided that the arrangement falls within the definition above. The definition of a child in care does not include a child who is adopted or has an appointed LAR/s.

Eligible: Qualified for enrollment into the study based upon strict adherence to inclusion/exclusion criteria.

Epoch: An epoch is a well defined part of a protocol that covers a set of consecutive timepoints. Generally, an epoch is self-contained and allows to perform a data analysis to address some of the trial objectives (e.g., primary, booster, yearly follow-ups,…).

eTrack: GSK's tracking tool for clinical trials.

Evaluable: Meeting all eligibility criteria, complying with the procedures defined in the protocol, and, therefore, included in the according-to-protocol (ATP) analysis.

Medically Attended Adverse Event: An event for which the child received medical attention defined as hospitalization, an emergency room visit or a visit to or from medical personnel (e.g., nurse practitioner or physician assistant or medical doctor) for any reason.

Protocol amendment: The International Conference on Harmonization (ICH) defines a protocol amendment as: 'A written description of a change(s) to or formal clarification of a protocol.' GSK Biologicals further details this to include a change to an approved protocol that affects the safety of subjects, scope of the investigation, study design, or scientific integrity of the study.

Randomization: Process of random attribution of treatment to children in order to reduce bias of selection.

SBIR: A central Internet randomization system.

Site Monitor: An individual assigned by the sponsor who is responsible for assuring proper conduct of clinical studies at one or more investigational sites.

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Solicited adverse event:	Adverse events (AEs) to be recorded as endpoints in the clinical study. The presence/occurrence/intensity of these events is actively solicited from the child or an observer during a specified post-vaccination follow-up period.
Sub-cohort:	A group of children for whom specific study procedures are used/ performed relative to the other sub-cohorts.
Subset:	A group of children who have the same study procedures at a given timepoint, but the biological assays performed on that sample will be different, relative to the other subsets.
Treatment:	Term used throughout the clinical study to denote a set of investigational product(s) or marketed product(s) or placebo intended to be administered to a child, identified by a unique number, according to the study randomization or treatment allocation.
Unsolicited adverse event:	Any adverse event (AE) reported in addition to those solicited during the clinical study. Also any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms will be reported as an unsolicited adverse event.

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TRADEMARKS

The following trademarks are used in the present protocol.

Note: In the body of the Concept Protocol, the names of the vaccines/products and/or medications will be written in italic font and without the subscript symbol ™ or ®.

Trademarks of the GlaxoSmithKline group of companies	Generic description
Priorix®*	Measles, mumps and rubella vaccine live
Havrix®	Hepatitis A vaccine (HAV)

* *Priorix* is not licensed in the US.

Trademarks not owned by the GlaxoSmithKline group of companies	Generic description
M-M-R®II (Merck & Co., Inc.) also called M-M-R Vax Pro® (distributed by Sanofi Pasteur/Merck Sharp and Dohme [SPMSD] in certain countries)*	Measles, mumps, and rubella virus vaccine live
Varivax® (Merck & Co., Inc.)	Varicella virus vaccine live (VV)
Prevnar®/Prevenar® (Pfizer Inc.)	Pneumococcal 7-valent conjugate vaccine (diphtheria CRM_{197} protein) (PCV-7)
Prevnar 13® (Pfizer Inc.)	Pneumococcal 13-valent conjugate vaccine (diphtheria CRM_{197} protein) (PCV-13)

* The Merck & Co., Inc.'s combined measles-mumps-rubella virus vaccine live is referred to as Com_MMR (Com_MMR_L1 and Com_MMR_L2, for lots 1 and 2) for the comparator vaccine throughout the protocol.

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1. INTRODUCTION

1.1. Background

Please refer to the current Investigator Brochure for a review of the pre-clinical and clinical studies, and the potential risks and benefits of GSK's candidate combined measles, mumps and rubella vaccine (Inv_MMR).

Measles, mumps and rubella are common viral illnesses of childhood. These highly infectious diseases and their complications are responsible for considerable morbidity and mortality throughout the world [WHO, 2000; WHO, 2001; WHO, 2004]. Measles can cause pneumonia and encephalitis. Mumps is associated with complications including aseptic meningitis, deafness and orchitis. Rubella symptoms in children include fever, swollen lymph nodes and rash; while rubella infection in pregnant women can cause congenital rubella syndrome. When immunization against these diseases is routinely practiced, significant reduction in disease incidence and associated complications has been reported [MMWR, 1998]. The trivalent Inv_MMR vaccine is licensed outside the US under the trade name of *Priorix* in over 100 countries, including Canada, Australia, and all countries in the European Union.

1.2. Rationale for the study and study design

1.2.1. Rationale for the study

This study is intended to support licensure of GSK Biologicals' trivalent combined measles, mumps and rubella vaccine (referred to as Inv_MMR vaccine in this document) in the US by generating immunogenicity and safety data in children 12 to 15 months of age. The US Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommends routine 2-dose vaccination with MMR vaccine at 12 to15 months and at 4 to 6 years of age [MMWR, 1998].

1.2.2. Rationale for the study design

This study is designed to evaluate consistency of the immune response to three different lots of Inv_MMR vaccine manufactured to target potencies. In addition, the study is designed to evaluate the immunogenicity of Inv_MMR vaccine in contrast to the US standard of care (*MMR II* / *M-M-R Vax Pro* vaccine referred to as Com_MMR throughout this document) when both are used as a first (primary) dose. In order to obtain more representative data on the comparator vaccine, the Com_MMR used in this study will consist of two lots designated Com_MMR_L1 and Com_MMR_L2. Throughout the study Com_MMR_L1 and Com_MMR_L2 will be analyzed as pooled lots.

In the US, the primary dose of measles, mumps and rubella-containing vaccine is routinely co-administered with *Varivax* (VV), *Havrix* (HAV) and *Prevnar 13* (PCV-13) at 12 to 15 months of age. Hence, in the US, the study will also evaluate the safety and immunogenicity of both Inv_MMR and Com_MMR vaccines when both are co-administered with these three vaccines. In other countries the study will evaluate safety and immunogenicity of Inv_MMR and Com_MMR vaccines when co-administered with *Varivax* and *Havrix*. Note: Given the heterogeneity in the use of pediatric pneumococcal

vaccines globally, and administration of these vaccines generally begins in infancy, *Prevnar 13* will be administered only to children enrolled in the US.

At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of Havrix and/or varicella vaccine to participants enrolled in non-US countries if local health departments do not routinely provide hepatitis A and varicella vaccination.

2. OBJECTIVES

2.1. Primary objectives

The co-primary objectives will be assessed in a hierarchical manner according to the order presented below. A co-primary objective can only be met if the statistical criteria for that objective are met as well as the statistical criteria for all previous co-primary objectives (see Section 10.3.1 for details).

All primary and secondary immunogenicity endpoints will be tested with an ELISA.

Note: all criteria will be assessed for each assay separately. With the exception of anti-pneumococcal antibodies, the criteria will be specific to children seronegative for the assay at pre-vaccination.

1. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

   Criteria:
   - For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for antibodies to measles, mumps, and rubella viruses.

2. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.

   Criteria:
   - For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses.

3. To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

   Criteria:
   - The lower limit of the two-sided 95% CI on the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses.

4. To demonstrate non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.

   Criteria:
   - The lower limit of the two-sided 95% CI on GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.

5. To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

   Criteria:
   - The lower limit of the two-sided 95% CI for the seroresponse rate for the pooled Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.

Refer to Section 10.1 for the definition of the primary endpoint.

2.2. Secondary objectives

1. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of seroresponse rate and GMC for antibodies to varicella zoster virus (VZV) at Day 42 (in a subset of children enrolled in the US).

   Criteria:
   - The lower limit of the two-sided 95% CI for the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rates for antibodies to VZV is ≥-10%.
   - The lower limit of the two-sided 95% CI on the GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to VZV.

2. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of GMC for antibodies to hepatitis A virus (HAV) at Day 42 (in a subset of children enrolled in the US).

   Criteria:
   - The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to HAV (post-dose 1) is ≥0.5.

3. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of antibodies to S. pneumoniae (PS) (13 serotypes), at Day 42 (in a subset of children administered Prevnar 13 in the US).

   Criteria:
   - The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.

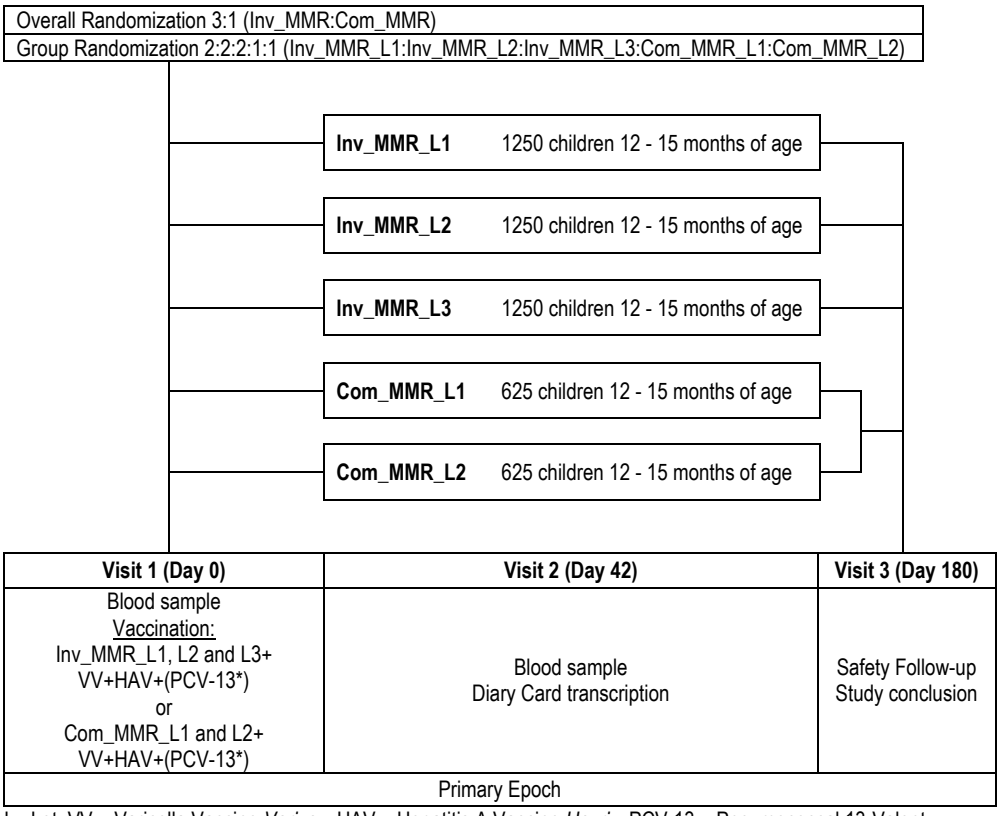
4. To assess the immunogenicity of Havrix with respect to the seroresponse rates for antibodies to HAV in the pooled Inv_MMR groups in contrast to the pooled Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).

5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with Varivax, Havrix (to all children) and Prevnar 13 (only to children enrolled in the US).

Refer to Section 10.2 for the definition of the secondary endpoints.

3. STUDY DESIGN OVERVIEW

Figure 1 Study design



L= Lot; VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* PCV-13 is only administered to children in the US

- **Experimental design:** Phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with five parallel groups.
- **Duration of the study:**
  - Primary Epoch: The study period is approximately 6 months starting at Visit 1 (Day 0) and ending with Visit 3 (Day 180).

Table 1 Study groups and epochs foreseen in the study

Study groups	Number of children	Age (Min/Max)	Primary Epoch
Inv_MMR_L1	1250	12 – 15 months	●
Inv_MMR_L2	1250	12 – 15 months	●
Inv_MMR_L3	1250	12 – 15 months	●
Com_MMR_L1	625	12 – 15 months	●
Com_MMR_L2	625	12 – 15 months	●

L = Lot

- **Control:** active control, Com_MMR_L1 and Com_MMR_L2 vaccine.
- **Co-administered vaccines:** All children will receive *Varivax* and *Havrix* as study vaccines, concomitantly with MMR vaccine at 12 to 15 months of age. *Prevnar 13* will be administered only to US children. At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of Havrix and/or varicella vaccine to participants enrolled in selected non-US countries if local health departments do not routinely provide hepatitis A and varicella vaccination. The second dose of Havrix and varicella vaccine is not part of the study procedures.
- **Vaccination schedule:** A single vaccination, with either one of the three Inv_MMR lots or one of two Com_MMR active control lots, along with the co-administered vaccines *Varivax*, *Havrix* (to all children) and *Prevnar 13*, (only to children enrolled in the US) will be administered at Visit 1 (12-15 months of age).
  - **Treatment groups:**

Table 2 Treatment groups

Treatment name	Vaccine / Product name	Treatment Groups				
		Inv_MMR_L1 (active)	Inv_MMR_L2 (active)	Inv_MMR_L3 (active)	Com_MMR_L1 (control)	Com_MMR_L2 (control)
Inv_MMR_L1	Inv_MMR_L1	X				
	Inv_MMR Diluent	X				
Inv_MMR_L2	Inv_MMR_L2		X			
	Inv_MMR Diluent		X			
Inv_MMR_L3	Inv_MMR_L3			X		
	Inv_MMR Diluent			X		
Com_MMR_L1	Com_MMR_L1				X	
	Com_MMR_L1 Diluent†				X	
Com_MMR_L2	Com_MMR_L2					X
	Com_MMR_L2 Diluent†					X
Varivax	*Varivax*	X	X	X	X	X
	Varivax Diluent	X	X	X	X	X
Havrix	*Havrix*	X	X	X	X	X
*Prevnar 13**	*Prevnar 13*	X	X	X	X	X

L= Lot
† The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
* *Prevnar*-13 will only be given to children enrolled in the US

- **Treatment allocation:** 5000 healthy children 12 to15 months of age will be randomized in a 2:2:2:1:1 ratio to receive either one dose of Inv_MMR_L1 (1250 children), one dose of Inv_MMR_L2 (1250 children), one dose of Inv_MMR_L3 (1250 children), or one dose of either Com_MMR_L1 (625 children) or Com_MMR_L2 (625 children). The vaccines *Havrix*, *Varivax* and *Prevnar 13* will be co-administered (as appropriate) with Inv_MMR vaccine or Com_MMR vaccine. The treatment allocation at the investigator site will be performed using a central randomization system on the Internet (SBIR). Overall, the randomization is 3:1 (Inv_MMR:Com_MMR).
- **Blinding:** observer-blind.
  - The study will be conducted in a double-blind fashion, with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots and in an observer-blind fashion for the comparison of the pooled lots of Inv_MMR vaccine versus the pooled Com_MMR vaccine lots.

Table 3 Blinding of study epochs

Study Epoch	Blinding
Primary Epoch	observer-blind

- **Visits:** Children from each treatment group will participate in three study visits (Day 0, Day 42 and Day 180).
- **Sampling:**
  - Blood samples will be collected from each child; one at Day 0 and one at Day 42.
- **Type of study:** self-contained.
- **Data collection:** Electronic Case Report Form (eCRF) encoded using remote data entry (RDE).

4. STUDY COHORT

4.1. Number of study children/centers

Target enrollment for the study will be 5000 children. There are three Inv_MMR consistency lots (L1, L2, and L3) (N=1250 each) and the active control Com_MMR vaccine that is split into two lots (L1 and L2) comprising two groups of equal size (N=625 each).

Table 4 Sub-cohorts

Sub-cohort name	Description	Estimated number of children
US	Children recruited in the US (This sub-cohort will receive *Prevnar 13* vaccination at Visit 1)*	2500
Non-US	Children recruited outside the US**	2500

* Only children recruited in the US.
** Non-US children will only be co-administered HAV and VV, with either Inv_MMR or Com_MMR at Visit 1.

Enrollment will be terminated when approximately 5000 children have been enrolled.

Refer to Section 10.3 for a detailed description of the criteria for the estimation of the sample size.

4.2. Inclusion criteria for enrollment

All children must satisfy ALL the following criteria at study entry:

- Male or female child between 12 and 15 months of age (e.g., from the 1 year birthday until the day before age 16 months) at the time of vaccination.
- The investigator believes that the parent(s) or Legally Acceptable Representative(s) (LAR(s)) of the child, can, and will comply with the requirements of the protocol (e.g., completion of the diary cards, return for follow-up visits, respects intervals between visits).
- Written informed consent obtained from the parent(s)/LAR(s) of the child.
- Child is in stable health as determined by investigator's clinical examination and assessment of child's medical history.

For US children only,

- Child that previously received a 3-dose series of *Prevnar 13* only (i.e., no doses given as *Prevnar/Prevenar*), with the last dose at least 60 days prior to study entry.

4.3. Exclusion criteria for enrollment

The following criteria should be checked at the time of study entry. If ANY exclusion criterion applies, the subject must not be included in the study:

- Child in care (refer to the GLOSSARY OF TERMS for the definition of child in care).
- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the period starting 30 days before the day of study vaccination (i.e., 30 days prior to Day 0) or planned use during the entire study period.
- Concurrently participating in another clinical study, in which the child has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device).
- Chronic administration (defined as 14 or more consecutive days) of immunosuppressants, or other immune-modifying drugs during the period starting 180 days prior to the first vaccine dose or any planned administration of immunosuppressive and immune-modifying drugs during the entire study.
  - For corticosteroids, this will mean prednisone, ≥0.5 mg/kg/day or equivalent.
  - Inhaled and topical steroids are allowed.

- Planned administration/ administration of a vaccine not foreseen by the study protocol during the period starting 30 days prior to study vaccination at Visit 1 and ending at Visit 2. Please Note:
  - **Inactivated** influenza (Flu) vaccine and *Haemophilus influenzae* type b conjugate vaccine (Hib) vaccines may be given at any time, including the day of study vaccination (Flu and Hib vaccines must be administered at a different location than the study vaccine/s).
  - Any other age appropriate vaccine may be given starting at Visit 2 and anytime thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting 180 days prior to study vaccination at Visit 1 or planned administration from the date of vaccination through the immunogenicity evaluation at Visit 2.
- History of measles, mumps, rubella, varicella/zoster and/or hepatitis A disease.
- Known exposure to measles, mumps, rubella and/or varicella/zoster during the period starting within 30 days prior to first study vaccination.
- Previous vaccination against measles, mumps, rubella, hepatitis A and/or varicella virus.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
- A family history of congenital or hereditary immunodeficiency.
- History of allergic disease or reactions likely to be exacerbated by any component of the vaccines, including hypersensitivity to neomycin, latex or gelatin.
- Blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- Acute disease at the time of enrollment. (Acute disease is defined as the presence of a moderate or severe illness with or without fever). Fever is defined as temperature ≥38.0°C/100.4°F by any age appropriate route. All vaccines can be administered to persons with a minor illness such as diarrhea, mild upper respiratory infection without fever.
- Active untreated tuberculosis based on medical history.
- Any other condition which, in the opinion of the investigator, prevents the child from participating in the study.

For US children only,

- Child that previously received a vaccination with heptavalent *Prevnar*/*Prevenar* (prior vaccination should be with 3 doses of *Prevnar 13* only).
- Child that previously received a fourth dose of any pneumococcal conjugate vaccine.

A list of criteria that may eliminate children from ATP analyses can be found in Sections 6.7.1, 6.8 and 10.4.

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5. CONDUCT OF THE STUDY

5.1. Regulatory and ethical considerations, including the informed consent process

The study will be conducted in accordance with all applicable regulatory requirements.

The study will be conducted in accordance with the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP), all applicable participant privacy requirements and the guiding principles of the Declaration of Helsinki.

The study has been designed and will be conducted in accordance with the ICH Harmonized Tripartite Guideline for clinical investigation of medicinal products in the pediatric population (ICH E11) and all other applicable ethical guidelines.

GSK will obtain favorable opinion/approval to conduct the study from the appropriate regulatory agency, in accordance with applicable regulatory requirements, prior to a site initiating the study in that country.

Conduct of the study includes, but is not limited to, the following:

- Institutional Review Board (IRB)/Independent Ethics Committee (IEC) review and favorable opinion/approval of study protocol and any subsequent amendments.
- Child's parent(s)/LAR(s) informed consent.
- Investigator reporting requirements as stated in the protocol.

GSK will provide full details of the above procedures to the investigator, either verbally, in writing, or both.

Freely given and written informed consent must be obtained from each child's parent(s)/LAR(s) as appropriate, prior to participation in the study.

GSK Biologicals will prepare a model Informed Consent Form (ICF) which will embody the ICH GCP and GSK Biologicals required elements. While it is strongly recommended that this model ICF is to be followed as closely as possible, the informed consent requirements given in this document are not intended to pre-empt any local regulations which require additional information to be disclosed for informed consent to be legally effective. Clinical judgment, local regulations and requirements should guide the final structure and content of the local version of the ICF.

The investigator has the final responsibility for the final presentation of the ICF, respecting the mandatory requirements of local regulations. The ICF generated by the investigator with the assistance of the sponsor's representative must be acceptable to GSK Biologicals and be approved (along with the protocol, and any other necessary documentation) by the IRB/IEC.

5.2. Subject identification and randomization of treatment

Target enrollment for the study will be 5000 children. There are three Inv_MMR consistency lots (L1, L2, and L3) (N=1250 each) and the active control Com_MMR vaccine that is split into two lots (L1 and L2) comprising two groups of equal size (N=625 each) (see Figure 1).

5.2.1. Subject identification

Subject numbers will be assigned sequentially to children participating in the study, according to the range of subject numbers allocated to each study center.

5.2.2. Randomization of treatment

5.2.2.1. Randomization of supplies

The randomization used to number the vaccines will be performed at GSK Biologicals, Rixensart, using MATEX, a program developed for use in SAS® (Cary, NC, USA) by GSK Biologicals.

A first list based on a randomization blocking scheme using a 2:2:2:1:1 randomization ratio will be used to number the MMR vaccines.

- Inv_MMR_L1
- Inv_MMR_L2
- Inv_MMR_L3
- Com_MMR_L1
- Com_MMR_L2

The vaccines from this list will be distributed to the study center while respecting the randomization block size.

To allow GSK Biologicals to take advantage of greater rates of recruitment than anticipated at individual centers in this multicenter study and to thus reduce the overall study recruitment period, a surplus of at least 20% of supplies will be prepared.

5.2.2.2. Treatment allocation to the child

The treatment allocation at the investigator site will be performed using SBIR. The treatment numbers will be allocated by MMR dose. The randomization algorithm will be stratified by country and within each country a minimization procedure accounting for center will be used.

When SBIR is not available, please refer to the SBIR user guide or the study procedures manual (SPM) for specific instructions.

After having checked the eligibility of the child and obtaining the Informed Consent Form (ICF), the site staff will access SBIR. Upon providing the child identification

number, the randomization system will use the randomization algorithm to determine the group allocation and the treatment number(s) to be used for the child for MMR vaccination (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 or Com_MMR_L2). For replacement dose, the system will allocate a new treatment number according to the treatment initially allocated.

For allocation of co-administered vaccines (*Havrix* and *Varivax* to all children, and *Prevnar 13* to the children in the US), the site staff will select a treatment number available for the vaccine dose to be used for the child. Please reference the SPM for further details.

All treatment numbers must be recorded in the eCRF on the 'Vaccine Administration' screen.

5.3. Method of blinding

The study will be conducted in a double-blind fashion with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots (Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3) and in an observer-blind fashion for the comparison of the pooled lots of Inv_MMR vaccine versus the pooled Com_MMR vaccine lots.

Data will be collected in an observer-blind manner. By observer-blind, it is meant that during the course of the study, the vaccine recipient and those responsible for the evaluation of any study endpoint (e.g., safety, reactogenicity, and efficacy will all be unaware of which vaccine was administered). To do so, vaccine preparation and administration will be done by authorized medical personnel who will not participate in any of the study clinical evaluation.

The laboratory in charge of the laboratory testing will be blinded to the treatment, and codes will be used to link the child and study (without any link to the treatment attributed to the child) to each sample.

5.4. General study aspects

Supplementary study conduct information, not mandated to be present in this protocol, is provided in the accompanying SPM. The SPM provides the investigator and the site personnel with administrative and detailed technical information that does not impact the safety of the study children.

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5.5. Outline of study procedures

Table 5 List of study procedures

Age at enrollment	12-15 months		
Epoch	*Primary Epoch*		
Type of contact	Visit 1	Visit 2	Visit 3
Timepoints	Day 0	Day 42	Day 180
Sampling timepoints	Pre-Vacc	Post-Vacc	
Informed consent	●		
Check inclusion/exclusion criteria	●		
Check contraindications, warnings and precautions	O		O [1]
Collect demography data	●		
Medical history	●		
Physical examination	●	O [2]	O [2]
Measure/record height and weight	●		
Vaccination history (protocol specific vaccines) 3	●		
Pre-vaccination body temperature	●		
Randomization and recording of treatment number	●		
Blood sampling for antibody determination (~5 mL)	●	●	
Study vaccinations	●		
Second dose of *Havrix* and/or varicella vaccine			x [1]
Distribution of Diary Cards	O	O	
Daily post-vaccination recording of solicited local adverse events by children's parent(s)/LAR(s) on Diary Cards (Day 0-3)	●		
Daily post-vaccination recording of solicited general adverse events by children's parent(s)/LAR(s) on Diary Cards for drowsiness, loss of appetite, and irritability (Day 0-14) and for fever, rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42) 4	●		
Recording of the occurrence of any post-vaccination unsolicited symptoms by children's parent(s)/LAR(s) on Diary Cards (Day 0-42)	●		
Recording of concomitant medication/vaccination by children's parent(s)/LAR(s) on Diary Cards (Day 0-through study end)	●	O	O
Investigator/designee medical evaluation of any measles/rubella or varicella-like rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42)	●		
Recording of any medications/vaccinations through Visit 2 (see Section 6.7.2)	●	●	
Recording of any forbidden investigational product (through study end)	●	●	●
Return of Diary Cards by parent(s)/LAR(s) and transcription by investigator/designee		●	● [5]
Recording of any intercurrent medical condition (see Section 6.8)	●	●	
Recording of all Serious Adverse Events (Day 0 through study end)	●	●	●
Recording of NOCD(s) and AEs prompting medically attended visits including ER visits (Day 0 through study end) [6]	●	●	●
Visit 2 investigator sign-off on data for the Day 42 analysis		●	
Study Conclusion			●
Final investigator signature			●

● is used to indicate a study procedure that requires documentation in the individual eCRF
x is used to indicate a procedure (that is not part of the study) that requires documentation in the individual eCRF
O is used to indicate a study procedure that does not require documentation in the individual eCRF
[1] At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. The second dose of HAV and varicella vaccine is not part of the study procedures.
[2] Physical exam at Visit 2 and Visit 3 only required if deemed necessary based on child's interim medical history. Findings are to be recorded only if symptom/abnormality is present.

[3] For US children only, child that previously received a 3-dose series of PCV-13 at least 60 days prior to study entry (see Section 4.2).
[4] Parent(s)/LAR(s) will contact the investigator immediately for any suspected measles/rubella, varicella-like rash, parotid/salivary gland swelling or suspected signs of meningism, including febrile convulsions occurring between Day 0 and Day 42 and will be asked to schedule a visit for evaluation by the investigator (see Section 8.2.2.2).
[5] Return of Diary Card for contraindicated medication / vaccination, any specific Adverse Events (AEs), and AEs prompting medically attended visits including Emergency Room (ER) visits until study end. .
[6] Events to be recorded will be new onset chronic disease(s) (NOCD(s)) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting medically attended visits including Emergency Room (ER) visits.

Table 6 Intervals between study visits

Visit	Optimal Visit Day*	Interval	Allowed interval
Visit 1	Day 0		
Visit 2	Day 42	Visit 1 → Visit 2	35 days - 77 days†
Visit 3	Day 180	Visit 1 → Visit 3	35 days -77 days

* Whenever possible the investigator should arrange study visits on this optimal visit day.
† Children will not be eligible for inclusion in the ATP immunogenicity analyses if study visits are outside the allowed interval.

5.6. Detailed description of study procedures

5.6.1. Procedures prior to study participation

5.6.1.1. Informed consent

Before performing any other study procedure, the signed informed consent of the child's parent(s)/LAR(s) needs to be obtained.

Refer to Section 5.1 for the requirements on how to obtain informed consent.

5.6.2. Procedures prior to vaccination

5.6.2.1. Check inclusion and exclusion criteria

Check all applicable inclusion and exclusion criteria as described in Sections 4.2 and 4.3, respectively, before enrollment.

5.6.2.2. Collect demographic data

Record demographic data such as date of birth, gender, ethnicity, geographic ancestry (race), in the child's eCRF.

5.6.2.3. Medical history

- Record any pre-existing conditions or signs and/or symptoms present in a child prior to the start of the study in the eCRF.
- Prior vaccination history with respect to measles, mumps, rubella-virus containing vaccines should be obtained for all participants, as well as a history of pneumococcal conjugate containing vaccination (for children enrolled in the US only).

- In addition, history of blood transfusions or human gamma globulin during the period starting 180 days prior to vaccination should also be obtained. Any chronic administration (14 or more consecutive days) of immunosuppressants or other immune modifying drugs during the period starting 180 days prior to study entry must be recorded in the eCRF.

5.6.2.4. Physical examination

- Perform a routine physical examination of the child, (as per local standard of care), including assessment of pre-vaccination body temperature, height and weight. Collected body system information, including any abnormal findings needs to be recorded in the eCRF.
- Physical examination after the first visit will be performed only if the child's parent(s)/LAR(s) indicate during questioning that there might be some underlying pathology(ies) or if deemed necessary by the Investigator or delegate. Treatment of any abnormality observed during this examination should be performed according to local medical practice outside this study or by referral to an appropriate health care provider.

5.6.3. Procedures during the study/primary epoch

Note that some of the procedures to be performed during the primary epoch (such as a physical exam as needed) are also performed prior to any subsequent vaccination (Section 5.6.2.).

5.6.3.1. Check and record concomitant medication/vaccination and intercurrent medical conditions

- Concomitant medication/vaccination must be recorded in the eCRF as described in Section 6.7. Refer also to Section 4.3 for details on the medications/vaccinations prohibited and/or allowed during the study.
- At Visit 2 it must be verified if the child has experienced or is experiencing any intercurrent medical condition listed in Section 6.8. If it is the case, the condition(s) must be recorded in the eCRF. In addition, any concomitant medications/ vaccinations given through Visit 2 must be recorded in the eCRF. Refer to Section 6.7.1.
- At Visit 3 the use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) must be recorded in the eCRF (see Section 6.7.1).

5.6.3.2. Check contraindications, warnings and precautions to vaccination

- Contraindications, warnings and precautions to vaccination are to be checked at the beginning of each vaccination visit. Refer to Sections 6.5 and 6.6.

5.6.3.3. Assess pre-vaccination body temperature

- The body temperature of all children needs to be measured prior to any study vaccine administration. If the child has fever on the day of vaccination (fever is defined as

temperature ≥38°C/100.4°F measured by any age appropriate route [Marcy, 2004]), the vaccination visit will be rescheduled.

5.6.3.4. Randomization

- At the first vaccination visit, randomization will occur as explained in Section 5.2.2

5.6.3.5. Blood sampling for safety or immune response assessments

- As specified in the List of Study Procedures in Section 5.5 (Table 5), blood samples are taken during certain study visits. Refer to the Module on Biospecimen Management in the SPM for general handling of blood samples.
- A volume of approximately 5 mL of whole blood should be drawn from all children for each analysis of humoral immune response at each pre-defined time point. After centrifugation, serum samples should be stored at or less than –20°C (–4°F). Alternatively storage at approximately –70°C to –80°C (–94°F to –112°F) until shipment is also acceptable.

5.6.3.6. Treatment number assignment

- At the vaccination visit, the child will be assigned a treatment number defining the MMR treatment he/she will be receiving. The treatment number must be recorded in the eCRF at the first visit.

5.6.3.7. Vaccination

- After completing the prerequisite procedures including blood sampling prior to vaccination, one dose of MMR study vaccine will be administered subcutaneously (SC) preferably in the triceps region of the left arm (refer to Section 6.3 for detailed description of the vaccine administration procedure) along with co-administered vaccines as appropriate. If the investigator or delegate determines that the child's health on the day of vaccination temporarily precludes vaccination, the visit should be rescheduled.
- The vaccinees will be observed closely for at least 30 minutes, with appropriate medical treatment readily available in case of anaphylaxis following the administration of vaccines.

5.6.3.8. Recording of AEs and SAEs

- Refer to Section 8.2 for procedures for the investigator to record AEs and SAEs. Refer to Section 8.3 for guidelines on how to report AEs and SAEs to GSK Biologicals.
- The child's parent(s)/LAR(s) will be instructed to contact the investigator immediately should the child manifest any signs or symptoms they perceive as serious.
- At Visit 1 diary cards will be provided to the child's parent(s)/LAR(s) to record:
  - Any solicited local AEs such as pain, redness and swelling (from Day 0 – Day 3).

  - Any solicited general AEs such as drowsiness, loss of appetite, and irritability (from Day 0 – Day 14).
  - Any solicited general AEs such as fever, rash (measles/rubella or varicella-like rash and other rash), parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (from Day 0 – Day 42).
  - Any unsolicited symptoms (from Day 0 – Day 42).
  - Any concomitant treatments/medications/vaccinations (from Day 0 – Day 42).
- At Visit 2 diary cards will be provided to the child's parent(s)/LAR(s) to record:
  - Any medication/ vaccination (from Day 42 to study end).
  - Any AEs (from Day 42 to study end).
- The child's parent(s)/LAR(s) will be instructed to return the completed diary card to the investigator at the next study visit.
- Collection and verification of completed diary cards will occur during discussion with the child's parent(s)/LAR(s) at post-vaccination visit(s). The investigator/ designee will transcribe the required collected information into the eCRF.
- Collection and verification of completed diary cards will occur during discussion with the child's parent(s)/LAR(s) at Visit 3. The investigator/ designee will transcribe the collected information on any NOCDs and AEs prompting a medically attended visit(s) including ER visits into the eCRF.
- Any unreturned diary cards will be sought from the child's parent(s)/LAR(s) through phone call(s) or any other convenient procedure.

5.6.3.9. Procedures during follow-up visits

Note that some of the procedures to be performed during the follow-up visits (such as blood sampling, recording of AEs) are also performed during the other visits of the primary epoch and are described in Section 5.6.3.1 up to Section 5.6.3.8.

5.6.3.10. Study conclusion

- The investigator will review safety data collected to ensure accuracy and completeness and will complete the Study Conclusion screen in the eCRF.
- A child who returns for the concluding Visit 3 (Day 180) is considered to have completed the study.

5.7. Biological sample handling and analysis

Please refer to the SPM for details of biospecimen management (handling, storage and shipment).

Samples will not be labeled with information that directly identifies the child but will be coded with the identification number for the child (subject number).

Collected samples may be used in other assays, for test improvement or test development of analytical methods related to the study vaccine(s) and its constituents or the disease under study to allow to achieve a more reliable measurement of the vaccine response. Under these circumstances, additional testing on the samples may be performed by GSK Biologicals outside the scope of this protocol.

Information on further investigations and their rationale can be obtained from GSK Biologicals. Any sample testing will be done in line with the consent of the individual child's parent(s)/LAR(s). Any human pharmacogenetic testing will require specific consent from the individual child's parent(s)/LAR(s) and the ethics committee approval. Any human immunodeficiency virus (HIV) testing will also require specific consent and ethics committee approval.

Refer also to the Investigator Agreement, where it is noted that the investigator cannot perform any other biological assays except those described in the protocol or its amendment(s).

If additional testing is performed, the marker priority ranking given in Section 5.7.4 may be changed.

Collected samples will be stored for up to 20 years (counting from when the last child performed the last study visit), unless local rules, regulations or guidelines require different timeframes or different procedures, which will then be in line with the child consent. These extra requirements need to be communicated formally to and discussed and agreed with GSK Biologicals.

5.7.1. Use of specified study materials

When materials are provided by GSK Biologicals, it is MANDATORY that all clinical samples (including serum samples) be collected and stored exclusively using those materials in the appropriate manner. The use of other materials could result in the exclusion of the child from the ATP analysis (See Section 10.4 for the definition of study cohorts to be evaluated). The investigator must ensure that his/her personnel and the laboratory(ies) under his/her supervision comply with this requirement. However, when GSK Biologicals does not provide material for collecting and storing clinical samples, appropriate materials from the investigator's site must be used. Refer to the Module on Clinical Trial Supplies in the SPM.

5.7.2. Biological samples

Biological samples will be collected as indicated in Table 7 (Refer to Section 5.6.3.5 and APPENDIX A).

Table 7 Biological samples

Sample type	Quantity	Unit	Time points
Blood	~ 5	ml	Visit 1
Blood	~ 5	ml	Visit 2

ml = Milliliter

5.7.3. Laboratory assays

Serological assays for the determination of antibodies against measles, mumps and rubella viruses will be performed by ELISA at GSK Biologicals' laboratory or in a validated laboratory designated by GSK Biologicals using standardized and validated procedures (refer to Table 8).

Table 8 Humoral Immunity (Antibody determination)

System	Component	Method	Kit / Manufacturer	Unit	Cut-off
Serum	Measles Virus Ab.IgG	ELISA	Dade Behring Enzygnost	mIU/mL	150
Serum	Rubella Virus Ab.IgG	ELISA	Dade Behring Enzygnost	IU/mL	4
Serum	Mumps Virus Jeryl Lynn 135 Ab.IgG	ELISA	PPD	EU/mL	5
Serum	Varicella Zoster Virus Ab.IgG	ELISA	Dade Behring Enzygnost	mIU/mL	25
Serum	Hepatitis A Virus Ab	ELISA	In-house	mIU/mL	15
Serum	*Streptococcus pneumoniae*. Polysaccharide 01 Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 03 Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 04 Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 05 Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 06A Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 06B Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 07F Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 09V Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 14 Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 18C Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 19A Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 19F Ab.IgG	TBC	TBC	TBC	TBC
Serum	*Streptococcus pneumoniae*. Polysaccharide 23F Ab.IgG	TBC	TBC	TBC	TBC

Ab = Antibody; IgG = Immunoglobulin class G
ELISA = Enzyme Linked Immunosorbent Assay; TBC= To be confirmed.
PPD = Pharmaceutical Product Development, Inc., (466 Devon Park Drive, Wayne, PA 19087-1816, USA).
IU = International Unit; mIU = Milli International Unit; EU = ELISA Unit; mL = Milliliter; µg = Microgram

Collected samples will be used for purposes related to the quality assurance of data generated within the scope of this protocol, such as for maintenance of assays described in this protocol and comparison between analytical methods and/or laboratories.

The addresses of the clinical laboratories for sample analysis in this study are:

GlaxoSmithKline Biologicals
Clinical Immunology
R & D Department/Building 7/44
Rue de l'Institut, 89
B-1330 Rixensart – Belgium

GSK Biologicals Global Vaccine Clinical Laboratory
Biospecimen Reception - Clinical Serology
525 Cartier blvd West - Laval - Quebec - Canada - H7V 3S8
Note : In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party Contract Research Organization (CRO) **(Amended: 26-FEB-2015)**
PPD, Inc.
466 Devon Park Drive
Wayne, PA 19087-1816 – USA

The GSK Biologicals' clinical laboratories have established a Quality System supported by procedures. The activities of GSK Biologicals' clinical laboratories are audited regularly for quality assessment by an internal (sponsor-dependent) but laboratory-independent Quality Department.

The central laboratory responsible for sample handling/processing for sites in the United States (including Puerto Rico) is BARC USA Inc. 5, Delaware Drive, Lake Success, NY 11042-1114, U.S.A.

Clinical laboratories contracted by GSK also conform to Good Laboratory Practice guidelines and operate in compliance with regulatory standards.

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5.7.4. Biological samples evaluation

5.7.4.1. Immunological read-outs

Table 9 Immunological read-outs

Blood sampling timepoint		Subset Name	No. of children	Components	Priority rank
Type of contact and timepoint	Sampling timepoint				
Visit 1 (Day 0)	Pre-Vacc	Subset A	1250	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				Hepatitis A Virus Ab	3
		Subset B	1250	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG	3
		Subset C	2500	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG	2
Visit 2 (Day 42)	Post-Vacc	Subset A	1250	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				Hepatitis A Virus Ab	3
		Subset B	1250	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG	3
		Subset C	2500	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG	2

Vacc = vaccination; Ab = Antibody; IgG = Immunoglobulin class G
Subset A: the first 1250 children enrolled in the US
Subset B: the next 1250 children enrolled in the US
Subset C: the other 2500 children enrolled

In case of insufficient blood sample volume to perform assays for all antibodies, the samples will be analyzed according to priority ranking provided in Table 9.

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5.7.5. Immunological correlates of protection

The following antibody thresholds are accepted by the FDA as endpoints defining active immunization offering clinical benefit:

- Measles ≥200 mIU/mL (ELISA)
- Mumps ≥10 EU/mL (ELISA)
- Rubella ≥10 IU/mL (ELISA).

The blood sample taken at Day 42 will be the timepoint used to determine sub-optimal responders, i.e., an individual immunological assay result which is below the threshold accepted by the FDA.

The investigator, even though remaining blinded with respect to each child's group attribution, will be told which child had a sub-optimal response as confirmed by the results of blood samples. A list of sub-optimal responders will be communicated to the investigators in a timely manner (no later than 12 months after the last sampling date of the last child enrolled). If the post-vaccination Day 42 immune response data indicate a sub-optimal seroresponse to either the investigational MMR vaccine or the competitor MMR vaccine, a rescue plan will be implemented and re-vaccination with M-M-R®II (or *Priorix* in ex-US settings where the vaccine is licensed) will be offered to children that fail to serorespond to measles, mumps or rubella virus components. Children intended to receive only one dose of varicella vaccine as part of this study (e.g., children enrolled in the US) and who fail to serorespond to varicella virus (i.e. achieve a post-vaccination titer ≥75 mIU/mL) will be offered re-vaccination with Varivax®. Children in ex-US countries that will be provided with a second dose of varicella vaccine, because they are enrolled in countries where it is not routinely provided (see Table 5), will not be considered sub-optimal responders based on their post dose 1 immune response.

6. STUDY VACCINES AND ADMINISTRATION

6.1. Description of study vaccines

The candidate live, attenuated Inv_MMR vaccine was developed and manufactured by GSK Biologicals. The Quality Control Standards and Requirements for the Inv_MMR vaccine are described in separate release protocols and the required approvals have been obtained.

The vaccines are labeled and packed according to applicable regulatory requirements. Commercial vaccines are assumed to comply with the specifications given in the manufacturer's Summary of Product Characteristics.

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Table 10 Study vaccines

Treatment name	Vaccine/product name	Formulation	Presentation	Volume	Number of doses
Inv_MMR_L1	Inv_MMR_L1	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	0.5 mL	1
Inv_MMR_L2	Inv_MMR_L2	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	0.5 mL	1
Inv_MMR_L3	Inv_MMR_L3	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	0.5 mL	1
Com_MMR_L1	Com_MMR_L1	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	Lyophilized pellet in a vial for reconstitution with water for injection	0.5 mL†	1
	Com_MMR_L1 Diluent‡	water for injection	Vial or a Syringe (depending on the country)	0.5 mL	1

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Treatment name	Vaccine/product name	Formulation	Presentation	Volume	Number of doses
Com_MMR_L2	Com_MMR_L2	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	Lyophilized pellet in a vial for reconstitution with water for injection	0.5 mL†	1
	Com_MMR_L2 Diluent‡	water for injection	Vial or a Syringe (depending on the country)	0.5 mL	1
Varivax	*Varivax*	A minimum of 1350 pfu of Oka/Merck varicella virus; sucrose approximately 25 mg; hydrolyzed gelatin 12.5 mg, sodium chloride 3.2 mg; monosodium L-glutamate 0.5 mg; sodium phosphate dibasic 0.45 mg; potassium phosphate monobasic 0.08 mg; potassium chloride 0.08 mg; residual components of MRC-5 cells including DNA and protein; and trace quantities of sodium phosphate monobasic; EDTA; neomycin; and fetal bovine serum	Lyophilized pellet in a vial for reconstitution with water for injection	0.5 mL†	2§
	Varivax Diluent	water for injection	Vial or Syringe (depending on the country)	0.5 mL	2§
Havrix	*Havrix*	720 EU of hepatitis A virus antigen; 0.25 mg aluminum (as hydroxide); amino acid supplement (0.3% w/v); in a phosphate-buffered saline solution and polysorbate 20 (0.05 mg/mL)	Suspension in vial/ pre-filled syringe	0.5 mL	2§
Prevnar 13	*Prevnar 13*	2.2 µg of the purified saccharides 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F; 4.4 mcg of the purified saccharide 6B; approximately 34 µg CRM_{197} carrier protein; 100 µg polysorbate 80; 295 µg succinate buffer; 125 µg aluminum as aluminum phosphate adjuvant	Suspension in vial/ pre-filled syringe	0.5 mL	1¥

L= Lot; CCID = Cell Culture Infectious Dose; TCID = Tissue Culture Infectious Dose; EU = ELISA Unit
ppm = Parts Per Million; pfu = Plaque Forming Unit; mL = Milliliter; mg = Milligram; mcg = Microgram; µg = Microgram
MRC = Medical Research Council; DNA = Deoxyribonucleic Acid; EDTA = Ethylenediamine-Tetraacetic Acid
CRM_{197} = Cross-Reactive Material (mutant diphtheria toxin)
† Volume after reconstitution

‡ The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
§ At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. Not applicable for subjects enrolled in US. The second dose of HAV and varicella vaccine is not part of the study procedures.
¥ PCV-13 will be administered to US children with a history of 3-doses of PCV-13 at least 60 days prior to study entry.

6.2. Storage and handling of study vaccines

All study vaccines to be administered to the children must be stored in a safe and locked place with no access by unauthorized personnel.

The study vaccines will be stored at the defined temperature ranges:

- All MMR vaccines (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 and Com_MMR_L2 lots) and all the respective diluents will be stored at 2°C to 8°C (36°F to 46°F).
- **Outside the US** *Havrix*, *Varivax* and *Varivax* diluent will be stored at 2°C to 8°C (36°F to 46°F).
- **In the US** *Varivax* will be stored at -15°C to -50°C (5°F to -58°F). The *Havrix*, *Prevnar 13* and *Varivax* diluent will be stored at 2°C to 8°C (36°F to 46°F).

(Note: Refrigerated *Varivax* vaccine will be used at non-US sites, while Frozen *Varivax* vaccine will be used at sites in the US).

Please refer to the Module on Clinical Trial Supplies in the SPM for more details on storage of the study vaccines. The storage temperature of the vaccines will be monitored daily with validated temperature monitoring device(s) and will be recorded as specified in the SPM.

The storage conditions will be assessed during pre-study activities under the responsibility of the sponsor study contact.

Any temperature excursion, outside the range of 0°C to +8°C (32°F to 46°F) for refrigerated vaccines, or -15°C to -50°C (5°F to -58°F) for frozen vaccines, must be reported to the sponsor as soon as detected. Following an exposure to a temperature excursion, vaccines will not be used until written approval has been given by the Sponsor.

Outside the US, adequate actions must be taken for refrigerated vaccines in case of temperature excursion between 0 and +2°C (32 and 36°F) which go back to the defined range +2 to +8°C (36 to 46°F). The impacted study vaccine(s)/product(s) can still be administered, but the site should avoid re-occurrence of temperature excursion.

Please refer to the Module on Clinical Trial Supplies in the SPM for details and instructions on the Temperature excursion process as well as packaging and accountability of the study vaccines.

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6.3. Dosage and administration of study vaccines

Table 11 Dosage and administration

Type of contact and timepoint	Dose	Treatment Group	Vaccine/Product	Route[1]	Site	Side[2]
Visit 1 (Day 0)	1	Inv_MMR_L1	Inv_MMR_L1	SC	Tricep region	Left
	1	Inv_MMR_L2	Inv_MMR_L2	SC	Tricep region	Left
	1	Inv_MMR_L3	Inv_MMR_L3	SC	Tricep region	Left
	1	Com_MMR_L1	Com_MMR_L1	SC	Tricep region	Left
	1	Com_MMR_L2	Com_MMR_L2	SC	Tricep region	Left
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Varivax*	SC	Tricep region	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Havrix*	IM	Anterolateral thigh	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Prevnar 13**	IM	Anterolateral thigh	Left

[1] Intramuscular (IM)/ Subcutaneous (SC)
[2] Left (L)/ Right (R)
* For US children only.

Inv_MMR, Com_MMR and *Varivax* should be given **subcutaneously** in the upper arm ("Triceps" region) by inserting the needle in a pinched-up fold of skin and subcutaneous tissue (to prevent injection into muscle). The Inv_MMR and Com_MMR vaccines will be injected in the left arm and the *Varivax* will be injected in the right arm. A 25-gauge needle, 5/8-inch (1.6 cm) long, is recommended. The needle should be changed between drawing the vaccine into the syringe and injecting it into the child.

The dose of Inv_MMR and Com_MMR for any age is 0.5 mL administered subcutaneously. These vaccines should be reconstituted by first withdrawing the entire volume of diluent to be used for reconstitution into the syringe. Note that some diluents may already be provided in pre-filled syringes. The Com_MMR_L1 diluent may be distinct from the Com_MMR_L2 diluent and for countries outside the US, Com_MMR diluents will be pre-packaged in a syringe. Inject all of the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. The vial must be shaken well until the pellet is completely dissolved. If the lyophilized vaccine cannot be dissolved, discard. Withdraw the entire contents of the reconstituted vaccine into the syringe and change the needle. Using a new needle, inject the total volume of reconstituted vaccine subcutaneously.

After reconstitution, the MMR vaccines should be injected promptly (within 30 minutes).

Due to potential color differences between the reconstituted Inv_MMR and Com_MMR, dedicated unblinded staff in each investigational site will be accountable for reconstitution and administration to each child.

Varivax should be reconstituted by first withdrawing 0.7 mL of diluent into a syringe. Inject all the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into a syringe and inject the total volume (about 0.5 mL) of reconstituted vaccine subcutaneously.

Havrix and *Prevnar 13* will be administered by **intramuscular injection** in the right and left thigh, respectively. The dosage for these co-administered vaccines is 0.5 mL.

Attenuated viruses in these vaccines are rapidly inactivated by alcohol and detergents, and care should be taken to avoid contact between the reconstituted vaccine and these substances. Ensure that the disinfected area of skin and/or vaccine vial(s) are completely dry prior to administering any vaccines.

All vaccine recipients will be observed closely for at least 30 minutes following the administration of vaccines with appropriate medical treatment readily available in case of a rare anaphylactic reaction.

6.4. Replacement of unusable vaccine doses

Additional vaccine doses will be provided to replace those that are unusable (see the Module on Clinical Trial Supplies in the SPM for details).

In addition to the vaccine doses provided for the planned number of children (including at least a 20% over-supply when applicable), additional doses will be supplied to replace those that are unusable.

The investigator or designee will use SBIR to obtain a new treatment number. The new treatment numbers will be allocated by dose to replace an unusable dose. The system will ensure, in a blinded manner, that the new vial matches the formulation the child was assigned to by randomization.

6.5. Contraindications to vaccination

See Exclusion criteria, Section 4.3.

6.6. Warnings and precautions

Refer to the approved product label/package insert for licensed vaccine(s).

It is recommended that members of the investigational team be immune to measles, mumps, rubella and varicella viruses. The measles and mumps components of commercial and investigational vaccines are produced in chick embryo cell culture and may therefore contain traces of egg protein. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., generalized urticaria, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg

ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after vaccination, although these types of reactions have been shown to be very rare. Individuals who have experienced anaphylaxis after egg ingestion should be vaccinated with extreme caution, with adequate treatment for anaphylaxis on hand should such a reaction occur.

If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that combined measles, mumps and rubella vaccines may cause a temporary depression of tuberculin skin sensitivity. As this anergy may last up to a maximum of six weeks, tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination with MMR vaccines.

Post-marketing experience with *Varivax* suggests that transmission of vaccine virus may occur rarely between healthy recipients of vaccines that develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has also been reported. Information will be given to the parent(s)/LAR(s) in the event that during the study period a household member becomes a susceptible high-risk individual. Susceptible high-risk individuals should avoid close association with vaccine recipients, and especially those vaccine recipients who develop a vaccine-associated rash, for up to six weeks. In circumstances where contact with high-risk individuals is unavoidable, the potential risk of transmission of vaccine virus should be weighed against the risk of acquiring and transmitting natural varicella virus. Susceptible high-risk individuals include :

- Residence in the same household as the following:
  - Newborn infants (0-4 weeks of age).
  - Pregnant women with a negative history of chickenpox disease and without recorded vaccination against chickenpox.
  - Pregnant women at or beyond 28 weeks gestation regardless of varicella vaccination status or varicella disease history.
  - Persons with known immunodeficiency.

The use of salicylates by vaccine recipients should be avoided for six weeks after vaccination with *Varivax* as Reye's Syndrome has been reported following the use of salicylates during natural varicella infection.

6.7. Concomitant medication/vaccination

At each study visit, the investigator should question the child's parent(s)/LAR(s) about any medication taken and vaccination received by the child.

All concomitant medication/vaccination, with the exception of vitamins and/or dietary supplements, are to be recorded in the eCRF (in the window defined by the protocol (see Section 6.7.2)). This also applies to concomitant medication administered

prophylactically in anticipation of reaction to the vaccination and any medication intended to treat an AE.

A prophylactic medication is a medication administered in the absence of ANY symptom and in anticipation of a reaction to the vaccination (e.g., an anti-pyretic is considered to be prophylactic when it is given in the absence of fever and any other symptom, to prevent fever from occurring [fever is defined as temperature ≥38.0°C/100.4°F]).

Similarly, concomitant medication administered for the treatment of a SAE, at any time, must be recorded on the SAE Report / SAE screens in the eCRF, as applicable. Refer to Section 8.1.2 for the definition of a SAE.

6.7.1. Medications/products that may lead to the elimination of a child from ATP analyses

The following criteria should be checked at each visit. If any become applicable during the study, it will not require withdrawal of the child from the study but may determine a child's evaluability in the according-to-protocol (ATP) analysis. See Section 10.4 for definition of study cohorts to be evaluated.

- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the entire study period.
- Chronic administration (defined as 14 or more consecutive days) of immunosuppressants, or other immune-modifying drugs, during the period starting at vaccination and ending at the immunogenicity evaluation at Visit 2.
  - For corticosteroids, this will mean prednisone ≥0.5 mg/kg/day, or equivalent.
  - Inhaled and topical steroids are allowed.
- Planned administration/ administration of a vaccine not foreseen by the study protocol during the study period starting at vaccination and ending at Visit 2.
  Please Note:
  - **Inactivated** Flu and Hib vaccines may be given at any time, including the day of study vaccination (Flu and Hib vaccines must be administered at a different location than the study vaccine/s).
  - Any ***other*** age appropriate vaccine may be given starting at Visit 2 and any time thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting at vaccination through the immunogenicity evaluation at Visit 2.

6.7.2. Time window for recording concomitant medication/vaccination in the CRF/eCRF

At each study visit, the investigator should question the child's parent(s)/LAR(s) about any medication taken and vaccination(s) received by the child.

All concomitant medications, with the exception of vitamins and/or dietary supplements, administered at ANY time during the period starting 30 days preceding the administration of the dose of study vaccine (i.e., 30 days prior to Day 0) and ending at Visit 2 after the administration of study vaccine must be recorded in the eCRF. Concomitant medication/vaccination should be recorded by the child's parent(s)/LAR(s) in the subject diary between Visit1 and Visit 2. The investigator will transcribe this information into the eCRF as indicated below.

Any medications specifically contraindicated, e.g., any immune-globulins, other blood products and any immune modifying drugs administered during the period starting 180 days prior to the vaccination through Visit 2 are to be recorded in the eCRF with the generic name of the medication (trade names are allowed for combination drugs only), medical indication, total daily dose, route of administration, start and end dates of treatment.

Any vaccine administered in the period starting 30 days before study vaccination through Visit 2 must be recorded in the eCRF. The second dose of HAV and/or varicella vaccine administered at Visit 3 must be recorded in the eCRF (see Section 5.5). In addition, administration of previous measles, mumps, and rubella virus containing vaccines regardless of when they were given must be recorded in the eCRF.

Any medication administered for the treatment of an AE should be recorded in the child's eCRF.

Any investigational medication or vaccine administered throughout the entire study must be recorded in the eCRF.

6.8. Intercurrent medical conditions that may lead to elimination from an ATP cohort

Children may be eliminated from the ATP cohort if they are confirmed to have an immunodeficiency condition, or if they develop measles, mumps, or rubella, in the interval between vaccination and the collection of the blood specimen for immunogenicity at the blood draw at Visit 2.

7. HEALTH ECONOMICS

Not applicable.

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8. ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

The investigator or site staff is responsible during the study for the detection and documentation of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE) as provided in this protocol.

Each child's parent(s)/LAR(s) will be instructed to contact the investigator immediately should their child manifest any signs or symptoms they perceive as serious.

8.1. Safety definitions

8.1.1. Definition of an adverse event

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also includes failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse.

Examples of an AE include:

- Significant or unexpected worsening or exacerbation of the condition/indication under study.
- Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency and/or intensity of the condition.
- New conditions detected or diagnosed after investigational product administration even though they may have been present prior to the start of the study.
- Signs, symptoms, or the clinical sequelae of a suspected interaction.
- Signs, symptoms, or the clinical sequelae of a suspected overdose of either investigational product or a concurrent medication (overdose per se should not be reported as an AE/SAE).
- Signs, symptoms temporally associated with vaccine administration.
- Significant failure of expected pharmacological or biological action.

Examples of an AE DO NOT include:

- Medical or surgical procedures (e.g., endoscopy, appendectomy); the condition that leads to the procedure is an AE.
- Situations where an untoward medical occurrence did not occur (e.g., convenience admission to a hospital, admission for routine examination).
- Anticipated day-to-day fluctuations of pre-existing disease(s) or condition(s) present or detected at the start of the study that do not worsen.

AEs may include pre- or post-treatment events that occur as a result of protocol-mandated procedures (i.e., invasive procedures, modification of child's previous therapeutic regimen).

NB: AEs to be recorded as endpoints (solicited AEs) are described in Section 8.1.3. All other AEs will be recorded as UNSOLICITED AEs.

Example of events to be recorded in the medical history section of the eCRF:

- Pre-existing conditions or signs and/or symptoms present in a child prior to the start of the study (i.e., prior to the first study vaccination).

8.1.2. Definition of a serious adverse event

A serious adverse event is any untoward medical occurrence that:

a. Results in death,

b. Is life-threatening,

   NB: The term 'life-threatening' in the definition of 'serious' refers to an event in which the child was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death, had it been more severe.

c. Requires hospitalization or prolongation of existing hospitalization,

   NB: In general, hospitalization signifies that the child has been admitted at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or in an out-patient setting. Complications that occur during hospitalization are also considered AEs. If a complication prolongs hospitalization or fulfils any other serious criteria, the event will also be considered serious. When in doubt as to whether 'hospitalization' occurred or was necessary, the AE should be considered serious.

   Hospitalization for elective treatment of a pre-existing condition (known or diagnosed prior to informed consent signature) that did not worsen from baseline is NOT considered an AE.

d. Results in disability/incapacity.

   NB: The term disability means a substantial disruption of a person's ability to conduct normal life functions. This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhea, influenza like illness, and accidental trauma (e.g., sprained ankle) which may interfere or prevent everyday life functions but do not constitute a substantial disruption.

Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the child or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also be considered serious. Examples of such events are invasive or malignant cancers, intensive treatment in an

emergency room or at home for allergic bronchospasm, blood dyscrasias, or convulsions that do not result in hospitalization.

8.1.3. Solicited adverse events

The following local (injection-site) adverse events will be solicited at the Inv_MMR and Com_MMR injection sites (Table 12):

Table 12 Solicited local adverse events at Inv_MMR and Com_MMR injection sites

Adverse Event	Solicited follow-up period
Pain at injection site	from Day 0 to Day 3 after vaccination
Redness at injection site	
Swelling at injection site	

These local injection site reactions will be recorded from Day 0 to Day 3 on the Diary Cards following vaccinations in both groups. Redness and swelling will be measured in millimeters and the greatest surface diameter will be recorded. Pain at injection site will be assessed.

The solicited general adverse events are shown in Table 13.

Table 13 Solicited general adverse events

Adverse Event	Solicited follow-up period
Drowsiness	from Day 0 to Day 14 after vaccination
Loss of appetite	
Irritability	
Varicella-like rash*	from Day 0 to Day 42 after vaccination
Measles/rubella-like rash*	
Other rash (not measles/rubella-like nor varicella-like)	
Fever (defined as temperature ≥38°C/100.4°F)**	
Parotid gland / Salivary gland swelling*	
Meningism including febrile convulsions*	

* To be confirmed by a physician.

** Fever is defined as temperature ≥38°C/100.4°F [Marcy, 2004]. The preferred route for recording temperature in this study will be axillary. Temperature will be recorded daily from Day 0 to Day 42 after vaccination. The child's parent(s)/LAR(s) are requested to record the child's body temperature each evening at bedtime. Should additional temperature measurements be performed at other times of day, the highest temperature will be recorded.

NB: Temperature will be recorded in the evening. Should additional temperature measurements be performed at other times of day, the highest temperature will be recorded in the eCRF.

8.1.4. Clinical laboratory parameters and other abnormal assessments qualifying as adverse events or serious adverse events

Abnormal laboratory findings (e.g., clinical chemistry, hematology, urinalysis) or other abnormal assessments that are judged by the investigator to be clinically significant will be recorded as AEs or SAEs if they meet the definition of an AE, as defined in Section 8.1.1 or of a SAE, as defined in Section 8.1.2. Clinically significant abnormal laboratory findings or other abnormal assessments that are detected during the study or are present at baseline and significantly worsen following the start of the study will be reported as AEs or SAEs.

The investigator will exercise his or her medical and scientific judgment in deciding whether an abnormal laboratory finding or other abnormal assessment is clinically significant.

8.1.5. Adverse events of specific interest

AEs of specific interest for safety monitoring include NOCDs (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting ER visits. Occurrences of AEs of specific interest, including NOCDs and AEs prompting ER visits, will be reported throughout the study, through a minimum of six months post-vaccination, whether or not they are considered to be possibly related to the treatment administration. Medical documentation of the events will be reported in appropriate targeted follow-up forms included in the eCRF. These events also have to be reported as AE or SAE as appropriate in the eCRF.

8.2. Detecting and recording adverse events and serious adverse events

8.2.1. Time period for detecting and recording adverse events and serious adverse events

All AEs starting from Day 0 through 42 days after the administration of study vaccine must be recorded on the Adverse Event screen in the child's eCRF, irrespective of intensity or whether or not they are considered vaccination-related. The standard time period for collecting and recording SAEs will begin at the first receipt of study vaccines and will be collected throughout the entire study. See Section 8.3 for instructions on reporting of SAEs.

SAEs that are related to the study vaccine(s) will be collected and recorded from the time of the first study vaccination until the child is discharged.

In addition to the above-mentioned reporting requirements and in order to fulfill international reporting obligations, SAEs that are related to study participation (i.e., protocol-mandated procedures, invasive tests, a change from existing therapy) or are related to a concurrent GSK medication/vaccine or any fatal SAE will be collected and recorded from the time the parent(s)/LAR(s) consents to have the child participate in the study until she/he is discharged.

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The standard time period for collecting and recording AEs of specific interest, including NOCDs and AEs prompting ER visits, will begin at the first receipt of study vaccine and will end at the last study visit or contact.

The standard time period for collecting and recording of AEs prompting a medically attended visit(s) will begin at the first receipt of study vaccine and will end at the last study visit or contact.

An overview of the protocol-required reporting periods for AEs, and SAEs is given in Table 14.

Table 14 Reporting periods and methods for adverse events and serious adverse events

	Visit 1 Vaccination			Visit 2 Follow-up	Visit 3 Conclusion
Optimal Visit Day	**Day 0**			**Day 42**	**Day 180**
Solicitation period	Day 0-3	Day 4-14	Day 15-42		
Study activity					
Reporting solicited local AEs	DC/RDE				
Reporting solicited drowsiness, loss of appetite or irritability	DC/RDE				
Reporting solicited fever, rash (measles / rubella or varicella-like rash, other rash), parotid/salivary gland swelling and any sign of meningism including febrile convulsions	DC/RDE				
Reporting unsolicited AEs	DC/RDE			DC	DC
Reporting NOCD(s) and AEs prompting a medically attended visit(s) (including ER visits)	***DC***/RDE			***DC***/RDE	***DC***/RDE
Reporting ALL SAEs	***DC***/RDE			***DC***/RDE	***DC***/RDE

AEs = Adverse Events; DC = Diary Card; RDE = Remote Data Entry; SAEs = Serious Adverse Events
NOCD = New Onset Chronic Disease; ER = Emergency Room.

A post-study AE/SAE is defined as any event that occurs outside of the AE/SAE reporting period defined in Table 14. Investigators are not obligated to actively seek AEs or SAEs in former study participants. However, if the investigator learns of any SAE at any time after a child has been discharged from the study, and he/she considers the event reasonably related to the investigational product, the investigator will promptly notify the Study Contact for Reporting SAEs.

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8.2.2. Evaluation of adverse events and serious adverse events

8.2.2.1. Active questioning to detect adverse events and serious adverse events

As a consistent method of soliciting AEs, the child's parent(s)/LAR(s) should be asked a non-leading question such as:

'*Has your child acted differently or felt different in any way since receiving the vaccine or since the last visit?*'

When an AE/SAE occurs, it is the responsibility of the investigator to review all documentation (e.g., hospital progress notes, laboratory, and diagnostics reports) relative to the event. The investigator will then record all relevant information regarding an AE/SAE on the eCRF or SAE Report screens as applicable. It is not acceptable for the investigator to send photocopies of the child's medical records to GSK Biologicals instead of the appropriate completed AE/SAE screens in the eCRF. However, there may be instances when copies of medical records for certain cases are requested by GSK Biologicals. In this instance, all participant identifiers will be blinded on the copies of the medical records prior to submission to GSK Biologicals.

The investigator will attempt to establish a diagnosis pertaining to the event based on signs, symptoms, and/or other clinical information. In such cases, the diagnosis should be documented as the AE/SAE and not the individual signs/symptoms.

8.2.2.2. Assessment of adverse events

8.2.2.2.1. Assessment of intensity

Intensity of the following AEs will be assessed as described in Table 15.

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Table 15 Intensity scales for solicited symptoms

Adverse Event	Intensity Grade	Parameter
Pain at injection site	0	None
	1	Minor reaction to touch (digital pressure)
	2	Cries/protests on touch (digital pressure)
	3	Cries when limb is moved/spontaneously painful
Local injection site redness (Record greatest surface diameter in mm)	0	None
	1	> 0-≤ 5mm
	2	> 5-≤ 20mm
	3	>20mm
Local injection site swelling (Record greatest surface diameter in mm)	0	None
	1	> 0-≤ 5mm
	2	> 5-≤ 20mm
	3	>20mm
Fever* body temperature in °C or °F, (axillary route preferred)	Temperature will be analyzed in 0.5°C increments from ≥38°C (≥100.4°F) Grade 3 fever is defined as >39.5°C. (103.1°F)	
Measles/rubella-like rash and varicella-like rash	1	1-50 lesions
	2	51-150 lesions
	3	>150 lesions
Other rash	1	Rash which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities
	2	Rash which is sufficiently discomforting to interfere with normal everyday activities
	3	Rash which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day care and would cause the parent(s)/LAR(s) to seek medical advice)
Parotid/salivary gland swelling	1	Swelling without difficulty moving the jaw
	2	Swelling with difficulty moving the jaw
	3	Swelling with accompanying general symptoms
Irritability/Fussiness	0	Behavior as usual
	1	Crying more than usual/ no effect on normal activity
	2	Crying more than usual/ interferes with normal activity
	3	Crying that cannot be comforted/ prevents normal activity
Drowsiness	0	Behavior as usual
	1	Drowsiness easily tolerated
	2	Drowsiness that interferes with normal activity
	3	Drowsiness that prevents normal activity
Loss of appetite	0	Appetite as usual
	1	Eating less than usual/ no effect on normal activity
	2	Eating less than usual/ interferes with normal activity
	3	Not eating at all
Meningism (any suspected signs including febrile convulsions)	1	An event which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities
	2	An event which is sufficiently discomforting to interfere with normal everyday activities
	3	An event which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day care and would cause the parent(s)/LAR(s) to seek medical advice)

*Fever is defined as temperature ≥38°C/100.4°F.
mm = Millimeter; °C = Degree Celsius;°F = Degree Fahrenheit

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The maximum intensity of local injection site redness/swelling will be graded based on child's parent(s)/LAR(s) measurements recorded on the Diary Card.

Temperature/ fever:. Temperature should be recorded daily, from Day 0 through Day 42. Parent(s)/LAR(s) are requested to record on the diary card the child's body temperature measured each evening at bedtime (while at home ONLY one temperature route [axillary preferred] should be used consistently for all measurements on a given child). Should additional temperature measurements be performed at other times of day, the highest temperature will be recorded.

Rash and parotid/salivary gland swelling and signs of meningism including febrile convulsions:

IMPORTANT: If **any** of the following symptoms below are suspected during the follow-up period after vaccination (Day 0-42), the parent(s)/LAR(s) **must** perform daily post-vaccination recording on the Diary Card and contact the investigator's center.

- **Rash/ exanthem:**

Parent(s)/LAR(s) will be provided with a description of rashes. Parent(s)/LAR(s) will be asked to contact the study site immediately if their child develops a rash that could be a measles/rubella or varicella-like rash (Day 0-42). If the investigator/designee also suspects that the rash could possibly be a measles/rubella-like rash or varicella-like rash, a visit should be arranged as soon as possible; ideally within 48 hours after rash onset, or as soon as possible thereafter.

The investigator's assessment of the rash will be recorded in the eCRF. If the investigator has not seen the rash, and other medically qualified person has assessed the rash during a medically attended visit, then this assessment will be recorded in eCRF. If the child was not seen by the investigator or other medically qualified person, the information about rash entered in eCRF should be the one recorded by the parent in the diary card.

The investigator will classify cases of the rash as follows:

(1) Measles/ rubella rashes (macular or maculo-papular rashes): presence of macules, discolored small patches or spots of the skin, neither elevated nor depressed below the skin's surface and/or papules, raised bumps on the skin usually <1 cm in diameter.

(2) Varicella-like rash (papulo-vesicular): simultaneous presence of papules and vesicles raised above the skin's surface.

(3) Or other types of rash (heat rash, etc…).

Duration of rash episode will be indicated, as well as the locality of the rash:

Measles/rubella-like or varicella-like rash:

- rash onset, i.e., date when the first lesion appears
- rash ended, i.e., date of the first day when no new lesion appears.

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Other Rash:

- start date, i.e., date when first symptom appears
- end date, i.e., date when the rash disappears/resolves.

Intensity of measles/rubella-like, or varicella-like rash will be assessed according to the maximum number of overall lesions as described in Table 15.

The outcome of each rash will be assessed as: recovered/resolved, recovering/resolving, not recovered/not resolved, recovered with sequelae/resolved with sequelae.

The investigator will assess the causality of rash episode.

- **Parotid/salivary gland swelling:**

If parotitis is clinically suspected (swelling / tenderness in the mandibular / submandibular region) during Day 0 to Day 42 after vaccination, the child will be seen by the investigator as soon as possible for an additional visit.

Only those cases diagnosed by the investigator/designee as parotitis are to be recorded as a solicited symptom in the eCRF. Other cases of swelling/tenderness in the mandibular/submandibular region that do not meet the criteria for parotitis clinically are to be reported as an unsolicited AE in the eCRF. Intensity will be recorded as described in Table 15. The outcome of each case will be assessed as described in 8.2.2.2.

- **Any suspected signs of meningism including febrile convulsions/seizures:**

If the child experiences febrile convulsions or presents any other neurological signs or symptoms indicative of meningism (i.e., neck stiffness with or without light intolerance (photophobia) and headache; or convulsion/seizure) during Day 0 to Day 42 follow-up after vaccination, the parent(s)/LAR(s) should contact the investigator immediately for follow-up. The investigator is requested to write a descriptive assessment of the case and evaluate the relationship to the study vaccination.

The investigator will be requested to document full case details and to provide a diagnosis. In the case of all seizures, including febrile seizures, the investigator should classify the level of diagnostic certainty regarding the seizure as guided by The Brighton Collaboration Seizure Working Group's case definitions of generalized convulsive seizure as an adverse event following immunization, as described in Table 16 [Bonhoeffer, 2004].

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Table 16 Brighton Collaboration levels of diagnostic certainty

Level 1 of diagnostic certainty
witnessed sudden loss of consciousness AND generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations
Level 2 of diagnostic certainty
history of unconsciousness AND generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations
Level 3 of diagnostic certainty
history of unconsciousness AND other generalized motor manifestations
Level 4 of diagnostic certainty
reported generalized convulsive seizure with insufficient evidence to meet the case definitions for Level 1, 2 or 3 of diagnostic certainty above
Level 5 of diagnostic certainty
Not a case of generalized convulsive seizure

For any case of **febrile convulsion**, the investigator is also asked to classify the event based on the definitions below [American Academy of Pediatrics, 2008]:

- **Simple Febrile Convulsion/Seizure**: defined as a brief (<15 minutes in duration) generalized tonic-clonic seizure that occurs once during a 24 hour period in a febrile child who does not have intracranial infection, metabolic disturbance or history of afebrile seizures. The neurologic examination in the post-ictal period should be no different from baseline, i.e., there should be no newly acquired neurologic deficits.
- **Complex Febrile Convulsion/Seizure**: defined as a generalized tonic-clonic seizure that is not a simple febrile seizure. For instance, any seizure that has at least one of the following characteristics should be defined as a complex seizure:
  - lasts 15 minutes or longer, or
  - has a focal/localized component, or
  - recurs within 24 hours, or
  - is associated with an abnormal post-ictal neurologic examination.

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The investigator will assess the maximum intensity that occurred over the duration of the event for all other AEs, i.e., unsolicited symptoms, including SAEs reported during the study. The assessment will be based on the investigator's clinical judgment. The intensity of each AE and SAE recorded in the eCRF or SAE Report screens, as applicable, should be assigned to one of the following categories:

1 (mild)	=	An AE which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities.
2 (moderate)	=	An AE which is sufficiently discomforting to interfere with normal everyday activities.
3 (severe)	=	An AE which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day-care and would cause the parent(s)/LAR(s) to seek medical advice.)

An AE that is assessed as Grade 3 (severe) should not be confused with a SAE. Grade 3 is a category utilized for rating the intensity of an event; and both AEs and SAEs can be assessed as Grade 3. An event is defined as 'serious' when it meets one of the pre-defined outcomes as described in Section 8.1.2.

AEs of specific interest:

AEs of specific interest for safety monitoring include NOCDs (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting ER visits.

Occurrences of AEs of specific interest, including NOCDs and AEs prompting ER visits, will be reported throughout the study, up to six months after the dose of MMR vaccine, whether or not they are considered to be possibly related to the treatment administration. Medical documentation of the events will be reported in appropriate targeted follow-up forms included in the eCRF. These events also have to be reported as AE or SAE as appropriate in the eCRF.

8.2.2.2.2. Assessment of causality

The investigator is obligated to assess the relationship between study vaccine(s) and the occurrence of each AE/SAE. The investigator will use clinical judgment to determine the relationship. Alternative plausible causes, based on natural history of the underlying diseases, concomitant therapy, other risk factors and the temporal relationship of the event to the investigational product will be considered and investigated. The investigator will also consult the Investigator Brochure and/or Product Information for marketed products, in the determination of his/her assessment.

There may be situations when a SAE has occurred and the investigator has minimal information to include in the initial report to GSK Biologicals. However, it is very important that the investigator always makes an assessment of causality for every event

prior to submission of the SAE to GSK Biologicals. The investigator may change his/her opinion of causality in light of follow-up information, amending the SAE information accordingly. The causality assessment is one of the criteria used when determining regulatory reporting requirements.

In case of concomitant administration of multiple vaccines, it may not be possible to determine the causal relationship of general AEs to the individual vaccines administered. The investigator should, therefore, assess whether the AE could be causally related to vaccination rather than to the individual vaccines/products.

All solicited local (injection site) reactions will be considered causally related to vaccination. Causality of all other AEs should be assessed by the investigator using the following question:

Is there a reasonable possibility that the AE may have been caused by the investigational product?

NO	:	The AE is not causally related to administration of the study vaccine(s). There are other, more likely causes and administration of the study vaccine(s) is not suspected to have contributed to the AE.
YES	:	There is a reasonable possibility that the vaccine(s) contributed to the AE.

Non-serious and serious AEs will be evaluated as two distinct events. If an event meets criteria to be determined 'serious' (see Section 8.1.2 for definition of serious adverse event), additional examinations/tests will be performed by the investigator in order to determine ALL possible contributing factors applicable to each SAE.

Possible contributing factors include:

- Medical history.
- Other medication.
- Protocol required procedure.
- Other procedure not required by the protocol.
- Lack of efficacy of the vaccine(s), if applicable.
- Erroneous administration.
- Other cause (specify).

The investigator should assess the causality of each SAE. The investigator will use clinical judgment to determine the relationship of SAEs to study procedures or to GSK concomitant medication. Alternative causes, such as natural history of the underlying diseases, concomitant therapy and other risk factors will be considered and investigated.

There may be situations when a SAE has occurred and the investigator has minimal information to include in the initial report to GSK Biologicals. However it is very

important that the investigator always makes an assessment of causality for every event prior to submission of the SAE to GSK Biologicals. The investigator may change his/her opinion of causality in light of follow-up information, amending the SAE information accordingly.

If an event meets the criteria to be determined 'serious' (refer to Section 8.1.2), it will be examined by the investigator to the extent to enable determination of all contributing factors applicable to each SAE.

Possible contributing factors include:

- Medical history.
- Concomitant medication.
- Protocol required procedure.
- Other procedure not required by the protocol.
- Other cause (specify).

8.2.2.3. Assessment of outcomes

Outcome of any non-serious AE occurring within 42 days post vaccination (i.e., unsolicited AE) or any SAE reported during the entire study will be assessed as:

- Recovered/resolved.
- Recovering/resolving.
- Not recovered/not resolved.
- Recovered with sequelae/resolved with sequelae.
- Fatal (SAEs only).

8.2.2.4. Medically attended visits

For each solicited and unsolicited symptom the child experiences, the child's parent(s)/LAR(s) will be asked if the child received medical attention defined as hospitalization, an emergency room visit or a visit to or from medical personnel (e.g., medical doctor) for any reason and this information will be recorded in the eCRF. Routine "well child" visit information will not be recorded in the eCRF.

8.3. Reporting of serious adverse events

8.3.1. Prompt reporting of serious adverse events to GSK Biologicals

SAEs that occur in the time period defined in Section 8.2 will be reported promptly to GSK within the timeframes described in Table 17, once the investigator determines that the event meets the protocol definition of a SAE.

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Table 17 Timeframes for submitting serious adverse event reports to GSK Biologicals

Type of Event	Initial Reports		Follow-up of Relevant Information on a Previous Report	
	Timeframe	Documents	Timeframe	Documents
All SAEs	24 hours*	SAE report/SAE screen	24 hours*	SAE report/SAE screen

* Timeframe allowed after receipt or awareness of the information.

8.3.2. Contact information for reporting serious adverse events to GSK Biologicals

Please see the Sponsor Information Sheet for contact details.

Study Contact for Reporting SAEs
Refer to the local study contact information document.
Back-up Study Contact for Reporting SAEs
24/24 hour and 7/7 day availability: GSK Biologicals Clinical Safety & Pharmacovigilance Fax:PPD

8.3.3. Completion and transmission of SAE reports to GSK Biologicals

Once an investigator becomes aware that a SAE has occurred in a study child, the investigator (or designate) must complete the information in the SAE screens of the eCRF WITHIN 24 HOURS. The SAE screens will always be completed as thoroughly as possible with all available details of the event. Even if the investigator does not have all information regarding a SAE, the SAE screens should still be completed within 24 hours. Once additional relevant information is received, the SAE screens in the eCRF should be updated WITHIN 24 HOURS.

The investigator will always provide an assessment of causality at the time of the initial report.

8.3.3.1. Back-up system in case the electronic SAE reporting system does not work

If the electronic SAE reporting system does not work, the investigator (or designate) must complete, then date and sign a SAE Report Form and fax it to the GSK Biologicals Clinical Safety and Pharmacovigilance department within 24 hours.

This back-up system should only be used if the electronic SAE reporting system is not working and NOT if the system is slow. As soon as the electronic SAE reporting system is working again, the investigator (or designate) must complete the SAE screens in the eCRF within 24 hours. The final valid information for regulatory reporting will be the information reported through the electronic SAE reporting system.

8.3.3.2. Updating of SAE information after freezing of the child's eCRF

When additional information is received on a SAE after freezing of the child's eCRF, new or updated information should be recorded on a SAE Report Form, with all changes signed and dated by the investigator. The updated form should be faxed to the GSK Biologicals Clinical Safety and Pharmacovigilance department or to the Study Contact for Reporting SAEs (refer to the Sponsor Information Sheet) WITHIN 24 HOURS of receipt of the follow-up information.

8.3.4. Regulatory reporting requirements for serious adverse events

The investigator will promptly report all SAEs to GSK in accordance with the procedures detailed in Section 8.4.1. GSK Biologicals has a legal responsibility to promptly notify, as appropriate, both the local regulatory authority and other regulatory agencies about the safety of a product under clinical investigation. Prompt notification of SAEs by the investigator to the Study Contact for Reporting SAEs is essential so that legal obligations and ethical responsibilities towards the safety of other children are met.

Investigator safety reports are prepared according to the current GSK policy and are forwarded to investigators as necessary. An investigator safety report is prepared for a SAE(s) that is both attributable to the investigational product and unexpected. The purpose of the report is to fulfill specific regulatory and Good Clinical Practice (GCP) requirements, regarding the product under investigation.

8.4. Follow-up of adverse events and serious adverse events

8.4.1. Follow-up of adverse events and serious adverse events

After the initial AE/SAE report, the investigator is required to proactively follow each child within the study and provide further information on the child's condition to GSK Biologicals.

All SAEs documented at a previous visit and designated as not recovered/not resolved or recovering/resolving will be reviewed at subsequent visits/contacts until the end of the study.

All AEs documented at a previous visit and designated as not recovered/not resolved or recovering/resolving will be reviewed at subsequent visits/contacts until study end.

AEs of specific interest (including NOCDs such as autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies; and AEs prompting ER visits) documented at a previous visit and designated as not recovered/not resolved or recovering/resolving will be reviewed at subsequent visits until study end.

Investigators will follow-up children:

- With SAEs or children withdrawn from the study as a result of an AE, until the event has resolved, subsided, stabilized, disappeared, or until the event is otherwise explained, or the child is lost to follow-up.
- Or, in the case of other non-serious AEs, until resolution or study end, or they are lost to follow-up.

Clinically significant laboratory abnormalities will be followed up until they have returned to normal, or a satisfactory explanation has been provided. Additional information (including but not limited to laboratory results) relative to the subsequent course of such abnormalities noted for any child must be made available to the Site Monitor.

GSK Biologicals may request that the investigator performs or arranges for the conduct of additional clinical tests or evaluations to elucidate as fully as possible the nature and/or causality of the AE or SAE. The investigator is obliged to assist. If a child dies during participation in the study or during a recognized follow-up period, GSK Biologicals will be provided with a copy of any available post-mortem findings, including histopathology.

8.5. Treatment of adverse events

Treatment of any AE is at the sole discretion of the investigator and according to current good medical practice. Any medication administered for the treatment of an AE should be recorded in the child's eCRF. Refer to Section 6.7.

8.6. Unblinding

GSK Biologicals' policy (which incorporates ICH E2A guidance, EU Clinical Trial Directive and US Federal Regulations) is to unblind the report of any SAE which is unexpected and attributable or suspected to be attributable to the investigational product, prior to regulatory reporting. The GSK Biologicals' Central Safety Physician is responsible for unblinding the treatment assignment in accordance with the specified timeframes for expedited reporting of SAEs (refer to Section 8.3.1).

8.7. Emergency unblinding

Unblinding of a subject's individual treatment code should occur only in the case of a medical emergency, or in the event of a serious medical condition, when knowledge of the study treatment is essential for the clinical management or welfare of the subject, as judged by the investigator.

The emergency unblinding process consists of the automated Internet-based system SBIR that allows the investigator to have unrestricted, immediate and direct access to the subject's individual study treatment.

The investigator has the option of contacting a GSK Biologicals' On-call Central Safety Physician (or Backup) if he/she needs medical advice or needs the support of GSK to perform the unblinding (i.e., he/she cannot access the automated Internet-based system).

Any emergency unblinding must be fully documented by using the Emergency Unblinding Documentation Form, which must be appropriately completed by the investigator and sent within 24 hours to GSK Biologicals.

GSK Biologicals' Contact information for Emergency Unblinding **24/24 hour and 7/7 day availability**
GSK Biologicals' Central Safety Physician: Outside US/Canada: PPD (GSK Biologicals Central Safety Physician on-call) US/Canada only: PPD (GSK Biologicals Central Safety Physician on-call) **GSK Biologicals' Central Safety Physician Back-up:** Outside US/Canada PPD US/Canada only: PPD **Emergency Unblinding Documentation Form transmission:** Outside US & Canada: Fax: PPD or PPD US/Canada only: Fax: PPD

8.8. Subject card

Study child's parent(s)/LAR(s) must be provided with the address and telephone number of the main contact for information about the clinical study.

The investigator (or designate) must therefore provide a "subject card" to each child's parent(s)/LAR(s). In an emergency situation this card serves to inform the responsible attending physician that the child is in a clinical study and that relevant information may be obtained by contacting the investigator.

The child's parent(s)/LAR(s) must be instructed to keep subject cards in their possession at all times.

9. CHILD COMPLETION AND WITHDRAWAL

9.1. Child completion

A child who returns for the concluding Visit 3 (Day 180) is considered to have completed the study.

9.2. Child withdrawal

Children who are withdrawn because of SAEs/AEs must be clearly distinguished from children who are withdrawn for other reasons. Investigators will follow children who are withdrawn as result of a SAE/AE until resolution of the event (see Section 8.3).

Withdrawals will not be replaced.

9.2.1. Child withdrawal from the study

From an analysis perspective, a 'withdrawal' from the study refers to any child who did not come back for the concluding visit or was not available for the concluding contact foreseen in the protocol.

All data collected until the date of withdrawal or last contact of the child will be used for the analysis.

A child is considered a 'withdrawal' from the study when no study procedure has occurred, no follow-up has been performed and no further information has been collected for this child from the date of withdrawal or last contact.

Investigators will make an attempt to contact the parent(s)/LAR(s) of those children who do not return for scheduled visits or follow-up.

Information relative to the withdrawal will be documented in the eCRF. The investigator will document whether the decision to withdraw a child from the study was made by the child's parent(s) or LAR(s), or by the investigator, as well as which of the following possible reasons was responsible for withdrawal:

- Serious adverse event.
- Non-serious adverse event.
- Protocol violation (specify).
- Consent withdrawal, not due to an adverse event.
- Moved from the study area.
- Lost to follow-up.
- Other (specify).

9.2.2. Child withdrawal from investigational vaccine

Not applicable.

10. DATA EVALUATION: CRITERIA FOR EVALUATION OF OBJECTIVES

Throughout this section, endpoints for the two lots of comparator Com_MMR vaccine (Com_MMR_L1 and Com_MMR_L2) will be analyzed as pooled lots.

10.1. Primary endpoint

- Immunogenicity of the MMR vaccines at Day 42.
  - Seroresponse to measles, mumps and rubella viruses (see Section 10.5 for definition).
  - Measles, mumps and rubella virus antibody concentrations.

10.2. Secondary endpoints

- Immunogenicity of the Varivax, Havrix and Prevnar 13 vaccines in a subset of children at Day 42.
  - Seroresponse to VZV (see Section 10.5 for definition).
  - VZV antibody concentrations.
  - HAV antibody concentrations.
  - Seroresponse to HAV (see Section 10.5 for definition).
  - Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.
- Complementary read-out for immunogenicity of the MMR vaccines at Day 42.
  - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
  - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms.
  - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
  - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
  - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.

- Unsolicited adverse events.
  - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest.
  - Occurrence of new onset chronic disease (NOCD) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting emergency room (ER) visits from Day 0 through the end of study.
- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 through the end of study.

10.3. Estimated sample size

The target will be to enroll 5000 children to be randomly assigned to five study groups (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 and Com_MMR_L2) in a 2:2:2:1:1 ratio. There will be approximately 1250 children in each Inv_MMR lot group; and approximately 625 children in each Com_MMR lot group. Assuming a 20% non-evaluable rate, the planned enrollment will result in 4000 evaluable children (1000 per Inv_MMR lot group; and 500 in each Com_MMR lot group).

10.3.1. Control on type I error

To control the type I error below 2.5%, a hierarchical procedure will be used for the primary and secondary objectives. Each objective can only be reached if all the associated criteria are met and all previous objectives have been reached (see Figure 2).

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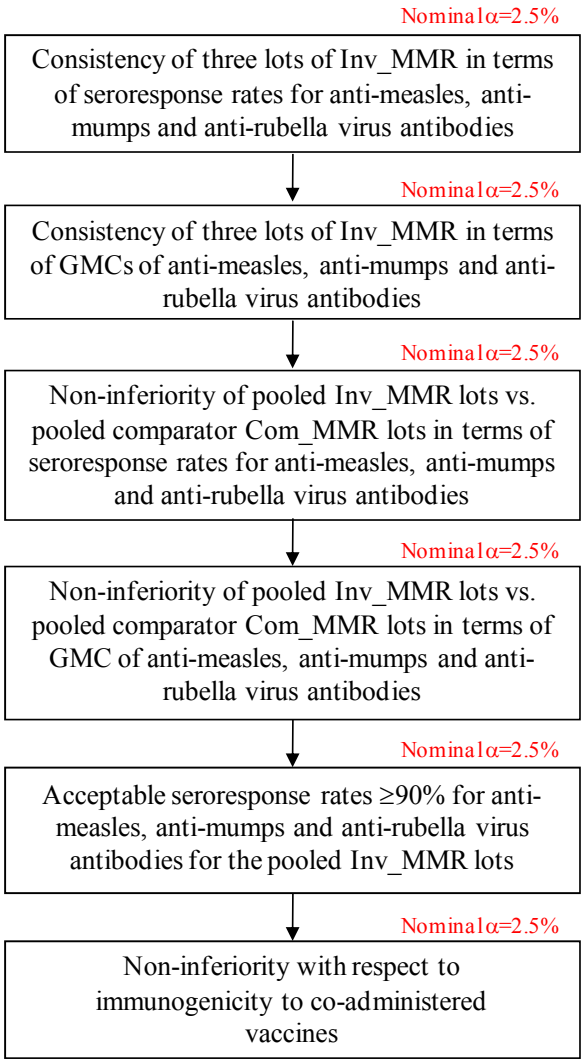
Figure 2 Sequence for evaluating the study objectives in order to control the overall type I error below 2.5%

An objective will be reached if its associated criterion is met and the previous objectives were reached



10.3.2. Power for lot-to-lot consistency

The lot-to-lot consistency of the Inv_MMR groups will be demonstrated if the lot-to-lot consistency criteria specific to each MMR antigen are met simultaneously (p-value <2.5%). Table 18 and Table 19 shows that the probability to reach the lot-to-lot consistency criterion is at least 97.46% [=100%-sum of type II errors].

Table 18 Probability to meet the consistency criteria with respect to seroresponse rates for antibodies to measles, mumps and rubella viruses among the three Inv_MMR groups

Vaccine component	Endpoints	Reference values*	Clinically acceptable bounds for consistency	Power N= 1000 vs. 1000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98%	[-5%,5%]	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94%	[-5%,5%]	99.58%	2.54%
Rubella	Seroresponse (≥ 10 IU/mL)	98%	[-5%,5%]	>99.99%	<0.01%
			Total	97.46%	2.54%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** Power obtained using the Power Analysis and Sample Size software (PASS 2005) (Likelihood Score [Miettinen and Nurminen approach [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value for the 3 lots & alpha=2.5%; the type II error was multiplied by 6 to account for the 6 pairwise lot comparisons.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

Table 19 Probability to meet the consistency criteria with respect to GMCs of antibodies to measles, mumps and rubella viruses among the three Inv_MMR lot groups

Vaccine component	Endpoints	Reference SD*	Clinically acceptable bounds for consistency	Power N= 1000 vs. 1000**	Type II error
Measles	GMC	0.50	[0.67,1.50]	>99.99%	<0.01%
Mumps	GMC	0.50	[0.67,1.50]	>99.99%	<0.01%
Rubella	GMC	0.44	[0.67,1.50]	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
SD = Standard Deviation (of the $\log_{10}$ transformed titer); GMC = Geometric Mean Concentration
Observed SDs for measles for the three lots of *Priorix* were 0.33, 0.34, and 0.34
Observed SDs for mumps for the three lots of *Priorix* were 0.41, 0.40, and 0.44
Observed SDs for rubella for the three lots of *Priorix* were 0.33, 0.34, and 0.34
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of equal means & alpha=2.5%; the type II error was multiplied by 6 to account for the 6 pairwise lot comparisons.

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10.3.3. Power for Non-inferiority to Com_MMR

The non-inferiority of the pooled Inv_MMR groups compared to Com_MMR will be demonstrated if the non-inferiority criteria specific to each MMR antigen are met simultaneously (p-value <2.5%) and lot-to-lot consistency has been demonstrated. Table 20 and Table 21 show that the probability to reach the non-inferiority criteria is at least 97.46% [= 100% - sum of type II error from Table 18, Table 19, Table 20, Table 21].

Table 20 Probability to meet the non-inferiority criteria with respect to seroresponse rate for antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups compared to the pooled Com_MMR lot groups

Vaccine component	Endpoints	Reference values* Pooled Inv_MMR vs. Com_MMR	Clinically acceptable limit for non-inferiority	Power N= 3000 vs. 1000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98% vs. 98%	-5%	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94% vs. 94%	-5%	>99.99%	<0.01%
Rubella	Seroresponse (≥ 10 IU/mL)	98% vs. 98%	-5%	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** Power obtained using PASS 2005 (Likelihood Score [Miettinen and Nurminen approach, [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value & alpha=2.5%.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

Table 21 Probability to meet the non-inferiority criteria with respect to GMCs of antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups compared to the pooled Com_MMR lot groups

Vaccine component	Endpoints	Reference ratio (Com_MMR over Inv_MMR lots)*	Reference SD*	Clinically acceptable limit for non-inferiority	Power N= 3000 vs. 1000**	Type II error
Measles	GMC	1	0.50	0.67	>99.99%	<0.01%
Mumps	GMC	1	0.53	0.67	>99.99%	<0.01%
Rubella	GMC	1	0.44	0.67	>99.99%	<0.01%
				Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
SD = Standard Deviation (of the log10 transformed titer); GMC = Geometric Mean Concentration
Observed SDs for measles for three lots of *Priorix* were 0.33, 0.34, and 0.34
Observed SDs for mumps (PPD ELISA) for the three lots of *Priorix* were 0.41, 0.40, and 0.44
Observed SDs for rubella for three lots of *Priorix* were 0.33, 0.34, and 0.34
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of a 1.2-fold difference in means & alpha=2.5%.

10.3.4. Power for a minimal seroresponse rate of pooled Inv_MMR lots

Assuming 20% of children are non-evaluable, an estimated 3000 children will be evaluable in the pooled Inv_MMR groups. Table 22 shows the probability to reach the immunogenicity criterion that the MMR seroresponse rate is at least 90% for measles, mumps and rubella.

Considering this is conditional to previous primary objectives the power to conclude on minimal MMR-seroresponse rate is at least 97.46% [= 100% - sum of type II error from Table 18, Table 19, Table 20, Table 21 and Table 22].

Table 22 Probability to meet the minimum level of seroresponse rate for antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups

Vaccine component	Endpoints	Reference values*	Acceptable lower limit	Power N= 3000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98%	90%	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94%	90%	>99.99%	<0.01%
Rubella	Seroresponse (≥ 10 IU/mL)	98%	90%	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** PASS 2005, 1-sided non-inferiority test on one proportion alpha = 2.5%, H0: p ≤ margin, Ha: p = reference value. The type II error was multiplied by 3 to account for the 3 lots.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

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10.3.5. Power for the secondary objectives

Anti-VZV antibodies will be tested in a subset of 2500 children enrolled in the US. Assuming 20% are non-evaluable, this analysis will be based on 1500 children in the pooled Inv_MMR groups and 500 children in the pooled Com_MMR groups. Anti-HAV antibodies and anti-PS antibodies will be tested in subsets of 1250 children enrolled in the US. Assuming 20% are non-evaluable, the analysis is based on 750 children in the pooled Inv_MMR groups and 250 children in the pooled Com_MMR groups.

The probability to meet the non-inferiority criteria associated to immunogenicity to co-administered vaccine is shown in Table 23 and Table 24 and will be demonstrated if the non-inferiority criteria specific to each antigen are met (p-value <2.5%) and non-inferiority and acceptability for MMR responses and lot-to-lot consistency have been demonstrated.

Table 23 Probability to meet the non-inferiority criteria with respect to VZV seroresponse rate

Vaccine component	Endpoints	Reference values*	Clinically acceptable limit for non-inferiority	Power N= 1500 vs. 500**	Type II error
VV	Seroresponse (≥ 75 mIU/mL)	95%	- 10%	>99.9%	<0.01%

VV = Varicella Vaccine *Varivax*
* Reference for sample size calculation: Study MMR-157 where the lowest observed seroresponse rate was 95% [92.5%; 98.0%]
** Power obtained using PASS 2005 (Likelihood Score [Miettinen and Nurminen approach, [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value for the 2 groups; N is based on the immuno subsets.
mIU = Milli International Unit; mL = Milliliter.

Table 24 Probability to meet the non-inferiority criteria with respect to GMC for antibodies associated to co-administered vaccines

Vaccine component	Reference SD*	Clinically acceptable limit for non-inferiority	N Inv_MMR lots vs. Com_MMR	Power**	Type II error
VV	0.4	1.5	1500 vs. 500	>99.99%	<0.01%
HAV	0.6	2	750 vs. 250	>99.99%	<0.01%

VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* Reference for sample size calculation: Study MMR-157
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of equal means & alpha=2.5%, N is based on the immuno subsets.
SD = Standard Deviation (of the $\log_{10}$ transformed titer)
Observed SDs for VZV for three lots of *Priorix* were 0.24, 0.26, and 0.27
Observed SDs for HAV for the three lots of *Priorix* were 0.38, 0.39, and 0.43

10.4. Study cohorts to be evaluated

10.4.1. Total vaccinated cohort

The **Total Vaccinated cohort** will include all vaccinated children.

- An immunogenicity analysis based on the Total Vaccinated cohort will include all vaccinated children for whom immunogenicity data are available.
- A safety analysis based on the Total Vaccinated cohort will include all vaccinated children with at least one vaccine administration of either Inv_MMR or Com_MMR lots documented.

10.4.2. According-to-protocol cohort for analysis of safety

The **ATP cohort for analysis of safety** will include eligible children:

- who have received at least one MMR study vaccine/comparator as per protocol
- who have not received a vaccine leading to exclusion from the ATP cohort in the protocol as described in Section 6.7.1 up to Visit 2
- for whom the randomization code has not been broken
- for whom the administration route of study vaccine(s) is known/correct.

10.4.3. According-to-protocol cohort for analysis of immunogenicity

The **ATP cohort for analysis of immunogenicity** will include all eligible children from the ATP cohort for safety:

- with pre-vaccination and post-dose serology results available for at least one antigen of measles, mumps, or rubella
- who are below the assay cut-off for at least one vaccine antigen for MMR at pre-vaccination
- who do not meet any elimination criteria up to the Visit 2 blood sample (see Sections 6.7.1 and 6.8)
- who complied with the post dose blood sample schedule, i.e., 35-77 days between vaccination at Visit 1 and the blood draw at Visit 2.

10.5. Derived and transformed data

For the analysis of immunogenicity, the following definitions will be applied.

Seroresponse for MMR is defined as follows:

- For measles virus, a seroresponse is defined as post-vaccination anti-measles virus antibody concentration ≥200 mIU/mL (ELISA, Enzygnost) among children who were seronegative (antibody concentration <150 mIU/mL) before vaccination.

- For mumps virus, a seroresponse is defined as post-vaccination anti-mumps virus antibody concentration ≥10 EU/mL (ELISA, PPD) among children who were seronegative (antibody concentration <5 EU/mL) before vaccination.
- For rubella virus, a seroresponse is defined as post-vaccination anti-rubella virus antibody concentration ≥10 IU/mL (ELISA, Enzygnost) among children who were seronegative (antibody concentration <4 IU/mL) before vaccination.

Seroresponse for *Varivax* is defined as follows:

- For VV, a seroresponse is defined as post-vaccination anti-VZV antibody concentration ≥75 mIU/mL among children who were seronegative (antibody concentration <25 mIU/mL) before vaccination.

Antibody response for *Havrix* is defined as follows:

- For HAV, an antibody response is defined as post-vaccination concentration equal to or above the cut-off of 15 mIU/mL in children below the assay cut-off of 15 mIU/mL before vaccination, or ≥ 2-fold increase in antibody concentration in children ≥ 15 mIU/mL before vaccination.

GMC/T calculation:

The GMC calculation for antibody to varicella virus will be performed by taking the anti-log of the mean of the log concentration transformations of all values equal to or above Limit of Quantitation (LOQ) (40 mIU/mL), with anti-VZV antibody concentrations between LOQ and Limit of Detection (LOD) (25 mIU/mL) given a value of 25 mIU/mL. By convention, values <25 mIU/mL will be given an arbitrary value of 12.5 mIU/mL.

For other antigens, the GMC calculation will be performed by taking the anti-log of the mean of the log concentration transformations. Antibody concentrations below the cut-off of the assay will be given an arbitrary value of half the cut-off for the purpose of GMC calculation.

Handling of missing immune results

For a given child and a given immunogenicity measurement, missing or non-evaluable measurements will not be replaced. Therefore, an analysis will exclude children with missing or non-evaluable measurements.

Handling of missing recording for reactogenicity and safety

For the analysis of solicited symptoms, only children with a completed solicited AE section of the eCRF will be considered.

Missing or non-evaluable measurements will not be replaced. Therefore the analysis of the solicited symptoms based on the Total vaccinated cohort will include only children/doses with documented safety data (i.e., symptom screen/sheet completed).

In the primary analysis of solicited symptoms, missing daily recordings will be replaced by the maximum value recorded for the child. For children reporting a symptom without a single daily recording (i.e., reporting fever as present in the absence of temperature measurement), missing daily recordings will be replaced by grade 1. A sensitivity analysis of the impact of missing data on the endpoints will be conducted if the percentage of children reporting a symptom without a single daily recording is above 1%.

For the analysis of unsolicited adverse events/serious adverse event/concomitant medication, all vaccinated children will be considered and children who did not report an event will be considered as children without an event.

10.6. Conduct of analyses

Any deviation(s) or change(s) from the original statistical plan outlined in this protocol will be described and justified in the final study report.

10.6.1. Sequence of analyses

The analysis will be performed in two steps:

- A final analysis of immunogenicity data ***for measles, mumps and rubella*** and solicited symptoms up to Day 42 will be performed as soon as all ***measles, mumps and rubella*** immunogenicity data and reactogenicity data (i.e. solicited symptoms) up to Visit 2 are available and cleaned. No clinical report will be written at this time. **(Amended: 26-FEB-2015)**
- A final analysis of ***immunogenicity*** data ***for the co-administered vaccines (i.e. VV, HAV and PCV-13)*** and unsolicited AEs from Day 0 to Day 42 following vaccination, and of SAEs and specific AEs covering the period from Day 0 to study end (including the 6-months safety follow-up) will be performed at the end of the study. **(Amended: 26-FEB-2015)**
- These two analyses will be combined in the final clinical report.

Following unblinding for the analysis up to Day 42, accessibility to group attribution will be limited to the statisticians until all study procedures pertaining to the active phase and the 6-months safety follow-up are completed for all children.

10.6.2. Statistical considerations for interim analyses

No interim analyses are planned.

10.7. Statistical methods

10.7.1. Methodology for computing CI

All CIs will be 95% CI.

The exact 95% CIs for a proportion within a group will be calculated using SAS. SAS will also be used to derive the standardized asymptotic 95% CI for the group difference in proportions (method 6 in [Newcombe, 1998]).

The 95% CI for GMCs will be obtained within each group separately. The 95% CI for the mean of log-transformed titer/concentration will be first obtained assuming that log-transformed values were normally distributed with unknown variance. The 95% CI for the GMCs will then be obtained by exponential-transformation of the 95% CI for the mean of log-transformed titer/concentration.

The 95% CI for GMC group ratio will be obtained using an Analysis of Variance (ANOVA) model on the logarithm-transformed titers. The ANOVA model will include the vaccine group as the fixed effect, the country effect (only for measles, mumps & rubella) and, for pneumococcal immunogenicity, the pre-vaccination log-transformed titer as the regressor. The model will assume equal variance in the log concentrations post vaccination. The between group GMC ratios and their 95% CI will be derived by exponential transformation of the corresponding group contrast in the model.

10.7.2. Analysis of demographics/baseline characteristics

Demographic characteristics (age at Visit 1 in months, geographic ancestry (race), ethnicity and gender) will be tabulated as a whole, for each Inv_MMR group, for the pooled Inv_MMR groups, and for the pooled Com_MMR groups.

The distribution of children enrolled among the study sites/countries will be tabulated as a whole, for each Inv_MMR group, for the pooled Inv_MMR groups, and for the pooled Com_MMR groups.

10.7.3. Analysis of immunogenicity

The analysis of immunogenicity will be based on the ATP cohort for immunogenicity. If, for any vaccine group, the percentage of enrolled children with serological results excluded from this ATP cohort is higher than 5%, a second analysis based on the Total Vaccinated cohort will be performed to complement the ATP analysis.

Except for anti-PS, the analysis post-vaccination of an assay described below will be based on the children seronegative for the assay at pre-vaccination.

All descriptive immunogenicity results will also be produced by country.

10.7.3.1. Within groups assessment

The following descriptive analyses will be performed for each Inv_MMR group, for the pooled Inv_MMR groups, and for the pooled Com_MMR groups at each blood sampling time point for which a serological result is available:

- Percentage of children above each specific cut-off and their exact 95% CIs will be tabulated. The specific cut-offs will be 150 and 200 mIU/mL for measles, 5 and 10 EU/mL for mumps and 4 and 10 IU/mL for rubella, respectively.
- Antibody concentrations will also be summarized by GMCs with their 95% CIs after vaccination.

- Antibody concentration distributions will be displayed as reverse cumulative curves for each antigen and each treatment group after vaccination.
- For measles, mumps and rubella, descriptive summaries by country will also be provided.

10.7.3.1.1. Between Inv_MMR lots analysis

At blood sampling post-vaccination, for measles, mumps and rubella:

- The 95% CI for the GMC ratio of each pair of Inv_MMR lots will be computed using an ANOVA model on the logarithm-transformed concentrations. The ANOVA model will include the three Inv_MMR lot groups and the country as fixed effects.
- The asymptotic standardized 95% CIs for the pair-wise differences in seroresponse across the three Inv_MMR lots will be computed.

10.7.3.2. Between Inv_MMR and Com_MMR group analysis

At blood sampling post-vaccination, for each antibody for which results are available:

- The asymptotic standardized 95% CIs for the difference in seroresponse rate and percentage of children with concentration/titer above each specific cut-off [pooled Inv_MMR lot group minus the pooled Com_MMR lot group] will be computed.
- The 95% CI for each group GMC/T group ratio [pooled Inv_MMR lot group over the pooled Com_MMR lot group] will be computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect, the country effect (only for measles, mumps & rubella) and, for pneumococcal immunogenicity, the pre-vaccination log-transformed concentration as the regressor. The vaccine groups will be the pooled Inv_MMR lot group and the pooled Com_MMR lot group.

10.7.3.3. Interpretation of analyses

Except for analyses addressing criteria specified in the objectives, comparative analyses will be exploratory with the aim to characterize the difference between groups in immunogenicity. These exploratory analyses should be interpreted with caution since there is no adjustment for multiplicity of endpoints.

With respect to primary and secondary objectives involving pre-specified criteria, the interpretation must be done according to a hierarchical procedure described in Section 10.3.1. For instance, the primary objective 3 can only be reached if all the associated criteria are met and the previous primary objectives have been reached. If an objective is not met, all subsequent comparisons will be purely descriptive.

10.7.4. Analysis of safety

The analysis of safety will be based on the Total Vaccinated cohort. If more than 5% of the vaccinated children are excluded from the ATP cohort for the analysis of safety, a second analysis based on the ATP cohort will be performed to complement the Total Vaccinated cohort analysis.

For each group (each Inv_MMR lot group, the pooled Inv_MMR lot group and the pooled Com_MMR lot group), the following results will be tabulated by Inv_MMR lot, pooled for the three Inv_MMR lots, and pooled for the two Com_MMR lots:

- the number and percentage of children (with exact 95% CIs) with at least one local, general, and any adverse event (solicited or unsolicited) during the 43-day follow-up period after vaccination (Day 0-42);
- the number and percentage of children (with exact 95% CIs) reporting each local solicited symptom during Days 0-3 for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically attended visit;
- the number and percentage of children (with exact 95% CIs) reporting general symptom (drowsiness, irritability and loss of appetite) during the 15-day follow-up period after vaccination (Days 0-14) for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically-attended visit;
- the number and percentage of children reporting fever by half degree (°C) cumulative increments from Days 0-14, from Days 5-12 and from Days 0-42 after vaccination. Similar tabulations will be performed for any fever with a causal relationship to vaccination and for any fever resulting in a medically attended visit. In addition, the prevalence of any and grade 3 fever will be presented graphically over time after vaccination. The distribution of maximum temperature recorded over 43 days after vaccination will be displayed as reverse cumulative curves for the pooled Inv_MMR lots and pooled Com_MMR lots;
- the number and percentage of children (with exact 95% CIs) reporting measles/rubella-like rash and varicella-like rash (Days 0-42, according to number of lesions), any rash (Days 0-42), parotid/salivary gland swelling (Days 0-42, according to intensity) and any sign of meningism/febrile convulsions (Days 0-42, according to intensity), after vaccination. Similar tabulations will be performed for general solicited adverse events with a causal relationship to vaccination and for solicited AEs resulting in a medically-attended visit;
- the number and percentage of children (with exact 95% CIs) for whom unsolicited adverse events are reported from Days 0-42. The verbatim reports of unsolicited symptoms will be reviewed by a physician and the signs and symptoms will be coded according to MedDRA, the Medical Dictionary for Regulatory Activities. Every verbatim term will be matched with the appropriate Preferred Term. Similar tabulations will be done for grade 3 unsolicited adverse events, for unsolicited adverse events related to vaccination and for unsolicited adverse events resulting in a medically attended visit;

- the number and percentage of children who received at least one concomitant medication from Days 0-14 and from Days 0-42 after vaccination. Additionally, the number and percentage of children receiving antipyretic drugs will also be calculated by group from Days 0-14 and from Days 0-42 after vaccination.
- Discontinuations due to AEs will be described in detail.
- The percentages of children who experienced at least one serious adverse event or who reported a NOCD (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies), or an AE leading to an ER visit, or an AE leading to a medically attended visit from Day 0 to study end, will be calculated.
- Descriptive listing of SAEs, any related SAEs to study participation, study withdrawals and deaths post-vaccination(s) for the entire study.

All safety results will also be produced by country.

11. ADMINISTRATIVE MATTERS

To comply with ICH GCP administrative obligations relating to data collection, monitoring, archiving data, audits, confidentiality and publications must be fulfilled.

11.1. Case Report Form/Remote Data Entry instructions

The investigator will keep a paper copy of each diary card and any data query forms of the final version of the data generated at the investigational site.

A validated computer application, will be used as the method for data collection.

In all cases, the study child's initials will not be collected nor transmitted to GSK. Study participant data necessary for analysis and reporting will be entered/transmitted into a validated database or data system. Clinical data management will be performed in accordance with applicable GSK standards and data cleaning procedures.

While completed eCRFs are reviewed by a Site Monitor at the study site, omissions or inconsistencies detected by subsequent eCRF review may necessitate clarification or correction of omissions or inconsistencies with documentation and approval by the investigator or appropriately qualified designee. In all cases, the investigator remains accountable for the study data.

eCRFs and diary cards, will be supplied by GSK for recording all data. Any questions or comments related to the eCRF should be directed to the assigned Site Monitor.

The investigator will be provided with a CD-ROM of the final version of the data generated at the investigational site once the database is archived and the study report is complete and approved by all parties.

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11.2. Monitoring by GSK Biologicals

Monitoring visits by a GSK Site Monitor are for the purpose of confirming that GSK Biologicals' sponsored studies are being conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and that are consistent with Good Clinical practice (GCP) and the applicable regulatory requirement(s) (verifying continuing compliance with the protocol, amendment(s), reviewing the investigational product accountability records, verifying that the site staff and facilities continue to be adequate to conduct the study).

The investigator must ensure provision of reasonable time, space and qualified personnel for monitoring visits.

Direct access to all study-site related and source data is mandatory for the purpose of monitoring review. The monitor will perform an eCRF review and a Source Document Verification (SDV). By SDV we understand verifying eCRF entries by comparing them with the source data that will be made available by the investigator for this purpose.

The Source Documentation Agreement Form describes the source data for the different data in the eCRF. This document should be completed and signed by the site monitor and investigator and should be filed in the monitor's and investigator's study file. Any data item for which the eCRF will serve as the source must be identified, agreed and documented in the source documentation agreement form.

For the eCRF, the monitor will mark completed and approved screens at each visit.

In accordance with applicable regulations, GCP, and GSK procedures, GSK monitors will contact the site prior to the start of the study to review with the site staff the protocol, study requirements, and their responsibilities to satisfy regulatory, ethical, and GSK requirements. When reviewing data collection procedures, the discussion will also include identification, agreement and documentation of data items for which the eCRF entries will serve as the source document.

GSK will monitor the study to verify that, amongst others, the:

- Data are authentic, accurate, and complete.
- Safety and rights of the study children are being protected.
- Study is conducted in accordance with the currently approved protocol and any amendments, any other study agreements, GCP and all applicable regulatory requirements.

The investigator and the head of the medical institution (where applicable) agrees to allow the monitor direct access to all relevant documents.

Upon completion or premature discontinuation of the study, the monitor will conduct site closure activities with the investigator or site staff, as appropriate, in accordance with applicable regulations, GCP, and GSK procedures.

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11.3. Archiving of data at study sites

Following closure of the study, the investigator must maintain all site study records in a safe and secure location. The records must be maintained to allow easy and timely retrieval, when needed (e.g., audit or inspection), and, whenever feasible, to allow any subsequent review of data in conjunction with assessment of the facility, supporting systems, and staff. Where permitted by applicable laws/regulations or institutional policy, some or all of these records can be maintained in a validated format other than hard copy (e.g., microfiche, scanned, electronic for studies with an eCRF); however, caution needs to be exercised before such action is taken. The investigator must assure that all reproductions are legible and are a true and accurate copy of the original and meet accessibility and retrieval standards, including re-generating a hard copy, if required. Furthermore, the investigator must ensure there is an acceptable back-up of these reproductions and that an acceptable quality control process exists for making these reproductions.

GSK will inform the investigator/institution of the time period for retaining these records to comply with all applicable regulatory requirements. However, the investigator/institution should seek the written approval of the sponsor before proceeding with the disposal of these records. The minimum retention time will meet the strictest standard applicable to that site for the study, as dictated by ICH GCP, any institutional requirements or applicable laws or regulations, or GSK standards/procedures; otherwise, the minimum retention period will default to 15 years.

The investigator/institution must notify GSK of any changes in the archival arrangements, including, but not limited to, the following: archival at an off-site facility, transfer of ownership of the records in the event the investigator leaves the site.

11.4. Audits

To ensure compliance with GCP and all applicable regulatory requirements, GSK may conduct a quality assurance audit. Regulatory agencies may also conduct a regulatory inspection of this study. Such audits/inspections can occur at any time during or after completion of the study. If an audit or inspection occurs, the investigator and institution agree to allow the auditor/inspector direct access to all relevant documents and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any relevant issues.

11.5. Posting of information on Clinicaltrials.gov

Study information from this protocol will be posted on clinicaltrials.gov before enrollment of children begins.

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11.6. Ownership, confidentiality and publication

11.6.1. Ownership

All information provided by GSK and all data and information generated by the site as part of the study (other than a study child's medical records) are the sole property of GSK.

All rights, title, and interests in any inventions, know-how or other intellectual or industrial property rights which are conceived or reduced to practice by site staff during the course of or as a result of the study are the sole property of GSK, and are hereby assigned to GSK.

If a written contract for the conduct of the study which includes ownership provisions inconsistent with this statement is executed between GSK and the study site, that contract's ownership provisions shall apply rather than this statement.

11.6.2. Confidentiality

Documented evidence that a potential investigator is aware and agrees to the confidential nature of the information related to the study must be obtained by means of a confidentiality agreement.

All information provided by GSK and all data and information generated by the site as part of the study (other than a child's medical records) will be kept confidential by the investigator and other site staff. This information and data will not be used by the investigator or other site personnel for any purpose other than conducting the study. These restrictions do not apply to: (i) information which becomes publicly available through no fault of the investigator or site staff; (ii) information which it is necessary to disclose in confidence to an IEC or IRB solely for the evaluation of the study; (iii) information which it is necessary to disclose in order to provide appropriate medical care to a study child; or (iv) study results which may be published as described in the next paragraph. If a written contract for the conduct of the study which includes confidentiality provisions inconsistent with this statement is executed, that contract's confidentiality provisions shall apply rather than this statement.

11.6.3. Publication

For multicenter studies, the first publication or disclosure of study results shall be a complete, joint multicenter publication or disclosure coordinated by GSK. Thereafter, any secondary publications will reference the original publication(s).

Prior to submitting for publication, presentation, use for instructional purposes, or otherwise disclosing the study results generated by the site (collectively, a 'Publication'), the investigator shall provide GSK with a copy of the proposed Publication and allow GSK a period to review the proposed Publication (at least twenty-one working days, or at least fifteen working days for abstracts/posters/presentations). Proposed Publications shall not include either GSK confidential information other than the study results or personal data on any child, such as name or initials.

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At GSK's request, the submission or other disclosure of a proposed Publication will be delayed a sufficient time to allow GSK to seek patent or similar protection of any inventions, know-how or other intellectual or industrial property rights disclosed in the proposed Publication.

If a written contract for the conduct of the study, which includes publication provisions inconsistent with this statement is executed, that contract's publication provisions shall apply rather than this statement.

11.6.4. Provision of study results to investigators, posting to the clinical trials registers and publication

Where required by applicable regulatory requirements, an investigator signatory will be identified for the approval of the clinical study report. The investigator will be provided reasonable access to statistical tables, figures, and relevant reports and will have the opportunity to review the complete study results at a GSK site or other mutually-agreeable location.

GSK will also provide the investigator with the full summary of the study results. The investigator is encouraged to share the summary results with the study children's parent(s)/LAR(s), as appropriate.

The results summary will be posted to the GSK Clinical Study Register no later than 12 months after the last subject's last visit (LSLV) or sooner if required by legal agreement, local law or regulation. In addition, a manuscript will be submitted to a peer-reviewed journal for publication within 18 months of LSLV. When manuscript publication in a peer-reviewed journal is not feasible, further study information will be posted to the GSK Clinical Study Register to supplement the results summary.

A manuscript will be progressed for publication in the scientific literature if the results provide important scientific or medical knowledge.

12. COUNTRY SPECIFIC REQUIREMENTS

Not applicable.

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13. REFERENCES

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APPENDIX A LABORATORY ASSAYS

Instructions for collection and handling of blood/serum samples:

For all children, approximately 5 mL of whole blood will be collected at the appropriate visit using serum separator tubes. After blood centrifugation and serum separation, samples will be stored at or less than -20°C/-4°F (alternatively at approximately -70°C/ -80°C is also acceptable) until sent to the sponsor. Serological assays will be performed at GlaxoSmithKline Biologicals central laboratory or PPD, a contract research organization, or any GSK validated lab using standardized, validated procedures with adequate controls. The samples will be tested in a blinded fashion for the presence of antibodies.

Measles virus and rubella virus antibody concentrations will be determined by commercial immunoassay kits according to GSK standard operating procedures (SOPs).

Mumps antibody concentration will be determined at PPD using a validated ELISA, which measures reactivity to the Jeryl Lynn strain of the mumps virus.

If additional testing is performed, the marker priority ranking may be changed.

Other laboratory assays may be performed to supplement determination of responses to the components of the vaccines administered in this study.

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APPENDIX B CLINICAL LABORATORIES

Table 25 GSK Biologicals' laboratories

Laboratory	Address
GSK Biologicals Global Vaccine Clinical Laboratory, Rixensart	Biospecimen Reception - B7/44 Rue de l'Institut, 89 - B-1330 Rixensart - Belgium
GSK Biologicals Global Vaccine Clinical Laboratory, North America-Laval*	Biospecimen Reception - Clinical Serology 525 Cartier blvd West - Laval - Quebec - Canada - H7V 3S8
GSK Biologicals Global Vaccine Clinical Laboratory, Wavre-Nord Noir Epine	Avenue Fleming, 20 - B-1300 Wavre - Belgium

Note : In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party Contract Research Organization (CRO) (Amended: 26-FEB-2015)

Table 26 Outsourced laboratories

Laboratory	Address
BARC USA Inc.	5, Delaware Drive Lake Success NY 11042-1114 USA
PPD, Inc.	466 Devon Park Drive Wayne, PA 19087-1816 – USA

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APPENDIX C AMENDMENTS AND ADMINISTRATIVE CHANGES TO THE PROTOCOL

GlaxoSmithKline Biologicals Clinical Research & Development **Protocol Amendment 1**	
eTrack study number and Abbreviated Title(s)	115648 (MMR-160)
Amendment number:	Amendment 1
Amendment date:	14 May 2014
Co-ordinating author:	PPD Scientific Writer, XPE Pharma for GSK Biologicals

Rationale/background for changes:

- Vaccination against influenza (with inactivated influenza vaccine) and *Haemophilus influenzae* type b can be given at any time before, during, or after the study, including the day of study vaccination. This is to correct a prior exclusion criterion which stated that it could be given at any time during the study. The intent has always been to allow these vaccinations at any time regardless of whether or not it was before, during or after the study period.
- For other MMR US Phase III studies, CBER has requested that all conditions leading to non-routine medically attended visits be collected for the entire study in the eCRF. It has been clarified throughout the protocol that From Visit 1 (Day 0) to study end (Day 180), all medically attended events will be recorded in the eCRF. Subjects' routine 'well child' doctor visits will not be recorded in the eCRF.
- Other minor corrections.

Amended text has been included in *bold italics* and deleted text in ~~strikethrough~~ in the following sections:

Cover page

Co-ordinating author	PPD ***Scientific writer, XPE Pharma***~~ZeroChaos~~ for GSK Biologicals
Contributing authors	• PPD Director, Clinical ***Research and*** Development ~~Manager~~***Leader, Vaccines for MMR and Varicella*** • PPD ***Director, Clinical Research and Development Leader*** • PPD Project Statistician • PPD ***Director, Statistical***

Manager

- PPD ***Study Delivery Lead***
- ~~PPD Global Study Manager~~
- ~~PPD Global Study Manager~~
- ~~PPD Study Data Manager~~
- ~~PPD Clinical Safety representative~~
- PPD ***Study Manager***
- PPD ***Study Data Manager***
- PPD ***Clinical Safety and Pharmacovigilance***
- PPD Clinical Immunology
- PPD Global Regulatory ***Affairs***
- PPD Vice President and Director, Global ~~Clinical R&D, Vaccines~~***Vaccine Development, GSK Biological***

Protocol Amendment 1 Sponsor Signatory Approval page

Sponsor signatory	***Ouzama Henry, Director, Clinical Research and Development Lead, Vaccines for MMR and Varicella*** ~~Bruce Innis, Vice President and Director, Global Clinical R&D, Vaccines~~

Glossary of terms

Protocol amendment:	***The International Conference on Harmonization (ICH) defines a protocol amendment as: 'A written description of a change(s) to or formal clarification of a protocol.' GSK Biologicals further details this to include a change to an approved protocol that affects the safety of subjects, scope of the investigation, study design, or scientific integrity of the study.***

Synopsis → Study design

At the end of the study ***or shortly after the study, depending on vaccine availability***, GSK will provide a second dose of *Havrix* and/or varicella vaccine to selected non-US countries if local health departments do not routinely provide hepatitis A and varicella

vaccination. Note that the second dose of *Havrix* and varicella vaccine is not part of the study procedures.

Section 1.2.2. → Rationale for the study design

At the end of the study ***or shortly after the study, depending on vaccine availability***, GSK will provide a second dose of *Havrix* and/or varicella vaccine to participants enrolled in non-US countries if local health departments do not routinely provide hepatitis A and varicella vaccination.

Section 3. → Study design overview

Co-administered vaccines: All children will receive *Varivax* and *Havrix* as study vaccines, concomitantly with MMR vaccine at 12 to 15 months of age. *Prevnar 13* will be administered only to US children. At the end of the study ***or shortly after the study, depending on vaccine availability***, GSK will provide a second dose of *Havrix* and/or varicella vaccine to participants enrolled in selected non-US countries if local health departments do not routinely provide hepatitis A and varicella vaccination. The second dose of *Havrix* and varicella vaccine is not part of the study procedures.

Section 4.2. → Inclusion criteria for enrollment

Child that previously received a 3-dose series of Prevnar 13 only (i.e., no doses given as Prevnar/Prevenar), with the last dose at least 60 days prior to study entry.

Section 4.3. → Exclusion criteria for enrollment

- Planned administration/ administration of a vaccine not foreseen by the study protocol during the period starting 30 days prior to study vaccination at Visit 1 and ending at Visit 2. Please Note:
  - **Inactivated** influenza (Flu) vaccine and *Haemophilus influenzae* type b conjugate vaccine (Hib) vaccines may be given at any time ~~during the study~~, including the day of study vaccination (Flu and Hib vaccines must be administered at a different location than the study vaccine/s).
  - Any ***age*** appropriate vaccine may be given starting at Visit 2 and anytime thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting 180 days prior to study vaccination at Visit 1 before entering the study or planned administration from the date of vaccination through the immunogenicity evaluation at Visit 2.

Section 5.2.2.2. → Treatment allocation to the child

After having checked the eligibility of the child and obtaining the Informed Consent Form (ICF), the site staff ~~in charge of the vaccination~~ will access SBIR. Upon providing the child identification number, the randomization system will use the randomization algorithm to determine the group allocation and the treatment number(s) to be used for the child for MMR vaccination (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3,

Com_MMR_L1 or Com_MMR_L2). For replacement dose, the system will allocate a new treatment number according to the treatment initially allocated.

For allocation of co-administered vaccines (*Havrix* and *Varivax* to all children, and *Prevnar 13* to the children in the US), the site staff ~~in charge of the vaccination~~ will select a treatment number available for the vaccine dose to be used for the child. Please reference the SPM for further details.

Section 5.5. → Outline of study procedures

Table 5 List of study procedures

Age at enrollment	**12-15 months**		
Epoch	***Primary Epoch***		
Type of contact	**Visit 1**	**Visit 2**	**Visit 3**
Timepoints	**Day 0**	**Day 42**	**Day 180**
Sampling timepoints	**Pre-Vacc**	**Post-Vacc**	
Informed consent	●		
Check inclusion/exclusion criteria	●		
Check contraindications, warnings and precautions	O		O[1]
Collect demography data	●		
Medical history	●		
Physical examination	●	O[2]	O[2]
Measure/record height and weight	●		
Vaccination history (protocol specific vaccines) 3	●		
Pre-vaccination body temperature	●		
Randomization and recording of treatment number	●		
Blood sampling for antibody determination (~5 mL)	●	●	
Study vaccinations	●		
Second dose of *Havrix* and/or varicella vaccine			×[1]
Distribution of Diary Cards	O	O	
Daily post-vaccination recording of solicited local adverse events by children's parent(s)/LAR(s) on Diary Cards (Day 0-3)	●		
Daily post-vaccination recording of solicited general adverse events by children's parent(s)/LAR(s) on Diary Cards for drowsiness, loss of appetite, and irritability (Day 0-14) and for fever, rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42) 4	●		
Recording of the occurrence of any post-vaccination unsolicited symptoms by children's parent(s)/LAR(s) on Diary Cards (Day 0-42)	●		
Recording of concomitant ~~treatment/~~medication/vaccination by children's parent(s)/LAR(s) on Diary Cards (Day 0-4~~2~~***through study end***)	●	***O***	***O***
~~Recording of concomitant treatment/medication/vaccination by children's parent(s)/LAR(s) on Diary Cards (Day 42 through study end)~~		~~●~~	
Investigator/designee medical evaluation of any measles/rubella or varicella-like rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42)	●		
Recording of any ~~treatments~~/medications/vaccinations ~~leading to elimination~~ through Visit 2 (see Section ~~6.7.1~~***6.7.2***)	●	●	
Recording of any forbidden investigational product (through study end)	●	●	●
Return of Diary Cards by parent(s)/LAR(s) and transcription by investigator/designee		●	●[5]
Recording of any intercurrent medical condition (see Section 6.8)	●	●	
Recording of all Serious Adverse Events (Day 0 through study end)	●	●	●

Age at enrollment	12-15 months		
Epoch	*Primary Epoch*		
Type of contact	Visit 1	Visit 2	Visit 3
Timepoints	Day 0	Day 42	Day 180
Sampling timepoints	Pre-Vacc	Post-Vacc	
Recording of NOCD(s) ~~medically attended visits~~ and AEs prompting ***medically attended visits*** including ER visits (Day 0 through study end) [6]	●	●	●
Visit 2 investigator sign-off on data for the Day 42 analysis		●	
Study Conclusion			●
Final investigator signature			●

● is used to indicate a study procedure that requires documentation in the individual eCRF
x is used to indicate a procedure (that is not part of the study) that requires documentation in the individual eCRF
O is used to indicate a study procedure that does not require documentation in the individual eCRF
1 At the end of the study ***or shortly after the study, depending on vaccine availability***, GSK will provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. The second dose of HAV and varicella vaccine is not part of the study procedures.
2 Physical exam at Visit 2 ***and Visit 3*** only required if deemed necessary based on child's interim medical history. Findings are to be recorded only if symptom/abnormality is present.
3 For US children only, child that previously received a 3-dose series of PCV-13 at least 60 days prior to study entry ***(see Section 4.2).***
4 Parent(s)/LAR(s) will contact the investigator **immediately** for any suspected measles/rubella, ~~or~~ varicella-like rash, parotid/salivary gland swelling or suspected signs of meningism, including febrile convulsions occurring between Day 0 and Day 42 and will be asked to schedule a visit for evaluation by the investigator ***(see Section 8.2.2.2).***
5 Return of Diary Card for contraindicated ~~treatment /~~ medication / vaccination***, any*** ~~and~~ specific Adverse Events (AEs) ***,and*** ~~medically attended events and~~ ***AEs prompting medically attended visits including Emergency Room (ER) visits until study end.***
6 Events to be recorded will be new onset chronic disease(s) (NOCD(s)) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies)***,and*** ~~medically attended visits and~~ AEs prompting ***medically attended visits including*** Emergency Room (ER) visits.

Table 6 Intervals between study visits

Visit	Optimal Visit Day*	Interval	Allowed interval
Visit 1	Day 0		
Visit 2	Day 42	Visit 1 → Visit 2	35 ***days*** - 77 days†
Visit 3	Day 180	Visit 1 → Visit 3	180 ***days*** - 210 days

* Whenever possible the investigator should arrange study visits on this optimal visit day.
† Children will not be eligible for inclusion in the ATP immunogenicity analyses if study visits are outside the allowed interval.

Section 5.6.3.1. → Check and record concomitant medication/vaccination and intercurrent medical conditions

At Visit 2 it must be verified if the child has experienced or is experiencing any intercurrent medical condition listed in Section 6.8. If it is the case, the condition(s) must be recorded in the eCRF. In addition, any ***concomitant*** ~~treatments/~~ medications/ vaccinations ***given through Visit 2*** ~~that may lead to the elimination of a child from ATP analyses~~ must be recorded in the eCRF. Refer to Section 6.7.1.

Section 5.6.3.8. → Recording of AEs and SAEs

- At Visit 2 diary cards will be provided to the child's parent(s)/LAR(s) to record:
  - Any medication/ vaccination (from Day 42 to study end).
  - Any AEs ~~prompting a medically attended visit(s)~~ (from Day 42 to study end).
- The child's parent(s)/LAR(s) will be instructed to return the completed diary card to the investigator at the next study visit.
- Collection and verification of completed diary cards will occur during discussion with the child's parent(s)/LAR(s) at post-vaccination visit(s). The investigator/ designee will transcribe the ***required*** collected information into the eCRF.
- Collection and verification of completed diary cards will occur during discussion with the child's parent(s)/LAR(s) at Visit 3. The investigator/ designee will transcribe the collected information on any NOCDs, ***and AEs prompting a medically attended visit(s) including ER*** ~~investigational products and medically attended~~ visits into the eCRF.

Section 5.7.3. → Laboratory assays

The central laboratory responsible for sample handling/processing ***for sites in the United States (including Puerto Rico)*** is BARC USA Inc. 5, Delaware Drive, Lake Success, NY 11042-1114, U.S.A.

Section 6.1. → Description of study vaccines

Table 10 Study vaccines

§ At the end of the study ***or shortly after the study, depending on vaccine availability***, GSK will provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. ***Not applicable for subjects enrolled in US.*** The second dose of HAV and varicella vaccine is not part of the study procedures.

Section 6.2. → Storage and handling of study vaccines

Outside the US ~~For refrigerated vaccines~~, adequate actions must be taken ***for refrigerated vaccines*** in case of temperature excursion between 0 and +2°C (32 and 36°F) ***which*** ~~to~~ go back to the defined range +2 to +8°C (36 to 46°F). The impacted study vaccine(s)/product(s) can still be administered, but the site should avoid re-occurrence of temperature excursion.

Section 6.3. → Dosage and administration of study vaccines

Attenuated viruses in these vaccines are rapidly inactivated by alcohol and detergents, and care should be taken to avoid contact between the reconstituted vaccine and these substances ~~(e.g., disinfection of the skin prior to vaccination)~~. ***Ensure the disinfected area of skin and/or vaccine vial(s) are completely dry prior to administering any vaccines.***

Section 6.4. → Replacement of unusable vaccine doses

The investigator ***or designee*** will use SBIR to obtain a new treatment number. The new treatment numbers will be allocated by dose to replace an unusable dose. The system will ensure, in a blinded manner, that the new vial matches the formulation the child was assigned to by randomization.

Section 6.6. → Warnings and precautions

Post-marketing experience with Varivax suggests that transmission of vaccine virus may occur rarely between healthy ***recipients of*** vacci~~n~~es that develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has also been reported. Information will be given to the parent(s)/LAR(s) in the event that during the study period a household member becomes a susceptible high-risk individual. Susceptible high-risk individuals should avoid close association with vaccine recipients, and especially those vaccine recipients who develop a vaccine-associated rash, for up to six weeks. In circumstances where contact with high-risk individuals is unavoidable, the potential risk of transmission of vaccine virus should be weighed against the risk of acquiring and transmitting natural varicella virus. Susceptible high-risk individuals include:

Section 6.7.1. → Medications/products that may lead to the elimination of a child from ATP analyses

- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the ~~period starting 30 days before the day of study vaccination (i.e., 30 days prior to Day 0) or planned use during the~~ entire study period.
- Planned administration/ administration of a vaccine not foreseen by the study protocol during the study period starting at vaccination and ending at Visit 2. Please Note:
  - **Inactivated** Flu and Hib vaccines may be given at any time ~~during the study~~, including the day of study vaccination (Flu and Hib vaccines must be administered at a different location than the study vaccine/s).
  - Any ***other*** age appropriate vaccine may be given starting at Visit 2 and any time thereafter.

Section 6.7.2. → Time window for recording concomitant medication/vaccination in the CRF/eCRF

All concomitant medications, with the exception of vitamins and/or dietary supplements, administered at ANY time during the period starting 30 days preceding the administration of the dose of study vaccine (i.e., 30 days prior to Day 0) and ending at ~~Day 42~~***Visit 2*** after the administration of study vaccine must be recorded in the eCRF. Concomitant medication/vaccination should be recorded by the child's parent(s)/LAR(s) in the subject diary between Visit1 and Visit 2. The investigator will transcribe this information into the eCRF as indicated below.

Any ~~treatments and/or~~ medications specifically contraindicated, e.g., any immune-globulins, other blood products and any immune modifying drugs administered during the period starting 180 days prior to the vaccination through Visit 2 are to be recorded ***in the eCRF*** with the generic name of the medication (trade names are allowed for combination drugs only), medical indication, total daily dose, route of administration, start and end dates of treatment.

Any vaccine ~~not foreseen in the study protocol~~ administered in the period starting 30 days before ***study vaccination through Visit 2***~~each dose of study vaccine and ending at Day 42 after each dose of study vaccine~~ must be recorded in the eCRF. ***The second dose of HAV and/or varicella vaccine administered at Visit 3 must be recorded in the eCRF (see Section 5.5).*** In addition, administration of previous measles, mumps, and rubella virus containing vaccines regardless of when they were given must be recorded in the eCRF.

Any medication administered for the treatment of an AE should be recorded in the child's eCRF.

Section 8.2.1. → Time period for detecting and recording adverse events and serious adverse events

All AEs starting from Day 0 through 42 days after the administration of study vaccine must be recorded on the Adverse Event screen in the child's eCRF, irrespective of intensity or whether or not they are considered vaccination-related. The standard time period for collecting and recording SAEs will begin at the first receipt of study vaccines and will be collected throughout the entire study. See Section ~~8.2.1~~***8.3*** for instructions on reporting of SAEs.

The standard time period for collecting and recording of AEs prompting a medically attended visit(s) will begin at the first receipt of study vaccine and will end at the last study visit or contact.

Table 14 Reporting periods and methods for adverse events and serious adverse events

	Visit 1 Vaccination			**Visit 2 Follow-up**	**Visit 3 Conclusion**
Optimal Visit Day	**Day 0**			**Day 42**	**Day 180**
Solicitation period	Day 0-3	Day	Da		
Study activity					
Reporting solicited local AEs	DC/RDE				
Reporting solicited drowsiness, loss of appetite or irritability	DC/RDE				
Reporting solicited fever, rash (measles / rubella or varicella-like rash, other rash), parotid/salivary gland swelling and any sign of meningism including febrile convulsions	DC/RDE				
Reporting unsolicited AEs	DC/RDE			DC	DC
Reporting NOCD(s)~~*~~ and AEs prompting a medically attended visit(s) (including ER visits)	***DC***/RDE			***DC***/RDE	***DC***/RDE
Reporting ALL SAEs	***DC***/RDE			***DC***/RDE	***DC***/RDE

AEs = Adverse Events; DC = Diary Card; RDE = Remote Data Entry; SAEs = Serious Adverse Events
NOCD = New Onset Chronic Disease; ER = Emergency Room.
~~* Occurrence of NOCD(s) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) up to 6 months after vaccination.~~

Section 8.2.2.2.1. → Assessment of intensity

The investigator's assessment of the rash will be recorded in the eCRF. If the investigator has not seen the rash, and other medically qualified person has assessed the rash during a medically attended visit, then this assessment will be recorded in eCRF. If the child was not seen by the investigator or other medically qualified person, the information about rash entered in eCRF should be the one recorded by the parent in the diary card.

AEs of specific interest:

Occurrences of AEs of specific interest, including NOCDs and AEs prompting ER visits, will be reported throughout the study, up to six months ~~post-vaccination~~***after the dose of MMR vaccine***, whether or not they are considered to be possibly related to the treatment administration. Medical documentation of the events will be reported in appropriate targeted follow-up forms included in the eCRF. These events also have to be reported as AE or SAE as appropriate in the eCRF.

Section 8.2.2.4. → Medically attended visits

For each solicited and unsolicited symptom the child experiences, the child's parent(s)/LAR(s) will be asked if the child received medical attention defined as hospitalization, an emergency room visit or a visit to or from medical personnel (e.g., medical doctor) for any reason and this information will be recorded in the eCRF. ***Routine "well child" visit information will not be recorded in the eCRF.***

Section 8.3.2. Contact information for reporting serious adverse events to GSK Biologicals

Study Contact for Reporting SAEs

~~See Sponsor Information Sheet for contact details~~ ***Refer to the local study contact information document.***

Section 8.4.1. → Follow-up of adverse events and serious adverse events

Or, in the case of other non-serious AEs, until ***resolution or study end,*** or they are lost to follow-up.

Section 10.7.1. → Methodology for computing CI

The exact 95% CIs for a proportion within a group will be calculated ***using SAS. SAS*** ~~from Proc StatXact 8.1 [Clopper, 1934]. Proc StatXact 8.1~~ will also be used to derive the standardized asymptotic 95% CI for the group difference in proportions (method 6 in [Newcombe, 1998]).

Section 10.7.4. → Analysis of safety

The percentages of children who experienced at least one serious adverse event ~~from the first study dose up to 6 months post-vaccination~~ or who reported a ~~chronic illness~~***NOCD*** (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies), or an AE leading to an ER visit, ***or an AE leading to a medically attended visit from Day 0 to study end,*** will be calculated.

Section 13. → REFERENCES

~~Clopper CJ, Pearson, E. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika. 1934;26:404-413.~~

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GlaxoSmithKline Biologicals

Clinical Research & Development

Protocol Amendment 2

eTrack study number and Abbreviated Title(s)	115648 (MMR-160)
Amendment number:	Amendment 2
Amendment date:	26 February 2015
Co-ordinating author:	PPD Scientific Writer

Rationale/background for changes:

- Following comments from CBER, the Streptococcus pneumoniae testing will not be the 22F ELISA currently listed but a validated assay accepted by CBER. The assessment of this assay is ongoing. As such, the secondary endpoint related to assessment of the percentage of subjects with Streptococcus pneumoniae antibody concentrations ≥0.05, 0.2, 0.5, and 1.0 µg/mL with the 22F ELISA has been removed. The need for any additional endpoints related to Streptococcus pneumoniae antibody testing will be reassessed once a CBER validated assay is selected.
- Serological assays for the determination of antibodies against measles, rubella and varicella viruses now will be performed by GSK Biologicals' laboratory in Laval, Canada. Note : In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party CRO
- Serological testing for the co-administered vaccines (i.e. VV, HAV and PCV-13) will be completed much later than the antibody determination for measles, mumps and rubella. Therefore the immunogenicity data analysis for the co-administered vaccines will be included in the final analysis performed at the end of the study.
- Other minor corrections.

Amended text has been included in *bold italics* and deleted text in ~~strikethrough~~ in the following sections:

Cover page

Co-ordinating author	PPD Scientific writer~~, XPE PharmaZeroChaos for GSK Biologicals~~
Contributing authors	• PPD Study Data Manager • PPD ***Director, Safety Evaluation and Risk Management***

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Abbreviations (added)

CBER	***Center for Biologics Evaluation and Research***
CRO	***Contract Research Organization***

Synopsis and Section 2.2 Secondary objectives

- Deleted 2nd objective # 5 ~~To assess the immunogenicity of Prevnar 13 with respect to concentrations ≥ the cut-offs of 0.05, 0.2, 0.5, and 1.0 µg/mL for antibodies to PS in the Inv_MMR vaccine groups or the Com_MMR groups at Day 42 (in a subset of children administered Prevnar 13 in the US).~~

Synopsis and Section 10.2 Secondary endpoints

- Deleted 2nd endpoint ~~Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations ≥0.05 µg/mL, ≥0.2 µg/mL, ≥0.5 µg/mL and ≥1.0 µg/mL.~~

Section 5.7.3 Laboratory Assays

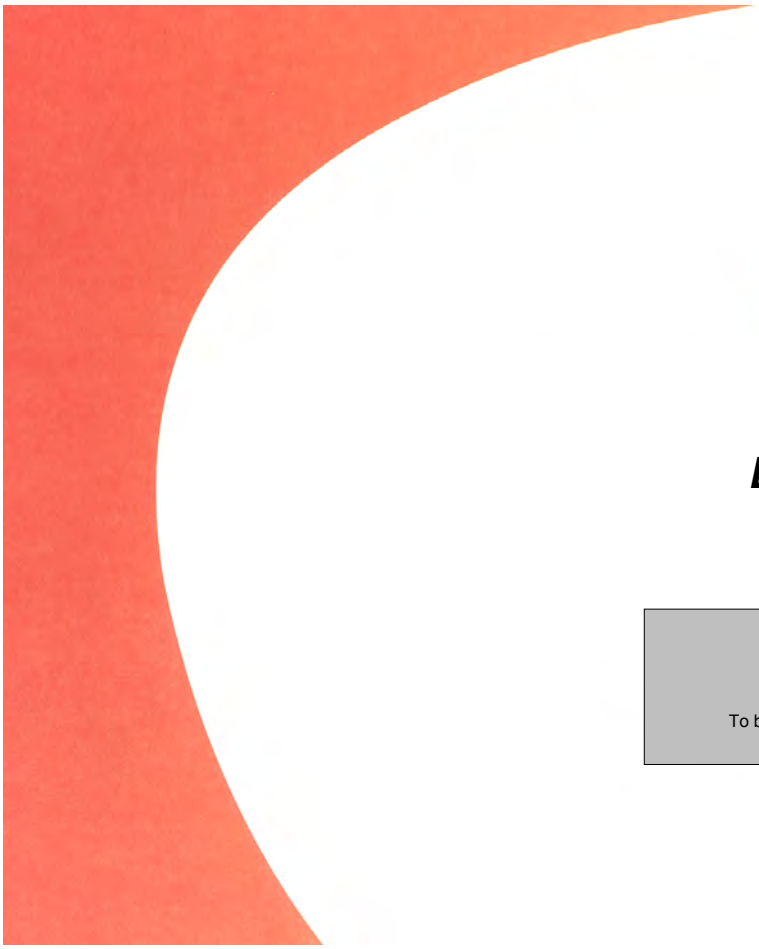
GSK Biologicals Global Vaccine Clinical Laboratory
Biospecimen Reception - Clinical Serology
525 Cartier blvd West - Laval - Quebec - Canada - H7V 3S8
Note : In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party Contract Research Organization (CRO).

Section 10.6.1 Sequence of analyses

The analysis will be performed in two steps:

- A final analysis of immunogenicity data ***for measles, mumps and rubella*** and solicited symptoms up to Day 42 will be performed as soon as all ***measles, mumps and rubella*** immunogenicity data and reactogenicity data (i.e. solicited symptoms) up to Visit 2 are available and cleaned. No clinical report will be written at this time.
- A final analysis of ***immunogenicity*** data ***for the co-administered vaccines (i.e. VV, HAV and PCV-13)*** and unsolicited AEs from Day 0 to Day 42 following vaccination, and of SAEs and specific AEs covering the period from Day 0 to study end (including the 6-months safety follow-up) will be performed at the end of the study.

Sample Case Report Form



Diary Card
DAY 0 – DAY 42

Subject number

|__|__|__|__|__|__|

To be completed by the Investigator or delegate

Protocol 115648
(MMR-160)

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.

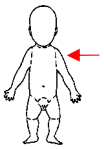
In case of hospitalization, please inform:
.....
.....

Diary Card template 13.2 - September 20, 2012

115648 (MMR-160)	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

LOCAL SYMPTOMS

Location of MMR Study Vaccination



Please report any of the following solicited local adverse events that occurred within 4 days (from Day 0 to Day 3) post vaccination

To be completed by the investigator or delegate:

Date of vaccination = Day 0: _____ **Injection Site**: _____ **Side**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did you receive any medical attention?*	Type of medical attention To be completed by the investigator or delegate
					Ongoing	Max intensity	End Date		
Injection site **Redness** → size (mm)	mm	mm	mm	mm	☐ No ☐ Yes →	mm		☐ No ☐ Yes →	HO/ER/MD |__|__|
Measure and record the greatest surface diameter (in mm).									
Injection site **Swelling** → size (mm)	mm	mm	mm	mm	☐ No ☐ Yes →	mm		☐ No ☐ Yes →	HO/ER/MD |__|__|
Measure and record the greatest surface diameter (in mm).									
Injection site **Pain** → intensity (0/1/2/3)	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	☐ No ☐ Yes →	1/2/3		☐ No ☐ Yes →	HO/ER/MD |__|__|
Intensity: **0**:Absent **1**:Minor reaction to touch **2**:Cries/protests on touch **3**:Cries when limb is moved / spontaneously painful									

* Medical attention = HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

Clarification(s) for Investigator or delegate only:

GlaxoSmithKline 115648 (MMR-160)	DIARY CARD	Subject Number
		|__|__|__|__|__|__| To be completed by the investigator or delegate

GENERAL SYMPTOMS

Please report any of the following solicited general adverse events that occurred within 15 days (from Day 0 to Day 14) post-vaccination.

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	After Day 14			Did you receive medical attention?*	Type of medical attention To be completed by the investigator or delegate
																Ongoing	Max Intensity	End Date		
Irritability/ Fussiness → Intensity (0/1/2/3)	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	☐ No ☐ Yes →	1/2/3		☐ No ☐ Yes →	HO/ER/MD ___
Intensity: **0**:Behavior as usual **1**:Crying more than usual / no effect on normal activity **2**:Crying more than usual / interferes with normal activity **3**:Crying that cannot be comforted / prevents normal activity																				
Drowsiness → intensity (0/1/2/3)	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	☐ No ☐ Yes →	1/2/3		☐ No ☐ Yes →	HO/ER/MD ___
Intensity: **0**:Behavior as usual **1**:Drowsiness easily tolerated **2**:Drowsiness that interferes with normal activity **3**:Drowsiness that prevents normal activity																				
Loss of appetite → intensity (0/1/2/3)	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	0/1/2/3	☐ No ☐ Yes →	1/2/3		☐ No ☐ Yes →	HO/ER/MD ___
Intensity: **0**:Appetite as usual **1**:Eating less than usual / no effect on normal activity **2**:Eating less than usual / interferes with normal activity **3**:Not eating at all																				

* **Medical attention** = HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

Clarification(s) for Investigator or delegate only:

Diary Card template 13.2 - September 20, 2012

GlaxoSmithKline **115648 (MMR-160)**	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

TEMPERATURE

DAY 0 TO DAY 14

From Day 0 to Day 42 post-vaccination, Please record subject's body temperature measured preferentially by the axillary route each evening at bedtime

- Only one route for temperature measurement (axillary preferred) should be used consistently.
- If temperature has been taken more than once a day, please report the highest value for the day.
- If multiple measures, take the maximum value.

Unit: [CE] ☐ Celsius (°C) [FA] ☐ Fahrenheit (°F)

Route: [A] ☐ Axillary (preferred) [O] ☐ Oral [R] ☐ Rectal [T] ☐ Tympanic [TA] ☐ Temporal

To be completed by the investigator or delegate: **Date of Day 0**: _____

	Temperature			if ≥ 38.0 °C or 100.4 °F	
	route if different A/O/R/T/TA		*tick if not taken* ↓	Did you receive any medical attention?*	**Type of medical attention** To be completed by the investigator or delegate
Day 0	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 1	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 2	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 3	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 4	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 5	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 6	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 7	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 8	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 9	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 10	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 11	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 12	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 13	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 14	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|

***Medically attended visit:** , HO:Hospitalization, ER:Emergency Room, MD:Medical Personnel (Refer to protocol for full definition)

Clarification(s) for Investigator or delegate only:

GlaxoSmithKline **115648 (MMR-160)**	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

To be completed by the investigator or delegate: **Date of Day 15**: _____

	Temperature			if ≥ 38.0 °C or 100.4 °F	
	route if different A/O/R/T/TA		*tick if not taken* ↓	Did you receive any medical attention?*	**Type of medical attention** To be completed by the investigator or delegate
Day 15	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 16	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 17	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 18	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	NO/HO/ER/MD |__|__|
Day 19	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 20	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 21	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 22	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 23	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 24	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 25	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 26	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 27	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 28	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 29	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|

***Medically attended visit:** HO:Hospitalization, ER:Emergency Room, MD:Medical Personnel (Refer to protocol for full definition)

Clarification(s) for Investigator or delegate only:

Diary Card template 13.2 - September 20, 2012

GlaxoSmithKline **115648 (MMR-160)**	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

DAY 30 TO DAY 42

To be completed by the investigator or delegate: **Date of Day 30**: _____

	Temperature			if ≥ 38.0 °C or 100.4 °F	
	route if different A/O/R/T/TA		*tick if not taken* ↓	Did you receive any medical attention?*	**Type of medical attention** To be completed by the investigator or delegate
Day 30	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 31	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 32	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 33	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 34	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 35	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 36	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 37	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 38	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 39	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 40	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 41	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|
Day 42	|__|	|__|__|.|__| (°C) |__|__|__|.|__| (°F)	☐	☐ No ☐ Yes	HO/ER/MD |__|__|

***Medically attended visit:** HO:Hospitalization, ER:Emergency Room, MD:Medical Personnel (Refer to protocol for full definition)

Clarification(s) for Investigator or delegate only:

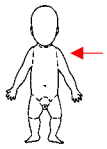
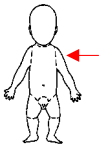
Diary Card template 13.2 - September 20, 2012

GlaxoSmithKline **115648 (MMR-160)**	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

RASH

Please report any rash that occurred within 43 days (from Day 0 to Day 42) post-vaccination.

The subject's parent(s)/LAR(s) will be asked to contact the study site immediately if their child develops a rash that could be a measles/rubella-like or varicella-like rash. (Please refer to the rash guidelines for more information)

Rash No.	**RA 1**	**RA 2**
Description	Appearance: ☐ Spots ☐ Blisters ☐ Bumps ☐ Crusts Color: ☐ Red/Pink ☐ White/yellow ☐ Black ☐ Brown Other: ----------	Appearance: ☐ Spots ☐ Blisters ☐ Bumps ☐ Crusts Color: ☐ Red/Pink ☐ White/yellow ☐ Black ☐ Brown Other:----------
	☐ Generalised ☐ Localised: ☐ MMR administration site-please refer to site and side filled in on top of diary card:  ☐ Other location, specify: _____	☐ Generalised ☐ Localised: ☐ MMR administration site- please refer to site and side filled in on top of diary card:  ☐ Other location, specify: _____
Start date:	|__|__| |__|__|__| |__|__|__|__| day month year	|__|__| |__|__|__| |__|__|__|__| day month year
End date:	|__|__| |__|__|__| |__|__|__|__| day month year	|__|__| |__|__|__| |__|__|__|__| day month year
Type of rash:	☐ Varicella-like rash →Maximum intensity: ☐ 1 – 50 lesions ☐ 51 – 150 lesions ☐ > 150 lesions ☐ Measles / rubella-like rash →Maximum intensity: ☐ 1 – 50 lesions ☐ 51 – 150 lesions ☐ > 150 lesions ☐ Other →Maximum intensity**: ☐ Mild ☐ Moderate ☐ Severe	☐ Varicella-like rash →Maximum intensity: ☐ 1 – 50 lesions ☐ 51 – 150 lesions ☐ > 150 lesions ☐ Measles / rubella-like rash →Maximum intensity: ☐ 1 – 50 lesions ☐ 51 – 150 lesions ☐ > 150 lesions ☐ Other →Maximum intensity**: ☐ Mild ☐ Moderate ☐ Severe
Did you receive any medical attention?*	☐ No ☐ Yes	☐ No ☐ Yes
Type of medical attention To be completed by the investigator or delegate	HO/ER/MD |__|__|	HO/ER/MD |__|__|

* **Medical attention** = HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

1: **Mild. Rash which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities;
2: **Moderate.** Rash which is sufficiently discomforting to interfere with normal everyday activities;
3: **Severe.** Rash which prevents normal, everyday activities (in a young child, such an event would, for example, prevent attendance at school and would cause the parent(s)/LAR(s) to seek medical advice).

Clarification(s) for Investigator or delegate only:

Diary Card template 13.2 - September 20, 2012

GlaxoSmithKline 115648 (MMR-160)	DIARY CARD	Subject Number |__|__|__|__|__|__| To be completed by the investigator or delegate

PAROTID / SALIVARY GLAND SWELLING EVENTS

Please report any **parotid / salivary gland swelling** that occurred within 43 days (from Day 0 to Day 42) post-vaccination.

If parotitis is clinically suspected (swelling /tenderness above or below the jaw line) during Day 0 to Day 42 after vaccination, the subject will have to be seen by the investigator as soon as possible for an additional visit.

PS No.	PS 1	PS 2
Description:	_____ _____ _____ _____	_____ _____ _____ _____
Start date:	|__|__| |__|__|__| |__|__|__|__| day month year	|__|__| |__|__|__| |__|__|__|__| day month year
End date:	|__|__| |__|__|__| |__|__|__|__| day month year	|__|__| |__|__|__| |__|__|__|__| day month year
Intensity:	☐ Swelling without difficulty moving the jaw ☐ Swelling with difficulty moving the jaw ☐ Swelling with accompanying general symptoms	☐ Swelling without difficulty moving the jaw ☐ Swelling with difficulty moving the jaw ☐ Swelling with accompanying general symptoms
Did you receive any medical attention?*	☐ No ☐ Yes	☐ No ☐ Yes
Type of medical attention To be completed by the investigator or delegate	HO/ER/MD |__|__|	NO/HO/ER/MD |__|__|

* **Medical attention** = HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

Clarification(s) for Investigator or delegate only:

Diary Card template 13.2 - September 20, 2012

GlaxoSmithKline 115648 (MMR-160)	DIARY CARD	Subject Number |__|__|__|__|__|__| To be completed by the investigator or delegate

SUSPECTED SIGNS OF MENINGISM INCLUDING FEBRILE CONVULSIONS/ SEIZURES

Please report **any suspected Signs of meningism (including febrile convulsions/seizures)** that occurred within 43 days (from Day 0 to Day 42) post- vaccination.

If the subject experiences febrile convulsions or presents any other neurological signs or symptoms indicative of meningism (i.e., neck stiffness with or without light intolerance (photophobia) and headache; or convulsion/seizure) during Day 0 to Day 42 follow-up after vaccination, the subject's parent(s)/LAR(s) should contact the investigator immediately for follow-up

FC No.	FC 1	FC 2
Description:	_____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____
Start date:	|__|__| |__|__|__| |__|__|__|__| day month year	|__|__| |__|__|__| |__|__|__|__| day month year
End date:	|__|__| |__|__|__| |__|__|__|__| day month year	|__|__| |__|__|__| |__|__|__|__| day month year
Intensity:	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Did you receive any medical attention?*	☐ No ☐ Yes	☐ No ☐ Yes
Type of medical attention To be completed by the investigator or delegate	HO/ER/MD |__|__|	HO/ER/MD |__|__|

*** Medical attention =** HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

1: **Mild.** An adverse event which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
2: **Moderate.** An adverse event which is sufficiently discomforting to interfere with normal everyday activities.
3: **Severe.** An adverse event which prevents normal, everyday activities. (In a young child, such an adverse event would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parents/guardians to seek medical advice).

Clarification(s) for Investigator or delegate only:

Diary Card template 13.2 - September 20, 2012

GlaxoSmithKline **115648 (MMR-160)**	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

ADVERSE EVENTS

Record any adverse event (= any illness, sign, symptom) other than the local and general symptoms solicited on the previous pages, which may have started or any medical condition which may have worsened since the study vaccination.

Illness/Sign/Symptom	To be filled in case of reaction at vaccine administration site		Max Intensity 1/2/3	Start Date	End Date	Did you receive medical attention ?*	Type of medical attention To be completed by the investigator or delegate
	Side	Site					
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |_|_|
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |__|__|
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |__|__|
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |__|__|

* **Medical attention** = HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

1: **Mild.** An adverse event which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
2: **Moderate.** An adverse event which is sufficiently discomforting to interfere with normal everyday activities.
3: **Severe.** An adverse event which prevents normal, everyday activities. (In a young child, such an adverse event would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parents/guardians to seek medical advice).

Clarification(s) for Investigator or delegate only:

VACCINATION

Record any vaccination received since the last study vaccination

Vaccination	Date of administration	Route* To be completed by the investigator or delegate

* **Route codes** = inhalation [IH], intraarticular [IR], intradermal [ID], intramuscular [IM], intranasal [IN], intravenous [IV], oral [PO], parenteral [PE], rectal [PR], subcutaneous [SC], sublingual [SL], topical [TO], transdermal [TD], vaginal [VA], other [OTH], unknown [UNK]

Clarification(s) for Investigator or delegate only:

115648 (MMR-160)	DIARY CARD	Subject Number |__|__|__|__|__|__|__| To be completed by the investigator or delegate

MEDICATION

Record any medication taken since the study vaccination.

Medication	Reason/Indication	Route To be completed by the investigator or delegate	Dose and frequency	Start Date	End Date

Clarification(s) for Investigator or delegate only:

115648 (MMR-160)	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

NOTES

PLEASE DO NOT FORGET TO RETURN THE DIARY CARD TO THE SITE

INVESTIGATOR'S OR DELEGATE'S SIGNATURE

Investigator's or delegate's signature: _____ Date: |__|__| |__|__|__| |__|__|__|__|

Printed Investigator's or delegate's name: _____

Diary Card template 13.2 - September 20, 2012

Diary Card

Subject number

|__|__|__|__|__|__|

To be completed by the Investigator or delegate

Protocol 115648 (MMR-160)

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.

Post Visit 2 (Day 42)

In case of hospitalization, please inform:
.....
.....

GlaxoSmithKline 115648 (MMR-160)	DIARY CARD	Subject Number |__|__|__|__|__|__| To be completed by the investigator or delegate

ADVERSE EVENTS

Record any adverse event (= any illness, sign, symptom) which may have started or any medical condition which may have worsened since Visit 2.

Illness/Sign/Symptom	To be filled in case of reaction at vaccine administration site		Max Intensity 1/2/3	Start Date	End Date	Did you receive medical attention ?*	Type of medical attention To be completed by the investigator or delegate
	Side	Site					
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |_|_|
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |__|__|
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |__|__|
	☐ Left ☐ Right	☐ Deltoid region ☐ Triceps region ☐ Thigh ☐ Buttock				☐ No ☐ Yes →	HO/ER/MD |__|__|

* **Medical attention** = HO: hospitalisation, ER: an emergency room visit or MD: a visit to or from medical personnel (medical doctor)

1: **Mild.** An adverse event which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
2: **Moderate.** An adverse event which is sufficiently discomforting to interfere with normal everyday activities.
3: **Severe.** An adverse event which prevents normal, everyday activities. (In a young child, such an adverse event would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parents/guardians to seek medical advice).

Clarification(s) for Investigator or delegate only:

VACCINATION

Record any vaccination received since the last study vaccination

Vaccination	Date of administration	Route* To be completed by the investigator or delegate

* **Route codes** = inhalation [IH], intraarticular [IR], intradermal [ID], intramuscular [IM], intranasal [IN], intravenous [IV], oral [PO], parenteral [PE], rectal [PR], subcutaneous [SC], sublingual [SL], topical [TO], transdermal [TD], vaginal [VA], other [OTH], unknown [UNK]

Clarification(s) for Investigator or delegate only:

Diary Card template 13.2 - August 23, 2012 Visit 2 until end of study

115648 (MMR-160)	DIARY CARD	Subject Number |__|__|__|__|__|__| To be completed by the investigator or delegate

MEDICATION

Record any medication taken since Visit 2.

Medication	Reason/Indication	Route To be completed by the investigator or delegate	Dose and frequency	Start Date	End Date

Clarification(s) for Investigator or delegate only:

115648 (MMR-160)	**DIARY CARD**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

NOTES

PLEASE DO NOT FORGET TO RETURN THE DIARY CARD TO THE SITE

INVESTIGATOR'S OR DELEGATE'S SIGNATURE

Investigator's or delegate's signature: _____ Date: |__|__| |__|__|__| |__|__|__|__|

Printed Investigator's or delegate's name: _____

Protocol *(eTrack number)*
115648

Abbreviated Title

MMR-160

Serious Adverse Event Report

Centre number |__|__|__|__|__|__|

Subject number |__|__|__|__|__|__|

GlaxoSmithKline Biologicals

Rue de l'Institut 89, B – 1330 Rixensart, Belgium
Tel: PPD

CRF template version 13.2 – August 14, 2012

DEFINITION OF A SERIOUS ADVERSE EVENT

A serious adverse event (SAE) is any untoward medical occurrence that:

- ☐ results in death,
- ☐ is life-threatening,

  NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death, if it were more severe.

- ☐ requires hospitalization or prolongation of existing hospitalization,

  NOTE: In general, hospitalization signifies that the subject has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or out-patient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfils any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred or was necessary, the AE should be considered serious.

  Hospitalization for elective treatment of a pre-existing condition that did not worsen from baseline is not considered an SAE.

- ☐ results in disability/incapacity, or

  NOTE: The term disability means a substantial disruption of a person's ability to conduct normal life functions. This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhoea, influenza, and accidental trauma (e.g. sprained ankle) which may interfere or prevent everyday life functions but do not constitute a substantial disruption.

- ☐ is a congenital anomaly/birth defect in the offspring of a study subject.

Medical or scientific judgement should be exercised in deciding whether reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the subject or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also be considered serious. Examples of such events are invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization.

See also the study protocol for possible additional specification (possible additional bullets g., h., …)

COLLECTION OF SERIOUS ADVERSE EVENTS

SAEs related to study participation (e.g. procedures, invasive tests, change from existing therapy) or SAEs related to GSK concurrent medication/vaccine or any fatal SAE will be collected and recorded from the time the subject consents to participate in the study until she/he is discharged.

For all other SAEs, the standard time period for collecting and recording SAEs will begin from the administration of the first dose of vaccine / placebo / comparator and will end minimum 30 days (see protocol) following administration of the last dose of vaccine / placebo / comparator for each subject.

INSTRUCTIONS FOR REPORTING SERIOUS ADVERSE EVENT (SAE)

SAEs MUST BE REPORTED TO GSK STUDY CONTACT WITHIN 24 HOURS

1. COMPLETE THE SAE PAGES

Complete these pages as fully and accurately as possible in order to allow GSK's safety department to make an assessment of the initially reported information and to minimize the time you spend dealing with data queries.

Ensure that all information reported on the SAE pages is consistent with information given on CRF pages :

- Demographics
- General Medical History / Physical Examination
- Vaccine administration page(s) (for administered doses)
- Medication
- Concomitant Vaccination

2. SIGN AND DATE THE LAST PAGE

3. FAX THE SAE PAGE TO GSK BIOLOGICALS

Refer to the study protocol for contact information.

GUIDELINES FOR COMPLETING SERIOUS ADVERSE EVENT REPORT

SAE Case No.	This box is mandatory and has to be completed before faxing the SAE report. Attribute a sequential number to each new SAE case, starting from 01 for each subject.
GSK receipt date	To be completed by GSK only. The GSK receipt date is the date on which the first GSK employee/designee is notified of the SAE.
Potential immune mediated diseases (pIMD)	If specified in the protocol, report non-serious pIMDs in the SAE report.

SECTION 1

Event	A separate report should be used for each SAE. However if multiple SAEs are temporarily or clinically related then these may be reported on the same page. Avoid recording the narrative and only enter the diagnosis (if known); otherwise enter the sign or symptom. Signs and symptoms should not be collapsed; see example below. ***wrong*** 1: FEVER/HEADACHE/EAR PAIN ***correct*** 1: OTITIS MEDIA or 1: FEVER 2: HEADACHE 3: EAR PAIN
Start date	The start date should document the date of the first occurrence of the SAE. This is generally the start date of the signs/symptoms and not necessarily the date that the event met the definition of serious.
Outcome	All SAEs must be followed until the events are resolved, the condition stabilises, the events are otherwise explained, or the subject is lost to follow-up. Indicate if the event was "Recovered/Resolved" or Recovered/Resolved with sequelae". If the SAE is ongoing at the time the subject completed the study or becomes lost to follow-up, the outcome must be recorded as "Recovering/Resolving" or "Not recovered/Not resolved". Also enter "Not recovered/Nor resolved" if the SAE was ongoing at the time of death, but was not the cause of death, enter fatal for the SAE which was the direct cause of death.
End date	Record the date of resolution of the event (which is not necessarily the end date of hospitalisation) or the date of death as applicable. Leave blank only if the outcome of the event is "Not resolved" – " Recovering/Resolving".
Maximum Intensity	Record the maximum intensity that occurred over the duration of the event (see the study protocol for the definition of intensity). Amend the intensity if it increases. Enter X (not Applicable) if grading can not be applied. For example, intensity for 'broken leg'.
Relationship to investigational product(s)	This box is mandatory and has to be completed before faxing the report. It is a regulatory requirement for investigators to assess relationship to investigational product(s) based on available information. The assessment should be reviewed on receipt of any new information and amended if necessary. 'A reasonable possibility' is meant to convey that there are facts/evidence or arguments to suggest a causal relationship. Facts/evidence or arguments that may support 'a reasonable possibility' include, e.g., a temporal relationship, a pharmacologically-predicted event, or positive dechallenge or rechallenge. Confounding factors, such as concomitant medication, a concurrent illness, or relevant medical history, should also be considered.
Action taken with investigational product(s) as a result of the SAE	If the administration of the investigational product was stopped permanently enter **1-Investigational product(s) withdrawn**. If the administration of the investigational product was not modified and all scheduled doses were given enter **2-Dose not changed**. If the administration of investigational product was temporarily interrupted but then restarted enter **3-Dose Interrupted**. If the subject did not receive the investigational product dose at the time of the event or if the subject has received all doses or if the subject died and there was no prior decision to discontinue investigational product enter **X-Not applicable**.

GUIDELINES FOR COMPLETING SERIOUS ADVERSE EVENT REPORT

SECTION 2

Seriousness	**Requires hospitalisation or prolongation of existing hospitalisation** The following cases are not defined as serious AEs and no SAE report is no to be submitted : • Hospitalization for elective surgery related to a pre-existing condition which did not increase in severity or frequency following initiation of the study • Hospitalisation for routine clinical procedure or for social reason (e.g. : elderly person had an extension of hospitalization because of non availability of a room in a resting home) that are not the result of an adverse event. These latter cases have to be recorded in the CRF only. If the hospitalisation arises from a pre-existing condition or was planned prior to the first vaccination, it should be recorded in the Medical History page of the CRF. If the hospitalisation was planned after the first vaccination, it should be recorded in the AE pages. In both cases, it should be recorded as “Hospitalisation” (not an adverse event) or “Hospitalisation for social reason” (not an adverse event) or “Elective surgery” (not an adverse event) and the relationship to vaccination will be checked “No”.

SECTION 4

If the administration of the investigational product(s) was stopped, did the reported event(s) recur after further investigational product(s) were administered? If deliberate or inadvertent administration of further dose(s) of investigational product(s) to the subject occurred, did the reported adverse event recur?

SECTION 5

Possible causes of SAE other than the investigational product To be completed in any case, whether relationship is “Yes” or “No”. Indicate all possible explanations/circumstances which may have contributed to the SAE.

SECTION 8

Relevant Concomitant Medications Include any concomitant medications which may have contributed to the event. There is no need to list medications which are definitely not linked to the event.

SECTION 9

Vaccine name	Vaccine should be given as described on the CRF vaccination page (or protocol). In case of multiple vaccinations on the same day, it is important to also mention if the vaccines were administered mixed or separetely.

GlaxoSmithKline

Protocol (eTrack number) |_1_|_1_|_5_|_6_|_4_|_8_|	Country	Centre Number	Subject Number
Abbreviated Title MMR-160	_____	|__|__|__|__|__|__|	|__|__|__|__|__|__|

SERIOUS ADVERSE EVENT (SAE)

SAE Case No. \|__\|__\| GSK receipt date: \|__\|__\|__\|__\|__\|__\|__\|__\|

☐ 1. Initial report ☐ 2. First follow-up ☐ 3. Second follow-up ☐ 4. Third follow-up

SECTION 1

SAE No.	Event	Tick (✓) if NOCD ↓	Start date	Outcome	End date	Maximum intensity	Action taken with investigational product(s) as a result of the SAE	Withdrawal	Relationship to investigational product(s)	Medically attended visit
	Diagnosis only (if known), otherwise sign / symptom		Day Month Year (DD MMM YYYY)	**1**: Recovered/Resolved **2**: Recovering/Resolving **3**: Not recovered/ Not resolved **4**: Recovered/Resolved with sequelae **5**: Fatal	If fatal, record date of death Day Month Year (DD MMM YYYY)	**1**: Mild **2**: Moderate **3**: Severe **X**:Not applicable	**1**: Investigational product(s) withdrawn **2**: Dose not changed **3**: Dose Interrupted **X**: Not applicable	Did the subject withdraw from study as a result of this SAE? **Y**=Yes **N**=No	Is there a reasonable possibility that the SAE may have been caused by the investigational product? **Y**=Yes **N**=No	**HO**:Hospitalisation **ER**:Emergency Room **MD**:Medical Personnel Refer to protocol for full definition
1		☐	|__|__|__|__|__|__|__|__|		|__|__|__|__|__|__|__|__|					
2		☐	|__|__|__|__|__|__|__|__|		|__|__|__|__|__|__|__|__|					
3		☐	|__|__|__|__|__|__|__|__|		|__|__|__|__|__|__|__|__|					

If fatal, was a post-mortem/autopsy performed? ☐ No ☐ Yes → *Summarize findings in Section 11 Narrative Remarks of this SAE form.*

SECTION 2 – Seriousness *specify reason(s) for considering this a SAE, tick all that apply:*

☐ Results in death
☐ Is life threatening
☐ Requires hospitalisation or prolongation of existing hospitalisation
→ date of admission \|__\|__\|__\|__\|__\|__\|__\|__\|
→ date of discharge \|__\|__\|__\|__\|__\|__\|__\|__\|

☐ Results in disability / incapacity
☐ Congenital anomaly / birth defect in the offspring
☐ Other (clinically significant / intervention required) (see definition of SAE)
→ specify _____

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GlaxoSmithKline

Protocol (eTrack number) |_1_|_1_|_5_|_6_|_4_|_8_|	Country	Centre Number	Subject Number
Abbreviated Title MMR-160	_____	|__|__|__|__|__|__|	|__|__|__|__|__|__|

SECTION 3 - Demography Data

Date of birth: (Day Month Year) |__|__|__|__|__|__|__|__|	Sex: ☐ Male ☐ Female	Weight: |__|__|__|.|__| kg	US only Pounds: |__|__|__| Ounces: |__|__|

SECTION 4

If the administration of the investigational product(s) was stopped, did the reported event(s) recur after further investigational product(s) were administered?

☐ No ☐ Yes ☐ Unknown at this time ☐ Not applicable

SECTION 5 – Possible causes of SAE other than investigational product: *(tick all that apply)*

- ☐ Disease under study *(not applicable for prophylactic vaccine studies)*
- ☐ Medical condition(s) *(record in Section 6)*
- ☐ Lack of efficacy
- ☐ Withdrawal of investigational product
- ☐ Concomitant medication *(record in Section 8)*
- ☐ Activity related to study participation (e.g. procedures)
- ☐ Other, specify: _____

_____

SECTION 6 – Relevant Medical Conditions

Specify any RELEVANT past or current medical disorders, allergies, surgeries, etc., that can help explain the SAE	Date of onset Day Month Year (DD MMM YY)	Condition present at time of SAE	If No, date of last occurrence Day Month Year (DD MMM YY)
	|__|__||__|__|__||__|__|	☐ Yes ☐ No →	|__|__||__|__|__||__|__|
	|__|__||__|__|__||__|__|	☐ Yes ☐ No →	|__|__||__|__|__||__|__|
	|__|__||__|__|__||__|__|	☐ Yes ☐ No →	|__|__||__|__|__||__|__|

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Protocol (eTrack number) |_1_|_1_|_5_|_6_|_4_|_8_|	Country	Centre Number	Subject Number
Abbreviated Title MMR-160	_____	|__|__|__|__|__|__|	|__|__|__|__|__|__|

SECTION 7 – Other relevant risk factors:

specify any family or social history (smoking, diet, drug abuse, occupational hazard) relevant to the SAE:

SECTION 8 – Relevant Concomitant Medications

*(include details of any concomitant medication(s) **which may have contributed to the event**)*

Medication/Treatment Name (Trade name preferred)	Dose	Unit	Frequency	Route	Taken prior to study?	Date started Day Month Year (DD MMM YY)	Date stopped Day Month Year (DD MMM YY)	Ongoing	Reason for medication
					☐ No ☐ Yes	|__|__|__|__|__|__|	|__|__|__|__|__|__|	☐ No ☐ Yes	
					☐ No ☐ Yes	|__|__|__|__|__|__|	|__|__|__|__|__|__|	☐ No ☐ Yes	
					☐ No ☐ Yes	|__|__|__|__|__|__|	|__|__|__|__|__|__|	☐ No ☐ Yes	
					☐ No ☐ Yes	|__|__|__|__|__|__|	|__|__|__|__|__|__|	☐ No ☐ Yes	

SECTION 9 – Details of investigational product(s)

Vaccine name (in case of multiple vaccination, please specify if vaccines were administered mixed or separately)	Dose N°	Lot N°	Route / site	Date of administration Day Month Year (DD MMM YY)
				|__|__|__|__|__|__|
				|__|__|__|__|__|__|
				|__|__|__|__|__|__|
				|__|__|__|__|__|__|

Was the randomization code broken on the investigational site's request? ☐ No ☐ Yes ☐ Not applicable

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Protocol (eTrack number) |_1_|_1_|_5_|_6_|_4_|_8_|	Country	Centre Number	Subject Number
Abbreviated Title MMR-160	_____	|__|__|__|__|__|__|	|__|__|__|__|__|__|

SECTION 10 – Details of relevant assessments	(provide details of any other tests/procedures which were carried out to diagnose or confirm the SAE, e.g. laboratory data with units and normal range)

SECTION 11 – Narrative remarks (description of signs/symptoms and details of **TREATMENT** given for SAE)

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SECTION 12 – SAE additional / follow-up information *(use this page to provide any additional details on the SAE not already captured on the previous pages)*

Investigator's Signature	1. Initial report	2. First follow-up	3. Second follow-up	4. Third follow-up
Date (Day Month Year)	| __ __ | __ __ __ | __ __ __ __ |	| __ __ | __ __ __ | __ __ __ __ |	| __ __ | __ __ __ | __ __ __ __ |	| __ __ | __ __ __ | __ __ __ __ |
Investigator's Name (print)				

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115648 (MMR-160)

			Centre No.	UHS form version
			|__|__|__|__|__|__|	|__|

USE OF HUMAN SAMPLES BY GSK

In addition to the tests described in the study protocol, please check what may also be done with the subject samples as per the Informed Consent Form (ICF) in use at your center.

☐ Yes ☐ No [type 3a tests] Use of samples to improve tests and develop new tests linked to study vaccine(s)/product(s) or the disease under study. These tests will never include tests related to genes' hereditary characteristics.

☐ Yes ☐ No [type 3b tests] ***With the prior permission of independent Ethics Committee / Institutional Review Board:***
Use of samples to improve tests and develop new tests linked to study vaccine(s)/product(s) or the disease under study. These tests will never include tests related to genes' hereditary characteristics.

☐ Yes ☐ No [type 4 tests] ***With the prior permission of the subject's parent(s) or legally acceptable representative (LAR[s]):***
GSK may perform future research on collected samples. Any research undertaken with samples collected will be performed after obtaining approval for the research by an IRB/IEC.

Please check GSK Biologicals sample storage period specified in the ICF in use at your center.

☐ up to 20 years

☐ Other, specify: _____

If new version of UHS:

Date at which the new ICF version was first signed by the subject's parent(s) or Legally Acceptable Representative (LAR[s]): |__|__| |__|__|__|__| |__|__|__|__|
day month year

Complete and submit a *new Use of Human Samples by GSK* form for each change in the ICF that affects the use of samples.

INVESTIGATOR'S SIGNATURE

Investigator's signature: _____ Date: |__|__| |__|__|__|__| |__|__|__|__|
day month year

Printed Investigator's name: _____

TRAINING APPLICATION

DEMOGRAPHY

Date of Birth : DEMOG.DOB_RAW

Gender : DEMOG.SEX

Ethnicity: DEMOG.ETHNIC

Geographic Ancestry : DEMOG.RACE Please specify : DEMOG.RACE_OTH

SUBJECT SUB-COHORT

CRIT_VAL.VALUE

INFORMED CONSENT

Date of Visit

ACTDATES.ACTRDATE

INFORMED CONSENT

I certify that Informed Consent has been obtained prior to any study procedure.

Informed Consent Date :

CONSENT.CONS_DAT

Did the subject's parent(s) or Legally Acceptable Representative (LAR[s]) agree that the biological samples(s) of his/her child may be used by GSK Biologicals for further research that is NOT RELATED to the study or the disease(s) under study?

CONS_LAB.CONSLABQ

CONS_LAB.CONSLABA

ELIGIBILITY CHECK

Did the subject meet all the entry criteria? ELISHEET.ELIGIBIL --> tick all boxes corresponding to violations of any inclusion/exclusion criteria.

Do not enter the subject into the study if he/she failed any of the inclusion or exclusion criteria below.

INCLUSION CRITERIA: Tick the boxes corresponding to any of the inclusion criteria the subject failed.

ELIGIBIL.CRIT_ANS

- [ ] Male or ELIGIBIL.CRIT_NR) 12 and 15 months of age at the time of vaccination
- [ ] Investigator believes Parent/LAR of child can/will comply with the protocol requirements
- [ ] Written informed consent obtained from the parent/LAR of the child
- [ ] Child is in stable health as determined by physical exam assessment of medical history
- [ ] Previously received a 3-dose series of Prevnar 13 at least 60 days prior to the study

EXCLUSION CRITERIA: Tick the boxes corresponding to any of the exclusion criteria that disqualified the subject from entry.

- [ ] Child in Care
- [ ] Use of invest./non-registered product 30 days before study vaccination or planned use during study
- [ ] Concurrent participation in another clinical study with invest. or non-invest. product/device
- [ ] Chronic admin. of immunosuppressant/immune-modifying drugs within 180days before Day0/during study
- [ ] Planned or admin. of vaccine not foreseen by protocol, 30 days before study vacc. ending at V2
- [ ] Adm. of immunoglobulins/blood products w/in180 days before study entry or planned through V2
- [ ] History of measles, mumps, rubella varicella/zoster and/or Hepatitis A diseases
- [ ] Known exposure measles, mumps, rubella, and/or varicella/zoster at 30 days prior to 1st study vacc.
- [ ] Previous vaccination against measles, mumps, rubella, hepatitis A and/or varicella virus
- [ ] Any confirmed/suspected immunosuppressive or immunodeficient condition based on med hist./Phys exam
- [ ] A family history of congenital or hereditary immunodeficiency
- [ ] History of allergic disease or reactions likely to be exacerbated by any vaccine component
- [ ] Blood dyscrasias,leukemia,lymphomas/other malignant neoplasms affecting bone marrow/lymphatic systm
- [ ] Acute disease at the time of enrollment.
- [ ] Active untreated tuberculosis based on medical history
- [ ] Any condition which, in the opinion of the investigator, prevents the subject from participation
- [ ] Child that previously received vaccination with heptavalent Prevnar/Prevenar
- [ ] Child that previously received a fourth dose of any pneumococcal conjugate vaccine

ELIGIBILITY CHECK

Did the subject meet all the entry criteria? ELISHEET.ELIGIBIL --> tick all boxes corresponding to violations of any inclusion/exclusion criteria.

Do not enter the subject into the study if he/she failed any of the inclusion or exclusion criteria below.

INCLUSION CRITERIA: Tick the boxes corresponding to any of the inclusion criteria the subject failed.

ELIGIBIL.CRIT_ANS

- [ ] Male or ELIGIBIL.CRIT_NR) 12 and 15 months of age at the time of vaccination
- [ ] Investigator believes Parent/LAR of child can/will comply with the protocol requirements
- [ ] Written informed consent obtained from the parent/LAR of the child
- [ ] Child is in stable health as determined by physical exam _assessment of medical history

EXCLUSION CRITERIA: Tick the boxes corresponding to any of the exclusion criteria that disqualified the subject from entry.

- [ ] Child in Care
- [ ] Use of invest./non-registered product 30 days before study vaccination or planned use during study
- [ ] Concurrent participation in another clinical study with invest. or non-invest. product/device
- [ ] Chronic admin. of immunosuppressant/immune-modifying drugs within 180days before Day0/during study
- [ ] Planned or admin. of vaccine not foreseen by protocol, 30 days before study vacc._ending at V2
- [ ] Adm. of immunoglobulins/blood products w/in180 days before study entry or planned through V2
- [ ] History of measles, mumps, rubella varicella/zoster and/or Hepatitis A diseases
- [ ] Known exposure measles, mumps, rubella, and/or varicella/zoster at 30 days prior to 1st study vacc.
- [ ] Previous vaccination against measles, mumps, rubella, hepatitis A and/or varicella virus
- [ ] Any confirmed/suspected immunosuppressive or immunodeficient condition based on med hist./Phys exam
- [ ] A family history of congenital or hereditary immunodeficiency
- [ ] History of allergic disease or reactions likely to be exacerbated by any vaccine component
- [ ] Blood dyscrasias,leukemia,lymphomas/other malignant neoplasms affecting bone marrow/lymphatic systm
- [ ] Acute disease at the time of enrollment.
- [ ] Active untreated tuberculosis based on medical history
- [ ] Any condition which, in the opinion of the investigator, prevents the subject from participation

GENERAL MEDICAL HISTORY

Are you aware of any pre-existing conditions, signs (abnormal physical exam findings) or symptoms present prior to the start of the study?

--> please give diagnosis and select appropriate Past/Current box(es)

GENHIST.MED_COND

Please report medication(s) as specified in the protocol and fill in the medication section

MedDRA System Organ Class	Diagnosis	Past/Current
DIAGNOS.DIAGTERM	DIAGNOS.DIAGNOSI	DIAGNOS.DIAGSTAT

GENERAL MEDICAL HISTORY / EXAMINATION

PREVNAR 13 HISTORY

Has the subject previously received a 3-dose series of Prevnar 13 at least 60 days prior to study entry? HIST_SHT.HIST_FLG --> please complete the following table

* Enter approximate date in case the exact date is unknown

(Subject not eligible)

Route	Dose number	Date of vaccination *
HIST_VAC.MED_ROUT	HIST_VAC.NB_DOSE 1	HIST_VAC.HIST_DAT
	2	
	3	

VITAL SIGNS

VS.VSTEST

Height

VS.VSORRES

VS.VSORRESU

VS.VSTEST

Height

VS.VSORRES

inches

VS.VSORRESU

VS.VSTEST

Weight

VS.VSORRES

VS.VSORRESU

VS.VSTEST

Weight

VS.VSORRES

ounces

VS.VSORRESU

BLOOD SAMPLE

Has a blood sample been taken for antibody determination?

LABSHEET.SAMPTAKE --> Date if different from visit date : LABSHEET.SAMPRDAT

For GSK: Reconciled (CDR only)

LABSHEET.RECONCIL

VACCINE ADMINISTRATION - DOSE 1

Pre-vaccination temperature: VS.VSORRES VS.VSORRESU Route : VS.VSLOC (preferred)

Has MMR Vaccine been administered?

VACCPROD.V_ADM --> Date of administration: VAC_INFO.VACCRDAT
(if different from visit date)

--> Please give reason next page

--> Administered Treatment Number VACC_TRT.V_TRT

VACCPROD.P_ROUTE

VACCPROD.P_AP

--> Protocol Injection Site/Side/Route VACCPROD.P_SITE VACCPROD.P_SIDE Site : VACCPROD.P_APSITE

--> Has the vaccine been administered according to the protocol injection site, side, Side : VACCPROD.P_APSIDE

Specify Route : VACCPROD.P_APROUT

--> If relevant, comment on administration:

VACCPROD.VADM_COM

VACCINE ADMINISTRATION - DOSE 1

Has Varivax Vaccine been administered ? VACCPROD.V_ADM

--> Administered Treatment Number :

--> Please give reason next page

--> Protocol Injection Site/Side/Route VACCPROD.P_SITE VACCPROD.P_SIDE VACCPROD.P_ROUTE

--> Has the vaccine been administered according to the protocol injection site, side, route ? VACCPROD.P_AP

Specify Site : VACCPROD.P_APSITE

Side : VACCPROD.P_APSIDE

Route : VACCPROD.P_APROUT

--> If relevant, comment on administration:

VACCPROD.VADM_COM

VACC_TRT.V_TRT

Has Havrix Vaccine been administered?

--> Administered Treatment Number :

--> Please give reason next page

--> Protocol Injection Site/Side/Route Anterolateral Thigh | Right | Intramusculary

--> Has the vaccine been administered according to the protocol injection site, side, route ?

Specify Site :

Side :

Route :

--> If relevant, comment on administration:

VACCINE ADMINISTRATION - DOSE 1

Has Prevnar 13 Vaccine been administered?

VACCPROD.V_ADM

--> Please give reason next page

--> Administered Treatment Number VACC_TRT.V_TRT

VACCPROD.P_SIDE VACCPROD.P_ROUTE

VACCPROD.P_AP

--> Protocol Injection Site/Side/Route VACCPROD.P_SITE

Site : VACCPROD.P_APSITE

Side : VACCPROD.P_APSIDE

--> Has the vaccine been administered according to the protocol injection site, side,

Specify Route : VACCPROD.P_APROUT

--> If relevant, comment on administration:

VACCPROD.VADM_COM

VACCINE ADMINISTRATION

Have protocol required vaccines been administered ?

If at least one vaccination is not done,

--> Please tick the major reason for non administration

VAC_INFO.V_REAS

--> Please specify AE No. VAC_INFO.AE_NB

--> Please specify if you submit SAE report

--> Please specify : (e.g.: consent withdrawal, Protocol violation, ...)

--> Please specify SAE Case No. VAC_INFO.SAE_CASE

--> Please complete Non-serious Adverse Event section

VAC_INFO.V_OTH

--> Who made the decision ? VAC_INFO.DECISION

SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS

GlaxoSmithKline

MMR Vaccine injection site

Has the subject experienced any of the following signs/symptoms between Day 0 and Day 3 ?

SOLSHEET.SOL_YN please tick No/Yes for each sign/symptom and complete further as necessary.

If any of these adverse events meets the definition of serious, complete and submit a Serious Adverse Event report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

Local Sign/Symptoms	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing	After Day 3: Max Size	After Day 3: Date of last day of sign/symptoms	Medically attended visit
SOLVAL.SYMP_COD SOLAE.SYMP_COD	Size (mm):						Tick box if continuing at end of study :	
SOLAE.SYMP_EXP	SOLVAL.SYMP_VAL				SOLAE.SYMP_ONG	SOLAE.SYMP_MAX	SOLAE.SYMP_LST or SOLAE.SYMPCONT	SOLAE.MED_TYPE
Swelling	Size (mm):						Tick box if continuing at end of study :	
							or	

Local Sign/Symptoms	Day 0	Day 1	Day 2	Day 3	After Day 3	Medically attended visit

SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS

Sign/Symptoms	Day 0	Day 1	Day 2	Day 3	Ongoing	Max Intensity	Date of last day of sign/symptoms
SOLVAL.SYMP_COD SOLAE.SYMP_COD Intensity: 0/1/2/3 see Adverse Events definitions							Tick box if continuing at end of study :
SOLAE.SYMP_EXP	SOLVAL.SYMP_VAL				SOLAE.SYMP_ONG	SOLAE.SYMP_MAX	or ☐ SOLAE.MED_TYPE SOLAE.SYMP_LST — SOLAE.SYMPCONT

SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS

Has the subject experienced any general solicited signs/symptoms during the appropriate follow up period?

SOLSHEET.SOL_YN

Please select NO/YES for each sign/symptom and complete further as necessary.

--> Please complete the Temperature section

*** Relationship to investigational product:**

Is there a reasonable possibility that the AE may have been caused by the investigational product.

If any of these adverse events meets the definition of serious, complete and submit a Serious Adverse Event report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

General Sign/Symptom	Days 0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
SOLVAL.SYMP_COD SOLAE.SYMP_COD ness	Intensity : 0/1/2/3 see Adverse Events definitions														
SOLAE.SYMP_EXP	SOLVAL.SYMP_VAL														

After Day 14				
Ongoing	Max Intensity	Date of last day of sign/symptoms Tick box if continuing at end of study :	Rel. to inv. product *	Medically attended visit
SOLAE.SYMP_ONG	SOLAE.SYMP_MAX	SOLAE.SYMP_LST or SOLAE.SYMPCONT	SOLAE.CAUSAL	SOLAE.MED_TYPE

Drowsiness	Intensity : 0/1/2/3 see Adverse Events definitions														

After Day 14				
Ongoing	Max Intensity	Date of last day of sign/symptoms Tick box if continuing at end of study :	Rel. to inv. product *	Medically attended visit
		or		

SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS

GlaxoSmithKline

Loss Of Appetite

Intensity : 0/1/2/3 see Adverse Events definitions

Ongoing	After Day 14 Max Intensity	Date of last day of sign/symptoms Tick box if continuing at end of study :		Rel. to inv. product *	Medically attended visit
			or ☐		

SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS

Record daily temperature during the solicited period, regardless of signs/symptoms. Additional information (i.e., causality, etc) is collected if the temperature is > 38°C /100.4°F.

Fever	SOLAE.SYMP_EXP	Please complete the Temperature section Note: daily temperatures must still be recorded regardless of whether or not fever is present
Rash / Exanthem		Please complete the Rash / Exanthem section
Parotid / Salivary gland swelling	SOLAE.SYMP_EXP	Please complete the Parotid / Salivary gland swelling section
Suspected signs of meningism including febrile convulsions/seizures		Please complete the Suspected signs of meningism (including febrile convulsions/seizures) section

Parotid / Salivary gland swelling: Only those cases diagnosed as parotitis are to be recorded as a solicited symptom. Other cases of swelling/tenderness in the mandibular/submandibular region that do not meet the criteria for parotitis clinically are to be reported as an unsolicited AE.

If any of these adverse events meets the protocol definition of serious, complete a Serious Adverse Event Report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

Temperature (Post Dose 1)

Record direct temperature measurements within 42 days post-vaccination.

Unit : TE_SHT.SYMP_UNI Route : TE_SHT.SYMP_T_S (preferred)

Observation day	Temperature			If >= 38 ° C or 100.4 ° F	
	Route if different:	Value	Tick if not taken :	Relationship to investigational product *	Medical attended visit
TE_VAL.OBSDAY	TE_VAL.ROUT_DIF	TE_VAL.SYMP_VAL	TE_VAL.T_N_TAK	TE_VAL.CAUSAL	TE_VAL.MED_TYPE
0					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

*** Relationship to investigational products:**

Is there a reasonable possibility that the temperature above threshold may have been caused by the investigational product ?

Temperature (Post Dose 1)

16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					

Temperature (Post Dose 1)

37					
38					
39					
40					
41					
42					

If any antipyretics have been taken, do not forget to record them in the Medication section.

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

RASH / EXANTHEM

Please report any rash/exanthem event that occurred from Day 0 to Day 42 post-vaccination.

Rash No. RA 1 RASH.AE_NB

Description: RASH.AE_DESC

For GSK - CDR RASH.MD_MOD For GSK - MON RASH.AE_TRANS MedDRA RASH.MD_CODE RASH.MD_FLAG

Generalised / Localised: RASH.GEN_LG

Site: MMR RASH.LOC_SITE

Specify: RASH.LOC_SPE

Start date: RASH.AE_SRDAT

End date: RASH.AE_ERDAT

Type of rash: RASH.RA_TYPE

-> Maximum intensity: RASH.RA_INTEN lesions

Is there a reasonable possibility that the AE may have been caused by the investigational product? RASH.CAUSAL

Outcome: RASH.OUTCOME

Medically attended visit: RASH.MED_TYPE

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

PAROTID / SALIVARY GLAND SWELLING EVENTS

Please report any parotid / salivary gland swelling occurring from Day 0 – Day 42 post-vaccination. Only those cases diagnosed as parotitis are to be recorded as a solicited symptom. Other cases of swelling/tenderness in the mandibular/submandibular region that do not meet the criteria for parotitis clinically are to be reported as an unsolicited AE.

PS No. PAROTID.AE_NB

Description: PAROTID.AE_DESC

For GSK - CDR PAROTID.MD_MOD For GSK - MON PAROTID.AE_TRANS MedDRA PAROTID.MD_GC PAROTID.MD_FLAG

Start date: PAROTID.AE_SRDAT

End date: PAROTID.AE_ERDAT

Intensity: PAROTID.AE_INTEN

Is there a reasonable possibility that the AE may have been caused by the investigational product? PAROTID.CAUSAL

Outcome: PAROTID.OUTCOME

Medically attended visit: PAROTID.MED_TYPE

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

SIGNS OF MENINGISM (INCLUDING FEBRILE CONVULSIONS)

Please report any suspected signs of meningism including febrile convulsions/seizures occurring from Day 0 to Day 42 Post-vaccination.

FC No. FC FEB_CONV.AE_NB

Description: FEB_CONV.AE_DESC

For GSK - CDR FEB_CONV.MD_MOD For GSK - MON FEB_CONV.AE_TRANS MedDRA FEB_CONV.MD_C FEB_CONV.MD_FLAG

Start date: FEB_CONV.AE_SRDAT

End date: FEB_CONV.AE_ERDAT

Intensity: FEB_CONV.AE_INTEN

Does this event meet the criteria for febrile convulsion? FEB_CONV.CRIT_FC

-> Classification? FEB_CONV.FC_INTEN

Does this event correspond to convulsions/seizures? FEB_CONV.CONV_FLG

--> Level of diagnostic certainty (Brighton Collaboration): FEB_CONV.DIAG_LEV

Is there a reasonable possibility that the AE may have been caused by the investigational product? FEB_CONV.CAUSAL

Outcome: FEB_CONV.OUTCOME

Medically attended visit: FEB_CONV.MED_TYPE

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report to GSK Biologicals Study Contact for SAE reporting within 24 hours.

CHECK FOR STUDY CONTINUATION

Did the subject return for this visit ? --> Go to next page
VIS_INFO.VIS_FLG

--> Major Reason. Please select the major reason :

VIS_INFO.V_REAS -- > Please complete Non-serious Adverse Event section

Please specify : --> Please specify AE No. *or solicited AE code* VIS_INFO.SYMP_COD
VIS_INFO.AE_NB

VIS_INFO.REAS_COM

--> Please complete and submit SAE report

--> Please specify SAE Case No. VIS_INFO.SAE_CASE

--> Excepting for the death,

Who made the decision ? VIS_INFO.DECISION

--> Study discontinuation

Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study :
VIS_INFO.DISCNT

In this case, terminate the CRF:

Complete Medication, Concomitant Vaccination, (S)AE sections and End of Epoch(s) (Study Conclusion) as appropriate.

LABORATORY TESTS

Date of Visit :

ACTDATES.ACTRDATE

BLOOD SAMPLE

Has a blood sample been taken for antibody determination?

For GSK: Reconciled (CDR only)

LABSHEET.SAMPTAKE --> Date if different from visit date : LABSHEET.SAMPRDAT

LABSHEET.RECONCIL

CHECK FOR STUDY CONTINUATION

Did the subject return for this visit ? VIS_INFO.VIS_FLG --> Go to next page

--> Major Reason. Please select the major reason :

VIS_INFO.V_REAS -- > Please complete Non-serious Adverse Event section

Please specify : --> Please specify AE No. VIS_INFO.AE_NB *or solicited AE code* VIS_INFO.SYMP_COD

VIS_INFO.REAS_COM

--> Please complete and submit SAE report

--> Please specify SAE Case No. VIS_INFO.SAE_CASE

--> Excepting for the death,

Who made the decision ? VIS_INFO.DECISION

Date of Visit :

ACTDATES.ACTRDATE

Please record the date of visit for the subject

CONCOMITANT VACCINATION

Have any vaccines other than the study vaccine(s) been administered during the time frame as specified in the protocol?

--> Please complete the following table.

Trade / (Generic) Name	Route	Administration date
VACC_CON.TRADNAME	VACC_CON.MED_ROUT	VACC_CON.MEDSRDAT
For GSK - MON profile only: VACC_CON.GSK_MOD	For GSK - SAF: VACC_CON.TH_MOD	
For GSK - CDR profile only:		

MEDICATION

In case of a SAE, please note the following :

Treatment of Serious Adverse Event recorded in the SAE report screen parts 4 must not be recorded here.

Have any medications been administered during the time frame as specified in the protocol?

--> Please complete the following table

Trade / Generic Name	Medical indication	Total daily dose	Start and end date
MEDIC.TRADNAME For GSK - CDR MEDIC.GSK_MOD For GSK - MON MEDIC.GSK_FLAG MEDIC.GSK_COD	MEDIC.MEDINDIC MEDIC.PROPH_CK ☐ in anticipation of study vaccine reaction ☐ chronic use MEDIC.CHRON_CK	**Dose:** MEDIC.MED_DOSE **Unit:** MEDIC.MED_UNIT **Route:** MEDIC.MED_ROUT	**Start:** MEDIC.MEDSRDAT **End:** MEDIC.MEDERDAT ☐ or tick if continuing at end of study MEDIC.CONT_END

MEDICATION

MEDICATION

In case of a SAE, please note the following :

Treatment of Serious Adverse Event recorded in the SAE report screen parts 4 must not be recorded here.

Have any medications been administered during the time frame as specified in the protocol?

--> Please complete the following table

Trade / Generic Name	Medical indication	Total daily dose	Start and end date
MEDIC.TRADNAME For GSK - CDR MEDIC.GSK_MOD For GSK - MON MEDIC.GSK_FLAG MEDIC.GSK_COD	MEDIC.MEDINDIC MEDIC.PROPH_CK ☐ in anticipation of study vaccine reaction ☐ chronic use MEDIC.CHRON_CK	**Dose:** MEDIC.MED_DOSE **Unit:** MEDIC.MED_UNIT **Route:** MEDIC.MED_ROUT	**Start:** MEDIC.MEDSRDAT **End:** MEDIC.MEDERDAT ☐ or tick if continuing at end of study MEDIC.CONT_END

MEDICATION

Serious AE Flag

Has any Serious Adverse Event occurred during the study according to protocol requirement?

=> Check if SAE report has been submitted to GSK Biologicals

GlaxoSmithKline

SAE Case No. AE.SAE_CASE

For GSK: Original paper SAE received at GSK Bio? Original SAE encoded by investigator AE.DOC_REC

Serious Adverse Event (SAE) Details

Please enter 1 SAE/Diagnosis per event field

AE.SAE_NB

SAE # 1 * **Event** Diagnosis only (if known), otherwise sign/symptom AE.AE_DESC OC_AE.AE_DESC

New Onset of Chronic Disease AE.CHRONIC

New Onset of Chronic Disease (GSK only) AE.GSK_NOCD

for GSK - MON profile only:

MedDRA AE.MD_CODE

for GSK - Safety profile : AE.MD_MOD

Start date: AE.AE_SRDAT OC_AE.STRT_DT

Outcome: AE.OUTCOME OC_AE.OC_OUTC

End date: AE.AE_ERDAT OC_AE.END_DT

AE start ? - For incomplete start date AE.AE_VACC

* Relationship to investigational product(s): AE.CAUSAL OC_AE.OC_REL

Max Intensity: AE.AE_INTEN OC_AE.OC_SEVC

Provide rationale in screen 10

Action taken: OC_SAE.SAE_ACT

Patient withdrawn from Clinical study due to this SAE: OC_SAE.WITHDRAW

Medically attended visit: AE.MED_TYPE

* SAE due to study specific procedure: OC_SAE.REL_PART

AE Subtype: OC_SAE.AE_SUBT SAE in active phase

Serious Adverse Event (Part 1/11)

* These fields must be completed to save the screen

DO NOT FORGET TO SUBMIT in Screen 11

Seriousness (according to protocol definitions)

Results in death OC_CRIT.S2_DEATH

Date of Death OC_CRIT.S2_DEATH_DT

Autopsy performed ? OC_CRIT.S2_AUTOPSY

Summarize findings in Screen 10 (Narrative Remarks)

Cause of death	For GSK	MedDra code
OC_DEATH.S2_CAUSE_DEATH	OC_DEATH.S2_TRANS	OC_DEATH.S2_MD_CODE
	For Safety : OC_DEATH.S2_MD_MOD	

Is life threatening OC_CRIT.S2_LIFE_THR Subject was at risk of death at time of event

Requires hospitalisation or prolongation of hospitalisation OC_CRIT.S2_REQ_HOSP OC_CASE.OC_HOSP If several hospitalisations for this SAE: enter further dates only in Screen 10 (Narrative Remarks)

Date of admission: OC_CRIT.S2_HOSP_ST_DT Date of discharge: OC_CRIT.S2_HOSP_END_DT

Results in disability/incapacity OC_CRIT.S2_INCAPACITY substantial/permanent

Congenital anomaly No OC_CRIT.S2_ANOMALY For offspring only

Other OC_CRIT.S2_CLIN_SIGN Please specify in Screen 10 (Narrative Remarks)

DO NOT FORGET TO SUBMIT in Screen 11

Demographic Data

Is the SAE linked to a 'Pregnancy episode' ? OC_DEMOG.S3_PREG_STATUS OC_CASE.OC_PREGC

Does the case involve Parent or Child ? OC_DEMOG.S3_PC_INDIC AE.S3_PC_INDIC OC_CASE.OC_INDPC

Weight at time of SAE: OC_DEMOG.S3_WEIGHT_SAF Unit: OC_DEMOG.S3_WEIGHT_UNIT

Date of Birth: OC_DEMOG.S3_DOB_CHILD OC_DEMOG.S3_DOB_SAF OC_CASE.DOB_RAW or Age group: OC_DEMOG.S3_AGE_GRP

Age: OC_DEMOG.S3_AGE_SAF Unit: OC_DEMOG.S3_AGE_SAF_UNIT

Sex: OC_DEMOG.S3_SEX_CHILD OC_DEMOG.S3_SEX_SAF

Date of first onset: OC_DEMOG.S3_FIRST_ONSET

Date of outcome: OC_DEMOG.S3_DATE_OUTCOME

Duration: OC_DEMOG.S3_DURATION_VALUE Unit: OC_DEMOG.S3_DURATION_UNIT

Outcome: OC_DEMOG.S3_OUTCOME

Relationship: OC_DEMOG.S3_RELATION

Study vaccine(s) for SAFETY Team ONLY

Visit	Vacc. Date	Stud. Vacc.	Not Adm.	No info	Treatment nb	Dose nb	Upd TTO?	Time to Onset	Unit	Sae dose link?	Action Drug ?
OC_STDVA.S3_ACT_DESC_SAF	OC_STDVA.S3_DATE_VAC				OC_STDVA.S3_TRE	OC_STDVA.S3_P_DOSE	OC_STDVA.S3_UPD_TTO	OC_STDVA.S3_TTO_VAL	OC_STDVA.S3_TTO_UNIT	OC_STDVA.S3_SAE_REL	OC_STDVA.S3_ACTIONDRUG

DO NOT FORGET TO SUBMIT in Screen 11

Treatment of Serious Adverse Event ?

OC_MDLAB.S4_TREAT_YN

(and associated events)

Drug Name: MEDIC.TRADNAME (Generic name preferred)

Modified term: MEDIC.GSK_MOD GSK drug code: MEDIC.GSK_COD

(SAF) Therapy Mod.: OC_MDSAF.S4_TH_MOD Therapy code: OC_MDSAF.S4_TH_CODE

Start Date : MEDIC.MEDSRDAT tick box if continuing MEDIC.CONT_END Stop Date : MEDIC.MEDERDAT

Total Daily Dose (Value + Unit): MEDIC.MED_DOSE MEDIC.MED_UNIT Route: MEDIC.MED_ROUT

Reason for medication: MEDIC.MEDINDIC **For GSK:** OC_MDSAF.S4_TRANS

DO NOT FORGET TO SUBMIT in Screen 11

Relevant Lab Test Details ?

OC_LABSH.S5_LAB_YN

Enter exams information in Screen 10 (Narrative Remarks)

Type of sample	Lab test	Test Date	Test Result	Test Units	Low Norm	High Norm	For GSK (SAF) :	MedDra
OC_LABRS.S5_LAB_TYPE	OC_LABRS.S5_TEST_NAME	OC_LABRS.S5_TEST_DATE	OC_LABRS.S5_TEST_RESULT	OC_LABRS.S5_TEST_UNIT	OC_LABRS.S5_LOW_NORM	OC_LABRS.S5_HIGH_NORM	OC_LABRS.S5_MD_MOD	OC_LABRS.S5_MD_CODE

Do NOT use the following symbols: \ (backward slash), é, Ä, ß, µ (non-English language symbols), °C (superscripts), ¾ (fractions), symbols < and > and quotation marks

Enter "over" instead of ">" and "below" instead of "<"

DO NOT FORGET TO SUBMIT in Screen 11

Possible causes of SAE other than investigational product ?

For therapeutic study only :

Disease under study ? OC_PSSAF.S6_DISEASE Not Applicable

Withdrawal of investigational product? OC_PSSAF.S6_WITHDRAWAL Not Applicable

For all studies :

If the SAE is possibly due to Concomitant Medication(s) => complete Screen 7 OC_PSSAF.S6_CM_FLG

If the SAE is possibly due to other Vaccination(s) => complete Screen 8 OC_PSSAF.S6_CV_FLG

If the SAE is possibly due to Medical Condition(s) => complete Screen 9 OC_PSSAF.S6_MH_FLG

SAE due to study specific procedure OC_PSSAF.S6_REL_STD *(information will be derived from Screen 1)*

Lack of efficacy ? OC_PSSAF.S6_LACK_EFF

Other ? OC_PSSAF.S6_OTHER_CASE Specify: OC_PSSAF.S6_OTH_SPEC

e.g.: bacterial infection, viral infection, incidental illness, trauma, accident...

Do NOT repeat SAE or Medical Condition

DO NOT FORGET TO SUBMIT in Screen 11

Relevant Concomitant/Past medication ?

OC_CMFLG.S7_CONC_MED

Enter Treatment of SAE in Screen 4

OC_CMMED.S7_QUESTION_GEN

May this medication have contributed to the SAE?

Manufacturer needed for regulatory reporting

Drug Name: (Generic name preferred) OC_CMMED.S7_TRADNAME

for GSK: OC_CMMED.S7_MD_TRANS

Modified term: OC_CMMED.S7_GSK_MOD

GSK Drug code: OC_CMMED.S7_GSK_COD

(SAF) Therapy Mod.: OC_CMMED.S7_TH_MOD

Therapy Code: OC_CMMED.S7_TH_CODE

OC_CMMED.S7_MEDSRDAT

Start Date:

tick box if continuing

OC_CMMED.S7_COND_END

Stop Date: OC_CMMED.S7_MEDERDAT

OC_CMMED.S7_TTO_D_VAL

Total Daily Dose (Value + Unit):

OC_CMMED.S7_TTO_D_UNIT

Route: OC_CMMED.S7_MED_ROUTE

Manufacturer: OC_CMMED.S7_MANUFACT

If manufacturer known but not listed, select Other
If manufacturer unobtainable, select Unk Manufacturer

Reason for medication: OC_CMMED.S7_MEDINDIC

for GSK: OC_CMMED.S7_TRANS

For Safety: OC_CMMED.S7_MD_MOD

MedDra --> OC_CMMED.S7_MD_CODE

OC_CMMED.S7_UPD_TTO

Upd ? (only for Safety)

Time to onset:

OC_CMMED.S7_ONSET_TTO

OC_CMMED.S7_ONSET_UNIT_TTO

Upd ? (only for Safety)

TTO since last dose:

OC_CMMED.S7_ONSET_UNIT_TTOSLD

OC_CMMED.S7_UPD_TTOSLD

OC_CMMED.S7_ONSET_TTOSLD

DO NOT FORGET TO SUBMIT in Screen 11

Vaccination other than investigational which may have contributed to the SAE ? OC_CVFLG.S8_CONC_VAC

Manufacturer needed for regulatory reporting

Vaccine Name: OC_CMVAC.S8_TRADNAME

Dose Form: OC_CMVAC.S8_DOSE_FORM

for GSK: OC_CMVAC.S8_MD_TRANS

Modified term: OC_CMVAC.S8_GSK_MOD

GSK Drug code: OC_CMVAC.S8_GSK_COD

(SAF) Therapy Mod.: OC_CMVAC.S8_TH_MOD

Therapy code: OC_CMVAC.S8_TH_CODE

If manufacturer known but not listed, select Other
If manufacturer unobtainable, select Unk Manufacturer

OC_CMVAC.S8_MEDSRDAT

OC_CMVAC.S8_MED_ROUTE

Vaccination Date: Route: Manufacturer: OC_CMVAC.S8_MANUFACT

OC_CMVAC.S8_TTO_D_VAL

Dosage (Value + Unit): Upd ? (only for Safety) Time to onset since last dose: OC_CMVAC.S8_ONSET_TIME

OC_CMVAC.S8_TTO_D_UNIT OC_CMVAC.S8_UPD_TTO OC_CMVAC.S8_ONSET_UNIT

DO NOT FORGET TO SUBMIT in Screen 11

Relevant Medical Condition ? OC_MDFLG.S9_MED_COND

May this medical condition have contributed to the SAE? OC_MDCON.S9_QUESTION_GEN

Condition	Onset Date	Continue ?	Outcome Date *(Date of last occurrence)*
OC_MDCON.S9_CONDIT	OC_MDCON.S9_ONSET_DATE	OC_MDCON.S9_CONT	OC_MDCON.S9_OUTC_DATE

For GSK: OC_MDCON.S9_TRANS

For Safety: OC_MDCON.S9_MD_MOD

MedDRA --> OC_MDCON.S9_MD_CODE

Other Relevant Risk Factors ? OC_MDFLG.S9_OTH_RISK

Specify any family or social history (smoking, diet, drug abuse, occupational hazard) relevant to the SAE

OC_MDFLG.S9_RISK_DET

DO NOT FORGET TO SUBMIT in Screen 11

Narrative Remarks

Please provide :

Clinical symptoms in chronological order, clinical evolution (hospitalisation, outcome, description of sequelae if any, etc.), description of exam result, treatments not enterable in screen 4 (e.g. surgery) and any other information useful for the medical assessment of the case (e.g. reason for diagnosis if not obvious or if diagnosis changed).

Do NOT enter all in CAPS, do NOT use tab or carriage return (use a wrapped text)

Do NOT use the following symbols: \ (backward slash), é, Ä, ß, µ (non-English language symbols), °C (superscripts), ¾ (fractions), symbols < and > and quotation marks

Only 2000 characters - If more place is needed, please add a row

1	OC_SAEDT.S10_REMARKS

DO NOT FORGET TO SUBMIT in Screen 11

Submission Screen

Please SUBMIT each time there is any follow-up or corrections

Never delete anything in this screen

Awareness date		Reviewed by SAF Team	Responsible Safety Person	Status
OC_CSREF.S1_START_INFO_DT	OC_CSREF.S1_ENDINV	OC_CSREF.S1_SAFCRDAT	OC_CSREF.S1_SAF_RESP	OC_CSREF.S1_REF_STATUS
	SUBMIT	OC_CSREF.S1_CASEREV		

Admin. Comments:

Country: OC_SAFAD.S1_COUNTRY_REP OC_CASE.OC_CTRY

Administration Details for Safety Team ONLY

Oceans id: OC_SAFAD.S1_OCEANS_ID

RDE Case id: OC_SAFAD.S1_CASE_NB

Case type: OC_SAFAD.S1_CASE_TYPE

Request additional upload: OC_SAFAD.REQ_DOWLOAD_SAF

Last upload date: OC_SAFAD.LAST_DOWLOAD

Next action date: OC_SAFAD.S1_NEXTRDAT

PHYSICIAN REVIEW

Reviewer Name

Last review date

Review Status

Comment

NON-SERIOUS AE AND INTERCURRENT MEDICAL CONDITIONS

(Please report serious adverse events only in the Serious Adverse Event report, not here)

Have any non-serious adverse events occurred during the time frame as specified in the protocol? ☐

--> please complete next page

NON-SERIOUS AE AND INTERCURRENT MEDICAL CONDITIONS

Event AE N°: AE.AE_NB

Diagnosis only (if known), otherwise sign/symptom

AE.AE_DESC

MedDRA AE.MD_FLAG AE.MD_CODE

for GSK - MON profile only:

for GSK - CDR profile only: AE.MD_MOD

New Onset of Chronical Diseases (GSK only) AE.GSK_NOCD

Please check box in case of new onset of chronic diseases AE.CHRONIC

Site

AE.AE_LG specify: AE.P_CODE

Start date

AE.AE_SRDAT

Tick if 30 min immediate post-vaccination AE.AEPOSTVC

AE start ? - For incomplete start date AE.AE_VACC

Outcome

AE.OUTCOME

End date

AE.AE_ERDAT

Maximum intensity

AE.AE_INTEN

Relationship to investigational product(s)

Is there a reasonable possibility that the AE may have been caused by the investigational product? AE.CAUSAL

Medically attended visit

AE.MED_TYPE

Please report serious adverse events only in the Serious Adverse Event report, not here.

NON-SERIOUS AE AND INTERCURRENT MEDICAL CONDITIONS

Event AE N°: AE.AE_NB

Diagnosis only (if known), otherwise sign/symptom

AE.AE_DESC

MedDRA AE.MD_FLAG AE.MD_CODE

for GSK - MON profile only:

for GSK - CDR profile only: AE.MD_MOD

New Onset of Chronical Diseases (GSK only) AE.GSK_NOCD

Please check box in case of new onset of chronic diseases AE.CHRONIC

Site

AE.AE_LG specify: AE.P_CODE

Start date

AE.AE_SRDAT

Tick if 30 min immediate post-vaccination AE.AEPOSTVC

AE start ? - For incomplete start date AE.AE_VACC

Outcome

AE.OUTCOME

End date

AE.AE_ERDAT

Maximum intensity

AE.AE_INTEN

Relationship to investigational product(s)

Is there a reasonable possibility that the AE may have been caused by the investigational product? AE.CAUSAL

Medically attended visit

AE.MED_TYPE

Please report serious adverse events only in the Serious Adverse Event report, not here.

STUDY CONCLUSION

LAST INFORMATION

Date of last contact
or date when the last information was collected on the subject's condition : CONCLUS.LC_RDAT

Was the subject in good condition at this date ? CONCLUS.LC_GC --> Give details in serious or non-serious adverse events section.

OCCURRENCE OF SERIOUS ADVERSE EVENT

Did the subject experience any Serious Adverse Event since the start of the study ? AESHEET.AE_FLAG

--> Check SAE report(s) have been submitted

List of investigators, IEC/IRB and distribution of subjects

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
Estonia						
PPD			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	43	0.9
			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	319	6.4
			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	24	0.5
			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	60	1.2

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD Estonia,	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	48	1.0
			PPD PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	7	0.1
Finland						
PPD (Co-ordinating Investigator)	-	All Centres	PPD PPD PPD PPD Finland	-		
PPD PPD PPD (Former PI)	PPD		PPD PPD PPD PPD Finland.	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530, Helsinki	127	2.5
PPD			PPD PPD PPD PPD Finland.	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	96	1.9

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	102	2.0
			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	48	1.0
			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	104	2.1
PPD PPD PPD (Former PI)	PPD		PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	142	2.8
PPD			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	103	2.1
PPD PPD (Former PI) PPD (Former PI)			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	144	2.9

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD	PPD		PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	172	3.4
PPD PPD (Former PI) PPD (Former PI)			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	113	2.3
PPD			PPD PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	199	4.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
Mexico						
PPD			PPD PPD PPD PPD PPD Mexico	Instituto Nacional de Pediatria, Comite de Investigacion y Comite de Etica en Investigacion, Av. Insurgentes Sur 3700-C, Insurgentes Cuiculco, Delegacion Coyoacan,Ciudad de Mexico, C.P. 04530, Mexico	330	6.6
			PPD PPD PPD Mexico	HOSPITAL GENERAL DE DURANGO, Comite de Investigacion y Comite de Etica en Investigacion, 5 de Febrero y Norman Fuentes s/n, Zona Centro, Durango, Durango, C.P., 34000, Mexico	64	1.3

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
Puerto Rico						
PPD			PPD PPD PPD PPD PPD PPD PPD Puerto Rico	Western Institutional Review Board 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115 Western Institutional Review Board, 3535 7th Avenue SW, Olympia, WA 98502-5010	16	0.3
Spain						
PPD			PPD PPD , Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	21	0.4
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	30	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	10	0.2
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	24	0.5
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	38	0.8
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	56	1.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	50	1.0
			PPD PPD , Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	7	0.1
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	20	0.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
United States						
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc. 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	40	0.8
			PPD PPD United States	St. Luke's Health System Institutional Review Board 190 E. Bannock Street, Denver Way,Boise, ID, 83712	40	0.8
			PPD PPD PPD	Chesapeake IRB 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	2	0.0
			PPD PPD PPD United States	Chesapeake Research Review, Inc. 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	18	0.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc. 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	8	0.2
			PPD PPD PPD United States	Inova Human Research Protection Program (HRPP) Claude Moore Health Education & Research Building - 3rd Floor Inova Fairfax Hospital 3300 Gallows Road Falls Church, Virginia 22042-3300	40	0.8

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	4	0.1
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	29	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD						
			PPD PPD PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	18	0.4
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	21	0.4
			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	150	3.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD PPD (Former PI)	PPD		PPD PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.4
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	30	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.4
			PPD PPD PPD PPD USA	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	54	1.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD		**	PPD PPD PPD USA, PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	--	--
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	48	1.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	32	0.6
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	59	1.2
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	134	2.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States, PPD	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	14	0.3
			PPD PPD PPD United States, PPD	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	13	0.3
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	25	0.5
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	118	2.4
			PPD PPD PPD , United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	83	1.7
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	169	3.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	57	1.1
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	29	0.6
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	1	0.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	103	2.1
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	27	0.5

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	45	0.9
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	80	1.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD PPD (Former PI) PPD (Former PI)	PPD		PPD PPD PPD United States	Biomedical Research Alliance of New York, LLC Institutional Review Board (BRANY), 1981 Marcus Avenue, Suite 210, Lake Success, NY 11042	13	0.3
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	44	0.9

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Boston University Medical Center, Office of the Institutional Review Board, 560 Harrison Ave, Suite 300 Boston, Massachusetts,02118-2526	83	1.7
		**	PPD PPD PPD United States	University of Louisville, Human Subjects Protection Program Office MedCenter One – Suite 200 501 E. Broadway Louisville, KY 40202-1798	--	--
			PPD PPD PPD United States	University of Louisville, Human Subjects Protection Program Office MedCenter One – Suite 200 501 E. Broadway Louisville, KY 40202-1798	37	0.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
	PPD PPD (formerly PPD					
PPD			PPD PPD PPD PPD PPD United States	Western Institutional Review Board 3535 7th Avenue SW, Olympia, WA 98502-5010 Western Institutional Review Board 1019 39th Avenue SE Suite 120 ,Puyallup, WA 98374-2115	5	0.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	63	1.3
			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	50	1.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	1	0.0
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	34	0.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	10	0.2
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	8	0.2

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	87	1.7
			PPD PPD PPD United States	Marshfield Clinic Research Foundation INSTITUTIONAL REVIEW BOARD 1000 North Oak Avenue Marshfield, WI 54449-5790	33	0.7
			PPD PPD PPD United States, PPD	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	26	0.5

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD PPD (Former PI)	PPD		PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.6
PPD			PPD PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	31	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	54	1.1
			PPD PPD PPD PPD United States	UTMB Health, Institutional Review Board 301 University Blvd. Galveston, TX 77550-0158	33	0.7
			PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	1	0.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	39	0.8
			PPD PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	24	0.5
			PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	35	0.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	27	0.5
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403	5	0.1
			PPD PPD PPD , United States	Western Institutional Review Board 3535 Seventh Ave SW Olympia WA 98502-5010 Western Institutional Review Board 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115	9	0.2
			PPD PPD PPD PPD United States	Upstate Medical University, Institutional Review Board for the Protection of Human Subjects, 750 East Adams Street, Syracruse, NY 13210	17	0.3

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Upstate Medical University, Institutional Review Board for the Protection of Human Subjects, 750 East Adams Street, Syracruse, NY 13210	37	0.7
			PPD PPD PPD , United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	63	1.3

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	42	0.8
			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403	4	0.1

* Number and percentage of subjects per center reflects the number of subjects effectively taken into account for the end of study statistical analysis.
** 32 Subjects, enrolled in center PPD were transferred to center PPD 14 subjects enrolled in center PPD were transferred to center PPD

Representative written information for patient and sample consent forms

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

Non-US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 01 (replace with Version of Local ICF)

Date: 06/AUG/2012 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is licensed in over 100 countries. More than 240

million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been licensed in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet licensed for sale. [Note to local team: Delete the previous 2 sentences if GSK MMR (Priorix) is licensed in your country.]

In this study the MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well when given at the same time as other licensed vaccines that your child normally receives.

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II, also called MMR VaxPro®). [Note to local team: Decide which product name to use and adjust as needed.]

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed]. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II/MMR VaxPro® vaccine.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the either the GSK MMR or the MMR®II/MMR VaxPro® [local team to delete vaccine name as needed].vaccination was not the best possible. If the study doctor believes your child would benefit from another shot of the MMR®II/MMR VaxPro® vaccine, he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive two additional shots at the first visit.

- *Havrix* which prevents hepatitis A virus
- *Varivax* which prevents chicken pox (varicella)

In some countries, these are common childhood vaccines that your child may normally get at this age, together with MMR vaccine.

In some countries where *Havrix* and varicella vaccination are not routinely given, GSK will offer your child a second shot of these two childhood vaccines, at the end of the study.

Here is a summary of what will happen at each visit:

	Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:

Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study.
	• You answer questions about your child's health.
	• The study doctor and/or nurse will:
	– Give your child a physical examination, including height and weight.
	– Take a blood sample (about a teaspoon).
	– Take your child's body temperature.
	– Give your child the vaccines and have you wait for 30 minutes after the shots.
	– Give you a diary card to write down safety information until the next visit.
	  – Day 0-3: write down any redness, pain or swelling at the site of the shots.
	  – Day 0-14: write down any drowsiness, loss of appetite and/or irritability your child experiences.
	  – Day 0-42: measure and write down your child's temperature. You will get a thermometer and will be shown how to do this.
	  – Day 0-42: write down other specific symptoms. These include rash, swollen glands and jerking movements or staring into space. We will explain these to you in detail. You will have to contact us if any of these specific symptoms occur.
	  – Day 0-42: write down any medication or other vaccines your child receives.
	• If you take your child to a doctor or nurse you will also need to write down this information on the diary card.

Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • Physical examination, only if needed. • Take a blood sample (about a teaspoon). • Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if you need emergency

care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

<u>Optional tests on your samples:</u>

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. The study staff may give your child medicine to help lessen side effects. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are **common**:

- Redness, pain or swelling at the site of the shot or of the limb where the shot is given
- Fever
- Common cold
- Rash

The following side effects are **less common**:

- Ear infection
- Swollen glands in the armpit, groins or any place on the body
- Loss of appetite or altered taste
- Fussiness and/or drowsiness
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Painful swelling of the salivary glands
- Diarrhea
- Vomiting
- Headache
- Stomach pain or nausea
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **rare**:

- Febrile convulsion (also called a “fit” with fever)
- Inflammation and/or infection of the gut leading to loss of body water and increased body salts
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)
- Stroke

- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord
- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness. It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol®) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution to persons with a history or family history of convulsions.

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash
- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not optimal.

If the tests results for measles, mumps, or rubella show that your child's response to the vaccine was not optimal, the study doctor will offer you another shot for your child, of MMR®II (or *Priorix* where the vaccine is licensed) at no cost to you.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you decide not to continue vaccination, study visits, etc.

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.
3. Study information will be labeled with a code number (for example,PPD . It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.
6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study

What happens if your child gets hurt while taking part in this study?

Note to local team: The type of compensation offered to research subjects who are injured during a clinical study differs in each country. It is the responsibility of GSK Biologicals' staff in each country to ensure that Local ICFs include the correct compensation-for-injury terms applicable to their country (see GUI_51905).

For phase II -III clinical research studies, GSK Biologicals' will comply with the ABPI Clinical Trials Compensation Guidelines (1991). The following wording should be used:

If your child is hurt by a vaccine or a clinical procedure that your child would not have been given outside this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For studies in which the GSK Biologicals' investigational vaccine is already marketed for the relevant indication and the protocol requires the subject to undergo a procedure that they would not otherwise undergo (e.g. sample collection), the following wording should be used:

If your child is hurt by clinical procedures needed only because your child is taking part in this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For GSK sponsored studies in Other Regions: In other countries where there is local compensation for injury requirements, the CMD staff preparing the Local ICF must apply the rules and conventions required locally.

Signing this consent form does not change any legal rights you or your child may have.

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) for study MMR-161, Version 01, dated: 06-AUG-2012, 14 pages [ICF version, date and number of pages, (to be updated locally)] including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- [For the US LOC only: **understand that by signing this form any of my identifiable medical information given to someone that is not a health care provider is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.**]
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

- I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent:

_____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

- I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

Non-US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 02 (replace with Version of Local ICF)

Date: 13/MAY/2014 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is approved for use in over 100 countries. More than

240 million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been approved for use in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet approved for use. [Note to local team: Delete the previous 2 sentences if GSK MMR (Priorix) is licensed in your country.]

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II, also called MMR VaxPro®). [Note to local team: Decide which product name to use and adjust as needed.]

The MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well when given at the same time as other approved vaccines that your child normally receives.

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future. You will not be paid for any part of this.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed]. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed]. Neither the doctor nor you, the parent/legally acceptable representative (LAR) will know or be able to choose which vaccine your child receives. The study doctor will be able to tell you what your child was given after the whole study is finished or in case of a medical emergency.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the either the GSK MMR or the MMR®II/MMR VaxPro® [local team to delete vaccine name as needed].vaccination was not good enough. If the study doctor believes your child would benefit from another shot of the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed], he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive two additional shots at the first visit.

- *Havrix* which prevents hepatitis A virus
- *Varivax* which prevents chicken pox (varicella)

Havrix and varicella vaccinations are common childhood vaccines that your child may normally get at this age, together with MMR vaccine. [Note to local team: Delete if this does not apply to your country],

Since *Havrix* and varicella vaccinations are not routinely given in your country, GSK will offer your child a second shot of these two childhood vaccines, at the end of the study or shortly after the study, depending on vaccines availability. [Note to local team: Delete if this does not apply to your country]

Here is a summary of what will happen at each visit:

	Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:
Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study. • You answer questions about your child's health. • The study doctor and/or nurse will: – Give your child a physical examination, including height and weight. – Take a blood sample (about a teaspoon). – Take your child's body temperature. – Give your child the vaccines and have you wait for 30 minutes after the shots. – Give you a diary card to write down safety information until the next visit and instruct you to call the clinic if your child has specific signs or symptoms. • If you take your child to a doctor or nurse you will also need to write down this information on the diary card.
Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • The study doctor and/or nurse will: • Give your child a physical examination, only if needed. • Take a blood sample (about a teaspoon). • Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if your child needs emergency care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

Optional tests on your samples:

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are very common (one in 10 or more doses):

- Redness/tenderness/swelling where the shot is given
- Low fever (37.5°C/99.5°F or more)
- Fussiness/irritability
- Fatigue
- Headache

The following side effects are **common (**events ≥1/100 to <1/10**)**:

- High fever (more than 39°C/102.2°F)
- Common cold
- Rash
- Feeling of general discomfort or uneasiness, not feeling well
- Drowsiness
- Loss of appetite
- Swelling of glands in the cheeks or neck
- Diarrhea, nausea, vomiting
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **less common (**events ≥1/1,000 to <1/100):

- Ear infection
- Rhinitis
- Abnormal crying
- Swollen glands in the armpit, groins or any place on the body
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Dizziness
- Stomach pain
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Flu- like illness

The following side effects are **rare** (events ≥1/10,000 to <1/1,000) and include side effects reported with the use of the vaccines after being approved:

- Convulsion (also called a “fit”) with or without fever
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)
- Stroke

- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord
- Inability to coordinate balance, gait, extremity and eye movements
- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination
- In rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination
- Joint inflammation/swelling
- Itchy pink-red blotches (usually on hands, legs)
- Damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage
- Rapid swelling of the skin of the face and possibly the hands that can be itchy or painful
- Low blood count (very rare)

Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

There may be other side effects that are not known now.

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness.

It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol® or Paracetamol) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution should be employed in administration of M-M-R II to persons with an individual or family history of seizures

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash
- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not good enough.

If the tests results for measles, mumps, or rubella show that your child's response to the vaccine was not good enough, the study doctor will offer you another shot for your child, of MMR®II (or *Priorix* where the vaccine is approved for use) at no cost to you.

When your child has blood taken, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you do not withdraw your consent but decide to leave the study (i.e., decide not to continue vaccination, study visits, etc.):

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's personal and medical information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.
3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.

6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study

What happens if your child gets hurt while taking part in this study?

Note to local team: The type of compensation offered to research subjects who are injured during a clinical study differs in each country. It is the responsibility of

GSK Biologicals' staff in each country to ensure that Local ICFs include the correct compensation-for-injury terms applicable to their country (see GUI_51905).

For phase II -III clinical research studies, GSK Biologicals' will comply with the ABPI Clinical Trials Compensation Guidelines (1991). The following wording should be used:

If your child is hurt by a vaccine or a clinical procedure that your child would not have been given outside this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For studies in which the GSK Biologicals' investigational vaccine is already marketed for the relevant indication and the protocol requires the subject to undergo a procedure that they would not otherwise undergo (e.g. sample collection), the following wording should be used:

If your child is hurt by clinical procedures needed only because your child is taking part in this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For GSK sponsored studies in Other Regions: In other countries where there is local compensation for injury requirements, the CMD staff preparing the Local ICF must apply the rules and conventions required locally.

Signing this consent form does not change any legal rights you or your child may have.

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) within this document for the 115648 (MMR-160) study, including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- know what will happen to my child's blood samples.
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No** ☐ **N/A**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study

☐ **Yes** ☐ **No**

Informed Consent Form Subject ID_____

CONFIDENTIAL
Study Identification 115648 (MMR-160)

I agree to have my child take part in this study.

Relationship of legally acceptable representative to the subject _____

_____

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent: _____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

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ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

INFORMATION LETTER

to the Informed Consent Form for Parents/Guardians

Non US Sub-cohort

[Country to be inserted]

Study Identification:	115648 (MMR-160)
Study Title:	Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.
Version and Date:	Version 01: 13 May 2014
Company Name:	**GlaxoSmithKline (GSK) Biologicals S.A.**
Subject Identification:	**Insert subject ID here** _____

This document should be presented to parents/guardians of subjects who are currently enrolled in study MMR-160 but completed the study vaccination, or who have now either completed or withdrawn from the study.

This document should be presented to the subject's parent / guardian in full; no page(s) or section(s) should be omitted.

Purpose of this document

Recently, new information became available in the study MMR-160, the study that your child is enrolled in or he/she has completed or withdrawn from. We would like to share this new information with you.

The purpose of this document is to provide you with new information on the side effects that may occur after each blood draw, the side effects or risks your child may experience after vaccination, and new information about the timing of the second dose of varicella and hepatitis A (*Havrix*) vaccines.

When your child gives blood, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.

Changes have been made in the list of side effects seen after the vaccines given in this study:

- The following side effects were added:
  - **very common:** fatigue.
  - **common:** high fever (more than 39°C/102.2°F); feeling of general discomfort or uneasiness, not feeling well.

- **less common:** rhinitis; abnormal crying; dizziness; flu-like illness.
- **rare:** convulsions (also called a "fit") with or without fever; in rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination; joint inflammation/swelling; itchy pink-red blotches (usually on hands, legs); damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage; rapid swelling of the skin of the face and possibly the hands that can be itchy or painful; inability to coordinate balance, gait, extremity and eye movements; low blood count (very rare).
- Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

➢ Inflammation and/or infection of the gut leading to loss of body water and increased body salts is not a risk associated with any of the vaccines received as part of this study.

➢ The following side effects were included in the original risk section of the ICF; however, the frequency of occurrence was changed:

- **From common to very common**: redness/tenderness/swelling where the shot is given; low fever (37.5°C/99.5°F or more).
- **From less common to very common:** fussiness/irritability; headache.
- **From less common to common:** drowsiness; loss of appetite; dryness of skin; difficulty or infrequent passing of stool; swelling of glands in the cheeks or neck; diarrhea, nausea, vomiting.

Since *Havrix* and varicella vaccinations are not routinely given in your country, GSK will offer your child a second shot of these two childhood vaccines, at the end of the study or shortly after the study, depending on vaccine availability.

If you have any questions, please contact your child's physician.

Investigator Name _____

Investigator signature _____

Date _____

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 01 (replace with Version of Local ICF)

Date: 06/AUG/2012 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is licensed in over 100 countries. More than 240

million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been licensed in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet licensed for sale.

In this study the MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well, when given at the same time as other licensed vaccines.

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II).

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.
- Has already received 3 shots of a pneumococcal vaccine, Prevnar 13® (not *Prevnar* or *Prevenar*), with no doses given at least 60 days prior to study entry.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II vaccine. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II vaccine.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the MMR vaccine (either the GSK MMR or MMR®II) or varicella vaccination was not the best possible. If the study doctor believes your child would benefit from another shot of the MMR®II or varicella vaccine, he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive three additional shots at the first visit.

- *Havrix* which prevents against hepatitis A virus
- *Varivax* which prevents against chicken pox (varicella)
- *Prevnar 13* which prevents pneumococcal (certain bacterial) infections

These are common childhood vaccines that your child would normally get at this age, together with MMR vaccine.

Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:

	What will happen at this visit

Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study.
	• You answer questions about your child's health.
	• The study doctor and/or nurse will:
	– Give your child a physical examination, including height and weight.
	– Take a blood sample (about a teaspoon).
	– Take your child's body temperature.
	– Give your child the vaccines and have you wait for 30 minutes after the shots.
	– Give you a diary card to write down safety information until the next visit.
	  – Day 0-3: write down any redness, pain or swelling at the site of the shots.
	  – Day 0-14: write down any drowsiness, loss of appetite and/or irritability your child experiences.
	  – Day 0-42: measure and write down your child's temperature. You will get a thermometer and will be shown how to do this.
	  – Day 0-42: write down other specific symptoms. These include rash, swollen glands and jerking movements or staring into space. We will explain these to you in detail. You will have to contact us if any of these specific symptoms occur.
	  – Day 0-42: write down any medication or other vaccines your child receives.
	• If you take your child to a doctor or nurse you will also need to write down this information on the diary card.

Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • Physical examination, only if needed. • Take a blood sample (about a teaspoon). • Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if you need emergency care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

Optional tests on your samples:

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. The study staff may give your child medicine to help lessen side effects. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are **common**:

- Redness, pain or swelling at the site of the shot or of the limb where the shot is given
- Fever
- Common cold
- Rash

The following side effects are **less common**:

- Ear infection
- Swollen glands in the armpit, groins or any place on the body
- Loss of appetite or altered taste
- Fussiness and/or drowsiness
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Painful swelling of the salivary glands
- Diarrhea
- Vomiting
- Headache
- Stomach pain or nausea
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **rare**:

- Febrile convulsion (also called a “fit” with fever)
- Inflammation and/or infection of the gut leading to loss of body water and increased body salts
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)
- Stroke
- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord

- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Bleeding or bruising more easily than normal due to a drop in number of a type of blood cells called platelets
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness. It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol®) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution to persons with a history or family history of convulsions.

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash

- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not optimal.

If the tests results for measles, mumps, rubella, or varicella show that your child's response to the vaccines were not optimal, the study doctor will offer you another shot for your child, of MMR®II or Varivax® at no cost to you.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

By letting your child be in this study, you will contribute to developing a second MMR vaccine available in the US. This will reduce the risk of having a shortage of this important vaccine in the future.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you decide not to continue vaccination, study visits, etc.

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies for example, the FDA in the US. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.
3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.
6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study.

You should know that once identifiable medical information about your child is given to someone that is not a health care provider, it is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.

What happens if your child gets hurt while taking part in this study?

GSK will help pay for your care if your child is hurt by the study vaccine or a procedure done to you as part of the study. GSK will pay for reasonable and necessary care for the injury that is not covered by the National Vaccine Injury Compensation Fund. GSK will not pay for any other expenses. To pay these medical expenses, GSK will need to know some information about you like your child's name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because GSK has to check to see if your child receives Medicare and if you do, report the payment it makes to Medicare. GSK will not use this information for any other purpose.

Signing this consent form does not change any legal rights you may have.]

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) for study MMR-160, Version 01, dated: 06-AUG-2012, 14 pages [ICF version, date and number of pages, (to be updated locally)] including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- **understand that by signing this form any of my identifiable medical information given to someone that is not a health care provider is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.**]
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study.

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

- I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent:

_____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

- I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 02 (replace with Version of Local ICF)

Date: 13/MAY/2014 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is approved for use in over 100 countries. More than

240 million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been approved for use in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet approved for use.

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II).

The MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well, when given at the same time as other approved vaccines.

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future. You will not be paid for any of this.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.
- Has already received 3 shots of a pneumococcal vaccine, Prevnar 13® (not *Prevnar* or *Prevenar*), with no doses given at least 60 days prior to study entry.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II vaccine. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II vaccine. Neither the doctor nor you, the parent/legally acceptable representative (LAR) will know or be able to choose which vaccine your child receives. The study doctor will be able to tell you what your child was given after the whole study is finished or in case of a medical emergency.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the MMR vaccine (either the GSK MMR or MMR®II) or varicella vaccination was not good enough. If the study doctor believes your child would benefit from another shot of the MMR®II or varicella vaccine, he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive three additional shots at the first visit.

- *Havrix* which prevents against hepatitis A virus
- *Varivax* which prevents against chicken pox (varicella)
- *Prevnar 13* which prevents pneumococcal (certain bacterial) infections

These are common childhood vaccines that your child would normally get at this age, together with MMR vaccine.

Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:

	What will happen at this visit
Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study. • You answer questions about your child's health. • The study doctor and/or nurse will: – Give your child a physical examination, including height and weight. – Take a blood sample (about a teaspoon). – Take your child's body temperature. – Give your child the vaccines and have you wait for 30 minutes after the shots. – Give you a diary card to write down safety information until the next visit and instruct you to call the clinic if your child has specific signs or symptoms. • If you take your child to a doctor or nurse you will also need to write down this information on the diary card.
Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • The study doctor and/or nurse will: – Give your child a physical examination, only if needed. – Take a blood sample (about a teaspoon). – Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if your child needs emergency care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

Optional tests on your samples:

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are very common (one in 10 or more doses):

- Redness/tenderness/swelling where the shot is given
- Low fever (37.5°C/99.5°F or more)
- Drowsiness
- Loss of appetite
- Fussiness/irritability
- Fatigue
- Headache

The following side effects are **common (**events ≥1/100 to <1/10**)**:

- High fever (more than 39°C/102.2°F)
- Common cold
- Rash
- Feeling of general discomfort or uneasiness, not feeling well
- Swelling of glands in the cheeks or neck
- Diarrhea, nausea, vomiting
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **less common (**events ≥1/1,000 to <1/100):

- Ear infection
- Rhinitis
- Abnormal crying
- Swollen glands in the armpit, groins or any place on the body
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Dizziness
- Stomach pain
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Flu- like illness

The following side effects are **rare** (events ≥1/10,000 to <1/1000) and include side effects reported with the use of the vaccines after being approved:

- Convulsion (also called a “fit”) with or without fever
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)

- Stroke
- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord
- Inability to coordinate balance, gait, extremity and eye movements
- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Bleeding or bruising more easily than normal due to a drop in number of a type of blood cells called platelets
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination
- In rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination
- Joint inflammation/swelling
- Itchy pink-red blotches (usually on hands, legs)
- Damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage
- Rapid swelling of the skin of the face and possibly the hands that can be itchy or painful
- Low blood count (very rare)

Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

There may be other side effects that are not known now

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in

children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness. It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol®) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution should be employed in administration of M-M-R II to persons with an individual or family history of seizures.

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash
- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not good enough.

If the tests results for measles, mumps, rubella, or varicella show that your child's response to the vaccines were not good enough, the study doctor will offer you another shot for your child, of MMR®II or Varivax® at no cost to you.

When your child has blood taken, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

By letting your child be in this study, you will contribute to developing a second MMR vaccine available in the US. This will reduce the risk of having a shortage of this important vaccine in the future.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you do not withdraw your consent but decide to leave the study (i.e., decide not to continue vaccination, study visits, etc.):

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's personal and medical information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies for example, the FDA in the US. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.

3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.
6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study.

You should know that once identifiable medical information about your child is given to someone that is not a health care provider, it is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.

What happens if your child gets hurt while taking part in this study?

GSK will help pay for your child's care if your child is hurt by the study vaccine or a procedure done to your child as part of the study. GSK will pay for reasonable and necessary care for the injury that is not covered by the National Vaccine Injury Compensation Fund. GSK will not pay for any other expenses. To pay these medical expenses, GSK will need to know some information about your child like your child's name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because GSK has to check to see if your child receives Medicare and if you do, report the payment it makes to Medicare. GSK will not use this information for any other purpose.

Signing this consent form does not change any legal rights you may have.]

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) within this document for the 115648 (MMR-160) study, including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- know what will happen to my child's blood samples.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- **understand that by signing this form any of my identifiable medical information given to someone that is not a health care provider is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.]**
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No** ☐ **N/A**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study.

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Relationship of legally acceptable representative to the subject _____

_____

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent: _____

Date: _____ day/ month/ year

Signature of person conducting consent: _____

Date: _____ day/ month/ year

I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____

Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

INFORMATION LETTER

to the Informed Consent Form for Parents/Guardians

US Sub-cohort

Study Identification:	115648 (MMR-160)
Study Title:	Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.
Version and Date:	Version 01: 13 May 2014
Company Name:	**GlaxoSmithKline (GSK) Biologicals S.A.**
Subject Identification:	**Insert subject ID here**

This document should be presented to parents/guardians of subjects who are currently enrolled in study MMR-160 but completed the study vaccination, or who have now either completed or withdrawn from the study.

This document should be presented to the subject's parent / guardian in full; no page(s) or section(s) should be omitted.

Purpose of this document

Recently, new information became available in the study MMR-160, the study that your child is enrolled in or he/she has completed or withdrawn from. We would like to share this new information with you.

The purpose of this document is to provide you with new information on the side effects that may occur after each blood draw and the side effects or risks your child may experience after vaccination.

- When your child gives blood, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.
- Changes have been made in the list of side effects seen after the vaccines given in this study:

➢ The following side effects were added:

- **very common:** fatigue.
- **common:** high fever (more than 39°C/102.2°F); feeling of general discomfort or uneasiness, not feeling well.
- **less common:** rhinitis; abnormal crying; dizziness; flu-like illness.

- **rare:** convulsions (also called a "fit") with or without fever; in rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination; joint inflammation/swelling; itchy pink-red blotches (usually on hands, legs); damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage; rapid swelling of the skin of the face and possibly the hands that can be itchy or painful; inability to coordinate balance, gait, extremity and eye movements; low blood count (very rare).
- Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

➢ Inflammation and/or infection of the gut leading to loss of body water and increased body salts is not a risk associated with any of the vaccines received as part of this study.

➢ The following side effects were included in the original risk section of the ICF; however, the frequency of occurrence was changed:

- **From common to very common**: redness/tenderness/swelling where the shot is given; low fever (37.5°C/99.5°F or more).
- **From less common to very common:** drowsiness; loss of appetite; fussiness/irritability; headache.
- **From less common to common:** dryness of skin; difficulty or infrequent passing of stool; swelling of glands in the cheeks or neck; diarrhea, nausea, vomiting.

If you have any questions, please contact your child/ward's physician.

Investigator Name _____

Investigator signature _____

Date _____

Investigator CVs or equivalent summaries of training and experience relevant to the performance of the clinical study

Pages 1197 to 1391 have been removed - Out of Scope of phase 1 of Policy 0070 - Investigator CVs

Signature of principal or coordinating investigator

GlaxoSmithKline Biologicals
Vaccines R&D
Investigator Approval Page

STUDY TITLE: A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Study: 115648 (MMR-160) Development Phase: IIIa

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Investigator:	Mercedes Macias Parra
Affiliation /investigational centre:	Instituto Nacional de Pediatria, Av. Insurgentes Sur 3700-C, Insurgentes Cuicuilco, Mexico City, Mexico, 04530
Signature of Investigator:	_____
Date:	_____

For internal use only

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GlaxoSmithKline Biologicals
Vaccines R&D
Sponsor Signatory Approval Page

Please note that by signing this page, you take responsibility for the content of the Study Report, including appendices

STUDY TITLE: A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Study: 115648 (MMR-160) Development Phase: IIIa

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Sponsor Signatory: Dominique Descamps

Title of Sponsor Signatory: Vice President of Vaccines Research & Development. GlaxoSmithKline Biologicals, SA

Signature: _____

Date: _____

For internal use only

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Listings of patients receiving test drug(s) /investigational product(s) from specific batches, where more than one batch was used

Not applicable.

Randomisation list

Randomisation list

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb
PPD	1	PPD	21	PPD	42	PPD	62	PPD	83	PPD	103	PPD	124
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	2		22		43		63		84		104		125
	2		23		43		64		84		105		125
	3		23		44		64		85		105		126
	3		24		44		65		85		106		126
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	21		41		62		82		103		123		144

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
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		145			166			186			207			227			248			268
		146			166			187			207			228			248			269
		146			167			187			208			228			249			269
		147			167			188			208			229			249			270
		147			168			188			209			229			250			270
		148			168			189			209			230			250			271
		148			169			189			210			230			251			271
		149			169			190			210			231			251			272
		149			170			190			211			231			252			272
		150			170			191			211			232			252			273
		150			171			191			212			232			253			273
		151			171			192			212			233			253			274
		151			172			192			213			233			254			274
		152			172			193			213			234			254			275
		152			173			193			214			234			255			275
		153			173			194			214			235			255			276
		153			174			194			215			235			256			276
		154			174			195			215			236			256			277
		154			175			195			216			236			257			277
		155			175			196			216			237			257			278
		155			176			196			217			237			258			278
		156			176			197			217			238			258			279
		156			177			197			218			238			259			279
		157			177			198			218			239			259			280
		157			178			198			219			239			260			280
		158			178			199			219			240			260			281
		158			179			199			220			240			261			281
		159			179			200			220			241			261			282
		159			180			200			221			241			262			282
		160			180			201			221			242			262			283
		160			181			201			222			242			263			283
		161			181			202			222			243			263			284
		161			182			202			223			243			264			284
		162			182			203			223			244			264			285
		162			183			203			224			244			265			285
		163			183			204			224			245			265			286
		163			184			204			225			245			266			286
		164			184			205			225			246			266			287
		164			185			205			226			246			267			287

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb
PPD		288
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb
PPD	431	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		575	PPD		595	PPD		616	PPD		636	PPD		657	PPD		677	PPD		698
		575			596			616			637			657			678			698
		576			596			617			637			658			678			699
		576			597			617			638			658			679			699
		577			597			618			638			659			679			700
		577			598			618			639			659			680			700
		578			598			619			639			660			680			701
		578			599			619			640			660			681			701
		579			599			620			640			661			681			702
		579			600			620			641			661			682			702
		580			600			621			641			662			682			703
		580			601			621			642			662			683			703
		581			601			622			642			663			683			704
		581			602			622			643			663			684			704
		582			602			623			643			664			684			705
		582			603			623			644			664			685			705
		583			603			624			644			665			685			706
		583			604			624			645			665			686			706
		584			604			625			645			666			686			707
		584			605			625			646			666			687			707
		585			605			626			646			667			687			708
		585			606			626			647			667			688			708
		586			606			627			647			668			688			709
		586			607			627			648			668			689			709
		587			607			628			648			669			689			710
		587			608			628			649			669			690			710
		588			608			629			649			670			690			711
		588			609			629			650			670			691			711
		589			609			630			650			671			691			712
		589			610			630			651			671			692			712
		590			610			631			651			672			692			713
		590			611			631			652			672			693			713
		591			611			632			652			673			693			714
		591			612			632			653			673			694			714
		592			612			633			653			674			694			715
		592			613			633			654			674			695			715
		593			613			634			654			675			695			716
		593			614			634			655			675			696			716
		594			614			635			655			676			696			717
		594			615			635			656			676			697			717
		595			615			636			656			677			697			718

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		718	PPD		739	PPD		759	PPD		780	PPD		800	PPD		821	PPD		841
		719			739			760			780			801			821			842
		719			740			760			781			801			822			842
		720			740			761			781			802			822			843
		720			741			761			782			802			823			843
		721			741			762			782			803			823			844
		721			742			762			783			803			824			844
		722			742			763			783			804			824			845
		722			743			763			784			804			825			845
		723			743			764			784			805			825			846
		723			744			764			785			805			826			846
		724			744			765			785			806			826			847
		724			745			765			786			806			827			847
		725			745			766			786			807			827			848
		725			746			766			787			807			828			848
		726			746			767			787			808			828			849
		726			747			767			788			808			829			849
		727			747			768			788			809			829			850
		727			748			768			789			809			830			850
		728			748			769			789			810			830			851
		728			749			769			790			810			831			851
		729			749			770			790			811			831			852
		729			750			770			791			811			832			852
		730			750			771			791			812			832			853
		730			751			771			792			812			833			853
		731			751			772			792			813			833			854
		731			752			772			793			813			834			854
		732			752			773			793			814			834			855
		732			753			773			794			814			835			855
		733			753			774			794			815			835			856
		733			754			774			795			815			836			856
		734			754			775			795			816			836			857
		734			755			775			796			816			837			857
		735			755			776			796			817			837			858
		735			756			776			797			817			838			858
		736			756			777			797			818			838			859
		736			757			777			798			818			839			859
		737			757			778			798			819			839			860
		737			758			778			799			819			840			860
		738			758			779			799			820			840			861
		738			759			779			800			820			841			861

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		862	PPD		882	PPD		903	PPD		923	PPD		944	PPD		964	PPD		985
		862			883			903			924			944			965			985
		863			883			904			924			945			965			986
		863			884			904			925			945			966			986
		864			884			905			925			946			966			987
		864			885			905			926			946			967			987
		865			885			906			926			947			967			988
		865			886			906			927			947			968			988
		866			886			907			927			948			968			989
		866			887			907			928			948			969			989
		867			887			908			928			949			969			990
		867			888			908			929			949			970			990
		868			888			909			929			950			970			991
		868			889			909			930			950			971			991
		869			889			910			930			951			971			992
		869			890			910			931			951			972			992
		870			890			911			931			952			972			993
		870			891			911			932			952			973			993
		871			891			912			932			953			973			994
		871			892			912			933			953			974			994
		872			892			913			933			954			974			995
		872			893			913			934			954			975			995
		873			893			914			934			955			975			996
		873			894			914			935			955			976			996
		874			894			915			935			956			976			997
		874			895			915			936			956			977			997
		875			895			916			936			957			977			998
		875			896			916			937			957			978			998
		876			896			917			937			958			978			999
		876			897			917			938			958			979			999
		877			897			918			938			959			979			1000
		877			898			918			939			959			980			1000
		878			898			919			939			960			980			1001
		878			899			919			940			960			981			1001
		879			899			920			940			961			981			1002
		879			900			920			941			961			982			1002
		880			900			921			941			962			982			1003
		880			901			921			942			962			983			1003
		881			901			922			942			963			983			1004
		881			902			922			943			963			984			1004
		882			902			923			943			964			984			1005

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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1005	PPD		1026	PPD		1046	PPD		1067	PPD		1087	PPD		1108	PPD		1128
		1006			1026			1047			1067			1088			1108			1129
		1006			1027			1047			1068			1088			1109			1129
		1007			1027			1048			1068			1089			1109			1130
		1007			1028			1048			1069			1089			1110			1130
		1008			1028			1049			1069			1090			1110			1131
		1008			1029			1049			1070			1090			1111			1131
		1009			1029			1050			1070			1091			1111			1132
		1009			1030			1050			1071			1091			1112			1132
		1010			1030			1051			1071			1092			1112			1133
		1010			1031			1051			1072			1092			1113			1133
		1011			1031			1052			1072			1093			1113			1134
		1011			1032			1052			1073			1093			1114			1134
		1012			1032			1053			1073			1094			1114			1135
		1012			1033			1053			1074			1094			1115			1135
		1013			1033			1054			1074			1095			1115			1136
		1013			1034			1054			1075			1095			1116			1136
		1014			1034			1055			1075			1096			1116			1137
		1014			1035			1055			1076			1096			1117			1137
		1015			1035			1056			1076			1097			1117			1138
		1015			1036			1056			1077			1097			1118			1138
		1016			1036			1057			1077			1098			1118			1139
		1016			1037			1057			1078			1098			1119			1139
		1017			1037			1058			1078			1099			1119			1140
		1017			1038			1058			1079			1099			1120			1140
		1018			1038			1059			1079			1100			1120			1141
		1018			1039			1059			1080			1100			1121			1141
		1019			1039			1060			1080			1101			1121			1142
		1019			1040			1060			1081			1101			1122			1142
		1020			1040			1061			1081			1102			1122			1143
		1020			1041			1061			1082			1102			1123			1143
		1021			1041			1062			1082			1103			1123			1144
		1021			1042			1062			1083			1103			1124			1144
		1022			1042			1063			1083			1104			1124			1145
		1022			1043			1063			1084			1104			1125			1145
		1023			1043			1064			1084			1105			1125			1146
		1023			1044			1064			1085			1105			1126			1146
		1024			1044			1065			1085			1106			1126			1147
		1024			1045			1065			1086			1106			1127			1147
		1025			1045			1066			1086			1107			1127			1148
		1025			1046			1066			1087			1107			1128			1148

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	1149		PPD	1169		PPD	1190		PPD	1210		PPD	1231		PPD	1251		PPD	1272	
	1149			1170			1190			1211			1231			1252			1272	
	1150			1170			1191			1211			1232			1252			1273	
	1150			1171			1191			1212			1232			1253			1273	
	1151			1171			1192			1212			1233			1253			1274	
	1151			1172			1192			1213			1233			1254			1274	
	1152			1172			1193			1213			1234			1254			1275	
	1152			1173			1193			1214			1234			1255			1275	
	1153			1173			1194			1214			1235			1255			1276	
	1153			1174			1194			1215			1235			1256			1276	
	1154			1174			1195			1215			1236			1256			1277	
	1154			1175			1195			1216			1236			1257			1277	
	1155			1175			1196			1216			1237			1257			1278	
	1155			1176			1196			1217			1237			1258			1278	
	1156			1176			1197			1217			1238			1258			1279	
	1156			1177			1197			1218			1238			1259			1279	
	1157			1177			1198			1218			1239			1259			1280	
	1157			1178			1198			1219			1239			1260			1280	
	1158			1178			1199			1219			1240			1260			1281	
	1158			1179			1199			1220			1240			1261			1281	
	1159			1179			1200			1220			1241			1261			1282	
	1159			1180			1200			1221			1241			1262			1282	
	1160			1180			1201			1221			1242			1262			1283	
	1160			1181			1201			1222			1242			1263			1283	
	1161			1181			1202			1222			1243			1263			1284	
	1161			1182			1202			1223			1243			1264			1284	
	1162			1182			1203			1223			1244			1264			1285	
	1162			1183			1203			1224			1244			1265			1285	
	1163			1183			1204			1224			1245			1265			1286	
	1163			1184			1204			1225			1245			1266			1286	
	1164			1184			1205			1225			1246			1266			1287	
	1164			1185			1205			1226			1246			1267			1287	
	1165			1185			1206			1226			1247			1267			1288	
	1165			1186			1206			1227			1247			1268			1288	
	1166			1186			1207			1227			1248			1268			1289	
	1166			1187			1207			1228			1248			1269			1289	
	1167			1187			1208			1228			1249			1269			1290	
	1167			1188			1208			1229			1249			1270			1290	
	1168			1188			1209			1229			1250			1270			1291	
	1168			1189			1209			1230			1250			1271			1291	
	1169			1189			1210			1230			1251			1271			1292	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1292	PPD		1313	PPD		1333	PPD		1354	PPD		1374	PPD		1395	PPD		1415
		1293			1313			1334			1354			1375			1395			1416
		1293			1314			1334			1355			1375			1396			1416
		1294			1314			1335			1355			1376			1396			1417
		1294			1315			1335			1356			1376			1397			1417
		1295			1315			1336			1356			1377			1397			1418
		1295			1316			1336			1357			1377			1398			1418
		1296			1316			1337			1357			1378			1398			1419
		1296			1317			1337			1358			1378			1399			1419
		1297			1317			1338			1358			1379			1399			1420
		1297			1318			1338			1359			1379			1400			1420
		1298			1318			1339			1359			1380			1400			1421
		1298			1319			1339			1360			1380			1401			1421
		1299			1319			1340			1360			1381			1401			1422
		1299			1320			1340			1361			1381			1402			1422
		1300			1320			1341			1361			1382			1402			1423
		1300			1321			1341			1362			1382			1403			1423
		1301			1321			1342			1362			1383			1403			1424
		1301			1322			1342			1363			1383			1404			1424
		1302			1322			1343			1363			1384			1404			1425
		1302			1323			1343			1364			1384			1405			1425
		1303			1323			1344			1364			1385			1405			1426
		1303			1324			1344			1365			1385			1406			1426
		1304			1324			1345			1365			1386			1406			1427
		1304			1325			1345			1366			1386			1407			1427
		1305			1325			1346			1366			1387			1407			1428
		1305			1326			1346			1367			1387			1408			1428
		1306			1326			1347			1367			1388			1408			1429
		1306			1327			1347			1368			1388			1409			1429
		1307			1327			1348			1368			1389			1409			1430
		1307			1328			1348			1369			1389			1410			1430
		1308			1328			1349			1369			1390			1410			1431
		1308			1329			1349			1370			1390			1411			1431
		1309			1329			1350			1370			1391			1411			1432
		1309			1330			1350			1371			1391			1412			1432
		1310			1330			1351			1371			1392			1412			1433
		1310			1331			1351			1372			1392			1413			1433
		1311			1331			1352			1372			1393			1413			1434
		1311			1332			1352			1373			1393			1414			1434
		1312			1332			1353			1373			1394			1414			1435
		1312			1333			1353			1374			1394			1415			1435

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb
PPD	1436	1436
	1437	1437
	1437	1438
	1438	1438
	1439	1439
	1439	1440
	1440	1440
	1441	1441
	1441	1442
	1442	1442
	1443	1443
	1443	1444
	1444	1444
	1445	1445
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	1447	1448
	1448	1448
	1449	1449
	1449	1450
	1450	1450
	1451	1451
	1451	1452
	1452	1452
	1453	1453
	1453	1454
	1454	1454
	1455	1455
	1455	1456

Trt.	Bl. No	nb
PPD	1456	1457
	1457	1457
	1458	1458
	1458	1459
	1459	1459
	1460	1460
	1460	1461
	1461	1461
	1462	1462
	1462	1463
	1463	1463
	1464	1464
	1464	1465
	1465	1465
	1466	1466
	1466	1467
	1467	1467
	1468	1468
	1468	1469
	1469	1469
	1470	1470
	1470	1471
	1471	1471
	1472	1472
	1472	1473
	1473	1473
	1474	1474
	1474	1475
	1475	1475
	1476	1476

Trt.	Bl. No	nb
PPD	1477	1477
	1477	1478
	1478	1478
	1479	1479
	1479	1480
	1480	1480
	1481	1481
	1481	1482
	1482	1482
	1483	1483
	1483	1484
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	1486	1486
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	1490	1490
	1490	1491
	1491	1491
	1492	1492
	1492	1493
	1493	1493
	1494	1494
	1494	1495
	1495	1495
	1496	1496
	1496	1497

Trt.	Bl. No	nb
PPD	1497	1498
	1498	1498
	1499	1499
	1499	1500
	1500	1500
	1501	1501
	1501	1502
	1502	1502
	1503	1503
	1503	1504
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	1505	1505
	1505	1506
	1506	1506
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	1509	1509
	1509	1510
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	1511	1511
	1511	1512
	1512	1512
	1513	1513
	1513	1514
	1514	1514
	1515	1515
	1515	1516
	1516	1516
	1517	1517
	1517	

Trt.	Bl. No	nb
PPD	1518	1518
	1518	1519
	1519	1519
	1519	1520
	1520	1520
	1520	1521
	1521	1521
	1521	1522
	1522	1522
	1522	1523
	1523	1523
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	1531	1531
	1531	1532
	1532	1532
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	1533	1533
	1533	1534
	1534	1534
	1534	1535
	1535	1535
	1535	1536
	1536	1536
	1536	1537
	1537	1537
	1537	1538
	1538	

Trt.	Bl. No	nb
PPD	1538	1539
	1539	1539
	1539	1540
	1540	1540
	1540	1541
	1541	1541
	1541	1542
	1542	1542
	1542	1543
	1543	1543
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	1556	1557
	1557	1557
	1557	1558
	1558	1558
	1558	

Trt.	Bl. No	nb
PPD	1559	1559
	1559	1560
	1560	1560
	1560	1561
	1561	1561
	1561	1562
	1562	1562
	1562	1563
	1563	1563
	1563	1564
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	1572	1573
	1573	1573
	1573	1574
	1574	1574
	1574	1575
	1575	1575
	1575	1576
	1576	1576
	1576	1577
	1577	1577
	1577	1578
	1578	1578
	1578	1579

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 2

Trt.	Bl. No	nb
PPD		1579
		1580
		1580
		1581
		1581
		1582
		1582
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		1597
		1597
		1598
		1598
		1599
		1599

Trt.	Bl. No	nb
PPD		1600
		1600
		1601
		1601
		1602
		1602
		1603
		1603
		1604
		1604
		1605
		1605
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		1616
		1617
		1617
		1618
		1618
		1619
		1619
		1620

Trt.	Bl. No	nb
PPD		1620
		1621
		1621
		1622
		1622
		1623
		1623
		1624
		1624
		1625
		1625

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	1	PPD	21	PPD	42	PPD	62	PPD	83	PPD	103	PPD	124
	1		22		42		63		83		104		124
	2		22		43		63		84		104		125
	2		23		43		64		84		105		125
	3		23		44		64		85		105		126
	3		24		44		65		85		106		126
	4		24		45		65		86		106		127
	4		25		45		66		86		107		127
	5		25		46		66		87		107		128
	5		26		46		67		87		108		128
	6		26		47		67		88		108		129
	6		27		47		68		88		109		129
	7		27		48		68		89		109		130
	7		28		48		69		89		110		130
	8		28		49		69		90		110		131
	8		29		49		70		90		111		131
	9		29		50		70		91		111		132
	9		30		50		71		91		112		132
	10		30		51		71		92		112		133
	10		31		51		72		92		113		133
	11		31		52		72		93		113		134
	11		32		52		73		93		114		134
	12		32		53		73		94		114		135
	12		33		53		74		94		115		135
	13		33		54		74		95		115		136
	13		34		54		75		95		116		136
	14		34		55		75		96		116		137
	14		35		55		76		96		117		137
	15		35		56		76		97		117		138
	15		36		56		77		97		118		138
	16		36		57		77		98		118		139
	16		37		57		78		98		119		139
	17		37		58		78		99		119		140
	17		38		58		79		99		120		140
	18		38		59		79		100		120		141
	18		39		59		80		100		121		141
	19		39		60		80		101		121		142
	19		40		60		81		101		122		142
	20		40		61		81		102		122		143
	20		41		61		82		102		123		143
	21		41		62		82		103		123		144

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		144	PPD		165	PPD		185	PPD		206	PPD		226	PPD		247	PPD		267
		145			165			186			206			227			247			268
		145			166			186			207			227			248			268
		146			166			187			207			228			248			269
		146			167			187			208			228			249			269
		147			167			188			208			229			249			270
		147			168			188			209			229			250			270
		148			168			189			209			230			250			271
		148			169			189			210			230			251			271
		149			169			190			210			231			251			272
		149			170			190			211			231			252			272
		150			170			191			211			232			252			273
		150			171			191			212			232			253			273
		151			171			192			212			233			253			274
		151			172			192			213			233			254			274
		152			172			193			213			234			254			275
		152			173			193			214			234			255			275
		153			173			194			214			235			255			276
		153			174			194			215			235			256			276
		154			174			195			215			236			256			277
		154			175			195			216			236			257			277
		155			175			196			216			237			257			278
		155			176			196			217			237			258			278
		156			176			197			217			238			258			279
		156			177			197			218			238			259			279
		157			177			198			218			239			259			280
		157			178			198			219			239			260			280
		158			178			199			219			240			260			281
		158			179			199			220			240			261			281
		159			179			200			220			241			261			282
		159			180			200			221			241			262			282
		160			180			201			221			242			262			283
		160			181			201			222			242			263			283
		161			181			202			222			243			263			284
		161			182			202			223			243			264			284
		162			182			203			223			244			264			285
		162			183			203			224			244			265			285
		163			183			204			224			245			265			286
		163			184			204			225			245			266			286
		164			184			205			225			246			266			287
		164			185			205			226			246			267			287

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		288	PPD		308	PPD		329	PPD		349	PPD		370	PPD		390	PPD		411
		288			309			329			350			370			391			411
		289			309			330			350			371			391			412
		289			310			330			351			371			392			412
		290			310			331			351			372			392			413
		290			311			331			352			372			393			413
		291			311			332			352			373			393			414
		291			312			332			353			373			394			414
		292			312			333			353			374			394			415
		292			313			333			354			374			395			415
		293			313			334			354			375			395			416
		293			314			334			355			375			396			416
		294			314			335			355			376			396			417
		294			315			335			356			376			397			417
		295			315			336			356			377			397			418
		295			316			336			357			377			398			418
		296			316			337			357			378			398			419
		296			317			337			358			378			399			419
		297			317			338			358			379			399			420
		297			318			338			359			379			400			420
		298			318			339			359			380			400			421
		298			319			339			360			380			401			421
		299			319			340			360			381			401			422
		299			320			340			361			381			402			422
		300			320			341			361			382			402			423
		300			321			341			362			382			403			423
		301			321			342			362			383			403			424
		301			322			342			363			383			404			424
		302			322			343			363			384			404			425
		302			323			343			364			384			405			425
		303			323			344			364			385			405			426
		303			324			344			365			385			406			426
		304			324			345			365			386			406			427
		304			325			345			366			386			407			427
		305			325			346			366			387			407			428
		305			326			346			367			387			408			428
		306			326			347			367			388			408			429
		306			327			347			368			388			409			429
		307			327			348			368			389			409			430
		307			328			348			369			389			410			430
		308			328			349			369			390			410			431

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb
PPD		431
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		472
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		575	PPD		595	PPD		616	PPD		636	PPD		657	PPD		677	PPD		698
		575			596			616			637			657			678			698
		576			596			617			637			658			678			699
		576			597			617			638			658			679			699
		577			597			618			638			659			679			700
		577			598			618			639			659			680			700
		578			598			619			639			660			680			701
		578			599			619			640			660			681			701
		579			599			620			640			661			681			702
		579			600			620			641			661			682			702
		580			600			621			641			662			682			703
		580			601			621			642			662			683			703
		581			601			622			642			663			683			704
		581			602			622			643			663			684			704
		582			602			623			643			664			684			705
		582			603			623			644			664			685			705
		583			603			624			644			665			685			706
		583			604			624			645			665			686			706
		584			604			625			645			666			686			707
		584			605			625			646			666			687			707
		585			605			626			646			667			687			708
		585			606			626			647			667			688			708
		586			606			627			647			668			688			709
		586			607			627			648			668			689			709
		587			607			628			648			669			689			710
		587			608			628			649			669			690			710
		588			608			629			649			670			690			711
		588			609			629			650			670			691			711
		589			609			630			650			671			691			712
		589			610			630			651			671			692			712
		590			610			631			651			672			692			713
		590			611			631			652			672			693			713
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		591			612			632			653			673			694			714
		592			612			633			653			674			694			715
		592			613			633			654			674			695			715
		593			613			634			654			675			695			716
		593			614			634			655			675			696			716
		594			614			635			655			676			696			717
		594			615			635			656			676			697			717
		595			615			636			656			677			697			718

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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD	718		PPD	739		PPD	759		PPD	780		PPD	800		PPD	821		PPD	841	
	719			739			760			780			801			821			842	
	719			740			760			781			801			822			842	
	720			740			761			781			802			822			843	
	720			741			761			782			802			823			843	
	721			741			762			782			803			823			844	
	721			742			762			783			803			824			844	
	722			742			763			783			804			824			845	
	722			743			763			784			804			825			845	
	723			743			764			784			805			825			846	
	723			744			764			785			805			826			846	
	724			744			765			785			806			826			847	
	724			745			765			786			806			827			847	
	725			745			766			786			807			827			848	
	725			746			766			787			807			828			848	
	726			746			767			787			808			828			849	
	726			747			767			788			808			829			849	
	727			747			768			788			809			829			850	
	727			748			768			789			809			830			850	
	728			748			769			789			810			830			851	
	728			749			769			790			810			831			851	
	729			749			770			790			811			831			852	
	729			750			770			791			811			832			852	
	730			750			771			791			812			832			853	
	730			751			771			792			812			833			853	
	731			751			772			792			813			833			854	
	731			752			772			793			813			834			854	
	732			752			773			793			814			834			855	
	732			753			773			794			814			835			855	
	733			753			774			794			815			835			856	
	733			754			774			795			815			836			856	
	734			754			775			795			816			836			857	
	734			755			775			796			816			837			857	
	735			755			776			796			817			837			858	
	735			756			776			797			817			838			858	
	736			756			777			797			818			838			859	
	736			757			777			798			818			839			859	
	737			757			778			798			819			839			860	
	737			758			778			799			819			840			860	
	738			758			779			799			820			840			861	
	738			759			779			800			820			841			861	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb
PPD		862
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1005	PPD		1026	PPD		1046	PPD		1067	PPD		1087	PPD		1108	PPD		1128
		1006			1026			1047			1067			1088			1108			1129
		1006			1027			1047			1068			1088			1109			1129
		1007			1027			1048			1068			1089			1109			1130
		1007			1028			1048			1069			1089			1110			1130
		1008			1028			1049			1069			1090			1110			1131
		1008			1029			1049			1070			1090			1111			1131
		1009			1029			1050			1070			1091			1111			1132
		1009			1030			1050			1071			1091			1112			1132
		1010			1030			1051			1071			1092			1112			1133
		1010			1031			1051			1072			1092			1113			1133
		1011			1031			1052			1072			1093			1113			1134
		1011			1032			1052			1073			1093			1114			1134
		1012			1032			1053			1073			1094			1114			1135
		1012			1033			1053			1074			1094			1115			1135
		1013			1033			1054			1074			1095			1115			1136
		1013			1034			1054			1075			1095			1116			1136
		1014			1034			1055			1075			1096			1116			1137
		1014			1035			1055			1076			1096			1117			1137
		1015			1035			1056			1076			1097			1117			1138
		1015			1036			1056			1077			1097			1118			1138
		1016			1036			1057			1077			1098			1118			1139
		1016			1037			1057			1078			1098			1119			1139
		1017			1037			1058			1078			1099			1119			1140
		1017			1038			1058			1079			1099			1120			1140
		1018			1038			1059			1079			1100			1120			1141
		1018			1039			1059			1080			1100			1121			1141
		1019			1039			1060			1080			1101			1121			1142
		1019			1040			1060			1081			1101			1122			1142
		1020			1040			1061			1081			1102			1122			1143
		1020			1041			1061			1082			1102			1123			1143
		1021			1041			1062			1082			1103			1123			1144
		1021			1042			1062			1083			1103			1124			1144
		1022			1042			1063			1083			1104			1124			1145
		1022			1043			1063			1084			1104			1125			1145
		1023			1043			1064			1084			1105			1125			1146
		1023			1044			1064			1085			1105			1126			1146
		1024			1044			1065			1085			1106			1126			1147
		1024			1045			1065			1086			1106			1127			1147
		1025			1045			1066			1086			1107			1127			1148
		1025			1046			1066			1087			1107			1128			1148

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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	1149		PPD	1169		PPD	1190		PPD	1210		PPD	1231		PPD	1251		PPD	1272	
	1149			1170			1190			1211			1231			1252			1272	
	1150			1170			1191			1211			1232			1252			1273	
	1150			1171			1191			1212			1232			1253			1273	
	1151			1171			1192			1212			1233			1253			1274	
	1151			1172			1192			1213			1233			1254			1274	
	1152			1172			1193			1213			1234			1254			1275	
	1152			1173			1193			1214			1234			1255			1275	
	1153			1173			1194			1214			1235			1255			1276	
	1153			1174			1194			1215			1235			1256			1276	
	1154			1174			1195			1215			1236			1256			1277	
	1154			1175			1195			1216			1236			1257			1277	
	1155			1175			1196			1216			1237			1257			1278	
	1155			1176			1196			1217			1237			1258			1278	
	1156			1176			1197			1217			1238			1258			1279	
	1156			1177			1197			1218			1238			1259			1279	
	1157			1177			1198			1218			1239			1259			1280	
	1157			1178			1198			1219			1239			1260			1280	
	1158			1178			1199			1219			1240			1260			1281	
	1158			1179			1199			1220			1240			1261			1281	
	1159			1179			1200			1220			1241			1261			1282	
	1159			1180			1200			1221			1241			1262			1282	
	1160			1180			1201			1221			1242			1262			1283	
	1160			1181			1201			1222			1242			1263			1283	
	1161			1181			1202			1222			1243			1263			1284	
	1161			1182			1202			1223			1243			1264			1284	
	1162			1182			1203			1223			1244			1264			1285	
	1162			1183			1203			1224			1244			1265			1285	
	1163			1183			1204			1224			1245			1265			1286	
	1163			1184			1204			1225			1245			1266			1286	
	1164			1184			1205			1225			1246			1266			1287	
	1164			1185			1205			1226			1246			1267			1287	
	1165			1185			1206			1226			1247			1267			1288	
	1165			1186			1206			1227			1247			1268			1288	
	1166			1186			1207			1227			1248			1268			1289	
	1166			1187			1207			1228			1248			1269			1289	
	1167			1187			1208			1228			1249			1269			1290	
	1167			1188			1208			1229			1249			1270			1290	
	1168			1188			1209			1229			1250			1270			1291	
	1168			1189			1209			1230			1250			1271			1291	
	1169			1189			1210			1230			1251			1271			1292	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1292	PPD		1313	PPD		1333	PPD		1354	PPD		1374	PPD		1395	PPD		1415
		1293			1313			1334			1354			1375			1395			1416
		1293			1314			1334			1355			1375			1396			1416
		1294			1314			1335			1355			1376			1396			1417
		1294			1315			1335			1356			1376			1397			1417
		1295			1315			1336			1356			1377			1397			1418
		1295			1316			1336			1357			1377			1398			1418
		1296			1316			1337			1357			1378			1398			1419
		1296			1317			1337			1358			1378			1399			1419
		1297			1317			1338			1358			1379			1399			1420
		1297			1318			1338			1359			1379			1400			1420
		1298			1318			1339			1359			1380			1400			1421
		1298			1319			1339			1360			1380			1401			1421
		1299			1319			1340			1360			1381			1401			1422
		1299			1320			1340			1361			1381			1402			1422
		1300			1320			1341			1361			1382			1402			1423
		1300			1321			1341			1362			1382			1403			1423
		1301			1321			1342			1362			1383			1403			1424
		1301			1322			1342			1363			1383			1404			1424
		1302			1322			1343			1363			1384			1404			1425
		1302			1323			1343			1364			1384			1405			1425
		1303			1323			1344			1364			1385			1405			1426
		1303			1324			1344			1365			1385			1406			1426
		1304			1324			1345			1365			1386			1406			1427
		1304			1325			1345			1366			1386			1407			1427
		1305			1325			1346			1366			1387			1407			1428
		1305			1326			1346			1367			1387			1408			1428
		1306			1326			1347			1367			1388			1408			1429
		1306			1327			1347			1368			1388			1409			1429
		1307			1327			1348			1368			1389			1409			1430
		1307			1328			1348			1369			1389			1410			1430
		1308			1328			1349			1369			1390			1410			1431
		1308			1329			1349			1370			1390			1411			1431
		1309			1329			1350			1370			1391			1411			1432
		1309			1330			1350			1371			1391			1412			1432
		1310			1330			1351			1371			1392			1412			1433
		1310			1331			1351			1372			1392			1413			1433
		1311			1331			1352			1372			1393			1413			1434
		1311			1332			1352			1373			1393			1414			1434
		1312			1332			1353			1373			1394			1414			1435
		1312			1333			1353			1374			1394			1415			1435

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1436	PPD		1456	PPD		1477	PPD		1497	PPD		1518	PPD		1538	PPD		1559
		1436			1457			1477			1498			1518			1539			1559
		1437			1457			1478			1498			1519			1539			1560
		1437			1458			1478			1499			1519			1540			1560
		1438			1458			1479			1499			1520			1540			1561
		1438			1459			1479			1500			1520			1541			1561
		1439			1459			1480			1500			1521			1541			1562
		1439			1460			1480			1501			1521			1542			1562
		1440			1460			1481			1501			1522			1542			1563
		1440			1461			1481			1502			1522			1543			1563
		1441			1461			1482			1502			1523			1543			1564
		1441			1462			1482			1503			1523			1544			1564
		1442			1462			1483			1503			1524			1544			1565
		1442			1463			1483			1504			1524			1545			1565
		1443			1463			1484			1504			1525			1545			1566
		1443			1464			1484			1505			1525			1546			1566
		1444			1464			1485			1505			1526			1546			1567
		1444			1465			1485			1506			1526			1547			1567
		1445			1465			1486			1506			1527			1547			1568
		1445			1466			1486			1507			1527			1548			1568
		1446			1466			1487			1507			1528			1548			1569
		1446			1467			1487			1508			1528			1549			1569
		1447			1467			1488			1508			1529			1549			1570
		1447			1468			1488			1509			1529			1550			1570
		1448			1468			1489			1509			1530			1550			1571
		1448			1469			1489			1510			1530			1551			1571
		1449			1469			1490			1510			1531			1551			1572
		1449			1470			1490			1511			1531			1552			1572
		1450			1470			1491			1511			1532			1552			1573
		1450			1471			1491			1512			1532			1553			1573
		1451			1471			1492			1512			1533			1553			1574
		1451			1472			1492			1513			1533			1554			1574
		1452			1472			1493			1513			1534			1554			1575
		1452			1473			1493			1514			1534			1555			1575
		1453			1473			1494			1514			1535			1555			1576
		1453			1474			1494			1515			1535			1556			1576
		1454			1474			1495			1515			1536			1556			1577
		1454			1475			1495			1516			1536			1557			1577
		1455			1475			1496			1516			1537			1557			1578
		1455			1476			1496			1517			1537			1558			1578
		1456			1476			1497			1517			1538			1558			1579

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 3

Trt.	Bl. No	nb
PPD		1579
		1580
		1580
		1581
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		1599

Trt.	Bl. No	nb
PPD		1600
		1600
		1601
		1601
		1602
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		1604
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		1617
		1617
		1618
		1618
		1619
		1619
		1620

Trt.	Bl. No	nb
PPD		1620
		1621
		1621
		1622
		1622
		1623
		1623
		1624
		1624
		1625
		1625

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 1

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD	1		PPD	42		PPD	83		PPD	124		PPD	165		PPD	206		PPD	247	
	2			43			84			125			166			207			248	
	3			44			85			126			167			208			249	
	4			45			86			127			168			209			250	
	5			46			87			128			169			210			251	
	6			47			88			129			170			211			252	
	7			48			89			130			171			212			253	
	8			49			90			131			172			213			254	
	9			50			91			132			173			214			255	
	10			51			92			133			174			215			256	
	11			52			93			134			175			216			257	
	12			53			94			135			176			217			258	
	13			54			95			136			177			218			259	
	14			55			96			137			178			219			260	
	15			56			97			138			179			220			261	
	16			57			98			139			180			221			262	
	17			58			99			140			181			222			263	
	18			59			100			141			182			223			264	
	19			60			101			142			183			224			265	
	20			61			102			143			184			225			266	
	21			62			103			144			185			226			267	
	22			63			104			145			186			227			268	
	23			64			105			146			187			228			269	
	24			65			106			147			188			229			270	
	25			66			107			148			189			230			271	
	26			67			108			149			190			231			272	
	27			68			109			150			191			232			273	
	28			69			110			151			192			233			274	
	29			70			111			152			193			234			275	
	30			71			112			153			194			235			276	
	31			72			113			154			195			236			277	
	32			73			114			155			196			237			278	
	33			74			115			156			197			238			279	
	34			75			116			157			198			239			280	
	35			76			117			158			199			240			281	
	36			77			118			159			200			241			282	
	37			78			119			160			201			242			283	
	38			79			120			161			202			243			284	
	39			80			121			162			203			244			285	
	40			81			122			163			204			245			286	
	41			82			123			164			205			246			287	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 1

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		288	PPD		329	PPD		370	PPD		411	PPD		452	PPD		493	PPD		534
		289			330			371			412			453			494			535
		290			331			372			413			454			495			536
		291			332			373			414			455			496			537
		292			333			374			415			456			497			538
		293			334			375			416			457			498			539
		294			335			376			417			458			499			540
		295			336			377			418			459			500			541
		296			337			378			419			460			501			542
		297			338			379			420			461			502			543
		298			339			380			421			462			503			544
		299			340			381			422			463			504			545
		300			341			382			423			464			505			546
		301			342			383			424			465			506			547
		302			343			384			425			466			507			548
		303			344			385			426			467			508			549
		304			345			386			427			468			509			550
		305			346			387			428			469			510			551
		306			347			388			429			470			511			552
		307			348			389			430			471			512			553
		308			349			390			431			472			513			554
		309			350			391			432			473			514			555
		310			351			392			433			474			515			556
		311			352			393			434			475			516			557
		312			353			394			435			476			517			558
		313			354			395			436			477			518			559
		314			355			396			437			478			519			560
		315			356			397			438			479			520			561
		316			357			398			439			480			521			562
		317			358			399			440			481			522			563
		318			359			400			441			482			523			564
		319			360			401			442			483			524			565
		320			361			402			443			484			525			566
		321			362			403			444			485			526			567
		322			363			404			445			486			527			568
		323			364			405			446			487			528			569
		324			365			406			447			488			529			570
		325			366			407			448			489			530			571
		326			367			408			449			490			531			572
		327			368			409			450			491			532			573
		328			369			410			451			492			533			574

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 1

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		575	PPD		616	PPD		657	PPD		698	PPD		739	PPD		780	PPD		821
		576			617			658			699			740			781			822
		577			618			659			700			741			782			823
		578			619			660			701			742			783			824
		579			620			661			702			743			784			825
		580			621			662			703			744			785			826
		581			622			663			704			745			786			827
		582			623			664			705			746			787			828
		583			624			665			706			747			788			829
		584			625			666			707			748			789			830
		585			626			667			708			749			790			831
		586			627			668			709			750			791			832
		587			628			669			710			751			792			833
		588			629			670			711			752			793			834
		589			630			671			712			753			794			835
		590			631			672			713			754			795			836
		591			632			673			714			755			796			837
		592			633			674			715			756			797			838
		593			634			675			716			757			798			839
		594			635			676			717			758			799			840
		595			636			677			718			759			800			841
		596			637			678			719			760			801			842
		597			638			679			720			761			802			843
		598			639			680			721			762			803			844
		599			640			681			722			763			804			845
		600			641			682			723			764			805			846
		601			642			683			724			765			806			847
		602			643			684			725			766			807			848
		603			644			685			726			767			808			849
		604			645			686			727			768			809			850
		605			646			687			728			769			810			851
		606			647			688			729			770			811			852
		607			648			689			730			771			812			853
		608			649			690			731			772			813			854
		609			650			691			732			773			814			855
		610			651			692			733			774			815			856
		611			652			693			734			775			816			857
		612			653			694			735			776			817			858
		613			654			695			736			777			818			859
		614			655			696			737			778			819			860
		615			656			697			738			779			820			861

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		862	PPD		903	PPD		944	PPD		985	PPD		1026	PPD		1067	PPD		1108
		863			904			945			986			1027			1068			1109
		864			905			946			987			1028			1069			1110
		865			906			947			988			1029			1070			1111
		866			907			948			989			1030			1071			1112
		867			908			949			990			1031			1072			1113
		868			909			950			991			1032			1073			1114
		869			910			951			992			1033			1074			1115
		870			911			952			993			1034			1075			1116
		871			912			953			994			1035			1076			1117
		872			913			954			995			1036			1077			1118
		873			914			955			996			1037			1078			1119
		874			915			956			997			1038			1079			1120
		875			916			957			998			1039			1080			1121
		876			917			958			999			1040			1081			1122
		877			918			959			1000			1041			1082			1123
		878			919			960			1001			1042			1083			1124
		879			920			961			1002			1043			1084			1125
		880			921			962			1003			1044			1085			1126
		881			922			963			1004			1045			1086			1127
		882			923			964			1005			1046			1087			1128
		883			924			965			1006			1047			1088			1129
		884			925			966			1007			1048			1089			1130
		885			926			967			1008			1049			1090			1131
		886			927			968			1009			1050			1091			1132
		887			928			969			1010			1051			1092			1133
		888			929			970			1011			1052			1093			1134
		889			930			971			1012			1053			1094			1135
		890			931			972			1013			1054			1095			1136
		891			932			973			1014			1055			1096			1137
		892			933			974			1015			1056			1097			1138
		893			934			975			1016			1057			1098			1139
		894			935			976			1017			1058			1099			1140
		895			936			977			1018			1059			1100			1141
		896			937			978			1019			1060			1101			1142
		897			938			979			1020			1061			1102			1143
		898			939			980			1021			1062			1103			1144
		899			940			981			1022			1063			1104			1145
		900			941			982			1023			1064			1105			1146
		901			942			983			1024			1065			1106			1147
		902			943			984			1025			1066			1107			1148

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1149	PPD		1190	PPD		1231	PPD		1272	PPD		1313	PPD		1354	PPD		1395
		1150			1191			1232			1273			1314			1355			1396
		1151			1192			1233			1274			1315			1356			1397
		1152			1193			1234			1275			1316			1357			1398
		1153			1194			1235			1276			1317			1358			1399
		1154			1195			1236			1277			1318			1359			1400
		1155			1196			1237			1278			1319			1360			1401
		1156			1197			1238			1279			1320			1361			1402
		1157			1198			1239			1280			1321			1362			1403
		1158			1199			1240			1281			1322			1363			1404
		1159			1200			1241			1282			1323			1364			1405
		1160			1201			1242			1283			1324			1365			1406
		1161			1202			1243			1284			1325			1366			1407
		1162			1203			1244			1285			1326			1367			1408
		1163			1204			1245			1286			1327			1368			1409
		1164			1205			1246			1287			1328			1369			1410
		1165			1206			1247			1288			1329			1370			1411
		1166			1207			1248			1289			1330			1371			1412
		1167			1208			1249			1290			1331			1372			1413
		1168			1209			1250			1291			1332			1373			1414
		1169			1210			1251			1292			1333			1374			1415
		1170			1211			1252			1293			1334			1375			1416
		1171			1212			1253			1294			1335			1376			1417
		1172			1213			1254			1295			1336			1377			1418
		1173			1214			1255			1296			1337			1378			1419
		1174			1215			1256			1297			1338			1379			1420
		1175			1216			1257			1298			1339			1380			1421
		1176			1217			1258			1299			1340			1381			1422
		1177			1218			1259			1300			1341			1382			1423
		1178			1219			1260			1301			1342			1383			1424
		1179			1220			1261			1302			1343			1384			1425
		1180			1221			1262			1303			1344			1385			1426
		1181			1222			1263			1304			1345			1386			1427
		1182			1223			1264			1305			1346			1387			1428
		1183			1224			1265			1306			1347			1388			1429
		1184			1225			1266			1307			1348			1389			1430
		1185			1226			1267			1308			1349			1390			1431
		1186			1227			1268			1309			1350			1391			1432
		1187			1228			1269			1310			1351			1392			1433
		1188			1229			1270			1311			1352			1393			1434
		1189			1230			1271			1312			1353			1394			1435

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 1

Trt.	Bl. No	nb
PPD		1436
		1437
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		1471
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		1474
		1475
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Trt.	Bl. No	nb
PPD		1477
		1478
		1479
		1480
		1481
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Trt.	Bl. No	nb
PPD		1518
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Trt.	Bl. No	nb
PPD		1559
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Trt.	Bl. No	nb
PPD		1600
		1601
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	1	PPD	21	PPD	42	PPD	62	PPD	83	PPD	103	PPD	124
	1		22		42		63		83		104		124
	2		22		43		63		84		104		125
	2		23		43		64		84		105		125
	3		23		44		64		85		105		126
	3		24		44		65		85		106		126
	4		24		45		65		86		106		127
	4		25		45		66		86		107		127
	5		25		46		66		87		107		128
	5		26		46		67		87		108		128
	6		26		47		67		88		108		129
	6		27		47		68		88		109		129
	7		27		48		68		89		109		130
	7		28		48		69		89		110		130
	8		28		49		69		90		110		131
	8		29		49		70		90		111		131
	9		29		50		70		91		111		132
	9		30		50		71		91		112		132
	10		30		51		71		92		112		133
	10		31		51		72		92		113		133
	11		31		52		72		93		113		134
	11		32		52		73		93		114		134
	12		32		53		73		94		114		135
	12		33		53		74		94		115		135
	13		33		54		74		95		115		136
	13		34		54		75		95		116		136
	14		34		55		75		96		116		137
	14		35		55		76		96		117		137
	15		35		56		76		97		117		138
	15		36		56		77		97		118		138
	16		36		57		77		98		118		139
	16		37		57		78		98		119		139
	17		37		58		78		99		119		140
	17		38		58		79		99		120		140
	18		38		59		79		100		120		141
	18		39		59		80		100		121		141
	19		39		60		80		101		121		142
	19		40		60		81		101		122		142
	20		40		61		81		102		122		143
	20		41		61		82		102		123		143
	21		41		62		82		103		123		144

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		144	PPD		165	PPD		185	PPD		206	PPD		226	PPD		247	PPD		267
		145			165			186			206			227			247			268
		145			166			186			207			227			248			268
		146			166			187			207			228			248			269
		146			167			187			208			228			249			269
		147			167			188			208			229			249			270
		147			168			188			209			229			250			270
		148			168			189			209			230			250			271
		148			169			189			210			230			251			271
		149			169			190			210			231			251			272
		149			170			190			211			231			252			272
		150			170			191			211			232			252			273
		150			171			191			212			232			253			273
		151			171			192			212			233			253			274
		151			172			192			213			233			254			274
		152			172			193			213			234			254			275
		152			173			193			214			234			255			275
		153			173			194			214			235			255			276
		153			174			194			215			235			256			276
		154			174			195			215			236			256			277
		154			175			195			216			236			257			277
		155			175			196			216			237			257			278
		155			176			196			217			237			258			278
		156			176			197			217			238			258			279
		156			177			197			218			238			259			279
		157			177			198			218			239			259			280
		157			178			198			219			239			260			280
		158			178			199			219			240			260			281
		158			179			199			220			240			261			281
		159			179			200			220			241			261			282
		159			180			200			221			241			262			282
		160			180			201			221			242			262			283
		160			181			201			222			242			263			283
		161			181			202			222			243			263			284
		161			182			202			223			243			264			284
		162			182			203			223			244			264			285
		162			183			203			224			244			265			285
		163			183			204			224			245			265			286
		163			184			204			225			245			266			286
		164			184			205			225			246			266			287
		164			185			205			226			246			267			287

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		288	PPD		308	PPD		329	PPD		349	PPD		370	PPD		390	PPD		411
		288			309			329			350			370			391			411
		289			309			330			350			371			391			412
		289			310			330			351			371			392			412
		290			310			331			351			372			392			413
		290			311			331			352			372			393			413
		291			311			332			352			373			393			414
		291			312			332			353			373			394			414
		292			312			333			353			374			394			415
		292			313			333			354			374			395			415
		293			313			334			354			375			395			416
		293			314			334			355			375			396			416
		294			314			335			355			376			396			417
		294			315			335			356			376			397			417
		295			315			336			356			377			397			418
		295			316			336			357			377			398			418
		296			316			337			357			378			398			419
		296			317			337			358			378			399			419
		297			317			338			358			379			399			420
		297			318			338			359			379			400			420
		298			318			339			359			380			400			421
		298			319			339			360			380			401			421
		299			319			340			360			381			401			422
		299			320			340			361			381			402			422
		300			320			341			361			382			402			423
		300			321			341			362			382			403			423
		301			321			342			362			383			403			424
		301			322			342			363			383			404			424
		302			322			343			363			384			404			425
		302			323			343			364			384			405			425
		303			323			344			364			385			405			426
		303			324			344			365			385			406			426
		304			324			345			365			386			406			427
		304			325			345			366			386			407			427
		305			325			346			366			387			407			428
		305			326			346			367			387			408			428
		306			326			347			367			388			408			429
		306			327			347			368			388			409			429
		307			327			348			368			389			409			430
		307			328			348			369			389			410			430
		308			328			349			369			390			410			431

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		431	PPD		452	PPD		472	PPD		493	PPD		513	PPD		534	PPD		554
		432			452			473			493			514			534			555
		432			453			473			494			514			535			555
		433			453			474			494			515			535			556
		433			454			474			495			515			536			556
		434			454			475			495			516			536			557
		434			455			475			496			516			537			557
		435			455			476			496			517			537			558
		435			456			476			497			517			538			558
		436			456			477			497			518			538			559
		436			457			477			498			518			539			559
		437			457			478			498			519			539			560
		437			458			478			499			519			540			560
		438			458			479			499			520			540			561
		438			459			479			500			520			541			561
		439			459			480			500			521			541			562
		439			460			480			501			521			542			562
		440			460			481			501			522			542			563
		440			461			481			502			522			543			563
		441			461			482			502			523			543			564
		441			462			482			503			523			544			564
		442			462			483			503			524			544			565
		442			463			483			504			524			545			565
		443			463			484			504			525			545			566
		443			464			484			505			525			546			566
		444			464			485			505			526			546			567
		444			465			485			506			526			547			567
		445			465			486			506			527			547			568
		445			466			486			507			527			548			568
		446			466			487			507			528			548			569
		446			467			487			508			528			549			569
		447			467			488			508			529			549			570
		447			468			488			509			529			550			570
		448			468			489			509			530			550			571
		448			469			489			510			530			551			571
		449			469			490			510			531			551			572
		449			470			490			511			531			552			572
		450			470			491			511			532			552			573
		450			471			491			512			532			553			573
		451			471			492			512			533			553			574
		451			472			492			513			533			554			574

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		575	PPD		595	PPD		616	PPD		636	PPD		657	PPD		677	PPD		698
		575			596			616			637			657			678			698
		576			596			617			637			658			678			699
		576			597			617			638			658			679			699
		577			597			618			638			659			679			700
		577			598			618			639			659			680			700
		578			598			619			639			660			680			701
		578			599			619			640			660			681			701
		579			599			620			640			661			681			702
		579			600			620			641			661			682			702
		580			600			621			641			662			682			703
		580			601			621			642			662			683			703
		581			601			622			642			663			683			704
		581			602			622			643			663			684			704
		582			602			623			643			664			684			705
		582			603			623			644			664			685			705
		583			603			624			644			665			685			706
		583			604			624			645			665			686			706
		584			604			625			645			666			686			707
		584			605			625			646			666			687			707
		585			605			626			646			667			687			708
		585			606			626			647			667			688			708
		586			606			627			647			668			688			709
		586			607			627			648			668			689			709
		587			607			628			648			669			689			710
		587			608			628			649			669			690			710
		588			608			629			649			670			690			711
		588			609			629			650			670			691			711
		589			609			630			650			671			691			712
		589			610			630			651			671			692			712
		590			610			631			651			672			692			713
		590			611			631			652			672			693			713
		591			611			632			652			673			693			714
		591			612			632			653			673			694			714
		592			612			633			653			674			694			715
		592			613			633			654			674			695			715
		593			613			634			654			675			695			716
		593			614			634			655			675			696			716
		594			614			635			655			676			696			717
		594			615			635			656			676			697			717
		595			615			636			656			677			697			718

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb
PPD		718
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Trt.	Bl. No	nb
PPD		739
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Trt.	Bl. No	nb
PPD		759
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Trt.	Bl. No	nb
PPD		780
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Trt.	Bl. No	nb
PPD		800
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Trt.	Bl. No	nb
PPD		821
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Trt.	Bl. No	nb
PPD		841
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	862		PPD	882		PPD	903		PPD	923		PPD	944		PPD	964		PPD	985	
	862			883			903			924			944			965			985	
	863			883			904			924			945			965			986	
	863			884			904			925			945			966			986	
	864			884			905			925			946			966			987	
	864			885			905			926			946			967			987	
	865			885			906			926			947			967			988	
	865			886			906			927			947			968			988	
	866			886			907			927			948			968			989	
	866			887			907			928			948			969			989	
	867			887			908			928			949			969			990	
	867			888			908			929			949			970			990	
	868			888			909			929			950			970			991	
	868			889			909			930			950			971			991	
	869			889			910			930			951			971			992	
	869			890			910			931			951			972			992	
	870			890			911			931			952			972			993	
	870			891			911			932			952			973			993	
	871			891			912			932			953			973			994	
	871			892			912			933			953			974			994	
	872			892			913			933			954			974			995	
	872			893			913			934			954			975			995	
	873			893			914			934			955			975			996	
	873			894			914			935			955			976			996	
	874			894			915			935			956			976			997	
	874			895			915			936			956			977			997	
	875			895			916			936			957			977			998	
	875			896			916			937			957			978			998	
	876			896			917			937			958			978			999	
	876			897			917			938			958			979			999	
	877			897			918			938			959			979			1000	
	877			898			918			939			959			980			1000	
	878			898			919			939			960			980			1001	
	878			899			919			940			960			981			1001	
	879			899			920			940			961			981			1002	
	879			900			920			941			961			982			1002	
	880			900			921			941			962			982			1003	
	880			901			921			942			962			983			1003	
	881			901			922			942			963			983			1004	
	881			902			922			943			963			984			1004	
	882			902			923			943			964			984			1005	

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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD	1005		PPD	1026		PPD	1046		PPD	1067		PPD	1087		PPD	1108		PPD	1128	
	1006			1026			1047			1067			1088			1108			1129	
	1006			1027			1047			1068			1088			1109			1129	
	1007			1027			1048			1068			1089			1109			1130	
	1007			1028			1048			1069			1089			1110			1130	
	1008			1028			1049			1069			1090			1110			1131	
	1008			1029			1049			1070			1090			1111			1131	
	1009			1029			1050			1070			1091			1111			1132	
	1009			1030			1050			1071			1091			1112			1132	
	1010			1030			1051			1071			1092			1112			1133	
	1010			1031			1051			1072			1092			1113			1133	
	1011			1031			1052			1072			1093			1113			1134	
	1011			1032			1052			1073			1093			1114			1134	
	1012			1032			1053			1073			1094			1114			1135	
	1012			1033			1053			1074			1094			1115			1135	
	1013			1033			1054			1074			1095			1115			1136	
	1013			1034			1054			1075			1095			1116			1136	
	1014			1034			1055			1075			1096			1116			1137	
	1014			1035			1055			1076			1096			1117			1137	
	1015			1035			1056			1076			1097			1117			1138	
	1015			1036			1056			1077			1097			1118			1138	
	1016			1036			1057			1077			1098			1118			1139	
	1016			1037			1057			1078			1098			1119			1139	
	1017			1037			1058			1078			1099			1119			1140	
	1017			1038			1058			1079			1099			1120			1140	
	1018			1038			1059			1079			1100			1120			1141	
	1018			1039			1059			1080			1100			1121			1141	
	1019			1039			1060			1080			1101			1121			1142	
	1019			1040			1060			1081			1101			1122			1142	
	1020			1040			1061			1081			1102			1122			1143	
	1020			1041			1061			1082			1102			1123			1143	
	1021			1041			1062			1082			1103			1123			1144	
	1021			1042			1062			1083			1103			1124			1144	
	1022			1042			1063			1083			1104			1124			1145	
	1022			1043			1063			1084			1104			1125			1145	
	1023			1043			1064			1084			1105			1125			1146	
	1023			1044			1064			1085			1105			1126			1146	
	1024			1044			1065			1085			1106			1126			1147	
	1024			1045			1065			1086			1106			1127			1147	
	1025			1045			1066			1086			1107			1127			1148	
	1025			1046			1066			1087			1107			1128			1148	

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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	1149		PPD	1169		PPD	1190		PPD	1210		PPD	1231		PPD	1251		PPD	1272	
	1149			1170			1190			1211			1231			1252			1272	
	1150			1170			1191			1211			1232			1252			1273	
	1150			1171			1191			1212			1232			1253			1273	
	1151			1171			1192			1212			1233			1253			1274	
	1151			1172			1192			1213			1233			1254			1274	
	1152			1172			1193			1213			1234			1254			1275	
	1152			1173			1193			1214			1234			1255			1275	
	1153			1173			1194			1214			1235			1255			1276	
	1153			1174			1194			1215			1235			1256			1276	
	1154			1174			1195			1215			1236			1256			1277	
	1154			1175			1195			1216			1236			1257			1277	
	1155			1175			1196			1216			1237			1257			1278	
	1155			1176			1196			1217			1237			1258			1278	
	1156			1176			1197			1217			1238			1258			1279	
	1156			1177			1197			1218			1238			1259			1279	
	1157			1177			1198			1218			1239			1259			1280	
	1157			1178			1198			1219			1239			1260			1280	
	1158			1178			1199			1219			1240			1260			1281	
	1158			1179			1199			1220			1240			1261			1281	
	1159			1179			1200			1220			1241			1261			1282	
	1159			1180			1200			1221			1241			1262			1282	
	1160			1180			1201			1221			1242			1262			1283	
	1160			1181			1201			1222			1242			1263			1283	
	1161			1181			1202			1222			1243			1263			1284	
	1161			1182			1202			1223			1243			1264			1284	
	1162			1182			1203			1223			1244			1264			1285	
	1162			1183			1203			1224			1244			1265			1285	
	1163			1183			1204			1224			1245			1265			1286	
	1163			1184			1204			1225			1245			1266			1286	
	1164			1184			1205			1225			1246			1266			1287	
	1164			1185			1205			1226			1246			1267			1287	
	1165			1185			1206			1226			1247			1267			1288	
	1165			1186			1206			1227			1247			1268			1288	
	1166			1186			1207			1227			1248			1268			1289	
	1166			1187			1207			1228			1248			1269			1289	
	1167			1187			1208			1228			1249			1269			1290	
	1167			1188			1208			1229			1249			1270			1290	
	1168			1188			1209			1229			1250			1270			1291	
	1168			1189			1209			1230			1250			1271			1291	
	1169			1189			1210			1230			1251			1271			1292	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1292	PPD		1313	PPD		1333	PPD		1354	PPD		1374	PPD		1395	PPD		1415
		1293			1313			1334			1354			1375			1395			1416
		1293			1314			1334			1355			1375			1396			1416
		1294			1314			1335			1355			1376			1396			1417
		1294			1315			1335			1356			1376			1397			1417
		1295			1315			1336			1356			1377			1397			1418
		1295			1316			1336			1357			1377			1398			1418
		1296			1316			1337			1357			1378			1398			1419
		1296			1317			1337			1358			1378			1399			1419
		1297			1317			1338			1358			1379			1399			1420
		1297			1318			1338			1359			1379			1400			1420
		1298			1318			1339			1359			1380			1400			1421
		1298			1319			1339			1360			1380			1401			1421
		1299			1319			1340			1360			1381			1401			1422
		1299			1320			1340			1361			1381			1402			1422
		1300			1320			1341			1361			1382			1402			1423
		1300			1321			1341			1362			1382			1403			1423
		1301			1321			1342			1362			1383			1403			1424
		1301			1322			1342			1363			1383			1404			1424
		1302			1322			1343			1363			1384			1404			1425
		1302			1323			1343			1364			1384			1405			1425
		1303			1323			1344			1364			1385			1405			1426
		1303			1324			1344			1365			1385			1406			1426
		1304			1324			1345			1365			1386			1406			1427
		1304			1325			1345			1366			1386			1407			1427
		1305			1325			1346			1366			1387			1407			1428
		1305			1326			1346			1367			1387			1408			1428
		1306			1326			1347			1367			1388			1408			1429
		1306			1327			1347			1368			1388			1409			1429
		1307			1327			1348			1368			1389			1409			1430
		1307			1328			1348			1369			1389			1410			1430
		1308			1328			1349			1369			1390			1410			1431
		1308			1329			1349			1370			1390			1411			1431
		1309			1329			1350			1370			1391			1411			1432
		1309			1330			1350			1371			1391			1412			1432
		1310			1330			1351			1371			1392			1412			1433
		1310			1331			1351			1372			1392			1413			1433
		1311			1331			1352			1372			1393			1413			1434
		1311			1332			1352			1373			1393			1414			1434
		1312			1332			1353			1373			1394			1414			1435
		1312			1333			1353			1374			1394			1415			1435

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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1436	PPD		1456	PPD		1477	PPD		1497	PPD		1518	PPD		1538	PPD		1559
		1436			1457			1477			1498			1518			1539			1559
		1437			1457			1478			1498			1519			1539			1560
		1437			1458			1478			1499			1519			1540			1560
		1438			1458			1479			1499			1520			1540			1561
		1438			1459			1479			1500			1520			1541			1561
		1439			1459			1480			1500			1521			1541			1562
		1439			1460			1480			1501			1521			1542			1562
		1440			1460			1481			1501			1522			1542			1563
		1440			1461			1481			1502			1522			1543			1563
		1441			1461			1482			1502			1523			1543			1564
		1441			1462			1482			1503			1523			1544			1564
		1442			1462			1483			1503			1524			1544			1565
		1442			1463			1483			1504			1524			1545			1565
		1443			1463			1484			1504			1525			1545			1566
		1443			1464			1484			1505			1525			1546			1566
		1444			1464			1485			1505			1526			1546			1567
		1444			1465			1485			1506			1526			1547			1567
		1445			1465			1486			1506			1527			1547			1568
		1445			1466			1486			1507			1527			1548			1568
		1446			1466			1487			1507			1528			1548			1569
		1446			1467			1487			1508			1528			1549			1569
		1447			1467			1488			1508			1529			1549			1570
		1447			1468			1488			1509			1529			1550			1570
		1448			1468			1489			1509			1530			1550			1571
		1448			1469			1489			1510			1530			1551			1571
		1449			1469			1490			1510			1531			1551			1572
		1449			1470			1490			1511			1531			1552			1572
		1450			1470			1491			1511			1532			1552			1573
		1450			1471			1491			1512			1532			1553			1573
		1451			1471			1492			1512			1533			1553			1574
		1451			1472			1492			1513			1533			1554			1574
		1452			1472			1493			1513			1534			1554			1575
		1452			1473			1493			1514			1534			1555			1575
		1453			1473			1494			1514			1535			1555			1576
		1453			1474			1494			1515			1535			1556			1576
		1454			1474			1495			1515			1536			1556			1577
		1454			1475			1495			1516			1536			1557			1577
		1455			1475			1496			1516			1537			1557			1578
		1455			1476			1496			1517			1537			1558			1578
		1456			1476			1497			1517			1538			1558			1579

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : GSK MMR Lot 1

Trt.	Bl. No	nb
PPD	1579	
	1580	
	1580	
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Trt.	Bl. No	nb
PPD	1600	
	1600	
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	1604	
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Trt.	Bl. No	nb
PPD	1620	
	1621	
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	1625	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 2

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD	1		PPD	42		PPD	83		PPD	124		PPD	165		PPD	206		PPD	247	
	2			43			84			125			166			207			248	
	3			44			85			126			167			208			249	
	4			45			86			127			168			209			250	
	5			46			87			128			169			210			251	
	6			47			88			129			170			211			252	
	7			48			89			130			171			212			253	
	8			49			90			131			172			213			254	
	9			50			91			132			173			214			255	
	10			51			92			133			174			215			256	
	11			52			93			134			175			216			257	
	12			53			94			135			176			217			258	
	13			54			95			136			177			218			259	
	14			55			96			137			178			219			260	
	15			56			97			138			179			220			261	
	16			57			98			139			180			221			262	
	17			58			99			140			181			222			263	
	18			59			100			141			182			223			264	
	19			60			101			142			183			224			265	
	20			61			102			143			184			225			266	
	21			62			103			144			185			226			267	
	22			63			104			145			186			227			268	
	23			64			105			146			187			228			269	
	24			65			106			147			188			229			270	
	25			66			107			148			189			230			271	
	26			67			108			149			190			231			272	
	27			68			109			150			191			232			273	
	28			69			110			151			192			233			274	
	29			70			111			152			193			234			275	
	30			71			112			153			194			235			276	
	31			72			113			154			195			236			277	
	32			73			114			155			196			237			278	
	33			74			115			156			197			238			279	
	34			75			116			157			198			239			280	
	35			76			117			158			199			240			281	
	36			77			118			159			200			241			282	
	37			78			119			160			201			242			283	
	38			79			120			161			202			243			284	
	39			80			121			162			203			244			285	
	40			81			122			163			204			245			286	
	41			82			123			164			205			246			287	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		288	PPD		329	PPD		370	PPD		411	PPD		452	PPD		493	PPD		534
		289			330			371			412			453			494			535
		290			331			372			413			454			495			536
		291			332			373			414			455			496			537
		292			333			374			415			456			497			538
		293			334			375			416			457			498			539
		294			335			376			417			458			499			540
		295			336			377			418			459			500			541
		296			337			378			419			460			501			542
		297			338			379			420			461			502			543
		298			339			380			421			462			503			544
		299			340			381			422			463			504			545
		300			341			382			423			464			505			546
		301			342			383			424			465			506			547
		302			343			384			425			466			507			548
		303			344			385			426			467			508			549
		304			345			386			427			468			509			550
		305			346			387			428			469			510			551
		306			347			388			429			470			511			552
		307			348			389			430			471			512			553
		308			349			390			431			472			513			554
		309			350			391			432			473			514			555
		310			351			392			433			474			515			556
		311			352			393			434			475			516			557
		312			353			394			435			476			517			558
		313			354			395			436			477			518			559
		314			355			396			437			478			519			560
		315			356			397			438			479			520			561
		316			357			398			439			480			521			562
		317			358			399			440			481			522			563
		318			359			400			441			482			523			564
		319			360			401			442			483			524			565
		320			361			402			443			484			525			566
		321			362			403			444			485			526			567
		322			363			404			445			486			527			568
		323			364			405			446			487			528			569
		324			365			406			447			488			529			570
		325			366			407			448			489			530			571
		326			367			408			449			490			531			572
		327			368			409			450			491			532			573
		328			369			410			451			492			533			574

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		575	PPD		616	PPD		657	PPD		698	PPD		739	PPD		780	PPD		821
		576			617			658			699			740			781			822
		577			618			659			700			741			782			823
		578			619			660			701			742			783			824
		579			620			661			702			743			784			825
		580			621			662			703			744			785			826
		581			622			663			704			745			786			827
		582			623			664			705			746			787			828
		583			624			665			706			747			788			829
		584			625			666			707			748			789			830
		585			626			667			708			749			790			831
		586			627			668			709			750			791			832
		587			628			669			710			751			792			833
		588			629			670			711			752			793			834
		589			630			671			712			753			794			835
		590			631			672			713			754			795			836
		591			632			673			714			755			796			837
		592			633			674			715			756			797			838
		593			634			675			716			757			798			839
		594			635			676			717			758			799			840
		595			636			677			718			759			800			841
		596			637			678			719			760			801			842
		597			638			679			720			761			802			843
		598			639			680			721			762			803			844
		599			640			681			722			763			804			845
		600			641			682			723			764			805			846
		601			642			683			724			765			806			847
		602			643			684			725			766			807			848
		603			644			685			726			767			808			849
		604			645			686			727			768			809			850
		605			646			687			728			769			810			851
		606			647			688			729			770			811			852
		607			648			689			730			771			812			853
		608			649			690			731			772			813			854
		609			650			691			732			773			814			855
		610			651			692			733			774			815			856
		611			652			693			734			775			816			857
		612			653			694			735			776			817			858
		613			654			695			736			777			818			859
		614			655			696			737			778			819			860
		615			656			697			738			779			820			861

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 2

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		862	PPD		903	PPD		944	PPD		985	PPD		1026	PPD		1067	PPD		1108
		863			904			945			986			1027			1068			1109
		864			905			946			987			1028			1069			1110
		865			906			947			988			1029			1070			1111
		866			907			948			989			1030			1071			1112
		867			908			949			990			1031			1072			1113
		868			909			950			991			1032			1073			1114
		869			910			951			992			1033			1074			1115
		870			911			952			993			1034			1075			1116
		871			912			953			994			1035			1076			1117
		872			913			954			995			1036			1077			1118
		873			914			955			996			1037			1078			1119
		874			915			956			997			1038			1079			1120
		875			916			957			998			1039			1080			1121
		876			917			958			999			1040			1081			1122
		877			918			959			1000			1041			1082			1123
		878			919			960			1001			1042			1083			1124
		879			920			961			1002			1043			1084			1125
		880			921			962			1003			1044			1085			1126
		881			922			963			1004			1045			1086			1127
		882			923			964			1005			1046			1087			1128
		883			924			965			1006			1047			1088			1129
		884			925			966			1007			1048			1089			1130
		885			926			967			1008			1049			1090			1131
		886			927			968			1009			1050			1091			1132
		887			928			969			1010			1051			1092			1133
		888			929			970			1011			1052			1093			1134
		889			930			971			1012			1053			1094			1135
		890			931			972			1013			1054			1095			1136
		891			932			973			1014			1055			1096			1137
		892			933			974			1015			1056			1097			1138
		893			934			975			1016			1057			1098			1139
		894			935			976			1017			1058			1099			1140
		895			936			977			1018			1059			1100			1141
		896			937			978			1019			1060			1101			1142
		897			938			979			1020			1061			1102			1143
		898			939			980			1021			1062			1103			1144
		899			940			981			1022			1063			1104			1145
		900			941			982			1023			1064			1105			1146
		901			942			983			1024			1065			1106			1147
		902			943			984			1025			1066			1107			1148

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 2

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1149	PPD		1190	PPD		1231	PPD		1272	PPD		1313	PPD		1354	PPD		1395
		1150			1191			1232			1273			1314			1355			1396
		1151			1192			1233			1274			1315			1356			1397
		1152			1193			1234			1275			1316			1357			1398
		1153			1194			1235			1276			1317			1358			1399
		1154			1195			1236			1277			1318			1359			1400
		1155			1196			1237			1278			1319			1360			1401
		1156			1197			1238			1279			1320			1361			1402
		1157			1198			1239			1280			1321			1362			1403
		1158			1199			1240			1281			1322			1363			1404
		1159			1200			1241			1282			1323			1364			1405
		1160			1201			1242			1283			1324			1365			1406
		1161			1202			1243			1284			1325			1366			1407
		1162			1203			1244			1285			1326			1367			1408
		1163			1204			1245			1286			1327			1368			1409
		1164			1205			1246			1287			1328			1369			1410
		1165			1206			1247			1288			1329			1370			1411
		1166			1207			1248			1289			1330			1371			1412
		1167			1208			1249			1290			1331			1372			1413
		1168			1209			1250			1291			1332			1373			1414
		1169			1210			1251			1292			1333			1374			1415
		1170			1211			1252			1293			1334			1375			1416
		1171			1212			1253			1294			1335			1376			1417
		1172			1213			1254			1295			1336			1377			1418
		1173			1214			1255			1296			1337			1378			1419
		1174			1215			1256			1297			1338			1379			1420
		1175			1216			1257			1298			1339			1380			1421
		1176			1217			1258			1299			1340			1381			1422
		1177			1218			1259			1300			1341			1382			1423
		1178			1219			1260			1301			1342			1383			1424
		1179			1220			1261			1302			1343			1384			1425
		1180			1221			1262			1303			1344			1385			1426
		1181			1222			1263			1304			1345			1386			1427
		1182			1223			1264			1305			1346			1387			1428
		1183			1224			1265			1306			1347			1388			1429
		1184			1225			1266			1307			1348			1389			1430
		1185			1226			1267			1308			1349			1390			1431
		1186			1227			1268			1309			1350			1391			1432
		1187			1228			1269			1310			1351			1392			1433
		1188			1229			1270			1311			1352			1393			1434
		1189			1230			1271			1312			1353			1394			1435

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Merck MMR Lot 2

Trt.	Bl. No	nb
PPD		1436
		1437
		1438
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Trt.	Bl. No	nb
PPD		1477
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Trt.	Bl. No	nb
PPD		1518
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		1600
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		1626
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Trt.	Bl. No	nb
PPD		1667
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		1913	PPD		1954	PPD		1995	PPD		2036	PPD		2077	PPD		2118	PPD		2159
		1914			1955			1996			2037			2078			2119			2160
		1915			1956			1997			2038			2079			2120			2161
		1916			1957			1998			2039			2080			2121			2162
		1917			1958			1999			2040			2081			2122			2163
		1918			1959			2000			2041			2082			2123			2164
		1919			1960			2001			2042			2083			2124			2165
		1920			1961			2002			2043			2084			2125			2166
		1921			1962			2003			2044			2085			2126			2167
		1922			1963			2004			2045			2086			2127			2168
		1923			1964			2005			2046			2087			2128			2169
		1924			1965			2006			2047			2088			2129			2170
		1925			1966			2007			2048			2089			2130			2171
		1926			1967			2008			2049			2090			2131			2172
		1927			1968			2009			2050			2091			2132			2173
		1928			1969			2010			2051			2092			2133			2174
		1929			1970			2011			2052			2093			2134			2175
		1930			1971			2012			2053			2094			2135			2176
		1931			1972			2013			2054			2095			2136			2177
		1932			1973			2014			2055			2096			2137			2178
		1933			1974			2015			2056			2097			2138			2179
		1934			1975			2016			2057			2098			2139			2180
		1935			1976			2017			2058			2099			2140			2181
		1936			1977			2018			2059			2100			2141			2182
		1937			1978			2019			2060			2101			2142			2183
		1938			1979			2020			2061			2102			2143			2184
		1939			1980			2021			2062			2103			2144			2185
		1940			1981			2022			2063			2104			2145			2186
		1941			1982			2023			2064			2105			2146			2187
		1942			1983			2024			2065			2106			2147			2188
		1943			1984			2025			2066			2107			2148			2189
		1944			1985			2026			2067			2108			2149			2190
		1945			1986			2027			2068			2109			2150			2191
		1946			1987			2028			2069			2110			2151			2192
		1947			1988			2029			2070			2111			2152			2193
		1948			1989			2030			2071			2112			2153			2194
		1949			1990			2031			2072			2113			2154			2195
		1950			1991			2032			2073			2114			2155			2196
		1951			1992			2033			2074			2115			2156			2197
		1952			1993			2034			2075			2116			2157			2198
		1953			1994			2035			2076			2117			2158			2199

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		2200	PPD		2241	PPD		2282	PPD		2323	PPD		2364	PPD		2405	PPD		2446
		2201			2242			2283			2324			2365			2406			2447
		2202			2243			2284			2325			2366			2407			2448
		2203			2244			2285			2326			2367			2408			2449
		2204			2245			2286			2327			2368			2409			2450
		2205			2246			2287			2328			2369			2410			2451
		2206			2247			2288			2329			2370			2411			2452
		2207			2248			2289			2330			2371			2412			2453
		2208			2249			2290			2331			2372			2413			2454
		2209			2250			2291			2332			2373			2414			2455
		2210			2251			2292			2333			2374			2415			2456
		2211			2252			2293			2334			2375			2416			2457
		2212			2253			2294			2335			2376			2417			2458
		2213			2254			2295			2336			2377			2418			2459
		2214			2255			2296			2337			2378			2419			2460
		2215			2256			2297			2338			2379			2420			2461
		2216			2257			2298			2339			2380			2421			2462
		2217			2258			2299			2340			2381			2422			2463
		2218			2259			2300			2341			2382			2423			2464
		2219			2260			2301			2342			2383			2424			2465
		2220			2261			2302			2343			2384			2425			2466
		2221			2262			2303			2344			2385			2426			2467
		2222			2263			2304			2345			2386			2427			2468
		2223			2264			2305			2346			2387			2428			2469
		2224			2265			2306			2347			2388			2429			2470
		2225			2266			2307			2348			2389			2430			2471
		2226			2267			2308			2349			2390			2431			2472
		2227			2268			2309			2350			2391			2432			2473
		2228			2269			2310			2351			2392			2433			2474
		2229			2270			2311			2352			2393			2434			2475
		2230			2271			2312			2353			2394			2435			2476
		2231			2272			2313			2354			2395			2436			2477
		2232			2273			2314			2355			2396			2437			2478
		2233			2274			2315			2356			2397			2438			2479
		2234			2275			2316			2357			2398			2439			2480
		2235			2276			2317			2358			2399			2440			2481
		2236			2277			2318			2359			2400			2441			2482
		2237			2278			2319			2360			2401			2442			2483
		2238			2279			2320			2361			2402			2443			2484
		2239			2280			2321			2362			2403			2444			2485
		2240			2281			2322			2363			2404			2445			2486

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		2487	PPD		2528	PPD		2569	PPD		2610	PPD		2651	PPD		2692	PPD		2733
		2488			2529			2570			2611			2652			2693			2734
		2489			2530			2571			2612			2653			2694			2735
		2490			2531			2572			2613			2654			2695			2736
		2491			2532			2573			2614			2655			2696			2737
		2492			2533			2574			2615			2656			2697			2738
		2493			2534			2575			2616			2657			2698			2739
		2494			2535			2576			2617			2658			2699			2740
		2495			2536			2577			2618			2659			2700			2741
		2496			2537			2578			2619			2660			2701			2742
		2497			2538			2579			2620			2661			2702			2743
		2498			2539			2580			2621			2662			2703			2744
		2499			2540			2581			2622			2663			2704			2745
		2500			2541			2582			2623			2664			2705			2746
		2501			2542			2583			2624			2665			2706			2747
		2502			2543			2584			2625			2666			2707			2748
		2503			2544			2585			2626			2667			2708			2749
		2504			2545			2586			2627			2668			2709			2750
		2505			2546			2587			2628			2669			2710			2751
		2506			2547			2588			2629			2670			2711			2752
		2507			2548			2589			2630			2671			2712			2753
		2508			2549			2590			2631			2672			2713			2754
		2509			2550			2591			2632			2673			2714			2755
		2510			2551			2592			2633			2674			2715			2756
		2511			2552			2593			2634			2675			2716			2757
		2512			2553			2594			2635			2676			2717			2758
		2513			2554			2595			2636			2677			2718			2759
		2514			2555			2596			2637			2678			2719			2760
		2515			2556			2597			2638			2679			2720			2761
		2516			2557			2598			2639			2680			2721			2762
		2517			2558			2599			2640			2681			2722			2763
		2518			2559			2600			2641			2682			2723			2764
		2519			2560			2601			2642			2683			2724			2765
		2520			2561			2602			2643			2684			2725			2766
		2521			2562			2603			2644			2685			2726			2767
		2522			2563			2604			2645			2686			2727			2768
		2523			2564			2605			2646			2687			2728			2769
		2524			2565			2606			2647			2688			2729			2770
		2525			2566			2607			2648			2689			2730			2771
		2526			2567			2608			2649			2690			2731			2772
		2527			2568			2609			2650			2691			2732			2773

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		2774
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Trt.	Bl. No	nb
PPD		2815
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Trt.	Bl. No	nb
PPD		2856
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Trt.	Bl. No	nb
PPD		2897
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Trt.	Bl. No	nb
PPD		2938
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Trt.	Bl. No	nb
PPD		2979
		2980
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Trt.	Bl. No	nb
PPD		3020
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		3061	PPD		3102	PPD		3143	PPD		3184	PPD		3225	PPD		3266	PPD		3307
		3062			3103			3144			3185			3226			3267			3308
		3063			3104			3145			3186			3227			3268			3309
		3064			3105			3146			3187			3228			3269			3310
		3065			3106			3147			3188			3229			3270			3311
		3066			3107			3148			3189			3230			3271			3312
		3067			3108			3149			3190			3231			3272			3313
		3068			3109			3150			3191			3232			3273			3314
		3069			3110			3151			3192			3233			3274			3315
		3070			3111			3152			3193			3234			3275			3316
		3071			3112			3153			3194			3235			3276			3317
		3072			3113			3154			3195			3236			3277			3318
		3073			3114			3155			3196			3237			3278			3319
		3074			3115			3156			3197			3238			3279			3320
		3075			3116			3157			3198			3239			3280			3321
		3076			3117			3158			3199			3240			3281			3322
		3077			3118			3159			3200			3241			3282			3323
		3078			3119			3160			3201			3242			3283			3324
		3079			3120			3161			3202			3243			3284			3325
		3080			3121			3162			3203			3244			3285			3326
		3081			3122			3163			3204			3245			3286			3327
		3082			3123			3164			3205			3246			3287			3328
		3083			3124			3165			3206			3247			3288			3329
		3084			3125			3166			3207			3248			3289			3330
		3085			3126			3167			3208			3249			3290			3331
		3086			3127			3168			3209			3250			3291			3332
		3087			3128			3169			3210			3251			3292			3333
		3088			3129			3170			3211			3252			3293			3334
		3089			3130			3171			3212			3253			3294			3335
		3090			3131			3172			3213			3254			3295			3336
		3091			3132			3173			3214			3255			3296			3337
		3092			3133			3174			3215			3256			3297			3338
		3093			3134			3175			3216			3257			3298			3339
		3094			3135			3176			3217			3258			3299			3340
		3095			3136			3177			3218			3259			3300			3341
		3096			3137			3178			3219			3260			3301			3342
		3097			3138			3179			3220			3261			3302			3343
		3098			3139			3180			3221			3262			3303			3344
		3099			3140			3181			3222			3263			3304			3345
		3100			3141			3182			3223			3264			3305			3346
		3101			3142			3183			3224			3265			3306			3347

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		3348	PPD		3389	PPD		3430	PPD		3471	PPD		3512	PPD		3553	PPD		3594
		3349			3390			3431			3472			3513			3554			3595
		3350			3391			3432			3473			3514			3555			3596
		3351			3392			3433			3474			3515			3556			3597
		3352			3393			3434			3475			3516			3557			3598
		3353			3394			3435			3476			3517			3558			3599
		3354			3395			3436			3477			3518			3559			3600
		3355			3396			3437			3478			3519			3560			3601
		3356			3397			3438			3479			3520			3561			3602
		3357			3398			3439			3480			3521			3562			3603
		3358			3399			3440			3481			3522			3563			3604
		3359			3400			3441			3482			3523			3564			3605
		3360			3401			3442			3483			3524			3565			3606
		3361			3402			3443			3484			3525			3566			3607
		3362			3403			3444			3485			3526			3567			3608
		3363			3404			3445			3486			3527			3568			3609
		3364			3405			3446			3487			3528			3569			3610
		3365			3406			3447			3488			3529			3570			3611
		3366			3407			3448			3489			3530			3571			3612
		3367			3408			3449			3490			3531			3572			3613
		3368			3409			3450			3491			3532			3573			3614
		3369			3410			3451			3492			3533			3574			3615
		3370			3411			3452			3493			3534			3575			3616
		3371			3412			3453			3494			3535			3576			3617
		3372			3413			3454			3495			3536			3577			3618
		3373			3414			3455			3496			3537			3578			3619
		3374			3415			3456			3497			3538			3579			3620
		3375			3416			3457			3498			3539			3580			3621
		3376			3417			3458			3499			3540			3581			3622
		3377			3418			3459			3500			3541			3582			3623
		3378			3419			3460			3501			3542			3583			3624
		3379			3420			3461			3502			3543			3584			3625
		3380			3421			3462			3503			3544			3585			3626
		3381			3422			3463			3504			3545			3586			3627
		3382			3423			3464			3505			3546			3587			3628
		3383			3424			3465			3506			3547			3588			3629
		3384			3425			3466			3507			3548			3589			3630
		3385			3426			3467			3508			3549			3590			3631
		3386			3427			3468			3509			3550			3591			3632
		3387			3428			3469			3510			3551			3592			3633
		3388			3429			3470			3511			3552			3593			3634

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		3635
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Trt.	Bl. No	nb
PPD		3676
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Trt.	Bl. No	nb
PPD		3717
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Trt.	Bl. No	nb
PPD		3758
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Trt.	Bl. No	nb
PPD		3799
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Trt.	Bl. No	nb
PPD		3840
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Trt.	Bl. No	nb
PPD		3881
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		3922	PPD		3963	PPD		4004	PPD		4045	PPD		4086	PPD		4127	PPD		4168
		3923			3964			4005			4046			4087			4128			4169
		3924			3965			4006			4047			4088			4129			4170
		3925			3966			4007			4048			4089			4130			4171
		3926			3967			4008			4049			4090			4131			4172
		3927			3968			4009			4050			4091			4132			4173
		3928			3969			4010			4051			4092			4133			4174
		3929			3970			4011			4052			4093			4134			4175
		3930			3971			4012			4053			4094			4135			4176
		3931			3972			4013			4054			4095			4136			4177
		3932			3973			4014			4055			4096			4137			4178
		3933			3974			4015			4056			4097			4138			4179
		3934			3975			4016			4057			4098			4139			4180
		3935			3976			4017			4058			4099			4140			4181
		3936			3977			4018			4059			4100			4141			4182
		3937			3978			4019			4060			4101			4142			4183
		3938			3979			4020			4061			4102			4143			4184
		3939			3980			4021			4062			4103			4144			4185
		3940			3981			4022			4063			4104			4145			4186
		3941			3982			4023			4064			4105			4146			4187
		3942			3983			4024			4065			4106			4147			4188
		3943			3984			4025			4066			4107			4148			4189
		3944			3985			4026			4067			4108			4149			4190
		3945			3986			4027			4068			4109			4150			4191
		3946			3987			4028			4069			4110			4151			4192
		3947			3988			4029			4070			4111			4152			4193
		3948			3989			4030			4071			4112			4153			4194
		3949			3990			4031			4072			4113			4154			4195
		3950			3991			4032			4073			4114			4155			4196
		3951			3992			4033			4074			4115			4156			4197
		3952			3993			4034			4075			4116			4157			4198
		3953			3994			4035			4076			4117			4158			4199
		3954			3995			4036			4077			4118			4159			4200
		3955			3996			4037			4078			4119			4160			4201
		3956			3997			4038			4079			4120			4161			4202
		3957			3998			4039			4080			4121			4162			4203
		3958			3999			4040			4081			4122			4163			4204
		3959			4000			4041			4082			4123			4164			4205
		3960			4001			4042			4083			4124			4165			4206
		3961			4002			4043			4084			4125			4166			4207
		3962			4003			4044			4085			4126			4167			4208

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		4209
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Trt.	Bl. No	nb
PPD		4250
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Trt.	Bl. No	nb
PPD		4291
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Trt.	Bl. No	nb
PPD		4332
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Trt.	Bl. No	nb
PPD		4373
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Trt.	Bl. No	nb
PPD		4414
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Trt.	Bl. No	nb
PPD		4455
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		4496	PPD		4537	PPD		4578	PPD		4619	PPD		4660	PPD		4701	PPD		4742
		4497			4538			4579			4620			4661			4702			4743
		4498			4539			4580			4621			4662			4703			4744
		4499			4540			4581			4622			4663			4704			4745
		4500			4541			4582			4623			4664			4705			4746
		4501			4542			4583			4624			4665			4706			4747
		4502			4543			4584			4625			4666			4707			4748
		4503			4544			4585			4626			4667			4708			4749
		4504			4545			4586			4627			4668			4709			4750
		4505			4546			4587			4628			4669			4710			4751
		4506			4547			4588			4629			4670			4711			4752
		4507			4548			4589			4630			4671			4712			4753
		4508			4549			4590			4631			4672			4713			4754
		4509			4550			4591			4632			4673			4714			4755
		4510			4551			4592			4633			4674			4715			4756
		4511			4552			4593			4634			4675			4716			4757
		4512			4553			4594			4635			4676			4717			4758
		4513			4554			4595			4636			4677			4718			4759
		4514			4555			4596			4637			4678			4719			4760
		4515			4556			4597			4638			4679			4720			4761
		4516			4557			4598			4639			4680			4721			4762
		4517			4558			4599			4640			4681			4722			4763
		4518			4559			4600			4641			4682			4723			4764
		4519			4560			4601			4642			4683			4724			4765
		4520			4561			4602			4643			4684			4725			4766
		4521			4562			4603			4644			4685			4726			4767
		4522			4563			4604			4645			4686			4727			4768
		4523			4564			4605			4646			4687			4728			4769
		4524			4565			4606			4647			4688			4729			4770
		4525			4566			4607			4648			4689			4730			4771
		4526			4567			4608			4649			4690			4731			4772
		4527			4568			4609			4650			4691			4732			4773
		4528			4569			4610			4651			4692			4733			4774
		4529			4570			4611			4652			4693			4734			4775
		4530			4571			4612			4653			4694			4735			4776
		4531			4572			4613			4654			4695			4736			4777
		4532			4573			4614			4655			4696			4737			4778
		4533			4574			4615			4656			4697			4738			4779
		4534			4575			4616			4657			4698			4739			4780
		4535			4576			4617			4658			4699			4740			4781
		4536			4577			4618			4659			4700			4741			4782

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		4783	PPD		4824	PPD		4865	PPD		4906	PPD		4947	PPD		4988	PPD		5029
		4784			4825			4866			4907			4948			4989			5030
		4785			4826			4867			4908			4949			4990			5031
		4786			4827			4868			4909			4950			4991			5032
		4787			4828			4869			4910			4951			4992			5033
		4788			4829			4870			4911			4952			4993			5034
		4789			4830			4871			4912			4953			4994			5035
		4790			4831			4872			4913			4954			4995			5036
		4791			4832			4873			4914			4955			4996			5037
		4792			4833			4874			4915			4956			4997			5038
		4793			4834			4875			4916			4957			4998			5039
		4794			4835			4876			4917			4958			4999			5040
		4795			4836			4877			4918			4959			5000			5041
		4796			4837			4878			4919			4960			5001			5042
		4797			4838			4879			4920			4961			5002			5043
		4798			4839			4880			4921			4962			5003			5044
		4799			4840			4881			4922			4963			5004			5045
		4800			4841			4882			4923			4964			5005			5046
		4801			4842			4883			4924			4965			5006			5047
		4802			4843			4884			4925			4966			5007			5048
		4803			4844			4885			4926			4967			5008			5049
		4804			4845			4886			4927			4968			5009			5050
		4805			4846			4887			4928			4969			5010			5051
		4806			4847			4888			4929			4970			5011			5052
		4807			4848			4889			4930			4971			5012			5053
		4808			4849			4890			4931			4972			5013			5054
		4809			4850			4891			4932			4973			5014			5055
		4810			4851			4892			4933			4974			5015			5056
		4811			4852			4893			4934			4975			5016			5057
		4812			4853			4894			4935			4976			5017			5058
		4813			4854			4895			4936			4977			5018			5059
		4814			4855			4896			4937			4978			5019			5060
		4815			4856			4897			4938			4979			5020			5061
		4816			4857			4898			4939			4980			5021			5062
		4817			4858			4899			4940			4981			5022			5063
		4818			4859			4900			4941			4982			5023			5064
		4819			4860			4901			4942			4983			5024			5065
		4820			4861			4902			4943			4984			5025			5066
		4821			4862			4903			4944			4985			5026			5067
		4822			4863			4904			4945			4986			5027			5068
		4823			4864			4905			4946			4987			5028			5069

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD	5070	
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Trt.	Bl. No	nb
PPD	5111	
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Trt.	Bl. No	nb
PPD	5152	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	5275	
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Trt.	Bl. No	nb
PPD	5316	
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		5357
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Trt.	Bl. No	nb
PPD		5398
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Trt.	Bl. No	nb
PPD		5439
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Trt.	Bl. No	nb
PPD		5480
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Trt.	Bl. No	nb
PPD		5521
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Trt.	Bl. No	nb
PPD		5562
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Trt.	Bl. No	nb
PPD		5603
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		5644	PPD		5685	PPD		5726	PPD		5767	PPD		5808	PPD		5849	PPD		5890
		5645			5686			5727			5768			5809			5850			5891
		5646			5687			5728			5769			5810			5851			5892
		5647			5688			5729			5770			5811			5852			5893
		5648			5689			5730			5771			5812			5853			5894
		5649			5690			5731			5772			5813			5854			5895
		5650			5691			5732			5773			5814			5855			5896
		5651			5692			5733			5774			5815			5856			5897
		5652			5693			5734			5775			5816			5857			5898
		5653			5694			5735			5776			5817			5858			5899
		5654			5695			5736			5777			5818			5859			5900
		5655			5696			5737			5778			5819			5860			5901
		5656			5697			5738			5779			5820			5861			5902
		5657			5698			5739			5780			5821			5862			5903
		5658			5699			5740			5781			5822			5863			5904
		5659			5700			5741			5782			5823			5864			5905
		5660			5701			5742			5783			5824			5865			5906
		5661			5702			5743			5784			5825			5866			5907
		5662			5703			5744			5785			5826			5867			5908
		5663			5704			5745			5786			5827			5868			5909
		5664			5705			5746			5787			5828			5869			5910
		5665			5706			5747			5788			5829			5870			5911
		5666			5707			5748			5789			5830			5871			5912
		5667			5708			5749			5790			5831			5872			5913
		5668			5709			5750			5791			5832			5873			5914
		5669			5710			5751			5792			5833			5874			5915
		5670			5711			5752			5793			5834			5875			5916
		5671			5712			5753			5794			5835			5876			5917
		5672			5713			5754			5795			5836			5877			5918
		5673			5714			5755			5796			5837			5878			5919
		5674			5715			5756			5797			5838			5879			5920
		5675			5716			5757			5798			5839			5880			5921
		5676			5717			5758			5799			5840			5881			5922
		5677			5718			5759			5800			5841			5882			5923
		5678			5719			5760			5801			5842			5883			5924
		5679			5720			5761			5802			5843			5884			5925
		5680			5721			5762			5803			5844			5885			5926
		5681			5722			5763			5804			5845			5886			5927
		5682			5723			5764			5805			5846			5887			5928
		5683			5724			5765			5806			5847			5888			5929
		5684			5725			5766			5807			5848			5889			5930

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		5931	PPD		5972	PPD		6013	PPD		6054	PPD		6095	PPD		6136	PPD		6177
		5932			5973			6014			6055			6096			6137			6178
		5933			5974			6015			6056			6097			6138			6179
		5934			5975			6016			6057			6098			6139			6180
		5935			5976			6017			6058			6099			6140			6181
		5936			5977			6018			6059			6100			6141			6182
		5937			5978			6019			6060			6101			6142			6183
		5938			5979			6020			6061			6102			6143			6184
		5939			5980			6021			6062			6103			6144			6185
		5940			5981			6022			6063			6104			6145			6186
		5941			5982			6023			6064			6105			6146			6187
		5942			5983			6024			6065			6106			6147			6188
		5943			5984			6025			6066			6107			6148			6189
		5944			5985			6026			6067			6108			6149			6190
		5945			5986			6027			6068			6109			6150			6191
		5946			5987			6028			6069			6110			6151			6192
		5947			5988			6029			6070			6111			6152			6193
		5948			5989			6030			6071			6112			6153			6194
		5949			5990			6031			6072			6113			6154			6195
		5950			5991			6032			6073			6114			6155			6196
		5951			5992			6033			6074			6115			6156			6197
		5952			5993			6034			6075			6116			6157			6198
		5953			5994			6035			6076			6117			6158			6199
		5954			5995			6036			6077			6118			6159			6200
		5955			5996			6037			6078			6119			6160			6201
		5956			5997			6038			6079			6120			6161			6202
		5957			5998			6039			6080			6121			6162			6203
		5958			5999			6040			6081			6122			6163			6204
		5959			6000			6041			6082			6123			6164			6205
		5960			6001			6042			6083			6124			6165			6206
		5961			6002			6043			6084			6125			6166			6207
		5962			6003			6044			6085			6126			6167			6208
		5963			6004			6045			6086			6127			6168			6209
		5964			6005			6046			6087			6128			6169			6210
		5965			6006			6047			6088			6129			6170			6211
		5966			6007			6048			6089			6130			6171			6212
		5967			6008			6049			6090			6131			6172			6213
		5968			6009			6050			6091			6132			6173			6214
		5969			6010			6051			6092			6133			6174			6215
		5970			6011			6052			6093			6134			6175			6216
		5971			6012			6053			6094			6135			6176			6217

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		6218
		6219
		6220
		6221
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		6256
		6257
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Trt.	Bl. No	nb
PPD		6259
		6260
		6261
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		6263
		6264
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		6297
		6298
		6299

Trt.	Bl. No	nb
PPD		6300
		6301
		6302
		6303
		6304
		6305
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		6338
		6339
		6340

Trt.	Bl. No	nb
PPD		6341
		6342
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		6378
		6379
		6380
		6381

Trt.	Bl. No	nb
PPD		6382
		6383
		6384
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		6422

Trt.	Bl. No	nb
PPD		6423
		6424
		6425
		6426
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		6463

Trt.	Bl. No	nb
PPD		6464
		6465
		6466
		6467
		6468
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		6500
		6501
		6502
		6503
		6504

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		6505	PPD		6546	PPD		6587	PPD		6628	PPD		6669	PPD		6710	PPD		6751
		6506			6547			6588			6629			6670			6711			6752
		6507			6548			6589			6630			6671			6712			6753
		6508			6549			6590			6631			6672			6713			6754
		6509			6550			6591			6632			6673			6714			6755
		6510			6551			6592			6633			6674			6715			6756
		6511			6552			6593			6634			6675			6716			6757
		6512			6553			6594			6635			6676			6717			6758
		6513			6554			6595			6636			6677			6718			6759
		6514			6555			6596			6637			6678			6719			6760
		6515			6556			6597			6638			6679			6720			6761
		6516			6557			6598			6639			6680			6721			6762
		6517			6558			6599			6640			6681			6722			6763
		6518			6559			6600			6641			6682			6723			6764
		6519			6560			6601			6642			6683			6724			6765
		6520			6561			6602			6643			6684			6725			6766
		6521			6562			6603			6644			6685			6726			6767
		6522			6563			6604			6645			6686			6727			6768
		6523			6564			6605			6646			6687			6728			6769
		6524			6565			6606			6647			6688			6729			6770
		6525			6566			6607			6648			6689			6730			6771
		6526			6567			6608			6649			6690			6731			6772
		6527			6568			6609			6650			6691			6732			6773
		6528			6569			6610			6651			6692			6733			6774
		6529			6570			6611			6652			6693			6734			6775
		6530			6571			6612			6653			6694			6735			6776
		6531			6572			6613			6654			6695			6736			6777
		6532			6573			6614			6655			6696			6737			6778
		6533			6574			6615			6656			6697			6738			6779
		6534			6575			6616			6657			6698			6739			6780
		6535			6576			6617			6658			6699			6740			6781
		6536			6577			6618			6659			6700			6741			6782
		6537			6578			6619			6660			6701			6742			6783
		6538			6579			6620			6661			6702			6743			6784
		6539			6580			6621			6662			6703			6744			6785
		6540			6581			6622			6663			6704			6745			6786
		6541			6582			6623			6664			6705			6746			6787
		6542			6583			6624			6665			6706			6747			6788
		6543			6584			6625			6666			6707			6748			6789
		6544			6585			6626			6667			6708			6749			6790
		6545			6586			6627			6668			6709			6750			6791

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		6792	PPD		6833	PPD		6874	PPD		6915	PPD		6956	PPD		6997	PPD		7038
		6793			6834			6875			6916			6957			6998			7039
		6794			6835			6876			6917			6958			6999			7040
		6795			6836			6877			6918			6959			7000			7041
		6796			6837			6878			6919			6960			7001			7042
		6797			6838			6879			6920			6961			7002			7043
		6798			6839			6880			6921			6962			7003			7044
		6799			6840			6881			6922			6963			7004			7045
		6800			6841			6882			6923			6964			7005			7046
		6801			6842			6883			6924			6965			7006			7047
		6802			6843			6884			6925			6966			7007			7048
		6803			6844			6885			6926			6967			7008			7049
		6804			6845			6886			6927			6968			7009			7050
		6805			6846			6887			6928			6969			7010			7051
		6806			6847			6888			6929			6970			7011			7052
		6807			6848			6889			6930			6971			7012			7053
		6808			6849			6890			6931			6972			7013			7054
		6809			6850			6891			6932			6973			7014			7055
		6810			6851			6892			6933			6974			7015			7056
		6811			6852			6893			6934			6975			7016			7057
		6812			6853			6894			6935			6976			7017			7058
		6813			6854			6895			6936			6977			7018			7059
		6814			6855			6896			6937			6978			7019			7060
		6815			6856			6897			6938			6979			7020			7061
		6816			6857			6898			6939			6980			7021			7062
		6817			6858			6899			6940			6981			7022			7063
		6818			6859			6900			6941			6982			7023			7064
		6819			6860			6901			6942			6983			7024			7065
		6820			6861			6902			6943			6984			7025			7066
		6821			6862			6903			6944			6985			7026			7067
		6822			6863			6904			6945			6986			7027			7068
		6823			6864			6905			6946			6987			7028			7069
		6824			6865			6906			6947			6988			7029			7070
		6825			6866			6907			6948			6989			7030			7071
		6826			6867			6908			6949			6990			7031			7072
		6827			6868			6909			6950			6991			7032			7073
		6828			6869			6910			6951			6992			7033			7074
		6829			6870			6911			6952			6993			7034			7075
		6830			6871			6912			6953			6994			7035			7076
		6831			6872			6913			6954			6995			7036			7077
		6832			6873			6914			6955			6996			7037			7078

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		7079	PPD		7120	PPD		7161	PPD		7202	PPD		7243	PPD		7284	PPD		7325
		7080			7121			7162			7203			7244			7285			7326
		7081			7122			7163			7204			7245			7286			7327
		7082			7123			7164			7205			7246			7287			7328
		7083			7124			7165			7206			7247			7288			7329
		7084			7125			7166			7207			7248			7289			7330
		7085			7126			7167			7208			7249			7290			7331
		7086			7127			7168			7209			7250			7291			7332
		7087			7128			7169			7210			7251			7292			7333
		7088			7129			7170			7211			7252			7293			7334
		7089			7130			7171			7212			7253			7294			7335
		7090			7131			7172			7213			7254			7295			7336
		7091			7132			7173			7214			7255			7296			7337
		7092			7133			7174			7215			7256			7297			7338
		7093			7134			7175			7216			7257			7298			7339
		7094			7135			7176			7217			7258			7299			7340
		7095			7136			7177			7218			7259			7300			7341
		7096			7137			7178			7219			7260			7301			7342
		7097			7138			7179			7220			7261			7302			7343
		7098			7139			7180			7221			7262			7303			7344
		7099			7140			7181			7222			7263			7304			7345
		7100			7141			7182			7223			7264			7305			7346
		7101			7142			7183			7224			7265			7306			7347
		7102			7143			7184			7225			7266			7307			7348
		7103			7144			7185			7226			7267			7308			7349
		7104			7145			7186			7227			7268			7309			7350
		7105			7146			7187			7228			7269			7310			7351
		7106			7147			7188			7229			7270			7311			7352
		7107			7148			7189			7230			7271			7312			7353
		7108			7149			7190			7231			7272			7313			7354
		7109			7150			7191			7232			7273			7314			7355
		7110			7151			7192			7233			7274			7315			7356
		7111			7152			7193			7234			7275			7316			7357
		7112			7153			7194			7235			7276			7317			7358
		7113			7154			7195			7236			7277			7318			7359
		7114			7155			7196			7237			7278			7319			7360
		7115			7156			7197			7238			7279			7320			7361
		7116			7157			7198			7239			7280			7321			7362
		7117			7158			7199			7240			7281			7322			7363
		7118			7159			7200			7241			7282			7323			7364
		7119			7160			7201			7242			7283			7324			7365

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		7366	PPD		7407	PPD		7448	PPD		7489	PPD		7530	PPD		7571	PPD		7612
		7367			7408			7449			7490			7531			7572			7613
		7368			7409			7450			7491			7532			7573			7614
		7369			7410			7451			7492			7533			7574			7615
		7370			7411			7452			7493			7534			7575			7616
		7371			7412			7453			7494			7535			7576			7617
		7372			7413			7454			7495			7536			7577			7618
		7373			7414			7455			7496			7537			7578			7619
		7374			7415			7456			7497			7538			7579			7620
		7375			7416			7457			7498			7539			7580			7621
		7376			7417			7458			7499			7540			7581			7622
		7377			7418			7459			7500			7541			7582			7623
		7378			7419			7460			7501			7542			7583			7624
		7379			7420			7461			7502			7543			7584			7625
		7380			7421			7462			7503			7544			7585			7626
		7381			7422			7463			7504			7545			7586			7627
		7382			7423			7464			7505			7546			7587			7628
		7383			7424			7465			7506			7547			7588			7629
		7384			7425			7466			7507			7548			7589			7630
		7385			7426			7467			7508			7549			7590			7631
		7386			7427			7468			7509			7550			7591			7632
		7387			7428			7469			7510			7551			7592			7633
		7388			7429			7470			7511			7552			7593			7634
		7389			7430			7471			7512			7553			7594			7635
		7390			7431			7472			7513			7554			7595			7636
		7391			7432			7473			7514			7555			7596			7637
		7392			7433			7474			7515			7556			7597			7638
		7393			7434			7475			7516			7557			7598			7639
		7394			7435			7476			7517			7558			7599			7640
		7395			7436			7477			7518			7559			7600			7641
		7396			7437			7478			7519			7560			7601			7642
		7397			7438			7479			7520			7561			7602			7643
		7398			7439			7480			7521			7562			7603			7644
		7399			7440			7481			7522			7563			7604			7645
		7400			7441			7482			7523			7564			7605			7646
		7401			7442			7483			7524			7565			7606			7647
		7402			7443			7484			7525			7566			7607			7648
		7403			7444			7485			7526			7567			7608			7649
		7404			7445			7486			7527			7568			7609			7650
		7405			7446			7487			7528			7569			7610			7651
		7406			7447			7488			7529			7570			7611			7652

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		7653	PPD		7694	PPD		7735	PPD		7776	PPD		7817	PPD		7858	PPD		7899
		7654			7695			7736			7777			7818			7859			7900
		7655			7696			7737			7778			7819			7860			7901
		7656			7697			7738			7779			7820			7861			7902
		7657			7698			7739			7780			7821			7862			7903
		7658			7699			7740			7781			7822			7863			7904
		7659			7700			7741			7782			7823			7864			7905
		7660			7701			7742			7783			7824			7865			7906
		7661			7702			7743			7784			7825			7866			7907
		7662			7703			7744			7785			7826			7867			7908
		7663			7704			7745			7786			7827			7868			7909
		7664			7705			7746			7787			7828			7869			7910
		7665			7706			7747			7788			7829			7870			7911
		7666			7707			7748			7789			7830			7871			7912
		7667			7708			7749			7790			7831			7872			7913
		7668			7709			7750			7791			7832			7873			7914
		7669			7710			7751			7792			7833			7874			7915
		7670			7711			7752			7793			7834			7875			7916
		7671			7712			7753			7794			7835			7876			7917
		7672			7713			7754			7795			7836			7877			7918
		7673			7714			7755			7796			7837			7878			7919
		7674			7715			7756			7797			7838			7879			7920
		7675			7716			7757			7798			7839			7880			7921
		7676			7717			7758			7799			7840			7881			7922
		7677			7718			7759			7800			7841			7882			7923
		7678			7719			7760			7801			7842			7883			7924
		7679			7720			7761			7802			7843			7884			7925
		7680			7721			7762			7803			7844			7885			7926
		7681			7722			7763			7804			7845			7886			7927
		7682			7723			7764			7805			7846			7887			7928
		7683			7724			7765			7806			7847			7888			7929
		7684			7725			7766			7807			7848			7889			7930
		7685			7726			7767			7808			7849			7890			7931
		7686			7727			7768			7809			7850			7891			7932
		7687			7728			7769			7810			7851			7892			7933
		7688			7729			7770			7811			7852			7893			7934
		7689			7730			7771			7812			7853			7894			7935
		7690			7731			7772			7813			7854			7895			7936
		7691			7732			7773			7814			7855			7896			7937
		7692			7733			7774			7815			7856			7897			7938
		7693			7734			7775			7816			7857			7898			7939

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	7940		PPD	7981		PPD	8022		PPD	8063		PPD	8104		PPD	8145		PPD	8186	
	7941			7982			8023			8064			8105			8146			8187	
	7942			7983			8024			8065			8106			8147			8188	
	7943			7984			8025			8066			8107			8148			8189	
	7944			7985			8026			8067			8108			8149			8190	
	7945			7986			8027			8068			8109			8150			8191	
	7946			7987			8028			8069			8110			8151			8192	
	7947			7988			8029			8070			8111			8152			8193	
	7948			7989			8030			8071			8112			8153			8194	
	7949			7990			8031			8072			8113			8154			8195	
	7950			7991			8032			8073			8114			8155			8196	
	7951			7992			8033			8074			8115			8156			8197	
	7952			7993			8034			8075			8116			8157			8198	
	7953			7994			8035			8076			8117			8158			8199	
	7954			7995			8036			8077			8118			8159			8200	
	7955			7996			8037			8078			8119			8160			8201	
	7956			7997			8038			8079			8120			8161			8202	
	7957			7998			8039			8080			8121			8162			8203	
	7958			7999			8040			8081			8122			8163			8204	
	7959			8000			8041			8082			8123			8164			8205	
	7960			8001			8042			8083			8124			8165			8206	
	7961			8002			8043			8084			8125			8166			8207	
	7962			8003			8044			8085			8126			8167			8208	
	7963			8004			8045			8086			8127			8168			8209	
	7964			8005			8046			8087			8128			8169			8210	
	7965			8006			8047			8088			8129			8170			8211	
	7966			8007			8048			8089			8130			8171			8212	
	7967			8008			8049			8090			8131			8172			8213	
	7968			8009			8050			8091			8132			8173			8214	
	7969			8010			8051			8092			8133			8174			8215	
	7970			8011			8052			8093			8134			8175			8216	
	7971			8012			8053			8094			8135			8176			8217	
	7972			8013			8054			8095			8136			8177			8218	
	7973			8014			8055			8096			8137			8178			8219	
	7974			8015			8056			8097			8138			8179			8220	
	7975			8016			8057			8098			8139			8180			8221	
	7976			8017			8058			8099			8140			8181			8222	
	7977			8018			8059			8100			8141			8182			8223	
	7978			8019			8060			8101			8142			8183			8224	
	7979			8020			8061			8102			8143			8184			8225	
	7980			8021			8062			8103			8144			8185			8226	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		8227
		8228
		8229
		8230
		8231
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		8260
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		8264
		8265
		8266
		8267

Trt.	Bl. No	nb
PPD		8268
		8269
		8270
		8271
		8272
		8273
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		8299
		8300
		8301
		8302
		8303
		8304
		8305
		8306
		8307
		8308

Trt.	Bl. No	nb
PPD		8309
		8310
		8311
		8312
		8313
		8314
		8315
		8316
		8317
		8318
		8319
		8320
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		8340
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Trt.	Bl. No	nb
PPD		8350
		8351
		8352
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		8358
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Trt.	Bl. No	nb
PPD		8391
		8392
		8393
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		8395
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		8397
		8398
		8399
		8400
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		8431

Trt.	Bl. No	nb
PPD		8432
		8433
		8434
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		8436
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		8466
		8467
		8468
		8469
		8470
		8471
		8472

Trt.	Bl. No	nb
PPD		8473
		8474
		8475
		8476
		8477
		8478
		8479
		8480
		8481
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		8509
		8510
		8511
		8512
		8513

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		8514	PPD		8555	PPD		8596	PPD		8637	PPD		8678	PPD		8719	PPD		8760
		8515			8556			8597			8638			8679			8720			8761
		8516			8557			8598			8639			8680			8721			8762
		8517			8558			8599			8640			8681			8722			8763
		8518			8559			8600			8641			8682			8723			8764
		8519			8560			8601			8642			8683			8724			8765
		8520			8561			8602			8643			8684			8725			8766
		8521			8562			8603			8644			8685			8726			8767
		8522			8563			8604			8645			8686			8727			8768
		8523			8564			8605			8646			8687			8728			8769
		8524			8565			8606			8647			8688			8729			8770
		8525			8566			8607			8648			8689			8730			8771
		8526			8567			8608			8649			8690			8731			8772
		8527			8568			8609			8650			8691			8732			8773
		8528			8569			8610			8651			8692			8733			8774
		8529			8570			8611			8652			8693			8734			8775
		8530			8571			8612			8653			8694			8735			8776
		8531			8572			8613			8654			8695			8736			8777
		8532			8573			8614			8655			8696			8737			8778
		8533			8574			8615			8656			8697			8738			8779
		8534			8575			8616			8657			8698			8739			8780
		8535			8576			8617			8658			8699			8740			8781
		8536			8577			8618			8659			8700			8741			8782
		8537			8578			8619			8660			8701			8742			8783
		8538			8579			8620			8661			8702			8743			8784
		8539			8580			8621			8662			8703			8744			8785
		8540			8581			8622			8663			8704			8745			8786
		8541			8582			8623			8664			8705			8746			8787
		8542			8583			8624			8665			8706			8747			8788
		8543			8584			8625			8666			8707			8748			8789
		8544			8585			8626			8667			8708			8749			8790
		8545			8586			8627			8668			8709			8750			8791
		8546			8587			8628			8669			8710			8751			8792
		8547			8588			8629			8670			8711			8752			8793
		8548			8589			8630			8671			8712			8753			8794
		8549			8590			8631			8672			8713			8754			8795
		8550			8591			8632			8673			8714			8755			8796
		8551			8592			8633			8674			8715			8756			8797
		8552			8593			8634			8675			8716			8757			8798
		8553			8594			8635			8676			8717			8758			8799
		8554			8595			8636			8677			8718			8759			8800

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	8801		PPD	8842		PPD	8883		PPD	8924		PPD	8965		PPD	9006		PPD	9047	
	8802			8843			8884			8925			8966			9007			9048	
	8803			8844			8885			8926			8967			9008			9049	
	8804			8845			8886			8927			8968			9009			9050	
	8805			8846			8887			8928			8969			9010			9051	
	8806			8847			8888			8929			8970			9011			9052	
	8807			8848			8889			8930			8971			9012			9053	
	8808			8849			8890			8931			8972			9013			9054	
	8809			8850			8891			8932			8973			9014			9055	
	8810			8851			8892			8933			8974			9015			9056	
	8811			8852			8893			8934			8975			9016			9057	
	8812			8853			8894			8935			8976			9017			9058	
	8813			8854			8895			8936			8977			9018			9059	
	8814			8855			8896			8937			8978			9019			9060	
	8815			8856			8897			8938			8979			9020			9061	
	8816			8857			8898			8939			8980			9021			9062	
	8817			8858			8899			8940			8981			9022			9063	
	8818			8859			8900			8941			8982			9023			9064	
	8819			8860			8901			8942			8983			9024			9065	
	8820			8861			8902			8943			8984			9025			9066	
	8821			8862			8903			8944			8985			9026			9067	
	8822			8863			8904			8945			8986			9027			9068	
	8823			8864			8905			8946			8987			9028			9069	
	8824			8865			8906			8947			8988			9029			9070	
	8825			8866			8907			8948			8989			9030			9071	
	8826			8867			8908			8949			8990			9031			9072	
	8827			8868			8909			8950			8991			9032			9073	
	8828			8869			8910			8951			8992			9033			9074	
	8829			8870			8911			8952			8993			9034			9075	
	8830			8871			8912			8953			8994			9035			9076	
	8831			8872			8913			8954			8995			9036			9077	
	8832			8873			8914			8955			8996			9037			9078	
	8833			8874			8915			8956			8997			9038			9079	
	8834			8875			8916			8957			8998			9039			9080	
	8835			8876			8917			8958			8999			9040			9081	
	8836			8877			8918			8959			9000			9041			9082	
	8837			8878			8919			8960			9001			9042			9083	
	8838			8879			8920			8961			9002			9043			9084	
	8839			8880			8921			8962			9003			9044			9085	
	8840			8881			8922			8963			9004			9045			9086	
	8841			8882			8923			8964			9005			9046			9087	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		9088	PPD		9129	PPD		9170	PPD		9211	PPD		9252	PPD		9293	PPD		9334
		9089			9130			9171			9212			9253			9294			9335
		9090			9131			9172			9213			9254			9295			9336
		9091			9132			9173			9214			9255			9296			9337
		9092			9133			9174			9215			9256			9297			9338
		9093			9134			9175			9216			9257			9298			9339
		9094			9135			9176			9217			9258			9299			9340
		9095			9136			9177			9218			9259			9300			9341
		9096			9137			9178			9219			9260			9301			9342
		9097			9138			9179			9220			9261			9302			9343
		9098			9139			9180			9221			9262			9303			9344
		9099			9140			9181			9222			9263			9304			9345
		9100			9141			9182			9223			9264			9305			9346
		9101			9142			9183			9224			9265			9306			9347
		9102			9143			9184			9225			9266			9307			9348
		9103			9144			9185			9226			9267			9308			9349
		9104			9145			9186			9227			9268			9309			9350
		9105			9146			9187			9228			9269			9310			9351
		9106			9147			9188			9229			9270			9311			9352
		9107			9148			9189			9230			9271			9312			9353
		9108			9149			9190			9231			9272			9313			9354
		9109			9150			9191			9232			9273			9314			9355
		9110			9151			9192			9233			9274			9315			9356
		9111			9152			9193			9234			9275			9316			9357
		9112			9153			9194			9235			9276			9317			9358
		9113			9154			9195			9236			9277			9318			9359
		9114			9155			9196			9237			9278			9319			9360
		9115			9156			9197			9238			9279			9320			9361
		9116			9157			9198			9239			9280			9321			9362
		9117			9158			9199			9240			9281			9322			9363
		9118			9159			9200			9241			9282			9323			9364
		9119			9160			9201			9242			9283			9324			9365
		9120			9161			9202			9243			9284			9325			9366
		9121			9162			9203			9244			9285			9326			9367
		9122			9163			9204			9245			9286			9327			9368
		9123			9164			9205			9246			9287			9328			9369
		9124			9165			9206			9247			9288			9329			9370
		9125			9166			9207			9248			9289			9330			9371
		9126			9167			9208			9249			9290			9331			9372
		9127			9168			9209			9250			9291			9332			9373
		9128			9169			9210			9251			9292			9333			9374

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		9375	PPD		9416	PPD		9457	PPD		9498	PPD		9539	PPD		9580	PPD		9621
		9376			9417			9458			9499			9540			9581			9622
		9377			9418			9459			9500			9541			9582			9623
		9378			9419			9460			9501			9542			9583			9624
		9379			9420			9461			9502			9543			9584			9625
		9380			9421			9462			9503			9544			9585			9626
		9381			9422			9463			9504			9545			9586			9627
		9382			9423			9464			9505			9546			9587			9628
		9383			9424			9465			9506			9547			9588			9629
		9384			9425			9466			9507			9548			9589			9630
		9385			9426			9467			9508			9549			9590			9631
		9386			9427			9468			9509			9550			9591			9632
		9387			9428			9469			9510			9551			9592			9633
		9388			9429			9470			9511			9552			9593			9634
		9389			9430			9471			9512			9553			9594			9635
		9390			9431			9472			9513			9554			9595			9636
		9391			9432			9473			9514			9555			9596			9637
		9392			9433			9474			9515			9556			9597			9638
		9393			9434			9475			9516			9557			9598			9639
		9394			9435			9476			9517			9558			9599			9640
		9395			9436			9477			9518			9559			9600			9641
		9396			9437			9478			9519			9560			9601			9642
		9397			9438			9479			9520			9561			9602			9643
		9398			9439			9480			9521			9562			9603			9644
		9399			9440			9481			9522			9563			9604			9645
		9400			9441			9482			9523			9564			9605			9646
		9401			9442			9483			9524			9565			9606			9647
		9402			9443			9484			9525			9566			9607			9648
		9403			9444			9485			9526			9567			9608			9649
		9404			9445			9486			9527			9568			9609			9650
		9405			9446			9487			9528			9569			9610			9651
		9406			9447			9488			9529			9570			9611			9652
		9407			9448			9489			9530			9571			9612			9653
		9408			9449			9490			9531			9572			9613			9654
		9409			9450			9491			9532			9573			9614			9655
		9410			9451			9492			9533			9574			9615			9656
		9411			9452			9493			9534			9575			9616			9657
		9412			9453			9494			9535			9576			9617			9658
		9413			9454			9495			9536			9577			9618			9659
		9414			9455			9496			9537			9578			9619			9660
		9415			9456			9497			9538			9579			9620			9661

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		9662
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		9699
		9700
		9701
		9702

Trt.	Bl. No	nb
PPD		9703
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Trt.	Bl. No	nb
PPD		9744
		9745
		9746
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		9780
		9781
		9782
		9783
		9784

Trt.	Bl. No	nb
PPD		9785
		9786
		9787
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		9789
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Trt.	Bl. No	nb
PPD		9826
		9827
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		9864
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Trt.	Bl. No	nb
PPD		9867
		9868
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		9906
		9907

Trt.	Bl. No	nb
PPD		9908
		9909
		9910
		9911
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		9948

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		9949	PPD		9990	PPD		10031	PPD		10072	PPD		10113	PPD		10154	PPD		10195
		9950			9991			10032			10073			10114			10155			10196
		9951			9992			10033			10074			10115			10156			10197
		9952			9993			10034			10075			10116			10157			10198
		9953			9994			10035			10076			10117			10158			10199
		9954			9995			10036			10077			10118			10159			10200
		9955			9996			10037			10078			10119			10160			10201
		9956			9997			10038			10079			10120			10161			10202
		9957			9998			10039			10080			10121			10162			10203
		9958			9999			10040			10081			10122			10163			10204
		9959			10000			10041			10082			10123			10164			10205
		9960			10001			10042			10083			10124			10165			10206
		9961			10002			10043			10084			10125			10166			10207
		9962			10003			10044			10085			10126			10167			10208
		9963			10004			10045			10086			10127			10168			10209
		9964			10005			10046			10087			10128			10169			10210
		9965			10006			10047			10088			10129			10170			10211
		9966			10007			10048			10089			10130			10171			10212
		9967			10008			10049			10090			10131			10172			10213
		9968			10009			10050			10091			10132			10173			10214
		9969			10010			10051			10092			10133			10174			10215
		9970			10011			10052			10093			10134			10175			10216
		9971			10012			10053			10094			10135			10176			10217
		9972			10013			10054			10095			10136			10177			10218
		9973			10014			10055			10096			10137			10178			10219
		9974			10015			10056			10097			10138			10179			10220
		9975			10016			10057			10098			10139			10180			10221
		9976			10017			10058			10099			10140			10181			10222
		9977			10018			10059			10100			10141			10182			10223
		9978			10019			10060			10101			10142			10183			10224
		9979			10020			10061			10102			10143			10184			10225
		9980			10021			10062			10103			10144			10185			10226
		9981			10022			10063			10104			10145			10186			10227
		9982			10023			10064			10105			10146			10187			10228
		9983			10024			10065			10106			10147			10188			10229
		9984			10025			10066			10107			10148			10189			10230
		9985			10026			10067			10108			10149			10190			10231
		9986			10027			10068			10109			10150			10191			10232
		9987			10028			10069			10110			10151			10192			10233
		9988			10029			10070			10111			10152			10193			10234
		9989			10030			10071			10112			10153			10194			10235

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	10236		PPD	10277		PPD	10318		PPD	10359		PPD	10400		PPD	10441		PPD	10482	
	10237			10278			10319			10360			10401			10442			10483	
	10238			10279			10320			10361			10402			10443			10484	
	10239			10280			10321			10362			10403			10444			10485	
	10240			10281			10322			10363			10404			10445			10486	
	10241			10282			10323			10364			10405			10446			10487	
	10242			10283			10324			10365			10406			10447			10488	
	10243			10284			10325			10366			10407			10448			10489	
	10244			10285			10326			10367			10408			10449			10490	
	10245			10286			10327			10368			10409			10450			10491	
	10246			10287			10328			10369			10410			10451			10492	
	10247			10288			10329			10370			10411			10452			10493	
	10248			10289			10330			10371			10412			10453			10494	
	10249			10290			10331			10372			10413			10454			10495	
	10250			10291			10332			10373			10414			10455			10496	
	10251			10292			10333			10374			10415			10456			10497	
	10252			10293			10334			10375			10416			10457			10498	
	10253			10294			10335			10376			10417			10458			10499	
	10254			10295			10336			10377			10418			10459			10500	
	10255			10296			10337			10378			10419			10460			10501	
	10256			10297			10338			10379			10420			10461			10502	
	10257			10298			10339			10380			10421			10462			10503	
	10258			10299			10340			10381			10422			10463			10504	
	10259			10300			10341			10382			10423			10464			10505	
	10260			10301			10342			10383			10424			10465			10506	
	10261			10302			10343			10384			10425			10466			10507	
	10262			10303			10344			10385			10426			10467			10508	
	10263			10304			10345			10386			10427			10468			10509	
	10264			10305			10346			10387			10428			10469			10510	
	10265			10306			10347			10388			10429			10470			10511	
	10266			10307			10348			10389			10430			10471			10512	
	10267			10308			10349			10390			10431			10472			10513	
	10268			10309			10350			10391			10432			10473			10514	
	10269			10310			10351			10392			10433			10474			10515	
	10270			10311			10352			10393			10434			10475			10516	
	10271			10312			10353			10394			10435			10476			10517	
	10272			10313			10354			10395			10436			10477			10518	
	10273			10314			10355			10396			10437			10478			10519	
	10274			10315			10356			10397			10438			10479			10520	
	10275			10316			10357			10398			10439			10480			10521	
	10276			10317			10358			10399			10440			10481			10522	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	10523	PPD	10564	PPD	10605	PPD	10646	PPD	10687	PPD	10728	PPD	10769
	10524		10565		10606		10647		10688		10729		10770
	10525		10566		10607		10648		10689		10730		10771
	10526		10567		10608		10649		10690		10731		10772
	10527		10568		10609		10650		10691		10732		10773
	10528		10569		10610		10651		10692		10733		10774
	10529		10570		10611		10652		10693		10734		10775
	10530		10571		10612		10653		10694		10735		10776
	10531		10572		10613		10654		10695		10736		10777
	10532		10573		10614		10655		10696		10737		10778
	10533		10574		10615		10656		10697		10738		10779
	10534		10575		10616		10657		10698		10739		10780
	10535		10576		10617		10658		10699		10740		10781
	10536		10577		10618		10659		10700		10741		10782
	10537		10578		10619		10660		10701		10742		10783
	10538		10579		10620		10661		10702		10743		10784
	10539		10580		10621		10662		10703		10744		10785
	10540		10581		10622		10663		10704		10745		10786
	10541		10582		10623		10664		10705		10746		10787
	10542		10583		10624		10665		10706		10747		10788
	10543		10584		10625		10666		10707		10748		10789
	10544		10585		10626		10667		10708		10749		10790
	10545		10586		10627		10668		10709		10750		10791
	10546		10587		10628		10669		10710		10751		10792
	10547		10588		10629		10670		10711		10752		10793
	10548		10589		10630		10671		10712		10753		10794
	10549		10590		10631		10672		10713		10754		10795
	10550		10591		10632		10673		10714		10755		10796
	10551		10592		10633		10674		10715		10756		10797
	10552		10593		10634		10675		10716		10757		10798
	10553		10594		10635		10676		10717		10758		10799
	10554		10595		10636		10677		10718		10759		10800
	10555		10596		10637		10678		10719		10760		10801
	10556		10597		10638		10679		10720		10761		10802
	10557		10598		10639		10680		10721		10762		10803
	10558		10599		10640		10681		10722		10763		10804
	10559		10600		10641		10682		10723		10764		10805
	10560		10601		10642		10683		10724		10765		10806
	10561		10602		10643		10684		10725		10766		10807
	10562		10603		10644		10685		10726		10767		10808
	10563		10604		10645		10686		10727		10768		10809

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD	10810		PPD	10851		PPD	10892		PPD	10933		PPD	10974		PPD	11015		PPD	11056	
	10811			10852			10893			10934			10975			11016			11057	
	10812			10853			10894			10935			10976			11017			11058	
	10813			10854			10895			10936			10977			11018			11059	
	10814			10855			10896			10937			10978			11019			11060	
	10815			10856			10897			10938			10979			11020			11061	
	10816			10857			10898			10939			10980			11021			11062	
	10817			10858			10899			10940			10981			11022			11063	
	10818			10859			10900			10941			10982			11023			11064	
	10819			10860			10901			10942			10983			11024			11065	
	10820			10861			10902			10943			10984			11025			11066	
	10821			10862			10903			10944			10985			11026			11067	
	10822			10863			10904			10945			10986			11027			11068	
	10823			10864			10905			10946			10987			11028			11069	
	10824			10865			10906			10947			10988			11029			11070	
	10825			10866			10907			10948			10989			11030			11071	
	10826			10867			10908			10949			10990			11031			11072	
	10827			10868			10909			10950			10991			11032			11073	
	10828			10869			10910			10951			10992			11033			11074	
	10829			10870			10911			10952			10993			11034			11075	
	10830			10871			10912			10953			10994			11035			11076	
	10831			10872			10913			10954			10995			11036			11077	
	10832			10873			10914			10955			10996			11037			11078	
	10833			10874			10915			10956			10997			11038			11079	
	10834			10875			10916			10957			10998			11039			11080	
	10835			10876			10917			10958			10999			11040			11081	
	10836			10877			10918			10959			11000			11041			11082	
	10837			10878			10919			10960			11001			11042			11083	
	10838			10879			10920			10961			11002			11043			11084	
	10839			10880			10921			10962			11003			11044			11085	
	10840			10881			10922			10963			11004			11045			11086	
	10841			10882			10923			10964			11005			11046			11087	
	10842			10883			10924			10965			11006			11047			11088	
	10843			10884			10925			10966			11007			11048			11089	
	10844			10885			10926			10967			11008			11049			11090	
	10845			10886			10927			10968			11009			11050			11091	
	10846			10887			10928			10969			11010			11051			11092	
	10847			10888			10929			10970			11011			11052			11093	
	10848			10889			10930			10971			11012			11053			11094	
	10849			10890			10931			10972			11013			11054			11095	
	10850			10891			10932			10973			11014			11055			11096	

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb
PPD	11097	PPD	11138	PPD	11179	PPD	11220	PPD	11261	PPD	11302	PPD	11343
	11098		11139		11180		11221		11262		11303		11344
	11099		11140		11181		11222		11263		11304		11345
	11100		11141		11182		11223		11264		11305		11346
	11101		11142		11183		11224		11265		11306		11347
	11102		11143		11184		11225		11266		11307		11348
	11103		11144		11185		11226		11267		11308		11349
	11104		11145		11186		11227		11268		11309		11350
	11105		11146		11187		11228		11269		11310		11351
	11106		11147		11188		11229		11270		11311		11352
	11107		11148		11189		11230		11271		11312		11353
	11108		11149		11190		11231		11272		11313		11354
	11109		11150		11191		11232		11273		11314		11355
	11110		11151		11192		11233		11274		11315		11356
	11111		11152		11193		11234		11275		11316		11357
	11112		11153		11194		11235		11276		11317		11358
	11113		11154		11195		11236		11277		11318		11359
	11114		11155		11196		11237		11278		11319		11360
	11115		11156		11197		11238		11279		11320		11361
	11116		11157		11198		11239		11280		11321		11362
	11117		11158		11199		11240		11281		11322		11363
	11118		11159		11200		11241		11282		11323		11364
	11119		11160		11201		11242		11283		11324		11365
	11120		11161		11202		11243		11284		11325		11366
	11121		11162		11203		11244		11285		11326		11367
	11122		11163		11204		11245		11286		11327		11368
	11123		11164		11205		11246		11287		11328		11369
	11124		11165		11206		11247		11288		11329		11370
	11125		11166		11207		11248		11289		11330		11371
	11126		11167		11208		11249		11290		11331		11372
	11127		11168		11209		11250		11291		11332		11373
	11128		11169		11210		11251		11292		11333		11374
	11129		11170		11211		11252		11293		11334		11375
	11130		11171		11212		11253		11294		11335		11376
	11131		11172		11213		11254		11295		11336		11377
	11132		11173		11214		11255		11296		11337		11378
	11133		11174		11215		11256		11297		11338		11379
	11134		11175		11216		11257		11298		11339		11380
	11135		11176		11217		11258		11299		11340		11381
	11136		11177		11218		11259		11300		11341		11382
	11137		11178		11219		11260		11301		11342		11383

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	11384	PPD	11425	PPD	11466	PPD	11507	PPD	11548	PPD	11589	PPD	11630
	11385		11426		11467		11508		11549		11590		11631
	11386		11427		11468		11509		11550		11591		11632
	11387		11428		11469		11510		11551		11592		11633
	11388		11429		11470		11511		11552		11593		11634
	11389		11430		11471		11512		11553		11594		11635
	11390		11431		11472		11513		11554		11595		11636
	11391		11432		11473		11514		11555		11596		11637
	11392		11433		11474		11515		11556		11597		11638
	11393		11434		11475		11516		11557		11598		11639
	11394		11435		11476		11517		11558		11599		11640
	11395		11436		11477		11518		11559		11600		11641
	11396		11437		11478		11519		11560		11601		11642
	11397		11438		11479		11520		11561		11602		11643
	11398		11439		11480		11521		11562		11603		11644
	11399		11440		11481		11522		11563		11604		11645
	11400		11441		11482		11523		11564		11605		11646
	11401		11442		11483		11524		11565		11606		11647
	11402		11443		11484		11525		11566		11607		11648
	11403		11444		11485		11526		11567		11608		11649
	11404		11445		11486		11527		11568		11609		11650
	11405		11446		11487		11528		11569		11610		11651
	11406		11447		11488		11529		11570		11611		11652
	11407		11448		11489		11530		11571		11612		11653
	11408		11449		11490		11531		11572		11613		11654
	11409		11450		11491		11532		11573		11614		11655
	11410		11451		11492		11533		11574		11615		11656
	11411		11452		11493		11534		11575		11616		11657
	11412		11453		11494		11535		11576		11617		11658
	11413		11454		11495		11536		11577		11618		11659
	11414		11455		11496		11537		11578		11619		11660
	11415		11456		11497		11538		11579		11620		11661
	11416		11457		11498		11539		11580		11621		11662
	11417		11458		11499		11540		11581		11622		11663
	11418		11459		11500		11541		11582		11623		11664
	11419		11460		11501		11542		11583		11624		11665
	11420		11461		11502		11543		11584		11625		11666
	11421		11462		11503		11544		11585		11626		11667
	11422		11463		11504		11545		11586		11627		11668
	11423		11464		11505		11546		11587		11628		11669
	11424		11465		11506		11547		11588		11629		11670

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb	Trt.	Bl. No nb
PPD	11671	PPD	11712	PPD	11753	PPD	11794	PPD	11835	PPD	11876	PPD	11917
	11672		11713		11754		11795		11836		11877		11918
	11673		11714		11755		11796		11837		11878		11919
	11674		11715		11756		11797		11838		11879		11920
	11675		11716		11757		11798		11839		11880		11921
	11676		11717		11758		11799		11840		11881		11922
	11677		11718		11759		11800		11841		11882		11923
	11678		11719		11760		11801		11842		11883		11924
	11679		11720		11761		11802		11843		11884		11925
	11680		11721		11762		11803		11844		11885		11926
	11681		11722		11763		11804		11845		11886		11927
	11682		11723		11764		11805		11846		11887		11928
	11683		11724		11765		11806		11847		11888		11929
	11684		11725		11766		11807		11848		11889		11930
	11685		11726		11767		11808		11849		11890		11931
	11686		11727		11768		11809		11850		11891		11932
	11687		11728		11769		11810		11851		11892		11933
	11688		11729		11770		11811		11852		11893		11934
	11689		11730		11771		11812		11853		11894		11935
	11690		11731		11772		11813		11854		11895		11936
	11691		11732		11773		11814		11855		11896		11937
	11692		11733		11774		11815		11856		11897		11938
	11693		11734		11775		11816		11857		11898		11939
	11694		11735		11776		11817		11858		11899		11940
	11695		11736		11777		11818		11859		11900		11941
	11696		11737		11778		11819		11860		11901		11942
	11697		11738		11779		11820		11861		11902		11943
	11698		11739		11780		11821		11862		11903		11944
	11699		11740		11781		11822		11863		11904		11945
	11700		11741		11782		11823		11864		11905		11946
	11701		11742		11783		11824		11865		11906		11947
	11702		11743		11784		11825		11866		11907		11948
	11703		11744		11785		11826		11867		11908		11949
	11704		11745		11786		11827		11868		11909		11950
	11705		11746		11787		11828		11869		11910		11951
	11706		11747		11788		11829		11870		11911		11952
	11707		11748		11789		11830		11871		11912		11953
	11708		11749		11790		11831		11872		11913		11954
	11709		11750		11791		11832		11873		11914		11955
	11710		11751		11792		11833		11874		11915		11956
	11711		11752		11793		11834		11875		11916		11957

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	11958	PPD	11999	PPD	12040	PPD	12081	PPD	12122	PPD	12163	PPD	12204
	11959		12000		12041		12082		12123		12164		12205
	11960		12001		12042		12083		12124		12165		12206
	11961		12002		12043		12084		12125		12166		12207
	11962		12003		12044		12085		12126		12167		12208
	11963		12004		12045		12086		12127		12168		12209
	11964		12005		12046		12087		12128		12169		12210
	11965		12006		12047		12088		12129		12170		12211
	11966		12007		12048		12089		12130		12171		12212
	11967		12008		12049		12090		12131		12172		12213
	11968		12009		12050		12091		12132		12173		12214
	11969		12010		12051		12092		12133		12174		12215
	11970		12011		12052		12093		12134		12175		12216
	11971		12012		12053		12094		12135		12176		12217
	11972		12013		12054		12095		12136		12177		12218
	11973		12014		12055		12096		12137		12178		12219
	11974		12015		12056		12097		12138		12179		12220
	11975		12016		12057		12098		12139		12180		12221
	11976		12017		12058		12099		12140		12181		12222
	11977		12018		12059		12100		12141		12182		12223
	11978		12019		12060		12101		12142		12183		12224
	11979		12020		12061		12102		12143		12184		12225
	11980		12021		12062		12103		12144		12185		12226
	11981		12022		12063		12104		12145		12186		12227
	11982		12023		12064		12105		12146		12187		12228
	11983		12024		12065		12106		12147		12188		12229
	11984		12025		12066		12107		12148		12189		12230
	11985		12026		12067		12108		12149		12190		12231
	11986		12027		12068		12109		12150		12191		12232
	11987		12028		12069		12110		12151		12192		12233
	11988		12029		12070		12111		12152		12193		12234
	11989		12030		12071		12112		12153		12194		12235
	11990		12031		12072		12113		12154		12195		12236
	11991		12032		12073		12114		12155		12196		12237
	11992		12033		12074		12115		12156		12197		12238
	11993		12034		12075		12116		12157		12198		12239
	11994		12035		12076		12117		12158		12199		12240
	11995		12036		12077		12118		12159		12200		12241
	11996		12037		12078		12119		12160		12201		12242
	11997		12038		12079		12120		12161		12202		12243
	11998		12039		12080		12121		12162		12203		12244

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	12245	PPD	12286	PPD	12327	PPD	12368	PPD	12409	PPD	12450	PPD	12491
	12246		12287		12328		12369		12410		12451		12492
	12247		12288		12329		12370		12411		12452		12493
	12248		12289		12330		12371		12412		12453		12494
	12249		12290		12331		12372		12413		12454		12495
	12250		12291		12332		12373		12414		12455		12496
	12251		12292		12333		12374		12415		12456		12497
	12252		12293		12334		12375		12416		12457		12498
	12253		12294		12335		12376		12417		12458		12499
	12254		12295		12336		12377		12418		12459		12500
	12255		12296		12337		12378		12419		12460		12501
	12256		12297		12338		12379		12420		12461		12502
	12257		12298		12339		12380		12421		12462		12503
	12258		12299		12340		12381		12422		12463		12504
	12259		12300		12341		12382		12423		12464		12505
	12260		12301		12342		12383		12424		12465		12506
	12261		12302		12343		12384		12425		12466		12507
	12262		12303		12344		12385		12426		12467		12508
	12263		12304		12345		12386		12427		12468		12509
	12264		12305		12346		12387		12428		12469		12510
	12265		12306		12347		12388		12429		12470		12511
	12266		12307		12348		12389		12430		12471		12512
	12267		12308		12349		12390		12431		12472		12513
	12268		12309		12350		12391		12432		12473		12514
	12269		12310		12351		12392		12433		12474		12515
	12270		12311		12352		12393		12434		12475		12516
	12271		12312		12353		12394		12435		12476		12517
	12272		12313		12354		12395		12436		12477		12518
	12273		12314		12355		12396		12437		12478		12519
	12274		12315		12356		12397		12438		12479		12520
	12275		12316		12357		12398		12439		12480		12521
	12276		12317		12358		12399		12440		12481		12522
	12277		12318		12359		12400		12441		12482		12523
	12278		12319		12360		12401		12442		12483		12524
	12279		12320		12361		12402		12443		12484		12525
	12280		12321		12362		12403		12444		12485		12526
	12281		12322		12363		12404		12445		12486		12527
	12282		12323		12364		12405		12446		12487		12528
	12283		12324		12365		12406		12447		12488		12529
	12284		12325		12366		12407		12448		12489		12530
	12285		12326		12367		12408		12449		12490		12531

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	12532	PPD	12573	PPD	12614	PPD	12655	PPD	12696	PPD	12737	PPD	12778
	12533		12574		12615		12656		12697		12738		12779
	12534		12575		12616		12657		12698		12739		12780
	12535		12576		12617		12658		12699		12740		12781
	12536		12577		12618		12659		12700		12741		12782
	12537		12578		12619		12660		12701		12742		12783
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	12554		12595		12636		12677		12718		12759		12800
	12555		12596		12637		12678		12719		12760		12801
	12556		12597		12638		12679		12720		12761		12802
	12557		12598		12639		12680		12721		12762		12803
	12558		12599		12640		12681		12722		12763		12804
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	12560		12601		12642		12683		12724		12765		12806
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	12562		12603		12644		12685		12726		12767		12808
	12563		12604		12645		12686		12727		12768		12809
	12564		12605		12646		12687		12728		12769		12810
	12565		12606		12647		12688		12729		12770		12811
	12566		12607		12648		12689		12730		12771		12812
	12567		12608		12649		12690		12731		12772		12813
	12568		12609		12650		12691		12732		12773		12814
	12569		12610		12651		12692		12733		12774		12815
	12570		12611		12652		12693		12734		12775		12816
	12571		12612		12653		12694		12735		12776		12817
	12572		12613		12654		12695		12736		12777		12818

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		12819
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		13024
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Trt.	Bl. No	nb
PPD		13065
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	13106	PPD	13147	PPD	13188	PPD	13229	PPD	13270	PPD	13311	PPD	13352
	13107		13148		13189		13230		13271		13312		13353
	13108		13149		13190		13231		13272		13313		13354
	13109		13150		13191		13232		13273		13314		13355
	13110		13151		13192		13233		13274		13315		13356
	13111		13152		13193		13234		13275		13316		13357
	13112		13153		13194		13235		13276		13317		13358
	13113		13154		13195		13236		13277		13318		13359
	13114		13155		13196		13237		13278		13319		13360
	13115		13156		13197		13238		13279		13320		13361
	13116		13157		13198		13239		13280		13321		13362
	13117		13158		13199		13240		13281		13322		13363
	13118		13159		13200		13241		13282		13323		13364
	13119		13160		13201		13242		13283		13324		13365
	13120		13161		13202		13243		13284		13325		13366
	13121		13162		13203		13244		13285		13326		13367
	13122		13163		13204		13245		13286		13327		13368
	13123		13164		13205		13246		13287		13328		13369
	13124		13165		13206		13247		13288		13329		13370
	13125		13166		13207		13248		13289		13330		13371
	13126		13167		13208		13249		13290		13331		13372
	13127		13168		13209		13250		13291		13332		13373
	13128		13169		13210		13251		13292		13333		13374
	13129		13170		13211		13252		13293		13334		13375
	13130		13171		13212		13253		13294		13335		13376
	13131		13172		13213		13254		13295		13336		13377
	13132		13173		13214		13255		13296		13337		13378
	13133		13174		13215		13256		13297		13338		13379
	13134		13175		13216		13257		13298		13339		13380
	13135		13176		13217		13258		13299		13340		13381
	13136		13177		13218		13259		13300		13341		13382
	13137		13178		13219		13260		13301		13342		13383
	13138		13179		13220		13261		13302		13343		13384
	13139		13180		13221		13262		13303		13344		13385
	13140		13181		13222		13263		13304		13345		13386
	13141		13182		13223		13264		13305		13346		13387
	13142		13183		13224		13265		13306		13347		13388
	13143		13184		13225		13266		13307		13348		13389
	13144		13185		13226		13267		13308		13349		13390
	13145		13186		13227		13268		13309		13350		13391
	13146		13187		13228		13269		13310		13351		13392

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		13393
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Trt.	Bl. No	nb
PPD		13434
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Trt.	Bl. No	nb
PPD		13475
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Trt.	Bl. No	nb
PPD		13516
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Trt.	Bl. No	nb
PPD		13557
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		13639
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		13680
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Trt.	Bl. No	nb
PPD		13721
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Trt.	Bl. No	nb
PPD		13762
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		13844
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		13967	PPD		14008	PPD		14049	PPD		14090	PPD		14131	PPD		14172	PPD		14213
		13968			14009			14050			14091			14132			14173			14214
		13969			14010			14051			14092			14133			14174			14215
		13970			14011			14052			14093			14134			14175			14216
		13971			14012			14053			14094			14135			14176			14217
		13972			14013			14054			14095			14136			14177			14218
		13973			14014			14055			14096			14137			14178			14219
		13974			14015			14056			14097			14138			14179			14220
		13975			14016			14057			14098			14139			14180			14221
		13976			14017			14058			14099			14140			14181			14222
		13977			14018			14059			14100			14141			14182			14223
		13978			14019			14060			14101			14142			14183			14224
		13979			14020			14061			14102			14143			14184			14225
		13980			14021			14062			14103			14144			14185			14226
		13981			14022			14063			14104			14145			14186			14227
		13982			14023			14064			14105			14146			14187			14228
		13983			14024			14065			14106			14147			14188			14229
		13984			14025			14066			14107			14148			14189			14230
		13985			14026			14067			14108			14149			14190			14231
		13986			14027			14068			14109			14150			14191			14232
		13987			14028			14069			14110			14151			14192			14233
		13988			14029			14070			14111			14152			14193			14234
		13989			14030			14071			14112			14153			14194			14235
		13990			14031			14072			14113			14154			14195			14236
		13991			14032			14073			14114			14155			14196			14237
		13992			14033			14074			14115			14156			14197			14238
		13993			14034			14075			14116			14157			14198			14239
		13994			14035			14076			14117			14158			14199			14240
		13995			14036			14077			14118			14159			14200			14241
		13996			14037			14078			14119			14160			14201			14242
		13997			14038			14079			14120			14161			14202			14243
		13998			14039			14080			14121			14162			14203			14244
		13999			14040			14081			14122			14163			14204			14245
		14000			14041			14082			14123			14164			14205			14246
		14001			14042			14083			14124			14165			14206			14247
		14002			14043			14084			14125			14166			14207			14248
		14003			14044			14085			14126			14167			14208			14249
		14004			14045			14086			14127			14168			14209			14250
		14005			14046			14087			14128			14169			14210			14251
		14006			14047			14088			14129			14170			14211			14252
		14007			14048			14089			14130			14171			14212			14253

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt.	Bl. No	nb
PPD		14254
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Trt.	Bl. No	nb
PPD		14295
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Trt.	Bl. No	nb
PPD		14336
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Trt.	Bl. No	nb
PPD		14377
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Trt.	Bl. No	nb
PPD		14418
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Trt.	Bl. No	nb
PPD		14459
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Trt.	Bl. No	nb
PPD		14500
		14501
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Varicella vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	14541	PPD	14582	PPD	14623
	14542		14583		14624
	14543		14584		14625
	14544		14585		
	14545		14586		
	14546		14587		
	14547		14588		
	14548		14589		
	14549		14590		
	14550		14591		
	14551		14592		
	14552		14593		
	14553		14594		
	14554		14595		
	14555		14596		
	14556		14597		
	14557		14598		
	14558		14599		
	14559		14600		
	14560		14601		
	14561		14602		
	14562		14603		
	14563		14604		
	14564		14605		
	14565		14606		
	14566		14607		
	14567		14608		
	14568		14609		
	14569		14610		
	14570		14611		
	14571		14612		
	14572		14613		
	14573		14614		
	14574		14615		
	14575		14616		
	14576		14617		
	14577		14618		
	14578		14619		
	14579		14620		
	14580		14621		
	14581		14622		

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		14626
		14627
		14628
		14629
		14630
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		14659
		14660
		14661
		14662
		14663
		14664
		14665
		14666

Trt.	Bl. No	nb
PPD		14667
		14668
		14669
		14670
		14671
		14672
		14673
		14674
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		14698
		14699
		14700
		14701
		14702
		14703
		14704
		14705
		14706
		14707

Trt.	Bl. No	nb
PPD		14708
		14709
		14710
		14711
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Trt.	Bl. No	nb
PPD		14749
		14750
		14751
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		14780
		14781
		14782
		14783
		14784
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		14786
		14787
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		14789

Trt.	Bl. No	nb
PPD		14790
		14791
		14792
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Trt.	Bl. No	nb
PPD		14831
		14832
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		14868
		14869
		14870
		14871

Trt.	Bl. No	nb
PPD		14872
		14873
		14874
		14875
		14876
		14877
		14878
		14879
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		14910
		14911
		14912

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		14913
		14914
		14915
		14916
		14917
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		14950
		14951
		14952
		14953

Trt.	Bl. No	nb
PPD		14954
		14955
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		14990
		14991
		14992
		14993
		14994

Trt.	Bl. No	nb
PPD		14995
		14996
		14997
		14998
		14999
		15000
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Trt.	Bl. No	nb
PPD		15036
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		15041
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		15073
		15074
		15075
		15076

Trt.	Bl. No	nb
PPD		15077
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Trt.	Bl. No	nb
PPD		15118
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Trt.	Bl. No	nb
PPD		15159
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		15200
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		15202
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		15204
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Trt.	Bl. No	nb
PPD		15241
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		15280
		15281

Trt.	Bl. No	nb
PPD		15282
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		15321
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Trt.	Bl. No	nb
PPD		15323
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Trt.	Bl. No	nb
PPD		15364
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Trt.	Bl. No	nb
PPD		15405
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Trt.	Bl. No	nb
PPD		15446
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		15487
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Trt.	Bl. No	nb
PPD		15528
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Trt.	Bl. No	nb
PPD		15569
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Trt.	Bl. No	nb
PPD		15610
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		15733
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		15774
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		15856
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Trt.	Bl. No	nb
PPD		15897
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		16020
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD	16061	
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Trt.	Bl. No	nb
PPD	16102	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	16266	
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Trt.	Bl. No	nb
PPD	16307	
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD	16635	
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Trt.	Bl. No	nb
PPD	16676	
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Trt.	Bl. No	nb
PPD	16717	
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Trt.	Bl. No	nb
PPD	16758	
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Trt.	Bl. No	nb
PPD	16799	
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Trt.	Bl. No	nb
PPD	16840	
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Trt.	Bl. No	nb
PPD	16881	
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		16922
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Trt.	Bl. No	nb
PPD		16963
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		17001
		17002
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Trt.	Bl. No	nb
PPD		17004
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Trt.	Bl. No	nb
PPD		17045
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Trt.	Bl. No	nb
PPD		17086
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Trt.	Bl. No	nb
PPD		17127
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Trt.	Bl. No	nb
PPD		17168
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Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		17209
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Trt.	Bl. No	nb
PPD		17250
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Trt.	Bl. No	nb
PPD		17291
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Trt.	Bl. No	nb
PPD		17332
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Trt.	Bl. No	nb
PPD		17373
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Trt.	Bl. No	nb
PPD		17414
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Trt.	Bl. No	nb
PPD		17455
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		17496
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Trt.	Bl. No	nb
PPD		17537
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Trt.	Bl. No	nb
PPD		17578
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Trt.	Bl. No	nb
PPD		17619
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Trt.	Bl. No	nb
PPD		17660
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Trt.	Bl. No	nb
PPD		17701
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Trt.	Bl. No	nb
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		17783	PPD		17824	PPD		17865	PPD		17906	PPD		17947	PPD		17988	PPD		18029
		17784			17825			17866			17907			17948			17989			18030
		17785			17826			17867			17908			17949			17990			18031
		17786			17827			17868			17909			17950			17991			18032
		17787			17828			17869			17910			17951			17992			18033
		17788			17829			17870			17911			17952			17993			18034
		17789			17830			17871			17912			17953			17994			18035
		17790			17831			17872			17913			17954			17995			18036
		17791			17832			17873			17914			17955			17996			18037
		17792			17833			17874			17915			17956			17997			18038
		17793			17834			17875			17916			17957			17998			18039
		17794			17835			17876			17917			17958			17999			18040
		17795			17836			17877			17918			17959			18000			18041
		17796			17837			17878			17919			17960			18001			18042
		17797			17838			17879			17920			17961			18002			18043
		17798			17839			17880			17921			17962			18003			18044
		17799			17840			17881			17922			17963			18004			18045
		17800			17841			17882			17923			17964			18005			18046
		17801			17842			17883			17924			17965			18006			18047
		17802			17843			17884			17925			17966			18007			18048
		17803			17844			17885			17926			17967			18008			18049
		17804			17845			17886			17927			17968			18009			18050
		17805			17846			17887			17928			17969			18010			18051
		17806			17847			17888			17929			17970			18011			18052
		17807			17848			17889			17930			17971			18012			18053
		17808			17849			17890			17931			17972			18013			18054
		17809			17850			17891			17932			17973			18014			18055
		17810			17851			17892			17933			17974			18015			18056
		17811			17852			17893			17934			17975			18016			18057
		17812			17853			17894			17935			17976			18017			18058
		17813			17854			17895			17936			17977			18018			18059
		17814			17855			17896			17937			17978			18019			18060
		17815			17856			17897			17938			17979			18020			18061
		17816			17857			17898			17939			17980			18021			18062
		17817			17858			17899			17940			17981			18022			18063
		17818			17859			17900			17941			17982			18023			18064
		17819			17860			17901			17942			17983			18024			18065
		17820			17861			17902			17943			17984			18025			18066
		17821			17862			17903			17944			17985			18026			18067
		17822			17863			17904			17945			17986			18027			18068
		17823			17864			17905			17946			17987			18028			18069

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		18070
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		18073
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Trt.	Bl. No	nb
PPD		18111
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Trt.	Bl. No	nb
PPD		18152
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Trt.	Bl. No	nb
PPD		18193
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD		18316
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		18357
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Trt.	Bl. No	nb
PPD		18398
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Trt.	Bl. No	nb
PPD		18439
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Trt.	Bl. No	nb
PPD		18480
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Trt.	Bl. No	nb
PPD		18521
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Trt.	Bl. No	nb
PPD		18562
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Trt.	Bl. No	nb
PPD		18603
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	18644	PPD	18685	PPD	18726	PPD	18767	PPD	18808	PPD	18849	PPD	18890
	18645		18686		18727		18768		18809		18850		18891
	18646		18687		18728		18769		18810		18851		18892
	18647		18688		18729		18770		18811		18852		18893
	18648		18689		18730		18771		18812		18853		18894
	18649		18690		18731		18772		18813		18854		18895
	18650		18691		18732		18773		18814		18855		18896
	18651		18692		18733		18774		18815		18856		18897
	18652		18693		18734		18775		18816		18857		18898
	18653		18694		18735		18776		18817		18858		18899
	18654		18695		18736		18777		18818		18859		18900
	18655		18696		18737		18778		18819		18860		18901
	18656		18697		18738		18779		18820		18861		18902
	18657		18698		18739		18780		18821		18862		18903
	18658		18699		18740		18781		18822		18863		18904
	18659		18700		18741		18782		18823		18864		18905
	18660		18701		18742		18783		18824		18865		18906
	18661		18702		18743		18784		18825		18866		18907
	18662		18703		18744		18785		18826		18867		18908
	18663		18704		18745		18786		18827		18868		18909
	18664		18705		18746		18787		18828		18869		18910
	18665		18706		18747		18788		18829		18870		18911
	18666		18707		18748		18789		18830		18871		18912
	18667		18708		18749		18790		18831		18872		18913
	18668		18709		18750		18791		18832		18873		18914
	18669		18710		18751		18792		18833		18874		18915
	18670		18711		18752		18793		18834		18875		18916
	18671		18712		18753		18794		18835		18876		18917
	18672		18713		18754		18795		18836		18877		18918
	18673		18714		18755		18796		18837		18878		18919
	18674		18715		18756		18797		18838		18879		18920
	18675		18716		18757		18798		18839		18880		18921
	18676		18717		18758		18799		18840		18881		18922
	18677		18718		18759		18800		18841		18882		18923
	18678		18719		18760		18801		18842		18883		18924
	18679		18720		18761		18802		18843		18884		18925
	18680		18721		18762		18803		18844		18885		18926
	18681		18722		18763		18804		18845		18886		18927
	18682		18723		18764		18805		18846		18887		18928
	18683		18724		18765		18806		18847		18888		18929
	18684		18725		18766		18807		18848		18889		18930

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		18931	PPD		18972	PPD		19013	PPD		19054	PPD		19095	PPD		19136	PPD		19177
		18932			18973			19014			19055			19096			19137			19178
		18933			18974			19015			19056			19097			19138			19179
		18934			18975			19016			19057			19098			19139			19180
		18935			18976			19017			19058			19099			19140			19181
		18936			18977			19018			19059			19100			19141			19182
		18937			18978			19019			19060			19101			19142			19183
		18938			18979			19020			19061			19102			19143			19184
		18939			18980			19021			19062			19103			19144			19185
		18940			18981			19022			19063			19104			19145			19186
		18941			18982			19023			19064			19105			19146			19187
		18942			18983			19024			19065			19106			19147			19188
		18943			18984			19025			19066			19107			19148			19189
		18944			18985			19026			19067			19108			19149			19190
		18945			18986			19027			19068			19109			19150			19191
		18946			18987			19028			19069			19110			19151			19192
		18947			18988			19029			19070			19111			19152			19193
		18948			18989			19030			19071			19112			19153			19194
		18949			18990			19031			19072			19113			19154			19195
		18950			18991			19032			19073			19114			19155			19196
		18951			18992			19033			19074			19115			19156			19197
		18952			18993			19034			19075			19116			19157			19198
		18953			18994			19035			19076			19117			19158			19199
		18954			18995			19036			19077			19118			19159			19200
		18955			18996			19037			19078			19119			19160			19201
		18956			18997			19038			19079			19120			19161			19202
		18957			18998			19039			19080			19121			19162			19203
		18958			18999			19040			19081			19122			19163			19204
		18959			19000			19041			19082			19123			19164			19205
		18960			19001			19042			19083			19124			19165			19206
		18961			19002			19043			19084			19125			19166			19207
		18962			19003			19044			19085			19126			19167			19208
		18963			19004			19045			19086			19127			19168			19209
		18964			19005			19046			19087			19128			19169			19210
		18965			19006			19047			19088			19129			19170			19211
		18966			19007			19048			19089			19130			19171			19212
		18967			19008			19049			19090			19131			19172			19213
		18968			19009			19050			19091			19132			19173			19214
		18969			19010			19051			19092			19133			19174			19215
		18970			19011			19052			19093			19134			19175			19216
		18971			19012			19053			19094			19135			19176			19217

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No	Trt.	Bl. No
PPD	19218	PPD	19259	PPD	19300	PPD	19341	PPD	19382	PPD	19423	PPD	19464
	19219		19260		19301		19342		19383		19424		19465
	19220		19261		19302		19343		19384		19425		19466
	19221		19262		19303		19344		19385		19426		19467
	19222		19263		19304		19345		19386		19427		19468
	19223		19264		19305		19346		19387		19428		19469
	19224		19265		19306		19347		19388		19429		19470
	19225		19266		19307		19348		19389		19430		19471
	19226		19267		19308		19349		19390		19431		19472
	19227		19268		19309		19350		19391		19432		19473
	19228		19269		19310		19351		19392		19433		19474
	19229		19270		19311		19352		19393		19434		19475
	19230		19271		19312		19353		19394		19435		19476
	19231		19272		19313		19354		19395		19436		19477
	19232		19273		19314		19355		19396		19437		19478
	19233		19274		19315		19356		19397		19438		19479
	19234		19275		19316		19357		19398		19439		19480
	19235		19276		19317		19358		19399		19440		19481
	19236		19277		19318		19359		19400		19441		19482
	19237		19278		19319		19360		19401		19442		19483
	19238		19279		19320		19361		19402		19443		19484
	19239		19280		19321		19362		19403		19444		19485
	19240		19281		19322		19363		19404		19445		19486
	19241		19282		19323		19364		19405		19446		19487
	19242		19283		19324		19365		19406		19447		19488
	19243		19284		19325		19366		19407		19448		19489
	19244		19285		19326		19367		19408		19449		19490
	19245		19286		19327		19368		19409		19450		19491
	19246		19287		19328		19369		19410		19451		19492
	19247		19288		19329		19370		19411		19452		19493
	19248		19289		19330		19371		19412		19453		19494
	19249		19290		19331		19372		19413		19454		19495
	19250		19291		19332		19373		19414		19455		19496
	19251		19292		19333		19374		19415		19456		19497
	19252		19293		19334		19375		19416		19457		19498
	19253		19294		19335		19376		19417		19458		19499
	19254		19295		19336		19377		19418		19459		19500
	19255		19296		19337		19378		19419		19460		19501
	19256		19297		19338		19379		19420		19461		19502
	19257		19298		19339		19380		19421		19462		19503
	19258		19299		19340		19381		19422		19463		19504

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		19505
		19506
		19507
		19508
		19509
		19510
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		19543
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Trt.	Bl. No	nb
PPD		19546
		19547
		19548
		19549
		19550
		19551
		19552
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		19554
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		19562
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		19576
		19577
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		19580
		19581
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		19583
		19584
		19585
		19586

Trt.	Bl. No	nb
PPD		19587
		19588
		19589
		19590
		19591
		19592
		19593
		19594
		19595
		19596
		19597
		19598
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Trt.	Bl. No	nb
PPD		19628
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		19655
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		19659
		19660
		19661
		19662
		19663
		19664
		19665
		19666
		19667
		19668

Trt.	Bl. No	nb
PPD		19669
		19670
		19671
		19672
		19673
		19674
		19675
		19676
		19677
		19678
		19679
		19680
		19681
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		19699
		19700
		19701
		19702
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		19705
		19706
		19707
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		19709

Trt.	Bl. No	nb
PPD		19710
		19711
		19712
		19713
		19714
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		19750

Trt.	Bl. No	nb
PPD		19751
		19752
		19753
		19754
		19755
		19756
		19757
		19758
		19759
		19760
		19761
		19762
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		19780
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		19784
		19785
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		19787
		19788
		19789
		19790
		19791

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		19792
		19793
		19794
		19795
		19796
		19797
		19798
		19799
		19800
		19801
		19802
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		19830
		19831
		19832

Trt.	Bl. No	nb
PPD		19833
		19834
		19835
		19836
		19837
		19838
		19839
		19840
		19841
		19842
		19843
		19844
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		19860
		19861
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		19864
		19865
		19866
		19867
		19868
		19869
		19870
		19871
		19872
		19873

Trt.	Bl. No	nb
PPD		19874
		19875
		19876
		19877
		19878
		19879
		19880
		19881
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Trt.	Bl. No	nb
PPD		19915
		19916
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Trt.	Bl. No	nb
PPD		19956
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		19958
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		19989
		19990
		19991
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		19995
		19996

Trt.	Bl. No	nb
PPD		19997
		19998
		19999
		20000
		20001
		20002
		20003
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Trt.	Bl. No	nb
PPD		20038
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		20078

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	20079	PPD	20120	PPD	20161	PPD	20202	PPD	20243	PPD	20284	PPD	20325
	20080		20121		20162		20203		20244		20285		20326
	20081		20122		20163		20204		20245		20286		20327
	20082		20123		20164		20205		20246		20287		20328
	20083		20124		20165		20206		20247		20288		20329
	20084		20125		20166		20207		20248		20289		20330
	20085		20126		20167		20208		20249		20290		20331
	20086		20127		20168		20209		20250		20291		20332
	20087		20128		20169		20210		20251		20292		20333
	20088		20129		20170		20211		20252		20293		20334
	20089		20130		20171		20212		20253		20294		20335
	20090		20131		20172		20213		20254		20295		20336
	20091		20132		20173		20214		20255		20296		20337
	20092		20133		20174		20215		20256		20297		20338
	20093		20134		20175		20216		20257		20298		20339
	20094		20135		20176		20217		20258		20299		20340
	20095		20136		20177		20218		20259		20300		20341
	20096		20137		20178		20219		20260		20301		20342
	20097		20138		20179		20220		20261		20302		20343
	20098		20139		20180		20221		20262		20303		20344
	20099		20140		20181		20222		20263		20304		20345
	20100		20141		20182		20223		20264		20305		20346
	20101		20142		20183		20224		20265		20306		20347
	20102		20143		20184		20225		20266		20307		20348
	20103		20144		20185		20226		20267		20308		20349
	20104		20145		20186		20227		20268		20309		20350
	20105		20146		20187		20228		20269		20310		20351
	20106		20147		20188		20229		20270		20311		20352
	20107		20148		20189		20230		20271		20312		20353
	20108		20149		20190		20231		20272		20313		20354
	20109		20150		20191		20232		20273		20314		20355
	20110		20151		20192		20233		20274		20315		20356
	20111		20152		20193		20234		20275		20316		20357
	20112		20153		20194		20235		20276		20317		20358
	20113		20154		20195		20236		20277		20318		20359
	20114		20155		20196		20237		20278		20319		20360
	20115		20156		20197		20238		20279		20320		20361
	20116		20157		20198		20239		20280		20321		20362
	20117		20158		20199		20240		20281		20322		20363
	20118		20159		20200		20241		20282		20323		20364
	20119		20160		20201		20242		20283		20324		20365

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	20366	PPD	20407	PPD	20448	PPD	20489	PPD	20530	PPD	20571	PPD	20612
	20367		20408		20449		20490		20531		20572		20613
	20368		20409		20450		20491		20532		20573		20614
	20369		20410		20451		20492		20533		20574		20615
	20370		20411		20452		20493		20534		20575		20616
	20371		20412		20453		20494		20535		20576		20617
	20372		20413		20454		20495		20536		20577		20618
	20373		20414		20455		20496		20537		20578		20619
	20374		20415		20456		20497		20538		20579		20620
	20375		20416		20457		20498		20539		20580		20621
	20376		20417		20458		20499		20540		20581		20622
	20377		20418		20459		20500		20541		20582		20623
	20378		20419		20460		20501		20542		20583		20624
	20379		20420		20461		20502		20543		20584		20625
	20380		20421		20462		20503		20544		20585		20626
	20381		20422		20463		20504		20545		20586		20627
	20382		20423		20464		20505		20546		20587		20628
	20383		20424		20465		20506		20547		20588		20629
	20384		20425		20466		20507		20548		20589		20630
	20385		20426		20467		20508		20549		20590		20631
	20386		20427		20468		20509		20550		20591		20632
	20387		20428		20469		20510		20551		20592		20633
	20388		20429		20470		20511		20552		20593		20634
	20389		20430		20471		20512		20553		20594		20635
	20390		20431		20472		20513		20554		20595		20636
	20391		20432		20473		20514		20555		20596		20637
	20392		20433		20474		20515		20556		20597		20638
	20393		20434		20475		20516		20557		20598		20639
	20394		20435		20476		20517		20558		20599		20640
	20395		20436		20477		20518		20559		20600		20641
	20396		20437		20478		20519		20560		20601		20642
	20397		20438		20479		20520		20561		20602		20643
	20398		20439		20480		20521		20562		20603		20644
	20399		20440		20481		20522		20563		20604		20645
	20400		20441		20482		20523		20564		20605		20646
	20401		20442		20483		20524		20565		20606		20647
	20402		20443		20484		20525		20566		20607		20648
	20403		20444		20485		20526		20567		20608		20649
	20404		20445		20486		20527		20568		20609		20650
	20405		20446		20487		20528		20569		20610		20651
	20406		20447		20488		20529		20570		20611		20652

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	20653	PPD	20694	PPD	20735	PPD	20776	PPD	20817	PPD	20858	PPD	20899
	20654		20695		20736		20777		20818		20859		20900
	20655		20696		20737		20778		20819		20860		20901
	20656		20697		20738		20779		20820		20861		20902
	20657		20698		20739		20780		20821		20862		20903
	20658		20699		20740		20781		20822		20863		20904
	20659		20700		20741		20782		20823		20864		20905
	20660		20701		20742		20783		20824		20865		20906
	20661		20702		20743		20784		20825		20866		20907
	20662		20703		20744		20785		20826		20867		20908
	20663		20704		20745		20786		20827		20868		20909
	20664		20705		20746		20787		20828		20869		20910
	20665		20706		20747		20788		20829		20870		20911
	20666		20707		20748		20789		20830		20871		20912
	20667		20708		20749		20790		20831		20872		20913
	20668		20709		20750		20791		20832		20873		20914
	20669		20710		20751		20792		20833		20874		20915
	20670		20711		20752		20793		20834		20875		20916
	20671		20712		20753		20794		20835		20876		20917
	20672		20713		20754		20795		20836		20877		20918
	20673		20714		20755		20796		20837		20878		20919
	20674		20715		20756		20797		20838		20879		20920
	20675		20716		20757		20798		20839		20880		20921
	20676		20717		20758		20799		20840		20881		20922
	20677		20718		20759		20800		20841		20882		20923
	20678		20719		20760		20801		20842		20883		20924
	20679		20720		20761		20802		20843		20884		20925
	20680		20721		20762		20803		20844		20885		20926
	20681		20722		20763		20804		20845		20886		20927
	20682		20723		20764		20805		20846		20887		20928
	20683		20724		20765		20806		20847		20888		20929
	20684		20725		20766		20807		20848		20889		20930
	20685		20726		20767		20808		20849		20890		20931
	20686		20727		20768		20809		20850		20891		20932
	20687		20728		20769		20810		20851		20892		20933
	20688		20729		20770		20811		20852		20893		20934
	20689		20730		20771		20812		20853		20894		20935
	20690		20731		20772		20813		20854		20895		20936
	20691		20732		20773		20814		20855		20896		20937
	20692		20733		20774		20815		20856		20897		20938
	20693		20734		20775		20816		20857		20898		20939

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	20940	PPD	20981	PPD	21022	PPD	21063	PPD	21104	PPD	21145	PPD	21186
	20941		20982		21023		21064		21105		21146		21187
	20942		20983		21024		21065		21106		21147		21188
	20943		20984		21025		21066		21107		21148		21189
	20944		20985		21026		21067		21108		21149		21190
	20945		20986		21027		21068		21109		21150		21191
	20946		20987		21028		21069		21110		21151		21192
	20947		20988		21029		21070		21111		21152		21193
	20948		20989		21030		21071		21112		21153		21194
	20949		20990		21031		21072		21113		21154		21195
	20950		20991		21032		21073		21114		21155		21196
	20951		20992		21033		21074		21115		21156		21197
	20952		20993		21034		21075		21116		21157		21198
	20953		20994		21035		21076		21117		21158		21199
	20954		20995		21036		21077		21118		21159		21200
	20955		20996		21037		21078		21119		21160		21201
	20956		20997		21038		21079		21120		21161		21202
	20957		20998		21039		21080		21121		21162		21203
	20958		20999		21040		21081		21122		21163		21204
	20959		21000		21041		21082		21123		21164		21205
	20960		21001		21042		21083		21124		21165		21206
	20961		21002		21043		21084		21125		21166		21207
	20962		21003		21044		21085		21126		21167		21208
	20963		21004		21045		21086		21127		21168		21209
	20964		21005		21046		21087		21128		21169		21210
	20965		21006		21047		21088		21129		21170		21211
	20966		21007		21048		21089		21130		21171		21212
	20967		21008		21049		21090		21131		21172		21213
	20968		21009		21050		21091		21132		21173		21214
	20969		21010		21051		21092		21133		21174		21215
	20970		21011		21052		21093		21134		21175		21216
	20971		21012		21053		21094		21135		21176		21217
	20972		21013		21054		21095		21136		21177		21218
	20973		21014		21055		21096		21137		21178		21219
	20974		21015		21056		21097		21138		21179		21220
	20975		21016		21057		21098		21139		21180		21221
	20976		21017		21058		21099		21140		21181		21222
	20977		21018		21059		21100		21141		21182		21223
	20978		21019		21060		21101		21142		21183		21224
	20979		21020		21061		21102		21143		21184		21225
	20980		21021		21062		21103		21144		21185		21226

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	21227	PPD	21268	PPD	21309	PPD	21350	PPD	21391	PPD	21432	PPD	21473
	21228		21269		21310		21351		21392		21433		21474
	21229		21270		21311		21352		21393		21434		21475
	21230		21271		21312		21353		21394		21435		21476
	21231		21272		21313		21354		21395		21436		21477
	21232		21273		21314		21355		21396		21437		21478
	21233		21274		21315		21356		21397		21438		21479
	21234		21275		21316		21357		21398		21439		21480
	21235		21276		21317		21358		21399		21440		21481
	21236		21277		21318		21359		21400		21441		21482
	21237		21278		21319		21360		21401		21442		21483
	21238		21279		21320		21361		21402		21443		21484
	21239		21280		21321		21362		21403		21444		21485
	21240		21281		21322		21363		21404		21445		21486
	21241		21282		21323		21364		21405		21446		21487
	21242		21283		21324		21365		21406		21447		21488
	21243		21284		21325		21366		21407		21448		21489
	21244		21285		21326		21367		21408		21449		21490
	21245		21286		21327		21368		21409		21450		21491
	21246		21287		21328		21369		21410		21451		21492
	21247		21288		21329		21370		21411		21452		21493
	21248		21289		21330		21371		21412		21453		21494
	21249		21290		21331		21372		21413		21454		21495
	21250		21291		21332		21373		21414		21455		21496
	21251		21292		21333		21374		21415		21456		21497
	21252		21293		21334		21375		21416		21457		21498
	21253		21294		21335		21376		21417		21458		21499
	21254		21295		21336		21377		21418		21459		21500
	21255		21296		21337		21378		21419		21460		21501
	21256		21297		21338		21379		21420		21461		21502
	21257		21298		21339		21380		21421		21462		21503
	21258		21299		21340		21381		21422		21463		21504
	21259		21300		21341		21382		21423		21464		21505
	21260		21301		21342		21383		21424		21465		21506
	21261		21302		21343		21384		21425		21466		21507
	21262		21303		21344		21385		21426		21467		21508
	21263		21304		21345		21386		21427		21468		21509
	21264		21305		21346		21387		21428		21469		21510
	21265		21306		21347		21388		21429		21470		21511
	21266		21307		21348		21389		21430		21471		21512
	21267		21308		21349		21390		21431		21472		21513

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	21514	PPD	21555	PPD	21596	PPD	21637	PPD	21678	PPD	21719	PPD	21760
	21515		21556		21597		21638		21679		21720		21761
	21516		21557		21598		21639		21680		21721		21762
	21517		21558		21599		21640		21681		21722		21763
	21518		21559		21600		21641		21682		21723		21764
	21519		21560		21601		21642		21683		21724		21765
	21520		21561		21602		21643		21684		21725		21766
	21521		21562		21603		21644		21685		21726		21767
	21522		21563		21604		21645		21686		21727		21768
	21523		21564		21605		21646		21687		21728		21769
	21524		21565		21606		21647		21688		21729		21770
	21525		21566		21607		21648		21689		21730		21771
	21526		21567		21608		21649		21690		21731		21772
	21527		21568		21609		21650		21691		21732		21773
	21528		21569		21610		21651		21692		21733		21774
	21529		21570		21611		21652		21693		21734		21775
	21530		21571		21612		21653		21694		21735		21776
	21531		21572		21613		21654		21695		21736		21777
	21532		21573		21614		21655		21696		21737		21778
	21533		21574		21615		21656		21697		21738		21779
	21534		21575		21616		21657		21698		21739		21780
	21535		21576		21617		21658		21699		21740		21781
	21536		21577		21618		21659		21700		21741		21782
	21537		21578		21619		21660		21701		21742		21783
	21538		21579		21620		21661		21702		21743		21784
	21539		21580		21621		21662		21703		21744		21785
	21540		21581		21622		21663		21704		21745		21786
	21541		21582		21623		21664		21705		21746		21787
	21542		21583		21624		21665		21706		21747		21788
	21543		21584		21625		21666		21707		21748		21789
	21544		21585		21626		21667		21708		21749		21790
	21545		21586		21627		21668		21709		21750		21791
	21546		21587		21628		21669		21710		21751		21792
	21547		21588		21629		21670		21711		21752		21793
	21548		21589		21630		21671		21712		21753		21794
	21549		21590		21631		21672		21713		21754		21795
	21550		21591		21632		21673		21714		21755		21796
	21551		21592		21633		21674		21715		21756		21797
	21552		21593		21634		21675		21716		21757		21798
	21553		21594		21635		21676		21717		21758		21799
	21554		21595		21636		21677		21718		21759		21800

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	21801	PPD	21842	PPD	21883	PPD	21924	PPD	21965	PPD	22006	PPD	22047
	21802		21843		21884		21925		21966		22007		22048
	21803		21844		21885		21926		21967		22008		22049
	21804		21845		21886		21927		21968		22009		22050
	21805		21846		21887		21928		21969		22010		22051
	21806		21847		21888		21929		21970		22011		22052
	21807		21848		21889		21930		21971		22012		22053
	21808		21849		21890		21931		21972		22013		22054
	21809		21850		21891		21932		21973		22014		22055
	21810		21851		21892		21933		21974		22015		22056
	21811		21852		21893		21934		21975		22016		22057
	21812		21853		21894		21935		21976		22017		22058
	21813		21854		21895		21936		21977		22018		22059
	21814		21855		21896		21937		21978		22019		22060
	21815		21856		21897		21938		21979		22020		22061
	21816		21857		21898		21939		21980		22021		22062
	21817		21858		21899		21940		21981		22022		22063
	21818		21859		21900		21941		21982		22023		22064
	21819		21860		21901		21942		21983		22024		22065
	21820		21861		21902		21943		21984		22025		22066
	21821		21862		21903		21944		21985		22026		22067
	21822		21863		21904		21945		21986		22027		22068
	21823		21864		21905		21946		21987		22028		22069
	21824		21865		21906		21947		21988		22029		22070
	21825		21866		21907		21948		21989		22030		22071
	21826		21867		21908		21949		21990		22031		22072
	21827		21868		21909		21950		21991		22032		22073
	21828		21869		21910		21951		21992		22033		22074
	21829		21870		21911		21952		21993		22034		22075
	21830		21871		21912		21953		21994		22035		22076
	21831		21872		21913		21954		21995		22036		22077
	21832		21873		21914		21955		21996		22037		22078
	21833		21874		21915		21956		21997		22038		22079
	21834		21875		21916		21957		21998		22039		22080
	21835		21876		21917		21958		21999		22040		22081
	21836		21877		21918		21959		22000		22041		22082
	21837		21878		21919		21960		22001		22042		22083
	21838		21879		21920		21961		22002		22043		22084
	21839		21880		21921		21962		22003		22044		22085
	21840		21881		21922		21963		22004		22045		22086
	21841		21882		21923		21964		22005		22046		22087

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	22088	PPD	22129	PPD	22170	PPD	22211	PPD	22252	PPD	22293	PPD	22334
	22089		22130		22171		22212		22253		22294		22335
	22090		22131		22172		22213		22254		22295		22336
	22091		22132		22173		22214		22255		22296		22337
	22092		22133		22174		22215		22256		22297		22338
	22093		22134		22175		22216		22257		22298		22339
	22094		22135		22176		22217		22258		22299		22340
	22095		22136		22177		22218		22259		22300		22341
	22096		22137		22178		22219		22260		22301		22342
	22097		22138		22179		22220		22261		22302		22343
	22098		22139		22180		22221		22262		22303		22344
	22099		22140		22181		22222		22263		22304		22345
	22100		22141		22182		22223		22264		22305		22346
	22101		22142		22183		22224		22265		22306		22347
	22102		22143		22184		22225		22266		22307		22348
	22103		22144		22185		22226		22267		22308		22349
	22104		22145		22186		22227		22268		22309		22350
	22105		22146		22187		22228		22269		22310		22351
	22106		22147		22188		22229		22270		22311		22352
	22107		22148		22189		22230		22271		22312		22353
	22108		22149		22190		22231		22272		22313		22354
	22109		22150		22191		22232		22273		22314		22355
	22110		22151		22192		22233		22274		22315		22356
	22111		22152		22193		22234		22275		22316		22357
	22112		22153		22194		22235		22276		22317		22358
	22113		22154		22195		22236		22277		22318		22359
	22114		22155		22196		22237		22278		22319		22360
	22115		22156		22197		22238		22279		22320		22361
	22116		22157		22198		22239		22280		22321		22362
	22117		22158		22199		22240		22281		22322		22363
	22118		22159		22200		22241		22282		22323		22364
	22119		22160		22201		22242		22283		22324		22365
	22120		22161		22202		22243		22284		22325		22366
	22121		22162		22203		22244		22285		22326		22367
	22122		22163		22204		22245		22286		22327		22368
	22123		22164		22205		22246		22287		22328		22369
	22124		22165		22206		22247		22288		22329		22370
	22125		22166		22207		22248		22289		22330		22371
	22126		22167		22208		22249		22290		22331		22372
	22127		22168		22209		22250		22291		22332		22373
	22128		22169		22210		22251		22292		22333		22374

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	22375	PPD	22416	PPD	22457	PPD	22498	PPD	22539	PPD	22580	PPD	22621
	22376		22417		22458		22499		22540		22581		22622
	22377		22418		22459		22500		22541		22582		22623
	22378		22419		22460		22501		22542		22583		22624
	22379		22420		22461		22502		22543		22584		22625
	22380		22421		22462		22503		22544		22585		22626
	22381		22422		22463		22504		22545		22586		22627
	22382		22423		22464		22505		22546		22587		22628
	22383		22424		22465		22506		22547		22588		22629
	22384		22425		22466		22507		22548		22589		22630
	22385		22426		22467		22508		22549		22590		22631
	22386		22427		22468		22509		22550		22591		22632
	22387		22428		22469		22510		22551		22592		22633
	22388		22429		22470		22511		22552		22593		22634
	22389		22430		22471		22512		22553		22594		22635
	22390		22431		22472		22513		22554		22595		22636
	22391		22432		22473		22514		22555		22596		22637
	22392		22433		22474		22515		22556		22597		22638
	22393		22434		22475		22516		22557		22598		22639
	22394		22435		22476		22517		22558		22599		22640
	22395		22436		22477		22518		22559		22600		22641
	22396		22437		22478		22519		22560		22601		22642
	22397		22438		22479		22520		22561		22602		22643
	22398		22439		22480		22521		22562		22603		22644
	22399		22440		22481		22522		22563		22604		22645
	22400		22441		22482		22523		22564		22605		22646
	22401		22442		22483		22524		22565		22606		22647
	22402		22443		22484		22525		22566		22607		22648
	22403		22444		22485		22526		22567		22608		22649
	22404		22445		22486		22527		22568		22609		22650
	22405		22446		22487		22528		22569		22610		22651
	22406		22447		22488		22529		22570		22611		22652
	22407		22448		22489		22530		22571		22612		22653
	22408		22449		22490		22531		22572		22613		22654
	22409		22450		22491		22532		22573		22614		22655
	22410		22451		22492		22533		22574		22615		22656
	22411		22452		22493		22534		22575		22616		22657
	22412		22453		22494		22535		22576		22617		22658
	22413		22454		22495		22536		22577		22618		22659
	22414		22455		22496		22537		22578		22619		22660
	22415		22456		22497		22538		22579		22620		22661

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	22662	PPD	22703	PPD	22744	PPD	22785	PPD	22826	PPD	22867	PPD	22908
	22663		22704		22745		22786		22827		22868		22909
	22664		22705		22746		22787		22828		22869		22910
	22665		22706		22747		22788		22829		22870		22911
	22666		22707		22748		22789		22830		22871		22912
	22667		22708		22749		22790		22831		22872		22913
	22668		22709		22750		22791		22832		22873		22914
	22669		22710		22751		22792		22833		22874		22915
	22670		22711		22752		22793		22834		22875		22916
	22671		22712		22753		22794		22835		22876		22917
	22672		22713		22754		22795		22836		22877		22918
	22673		22714		22755		22796		22837		22878		22919
	22674		22715		22756		22797		22838		22879		22920
	22675		22716		22757		22798		22839		22880		22921
	22676		22717		22758		22799		22840		22881		22922
	22677		22718		22759		22800		22841		22882		22923
	22678		22719		22760		22801		22842		22883		22924
	22679		22720		22761		22802		22843		22884		22925
	22680		22721		22762		22803		22844		22885		22926
	22681		22722		22763		22804		22845		22886		22927
	22682		22723		22764		22805		22846		22887		22928
	22683		22724		22765		22806		22847		22888		22929
	22684		22725		22766		22807		22848		22889		22930
	22685		22726		22767		22808		22849		22890		22931
	22686		22727		22768		22809		22850		22891		22932
	22687		22728		22769		22810		22851		22892		22933
	22688		22729		22770		22811		22852		22893		22934
	22689		22730		22771		22812		22853		22894		22935
	22690		22731		22772		22813		22854		22895		22936
	22691		22732		22773		22814		22855		22896		22937
	22692		22733		22774		22815		22856		22897		22938
	22693		22734		22775		22816		22857		22898		22939
	22694		22735		22776		22817		22858		22899		22940
	22695		22736		22777		22818		22859		22900		22941
	22696		22737		22778		22819		22860		22901		22942
	22697		22738		22779		22820		22861		22902		22943
	22698		22739		22780		22821		22862		22903		22944
	22699		22740		22781		22822		22863		22904		22945
	22700		22741		22782		22823		22864		22905		22946
	22701		22742		22783		22824		22865		22906		22947
	22702		22743		22784		22825		22866		22907		22948

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	22949	PPD	22990	PPD	23031	PPD	23072	PPD	23113	PPD	23154	PPD	23195
	22950		22991		23032		23073		23114		23155		23196
	22951		22992		23033		23074		23115		23156		23197
	22952		22993		23034		23075		23116		23157		23198
	22953		22994		23035		23076		23117		23158		23199
	22954		22995		23036		23077		23118		23159		23200
	22955		22996		23037		23078		23119		23160		23201
	22956		22997		23038		23079		23120		23161		23202
	22957		22998		23039		23080		23121		23162		23203
	22958		22999		23040		23081		23122		23163		23204
	22959		23000		23041		23082		23123		23164		23205
	22960		23001		23042		23083		23124		23165		23206
	22961		23002		23043		23084		23125		23166		23207
	22962		23003		23044		23085		23126		23167		23208
	22963		23004		23045		23086		23127		23168		23209
	22964		23005		23046		23087		23128		23169		23210
	22965		23006		23047		23088		23129		23170		23211
	22966		23007		23048		23089		23130		23171		23212
	22967		23008		23049		23090		23131		23172		23213
	22968		23009		23050		23091		23132		23173		23214
	22969		23010		23051		23092		23133		23174		23215
	22970		23011		23052		23093		23134		23175		23216
	22971		23012		23053		23094		23135		23176		23217
	22972		23013		23054		23095		23136		23177		23218
	22973		23014		23055		23096		23137		23178		23219
	22974		23015		23056		23097		23138		23179		23220
	22975		23016		23057		23098		23139		23180		23221
	22976		23017		23058		23099		23140		23181		23222
	22977		23018		23059		23100		23141		23182		23223
	22978		23019		23060		23101		23142		23183		23224
	22979		23020		23061		23102		23143		23184		23225
	22980		23021		23062		23103		23144		23185		23226
	22981		23022		23063		23104		23145		23186		23227
	22982		23023		23064		23105		23146		23187		23228
	22983		23024		23065		23106		23147		23188		23229
	22984		23025		23066		23107		23148		23189		23230
	22985		23026		23067		23108		23149		23190		23231
	22986		23027		23068		23109		23150		23191		23232
	22987		23028		23069		23110		23151		23192		23233
	22988		23029		23070		23111		23152		23193		23234
	22989		23030		23071		23112		23153		23194		23235

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	23236	PPD	23277	PPD	23318	PPD	23359	PPD	23400	PPD	23441	PPD	23482
	23237		23278		23319		23360		23401		23442		23483
	23238		23279		23320		23361		23402		23443		23484
	23239		23280		23321		23362		23403		23444		23485
	23240		23281		23322		23363		23404		23445		23486
	23241		23282		23323		23364		23405		23446		23487
	23242		23283		23324		23365		23406		23447		23488
	23243		23284		23325		23366		23407		23448		23489
	23244		23285		23326		23367		23408		23449		23490
	23245		23286		23327		23368		23409		23450		23491
	23246		23287		23328		23369		23410		23451		23492
	23247		23288		23329		23370		23411		23452		23493
	23248		23289		23330		23371		23412		23453		23494
	23249		23290		23331		23372		23413		23454		23495
	23250		23291		23332		23373		23414		23455		23496
	23251		23292		23333		23374		23415		23456		23497
	23252		23293		23334		23375		23416		23457		23498
	23253		23294		23335		23376		23417		23458		23499
	23254		23295		23336		23377		23418		23459		23500
	23255		23296		23337		23378		23419		23460		23501
	23256		23297		23338		23379		23420		23461		23502
	23257		23298		23339		23380		23421		23462		23503
	23258		23299		23340		23381		23422		23463		23504
	23259		23300		23341		23382		23423		23464		23505
	23260		23301		23342		23383		23424		23465		23506
	23261		23302		23343		23384		23425		23466		23507
	23262		23303		23344		23385		23426		23467		23508
	23263		23304		23345		23386		23427		23468		23509
	23264		23305		23346		23387		23428		23469		23510
	23265		23306		23347		23388		23429		23470		23511
	23266		23307		23348		23389		23430		23471		23512
	23267		23308		23349		23390		23431		23472		23513
	23268		23309		23350		23391		23432		23473		23514
	23269		23310		23351		23392		23433		23474		23515
	23270		23311		23352		23393		23434		23475		23516
	23271		23312		23353		23394		23435		23476		23517
	23272		23313		23354		23395		23436		23477		23518
	23273		23314		23355		23396		23437		23478		23519
	23274		23315		23356		23397		23438		23479		23520
	23275		23316		23357		23398		23439		23480		23521
	23276		23317		23358		23399		23440		23481		23522

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	23523	PPD	23564	PPD	23605	PPD	23646	PPD	23687	PPD	23728	PPD	23769
	23524		23565		23606		23647		23688		23729		23770
	23525		23566		23607		23648		23689		23730		23771
	23526		23567		23608		23649		23690		23731		23772
	23527		23568		23609		23650		23691		23732		23773
	23528		23569		23610		23651		23692		23733		23774
	23529		23570		23611		23652		23693		23734		23775
	23530		23571		23612		23653		23694		23735		23776
	23531		23572		23613		23654		23695		23736		23777
	23532		23573		23614		23655		23696		23737		23778
	23533		23574		23615		23656		23697		23738		23779
	23534		23575		23616		23657		23698		23739		23780
	23535		23576		23617		23658		23699		23740		23781
	23536		23577		23618		23659		23700		23741		23782
	23537		23578		23619		23660		23701		23742		23783
	23538		23579		23620		23661		23702		23743		23784
	23539		23580		23621		23662		23703		23744		23785
	23540		23581		23622		23663		23704		23745		23786
	23541		23582		23623		23664		23705		23746		23787
	23542		23583		23624		23665		23706		23747		23788
	23543		23584		23625		23666		23707		23748		23789
	23544		23585		23626		23667		23708		23749		23790
	23545		23586		23627		23668		23709		23750		23791
	23546		23587		23628		23669		23710		23751		23792
	23547		23588		23629		23670		23711		23752		23793
	23548		23589		23630		23671		23712		23753		23794
	23549		23590		23631		23672		23713		23754		23795
	23550		23591		23632		23673		23714		23755		23796
	23551		23592		23633		23674		23715		23756		23797
	23552		23593		23634		23675		23716		23757		23798
	23553		23594		23635		23676		23717		23758		23799
	23554		23595		23636		23677		23718		23759		23800
	23555		23596		23637		23678		23719		23760		23801
	23556		23597		23638		23679		23720		23761		23802
	23557		23598		23639		23680		23721		23762		23803
	23558		23599		23640		23681		23722		23763		23804
	23559		23600		23641		23682		23723		23764		23805
	23560		23601		23642		23683		23724		23765		23806
	23561		23602		23643		23684		23725		23766		23807
	23562		23603		23644		23685		23726		23767		23808
	23563		23604		23645		23686		23727		23768		23809

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	23810	PPD	23851	PPD	23892	PPD	23933	PPD	23974	PPD	24015	PPD	24056
	23811		23852		23893		23934		23975		24016		24057
	23812		23853		23894		23935		23976		24017		24058
	23813		23854		23895		23936		23977		24018		24059
	23814		23855		23896		23937		23978		24019		24060
	23815		23856		23897		23938		23979		24020		24061
	23816		23857		23898		23939		23980		24021		24062
	23817		23858		23899		23940		23981		24022		24063
	23818		23859		23900		23941		23982		24023		24064
	23819		23860		23901		23942		23983		24024		24065
	23820		23861		23902		23943		23984		24025		24066
	23821		23862		23903		23944		23985		24026		24067
	23822		23863		23904		23945		23986		24027		24068
	23823		23864		23905		23946		23987		24028		24069
	23824		23865		23906		23947		23988		24029		24070
	23825		23866		23907		23948		23989		24030		24071
	23826		23867		23908		23949		23990		24031		24072
	23827		23868		23909		23950		23991		24032		24073
	23828		23869		23910		23951		23992		24033		24074
	23829		23870		23911		23952		23993		24034		24075
	23830		23871		23912		23953		23994		24035		24076
	23831		23872		23913		23954		23995		24036		24077
	23832		23873		23914		23955		23996		24037		24078
	23833		23874		23915		23956		23997		24038		24079
	23834		23875		23916		23957		23998		24039		24080
	23835		23876		23917		23958		23999		24040		24081
	23836		23877		23918		23959		24000		24041		24082
	23837		23878		23919		23960		24001		24042		24083
	23838		23879		23920		23961		24002		24043		24084
	23839		23880		23921		23962		24003		24044		24085
	23840		23881		23922		23963		24004		24045		24086
	23841		23882		23923		23964		24005		24046		24087
	23842		23883		23924		23965		24006		24047		24088
	23843		23884		23925		23966		24007		24048		24089
	23844		23885		23926		23967		24008		24049		24090
	23845		23886		23927		23968		24009		24050		24091
	23846		23887		23928		23969		24010		24051		24092
	23847		23888		23929		23970		24011		24052		24093
	23848		23889		23930		23971		24012		24053		24094
	23849		23890		23931		23972		24013		24054		24095
	23850		23891		23932		23973		24014		24055		24096

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		24097
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Trt.	Bl. No	nb
PPD		24138
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Trt.	Bl. No	nb
PPD		24179
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Trt.	Bl. No	nb
PPD		24220
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Trt.	Bl. No	nb
PPD		24261
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	24384	PPD	24425	PPD	24466	PPD	24507	PPD	24548	PPD	24589	PPD	24630
	24385		24426		24467		24508		24549		24590		24631
	24386		24427		24468		24509		24550		24591		24632
	24387		24428		24469		24510		24551		24592		24633
	24388		24429		24470		24511		24552		24593		24634
	24389		24430		24471		24512		24553		24594		24635
	24390		24431		24472		24513		24554		24595		24636
	24391		24432		24473		24514		24555		24596		24637
	24392		24433		24474		24515		24556		24597		24638
	24393		24434		24475		24516		24557		24598		24639
	24394		24435		24476		24517		24558		24599		24640
	24395		24436		24477		24518		24559		24600		24641
	24396		24437		24478		24519		24560		24601		24642
	24397		24438		24479		24520		24561		24602		24643
	24398		24439		24480		24521		24562		24603		24644
	24399		24440		24481		24522		24563		24604		24645
	24400		24441		24482		24523		24564		24605		24646
	24401		24442		24483		24524		24565		24606		24647
	24402		24443		24484		24525		24566		24607		24648
	24403		24444		24485		24526		24567		24608		24649
	24404		24445		24486		24527		24568		24609		24650
	24405		24446		24487		24528		24569		24610		24651
	24406		24447		24488		24529		24570		24611		24652
	24407		24448		24489		24530		24571		24612		24653
	24408		24449		24490		24531		24572		24613		24654
	24409		24450		24491		24532		24573		24614		24655
	24410		24451		24492		24533		24574		24615		24656
	24411		24452		24493		24534		24575		24616		24657
	24412		24453		24494		24535		24576		24617		24658
	24413		24454		24495		24536		24577		24618		24659
	24414		24455		24496		24537		24578		24619		24660
	24415		24456		24497		24538		24579		24620		24661
	24416		24457		24498		24539		24580		24621		24662
	24417		24458		24499		24540		24581		24622		24663
	24418		24459		24500		24541		24582		24623		24664
	24419		24460		24501		24542		24583		24624		24665
	24420		24461		24502		24543		24584		24625		24666
	24421		24462		24503		24544		24585		24626		24667
	24422		24463		24504		24545		24586		24627		24668
	24423		24464		24505		24546		24587		24628		24669
	24424		24465		24506		24547		24588		24629		24670

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	24671	PPD	24712	PPD	24753	PPD	24794	PPD	24835	PPD	24876	PPD	24917
	24672		24713		24754		24795		24836		24877		24918
	24673		24714		24755		24796		24837		24878		24919
	24674		24715		24756		24797		24838		24879		24920
	24675		24716		24757		24798		24839		24880		24921
	24676		24717		24758		24799		24840		24881		24922
	24677		24718		24759		24800		24841		24882		24923
	24678		24719		24760		24801		24842		24883		24924
	24679		24720		24761		24802		24843		24884		24925
	24680		24721		24762		24803		24844		24885		24926
	24681		24722		24763		24804		24845		24886		24927
	24682		24723		24764		24805		24846		24887		24928
	24683		24724		24765		24806		24847		24888		24929
	24684		24725		24766		24807		24848		24889		24930
	24685		24726		24767		24808		24849		24890		24931
	24686		24727		24768		24809		24850		24891		24932
	24687		24728		24769		24810		24851		24892		24933
	24688		24729		24770		24811		24852		24893		24934
	24689		24730		24771		24812		24853		24894		24935
	24690		24731		24772		24813		24854		24895		24936
	24691		24732		24773		24814		24855		24896		24937
	24692		24733		24774		24815		24856		24897		24938
	24693		24734		24775		24816		24857		24898		24939
	24694		24735		24776		24817		24858		24899		24940
	24695		24736		24777		24818		24859		24900		24941
	24696		24737		24778		24819		24860		24901		24942
	24697		24738		24779		24820		24861		24902		24943
	24698		24739		24780		24821		24862		24903		24944
	24699		24740		24781		24822		24863		24904		24945
	24700		24741		24782		24823		24864		24905		24946
	24701		24742		24783		24824		24865		24906		24947
	24702		24743		24784		24825		24866		24907		24948
	24703		24744		24785		24826		24867		24908		24949
	24704		24745		24786		24827		24868		24909		24950
	24705		24746		24787		24828		24869		24910		24951
	24706		24747		24788		24829		24870		24911		24952
	24707		24748		24789		24830		24871		24912		24953
	24708		24749		24790		24831		24872		24913		24954
	24709		24750		24791		24832		24873		24914		24955
	24710		24751		24792		24833		24874		24915		24956
	24711		24752		24793		24834		24875		24916		24957

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	nb
PPD		24958
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		24995
		24996
		24997
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Trt.	Bl. No	nb
PPD		24999
		25000
		25001
		25002
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Trt.	Bl. No	nb
PPD		25040
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		25078
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Trt.	Bl. No	nb
PPD		25081
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Trt.	Bl. No	nb
PPD		25122
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		25162

Trt.	Bl. No	nb
PPD		25163
		25164
		25165
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Trt.	Bl. No	nb
PPD		25204
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	25245	PPD	25286	PPD	25327	PPD	25368	PPD	25409	PPD	25450	PPD	25491
	25246		25287		25328		25369		25410		25451		25492
	25247		25288		25329		25370		25411		25452		25493
	25248		25289		25330		25371		25412		25453		25494
	25249		25290		25331		25372		25413		25454		25495
	25250		25291		25332		25373		25414		25455		25496
	25251		25292		25333		25374		25415		25456		25497
	25252		25293		25334		25375		25416		25457		25498
	25253		25294		25335		25376		25417		25458		25499
	25254		25295		25336		25377		25418		25459		25500
	25255		25296		25337		25378		25419		25460		25501
	25256		25297		25338		25379		25420		25461		25502
	25257		25298		25339		25380		25421		25462		25503
	25258		25299		25340		25381		25422		25463		25504
	25259		25300		25341		25382		25423		25464		25505
	25260		25301		25342		25383		25424		25465		25506
	25261		25302		25343		25384		25425		25466		25507
	25262		25303		25344		25385		25426		25467		25508
	25263		25304		25345		25386		25427		25468		25509
	25264		25305		25346		25387		25428		25469		25510
	25265		25306		25347		25388		25429		25470		25511
	25266		25307		25348		25389		25430		25471		25512
	25267		25308		25349		25390		25431		25472		25513
	25268		25309		25350		25391		25432		25473		25514
	25269		25310		25351		25392		25433		25474		25515
	25270		25311		25352		25393		25434		25475		25516
	25271		25312		25353		25394		25435		25476		25517
	25272		25313		25354		25395		25436		25477		25518
	25273		25314		25355		25396		25437		25478		25519
	25274		25315		25356		25397		25438		25479		25520
	25275		25316		25357		25398		25439		25480		25521
	25276		25317		25358		25399		25440		25481		25522
	25277		25318		25359		25400		25441		25482		25523
	25278		25319		25360		25401		25442		25483		25524
	25279		25320		25361		25402		25443		25484		25525
	25280		25321		25362		25403		25444		25485		25526
	25281		25322		25363		25404		25445		25486		25527
	25282		25323		25364		25405		25446		25487		25528
	25283		25324		25365		25406		25447		25488		25529
	25284		25325		25366		25407		25448		25489		25530
	25285		25326		25367		25408		25449		25490		25531

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	Bl. nb
PPD		25532
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Trt.	Bl. No	Bl. nb
PPD		25573
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Trt.	Bl. No	Bl. nb
PPD		25614
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Trt.	Bl. No	Bl. nb
PPD		25655
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Trt.	Bl. No	Bl. nb
PPD		25696
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Trt.	Bl. No	Bl. nb
PPD		25737
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Trt.	Bl. No	Bl. nb
PPD		25778
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	25819	PPD	25860	PPD	25901	PPD	25942	PPD	25983	PPD	26024	PPD	26065
	25820		25861		25902		25943		25984		26025		26066
	25821		25862		25903		25944		25985		26026		26067
	25822		25863		25904		25945		25986		26027		26068
	25823		25864		25905		25946		25987		26028		26069
	25824		25865		25906		25947		25988		26029		26070
	25825		25866		25907		25948		25989		26030		26071
	25826		25867		25908		25949		25990		26031		26072
	25827		25868		25909		25950		25991		26032		26073
	25828		25869		25910		25951		25992		26033		26074
	25829		25870		25911		25952		25993		26034		26075
	25830		25871		25912		25953		25994		26035		26076
	25831		25872		25913		25954		25995		26036		26077
	25832		25873		25914		25955		25996		26037		26078
	25833		25874		25915		25956		25997		26038		26079
	25834		25875		25916		25957		25998		26039		26080
	25835		25876		25917		25958		25999		26040		26081
	25836		25877		25918		25959		26000		26041		26082
	25837		25878		25919		25960		26001		26042		26083
	25838		25879		25920		25961		26002		26043		26084
	25839		25880		25921		25962		26003		26044		26085
	25840		25881		25922		25963		26004		26045		26086
	25841		25882		25923		25964		26005		26046		26087
	25842		25883		25924		25965		26006		26047		26088
	25843		25884		25925		25966		26007		26048		26089
	25844		25885		25926		25967		26008		26049		26090
	25845		25886		25927		25968		26009		26050		26091
	25846		25887		25928		25969		26010		26051		26092
	25847		25888		25929		25970		26011		26052		26093
	25848		25889		25930		25971		26012		26053		26094
	25849		25890		25931		25972		26013		26054		26095
	25850		25891		25932		25973		26014		26055		26096
	25851		25892		25933		25974		26015		26056		26097
	25852		25893		25934		25975		26016		26057		26098
	25853		25894		25935		25976		26017		26058		26099
	25854		25895		25936		25977		26018		26059		26100
	25855		25896		25937		25978		26019		26060		26101
	25856		25897		25938		25979		26020		26061		26102
	25857		25898		25939		25980		26021		26062		26103
	25858		25899		25940		25981		26022		26063		26104
	25859		25900		25941		25982		26023		26064		26105

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	26106	PPD	26147	PPD	26188	PPD	26229	PPD	26270	PPD	26311	PPD	26352
	26107		26148		26189		26230		26271		26312		26353
	26108		26149		26190		26231		26272		26313		26354
	26109		26150		26191		26232		26273		26314		26355
	26110		26151		26192		26233		26274		26315		26356
	26111		26152		26193		26234		26275		26316		26357
	26112		26153		26194		26235		26276		26317		26358
	26113		26154		26195		26236		26277		26318		26359
	26114		26155		26196		26237		26278		26319		26360
	26115		26156		26197		26238		26279		26320		26361
	26116		26157		26198		26239		26280		26321		26362
	26117		26158		26199		26240		26281		26322		26363
	26118		26159		26200		26241		26282		26323		26364
	26119		26160		26201		26242		26283		26324		26365
	26120		26161		26202		26243		26284		26325		26366
	26121		26162		26203		26244		26285		26326		26367
	26122		26163		26204		26245		26286		26327		26368
	26123		26164		26205		26246		26287		26328		26369
	26124		26165		26206		26247		26288		26329		26370
	26125		26166		26207		26248		26289		26330		26371
	26126		26167		26208		26249		26290		26331		26372
	26127		26168		26209		26250		26291		26332		26373
	26128		26169		26210		26251		26292		26333		26374
	26129		26170		26211		26252		26293		26334		26375
	26130		26171		26212		26253		26294		26335		26376
	26131		26172		26213		26254		26295		26336		26377
	26132		26173		26214		26255		26296		26337		26378
	26133		26174		26215		26256		26297		26338		26379
	26134		26175		26216		26257		26298		26339		26380
	26135		26176		26217		26258		26299		26340		26381
	26136		26177		26218		26259		26300		26341		26382
	26137		26178		26219		26260		26301		26342		26383
	26138		26179		26220		26261		26302		26343		26384
	26139		26180		26221		26262		26303		26344		26385
	26140		26181		26222		26263		26304		26345		26386
	26141		26182		26223		26264		26305		26346		26387
	26142		26183		26224		26265		26306		26347		26388
	26143		26184		26225		26266		26307		26348		26389
	26144		26185		26226		26267		26308		26349		26390
	26145		26186		26227		26268		26309		26350		26391
	26146		26187		26228		26269		26310		26351		26392

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	26393	PPD	26434	PPD	26475	PPD	26516	PPD	26557	PPD	26598	PPD	26639
	26394		26435		26476		26517		26558		26599		26640
	26395		26436		26477		26518		26559		26600		26641
	26396		26437		26478		26519		26560		26601		26642
	26397		26438		26479		26520		26561		26602		26643
	26398		26439		26480		26521		26562		26603		26644
	26399		26440		26481		26522		26563		26604		26645
	26400		26441		26482		26523		26564		26605		26646
	26401		26442		26483		26524		26565		26606		26647
	26402		26443		26484		26525		26566		26607		26648
	26403		26444		26485		26526		26567		26608		26649
	26404		26445		26486		26527		26568		26609		26650
	26405		26446		26487		26528		26569		26610		26651
	26406		26447		26488		26529		26570		26611		26652
	26407		26448		26489		26530		26571		26612		26653
	26408		26449		26490		26531		26572		26613		26654
	26409		26450		26491		26532		26573		26614		26655
	26410		26451		26492		26533		26574		26615		26656
	26411		26452		26493		26534		26575		26616		26657
	26412		26453		26494		26535		26576		26617		26658
	26413		26454		26495		26536		26577		26618		26659
	26414		26455		26496		26537		26578		26619		26660
	26415		26456		26497		26538		26579		26620		26661
	26416		26457		26498		26539		26580		26621		26662
	26417		26458		26499		26540		26581		26622		26663
	26418		26459		26500		26541		26582		26623		26664
	26419		26460		26501		26542		26583		26624		26665
	26420		26461		26502		26543		26584		26625		26666
	26421		26462		26503		26544		26585		26626		26667
	26422		26463		26504		26545		26586		26627		26668
	26423		26464		26505		26546		26587		26628		26669
	26424		26465		26506		26547		26588		26629		26670
	26425		26466		26507		26548		26589		26630		26671
	26426		26467		26508		26549		26590		26631		26672
	26427		26468		26509		26550		26591		26632		26673
	26428		26469		26510		26551		26592		26633		26674
	26429		26470		26511		26552		26593		26634		26675
	26430		26471		26512		26553		26594		26635		26676
	26431		26472		26513		26554		26595		26636		26677
	26432		26473		26514		26555		26596		26637		26678
	26433		26474		26515		26556		26597		26638		26679

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	26680	PPD	26721	PPD	26762	PPD	26803	PPD	26844	PPD	26885	PPD	26926
	26681		26722		26763		26804		26845		26886		26927
	26682		26723		26764		26805		26846		26887		26928
	26683		26724		26765		26806		26847		26888		26929
	26684		26725		26766		26807		26848		26889		26930
	26685		26726		26767		26808		26849		26890		26931
	26686		26727		26768		26809		26850		26891		26932
	26687		26728		26769		26810		26851		26892		26933
	26688		26729		26770		26811		26852		26893		26934
	26689		26730		26771		26812		26853		26894		26935
	26690		26731		26772		26813		26854		26895		26936
	26691		26732		26773		26814		26855		26896		26937
	26692		26733		26774		26815		26856		26897		26938
	26693		26734		26775		26816		26857		26898		26939
	26694		26735		26776		26817		26858		26899		26940
	26695		26736		26777		26818		26859		26900		26941
	26696		26737		26778		26819		26860		26901		26942
	26697		26738		26779		26820		26861		26902		26943
	26698		26739		26780		26821		26862		26903		26944
	26699		26740		26781		26822		26863		26904		26945
	26700		26741		26782		26823		26864		26905		26946
	26701		26742		26783		26824		26865		26906		26947
	26702		26743		26784		26825		26866		26907		26948
	26703		26744		26785		26826		26867		26908		26949
	26704		26745		26786		26827		26868		26909		26950
	26705		26746		26787		26828		26869		26910		26951
	26706		26747		26788		26829		26870		26911		26952
	26707		26748		26789		26830		26871		26912		26953
	26708		26749		26790		26831		26872		26913		26954
	26709		26750		26791		26832		26873		26914		26955
	26710		26751		26792		26833		26874		26915		26956
	26711		26752		26793		26834		26875		26916		26957
	26712		26753		26794		26835		26876		26917		26958
	26713		26754		26795		26836		26877		26918		26959
	26714		26755		26796		26837		26878		26919		26960
	26715		26756		26797		26838		26879		26920		26961
	26716		26757		26798		26839		26880		26921		26962
	26717		26758		26799		26840		26881		26922		26963
	26718		26759		26800		26841		26882		26923		26964
	26719		26760		26801		26842		26883		26924		26965
	26720		26761		26802		26843		26884		26925		26966

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb	Trt.	Bl. No	Bl. nb
PPD		26967	PPD		27008	PPD		27049	PPD		27090	PPD		27131	PPD		27172	PPD		27213
		26968			27009			27050			27091			27132			27173			27214
		26969			27010			27051			27092			27133			27174			27215
		26970			27011			27052			27093			27134			27175			27216
		26971			27012			27053			27094			27135			27176			27217
		26972			27013			27054			27095			27136			27177			27218
		26973			27014			27055			27096			27137			27178			27219
		26974			27015			27056			27097			27138			27179			27220
		26975			27016			27057			27098			27139			27180			27221
		26976			27017			27058			27099			27140			27181			27222
		26977			27018			27059			27100			27141			27182			27223
		26978			27019			27060			27101			27142			27183			27224
		26979			27020			27061			27102			27143			27184			27225
		26980			27021			27062			27103			27144			27185			27226
		26981			27022			27063			27104			27145			27186			27227
		26982			27023			27064			27105			27146			27187			27228
		26983			27024			27065			27106			27147			27188			27229
		26984			27025			27066			27107			27148			27189			27230
		26985			27026			27067			27108			27149			27190			27231
		26986			27027			27068			27109			27150			27191			27232
		26987			27028			27069			27110			27151			27192			27233
		26988			27029			27070			27111			27152			27193			27234
		26989			27030			27071			27112			27153			27194			27235
		26990			27031			27072			27113			27154			27195			27236
		26991			27032			27073			27114			27155			27196			27237
		26992			27033			27074			27115			27156			27197			27238
		26993			27034			27075			27116			27157			27198			27239
		26994			27035			27076			27117			27158			27199			27240
		26995			27036			27077			27118			27159			27200			27241
		26996			27037			27078			27119			27160			27201			27242
		26997			27038			27079			27120			27161			27202			27243
		26998			27039			27080			27121			27162			27203			27244
		26999			27040			27081			27122			27163			27204			27245
		27000			27041			27082			27123			27164			27205			27246
		27001			27042			27083			27124			27165			27206			27247
		27002			27043			27084			27125			27166			27207			27248
		27003			27044			27085			27126			27167			27208			27249
		27004			27045			27086			27127			27168			27209			27250
		27005			27046			27087			27128			27169			27210			27251
		27006			27047			27088			27129			27170			27211			27252
		27007			27048			27089			27130			27171			27212			27253

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	27254	PPD	27295	PPD	27336	PPD	27377	PPD	27418	PPD	27459	PPD	27500
	27255		27296		27337		27378		27419		27460		27501
	27256		27297		27338		27379		27420		27461		27502
	27257		27298		27339		27380		27421		27462		27503
	27258		27299		27340		27381		27422		27463		27504
	27259		27300		27341		27382		27423		27464		27505
	27260		27301		27342		27383		27424		27465		27506
	27261		27302		27343		27384		27425		27466		27507
	27262		27303		27344		27385		27426		27467		27508
	27263		27304		27345		27386		27427		27468		27509
	27264		27305		27346		27387		27428		27469		27510
	27265		27306		27347		27388		27429		27470		27511
	27266		27307		27348		27389		27430		27471		27512
	27267		27308		27349		27390		27431		27472		27513
	27268		27309		27350		27391		27432		27473		27514
	27269		27310		27351		27392		27433		27474		27515
	27270		27311		27352		27393		27434		27475		27516
	27271		27312		27353		27394		27435		27476		27517
	27272		27313		27354		27395		27436		27477		27518
	27273		27314		27355		27396		27437		27478		27519
	27274		27315		27356		27397		27438		27479		27520
	27275		27316		27357		27398		27439		27480		27521
	27276		27317		27358		27399		27440		27481		27522
	27277		27318		27359		27400		27441		27482		27523
	27278		27319		27360		27401		27442		27483		27524
	27279		27320		27361		27402		27443		27484		27525
	27280		27321		27362		27403		27444		27485		27526
	27281		27322		27363		27404		27445		27486		27527
	27282		27323		27364		27405		27446		27487		27528
	27283		27324		27365		27406		27447		27488		27529
	27284		27325		27366		27407		27448		27489		27530
	27285		27326		27367		27408		27449		27490		27531
	27286		27327		27368		27409		27450		27491		27532
	27287		27328		27369		27410		27451		27492		27533
	27288		27329		27370		27411		27452		27493		27534
	27289		27330		27371		27412		27453		27494		27535
	27290		27331		27372		27413		27454		27495		27536
	27291		27332		27373		27414		27455		27496		27537
	27292		27333		27374		27415		27456		27497		27538
	27293		27334		27375		27416		27457		27498		27539
	27294		27335		27376		27417		27458		27499		27540

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Havrix vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	27541	PPD	27582	PPD	27623
	27542		27583		27624
	27543		27584		27625
	27544		27585		
	27545		27586		
	27546		27587		
	27547		27588		
	27548		27589		
	27549		27590		
	27550		27591		
	27551		27592		
	27552		27593		
	27553		27594		
	27554		27595		
	27555		27596		
	27556		27597		
	27557		27598		
	27558		27599		
	27559		27600		
	27560		27601		
	27561		27602		
	27562		27603		
	27563		27604		
	27564		27605		
	27565		27606		
	27566		27607		
	27567		27608		
	27568		27609		
	27569		27610		
	27570		27611		
	27571		27612		
	27572		27613		
	27573		27614		
	27574		27615		
	27575		27616		
	27576		27617		
	27577		27618		
	27578		27619		
	27579		27620		
	27580		27621		
	27581		27622		

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	27626	PPD	27667	PPD	27708	PPD	27749	PPD	27790	PPD	27831	PPD	27872
	27627		27668		27709		27750		27791		27832		27873
	27628		27669		27710		27751		27792		27833		27874
	27629		27670		27711		27752		27793		27834		27875
	27630		27671		27712		27753		27794		27835		27876
	27631		27672		27713		27754		27795		27836		27877
	27632		27673		27714		27755		27796		27837		27878
	27633		27674		27715		27756		27797		27838		27879
	27634		27675		27716		27757		27798		27839		27880
	27635		27676		27717		27758		27799		27840		27881
	27636		27677		27718		27759		27800		27841		27882
	27637		27678		27719		27760		27801		27842		27883
	27638		27679		27720		27761		27802		27843		27884
	27639		27680		27721		27762		27803		27844		27885
	27640		27681		27722		27763		27804		27845		27886
	27641		27682		27723		27764		27805		27846		27887
	27642		27683		27724		27765		27806		27847		27888
	27643		27684		27725		27766		27807		27848		27889
	27644		27685		27726		27767		27808		27849		27890
	27645		27686		27727		27768		27809		27850		27891
	27646		27687		27728		27769		27810		27851		27892
	27647		27688		27729		27770		27811		27852		27893
	27648		27689		27730		27771		27812		27853		27894
	27649		27690		27731		27772		27813		27854		27895
	27650		27691		27732		27773		27814		27855		27896
	27651		27692		27733		27774		27815		27856		27897
	27652		27693		27734		27775		27816		27857		27898
	27653		27694		27735		27776		27817		27858		27899
	27654		27695		27736		27777		27818		27859		27900
	27655		27696		27737		27778		27819		27860		27901
	27656		27697		27738		27779		27820		27861		27902
	27657		27698		27739		27780		27821		27862		27903
	27658		27699		27740		27781		27822		27863		27904
	27659		27700		27741		27782		27823		27864		27905
	27660		27701		27742		27783		27824		27865		27906
	27661		27702		27743		27784		27825		27866		27907
	27662		27703		27744		27785		27826		27867		27908
	27663		27704		27745		27786		27827		27868		27909
	27664		27705		27746		27787		27828		27869		27910
	27665		27706		27747		27788		27829		27870		27911
	27666		27707		27748		27789		27830		27871		27912

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt.	Bl. No	nb
PPD		27913
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Trt.	Bl. No	nb
PPD		27954
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Trt.	Bl. No	nb
PPD		27995
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Trt.	Bl. No	nb
PPD		28036
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		28074
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Trt.	Bl. No	nb
PPD		28077
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Trt.	Bl. No	nb
PPD		28118
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Trt.	Bl. No	nb
PPD		28159
		28160
		28161
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SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		28200	PPD		28241	PPD		28282	PPD		28323	PPD		28364	PPD		28405	PPD		28446
		28201			28242			28283			28324			28365			28406			28447
		28202			28243			28284			28325			28366			28407			28448
		28203			28244			28285			28326			28367			28408			28449
		28204			28245			28286			28327			28368			28409			28450
		28205			28246			28287			28328			28369			28410			28451
		28206			28247			28288			28329			28370			28411			28452
		28207			28248			28289			28330			28371			28412			28453
		28208			28249			28290			28331			28372			28413			28454
		28209			28250			28291			28332			28373			28414			28455
		28210			28251			28292			28333			28374			28415			28456
		28211			28252			28293			28334			28375			28416			28457
		28212			28253			28294			28335			28376			28417			28458
		28213			28254			28295			28336			28377			28418			28459
		28214			28255			28296			28337			28378			28419			28460
		28215			28256			28297			28338			28379			28420			28461
		28216			28257			28298			28339			28380			28421			28462
		28217			28258			28299			28340			28381			28422			28463
		28218			28259			28300			28341			28382			28423			28464
		28219			28260			28301			28342			28383			28424			28465
		28220			28261			28302			28343			28384			28425			28466
		28221			28262			28303			28344			28385			28426			28467
		28222			28263			28304			28345			28386			28427			28468
		28223			28264			28305			28346			28387			28428			28469
		28224			28265			28306			28347			28388			28429			28470
		28225			28266			28307			28348			28389			28430			28471
		28226			28267			28308			28349			28390			28431			28472
		28227			28268			28309			28350			28391			28432			28473
		28228			28269			28310			28351			28392			28433			28474
		28229			28270			28311			28352			28393			28434			28475
		28230			28271			28312			28353			28394			28435			28476
		28231			28272			28313			28354			28395			28436			28477
		28232			28273			28314			28355			28396			28437			28478
		28233			28274			28315			28356			28397			28438			28479
		28234			28275			28316			28357			28398			28439			28480
		28235			28276			28317			28358			28399			28440			28481
		28236			28277			28318			28359			28400			28441			28482
		28237			28278			28319			28360			28401			28442			28483
		28238			28279			28320			28361			28402			28443			28484
		28239			28280			28321			28362			28403			28444			28485
		28240			28281			28322			28363			28404			28445			28486

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	28487	PPD	28528	PPD	28569	PPD	28610	PPD	28651	PPD	28692	PPD	28733
	28488		28529		28570		28611		28652		28693		28734
	28489		28530		28571		28612		28653		28694		28735
	28490		28531		28572		28613		28654		28695		28736
	28491		28532		28573		28614		28655		28696		28737
	28492		28533		28574		28615		28656		28697		28738
	28493		28534		28575		28616		28657		28698		28739
	28494		28535		28576		28617		28658		28699		28740
	28495		28536		28577		28618		28659		28700		28741
	28496		28537		28578		28619		28660		28701		28742
	28497		28538		28579		28620		28661		28702		28743
	28498		28539		28580		28621		28662		28703		28744
	28499		28540		28581		28622		28663		28704		28745
	28500		28541		28582		28623		28664		28705		28746
	28501		28542		28583		28624		28665		28706		28747
	28502		28543		28584		28625		28666		28707		28748
	28503		28544		28585		28626		28667		28708		28749
	28504		28545		28586		28627		28668		28709		28750
	28505		28546		28587		28628		28669		28710		28751
	28506		28547		28588		28629		28670		28711		28752
	28507		28548		28589		28630		28671		28712		28753
	28508		28549		28590		28631		28672		28713		28754
	28509		28550		28591		28632		28673		28714		28755
	28510		28551		28592		28633		28674		28715		28756
	28511		28552		28593		28634		28675		28716		28757
	28512		28553		28594		28635		28676		28717		28758
	28513		28554		28595		28636		28677		28718		28759
	28514		28555		28596		28637		28678		28719		28760
	28515		28556		28597		28638		28679		28720		28761
	28516		28557		28598		28639		28680		28721		28762
	28517		28558		28599		28640		28681		28722		28763
	28518		28559		28600		28641		28682		28723		28764
	28519		28560		28601		28642		28683		28724		28765
	28520		28561		28602		28643		28684		28725		28766
	28521		28562		28603		28644		28685		28726		28767
	28522		28563		28604		28645		28686		28727		28768
	28523		28564		28605		28646		28687		28728		28769
	28524		28565		28606		28647		28688		28729		28770
	28525		28566		28607		28648		28689		28730		28771
	28526		28567		28608		28649		28690		28731		28772
	28527		28568		28609		28650		28691		28732		28773

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb	Trt.	Bl. No	nb
PPD		28774	PPD		28815	PPD		28856	PPD		28897	PPD		28938	PPD		28979	PPD		29020
		28775			28816			28857			28898			28939			28980			29021
		28776			28817			28858			28899			28940			28981			29022
		28777			28818			28859			28900			28941			28982			29023
		28778			28819			28860			28901			28942			28983			29024
		28779			28820			28861			28902			28943			28984			29025
		28780			28821			28862			28903			28944			28985			29026
		28781			28822			28863			28904			28945			28986			29027
		28782			28823			28864			28905			28946			28987			29028
		28783			28824			28865			28906			28947			28988			29029
		28784			28825			28866			28907			28948			28989			29030
		28785			28826			28867			28908			28949			28990			29031
		28786			28827			28868			28909			28950			28991			29032
		28787			28828			28869			28910			28951			28992			29033
		28788			28829			28870			28911			28952			28993			29034
		28789			28830			28871			28912			28953			28994			29035
		28790			28831			28872			28913			28954			28995			29036
		28791			28832			28873			28914			28955			28996			29037
		28792			28833			28874			28915			28956			28997			29038
		28793			28834			28875			28916			28957			28998			29039
		28794			28835			28876			28917			28958			28999			29040
		28795			28836			28877			28918			28959			29000			29041
		28796			28837			28878			28919			28960			29001			29042
		28797			28838			28879			28920			28961			29002			29043
		28798			28839			28880			28921			28962			29003			29044
		28799			28840			28881			28922			28963			29004			29045
		28800			28841			28882			28923			28964			29005			29046
		28801			28842			28883			28924			28965			29006			29047
		28802			28843			28884			28925			28966			29007			29048
		28803			28844			28885			28926			28967			29008			29049
		28804			28845			28886			28927			28968			29009			29050
		28805			28846			28887			28928			28969			29010			29051
		28806			28847			28888			28929			28970			29011			29052
		28807			28848			28889			28930			28971			29012			29053
		28808			28849			28890			28931			28972			29013			29054
		28809			28850			28891			28932			28973			29014			29055
		28810			28851			28892			28933			28974			29015			29056
		28811			28852			28893			28934			28975			29016			29057
		28812			28853			28894			28935			28976			29017			29058
		28813			28854			28895			28936			28977			29018			29059
		28814			28855			28896			28937			28978			29019			29060

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	29061	PPD	29102	PPD	29143	PPD	29184	PPD	29225	PPD	29266	PPD	29307
	29062		29103		29144		29185		29226		29267		29308
	29063		29104		29145		29186		29227		29268		29309
	29064		29105		29146		29187		29228		29269		29310
	29065		29106		29147		29188		29229		29270		29311
	29066		29107		29148		29189		29230		29271		29312
	29067		29108		29149		29190		29231		29272		29313
	29068		29109		29150		29191		29232		29273		29314
	29069		29110		29151		29192		29233		29274		29315
	29070		29111		29152		29193		29234		29275		29316
	29071		29112		29153		29194		29235		29276		29317
	29072		29113		29154		29195		29236		29277		29318
	29073		29114		29155		29196		29237		29278		29319
	29074		29115		29156		29197		29238		29279		29320
	29075		29116		29157		29198		29239		29280		29321
	29076		29117		29158		29199		29240		29281		29322
	29077		29118		29159		29200		29241		29282		29323
	29078		29119		29160		29201		29242		29283		29324
	29079		29120		29161		29202		29243		29284		29325
	29080		29121		29162		29203		29244		29285		29326
	29081		29122		29163		29204		29245		29286		29327
	29082		29123		29164		29205		29246		29287		29328
	29083		29124		29165		29206		29247		29288		29329
	29084		29125		29166		29207		29248		29289		29330
	29085		29126		29167		29208		29249		29290		29331
	29086		29127		29168		29209		29250		29291		29332
	29087		29128		29169		29210		29251		29292		29333
	29088		29129		29170		29211		29252		29293		29334
	29089		29130		29171		29212		29253		29294		29335
	29090		29131		29172		29213		29254		29295		29336
	29091		29132		29173		29214		29255		29296		29337
	29092		29133		29174		29215		29256		29297		29338
	29093		29134		29175		29216		29257		29298		29339
	29094		29135		29176		29217		29258		29299		29340
	29095		29136		29177		29218		29259		29300		29341
	29096		29137		29178		29219		29260		29301		29342
	29097		29138		29179		29220		29261		29302		29343
	29098		29139		29180		29221		29262		29303		29344
	29099		29140		29181		29222		29263		29304		29345
	29100		29141		29182		29223		29264		29305		29346
	29101		29142		29183		29224		29265		29306		29347

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	29348	PPD	29389	PPD	29430	PPD	29471	PPD	29512	PPD	29553	PPD	29594
	29349		29390		29431		29472		29513		29554		29595
	29350		29391		29432		29473		29514		29555		29596
	29351		29392		29433		29474		29515		29556		29597
	29352		29393		29434		29475		29516		29557		29598
	29353		29394		29435		29476		29517		29558		29599
	29354		29395		29436		29477		29518		29559		29600
	29355		29396		29437		29478		29519		29560		29601
	29356		29397		29438		29479		29520		29561		29602
	29357		29398		29439		29480		29521		29562		29603
	29358		29399		29440		29481		29522		29563		29604
	29359		29400		29441		29482		29523		29564		29605
	29360		29401		29442		29483		29524		29565		29606
	29361		29402		29443		29484		29525		29566		29607
	29362		29403		29444		29485		29526		29567		29608
	29363		29404		29445		29486		29527		29568		29609
	29364		29405		29446		29487		29528		29569		29610
	29365		29406		29447		29488		29529		29570		29611
	29366		29407		29448		29489		29530		29571		29612
	29367		29408		29449		29490		29531		29572		29613
	29368		29409		29450		29491		29532		29573		29614
	29369		29410		29451		29492		29533		29574		29615
	29370		29411		29452		29493		29534		29575		29616
	29371		29412		29453		29494		29535		29576		29617
	29372		29413		29454		29495		29536		29577		29618
	29373		29414		29455		29496		29537		29578		29619
	29374		29415		29456		29497		29538		29579		29620
	29375		29416		29457		29498		29539		29580		29621
	29376		29417		29458		29499		29540		29581		29622
	29377		29418		29459		29500		29541		29582		29623
	29378		29419		29460		29501		29542		29583		29624
	29379		29420		29461		29502		29543		29584		29625
	29380		29421		29462		29503		29544		29585		29626
	29381		29422		29463		29504		29545		29586		29627
	29382		29423		29464		29505		29546		29587		29628
	29383		29424		29465		29506		29547		29588		29629
	29384		29425		29466		29507		29548		29589		29630
	29385		29426		29467		29508		29549		29590		29631
	29386		29427		29468		29509		29550		29591		29632
	29387		29428		29469		29510		29551		29592		29633
	29388		29429		29470		29511		29552		29593		29634

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	29635	PPD	29676	PPD	29717	PPD	29758	PPD	29799	PPD	29840	PPD	29881
	29636		29677		29718		29759		29800		29841		29882
	29637		29678		29719		29760		29801		29842		29883
	29638		29679		29720		29761		29802		29843		29884
	29639		29680		29721		29762		29803		29844		29885
	29640		29681		29722		29763		29804		29845		29886
	29641		29682		29723		29764		29805		29846		29887
	29642		29683		29724		29765		29806		29847		29888
	29643		29684		29725		29766		29807		29848		29889
	29644		29685		29726		29767		29808		29849		29890
	29645		29686		29727		29768		29809		29850		29891
	29646		29687		29728		29769		29810		29851		29892
	29647		29688		29729		29770		29811		29852		29893
	29648		29689		29730		29771		29812		29853		29894
	29649		29690		29731		29772		29813		29854		29895
	29650		29691		29732		29773		29814		29855		29896
	29651		29692		29733		29774		29815		29856		29897
	29652		29693		29734		29775		29816		29857		29898
	29653		29694		29735		29776		29817		29858		29899
	29654		29695		29736		29777		29818		29859		29900
	29655		29696		29737		29778		29819		29860		29901
	29656		29697		29738		29779		29820		29861		29902
	29657		29698		29739		29780		29821		29862		29903
	29658		29699		29740		29781		29822		29863		29904
	29659		29700		29741		29782		29823		29864		29905
	29660		29701		29742		29783		29824		29865		29906
	29661		29702		29743		29784		29825		29866		29907
	29662		29703		29744		29785		29826		29867		29908
	29663		29704		29745		29786		29827		29868		29909
	29664		29705		29746		29787		29828		29869		29910
	29665		29706		29747		29788		29829		29870		29911
	29666		29707		29748		29789		29830		29871		29912
	29667		29708		29749		29790		29831		29872		29913
	29668		29709		29750		29791		29832		29873		29914
	29669		29710		29751		29792		29833		29874		29915
	29670		29711		29752		29793		29834		29875		29916
	29671		29712		29753		29794		29835		29876		29917
	29672		29713		29754		29795		29836		29877		29918
	29673		29714		29755		29796		29837		29878		29919
	29674		29715		29756		29797		29838		29879		29920
	29675		29716		29757		29798		29839		29880		29921

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	29922	PPD	29963	PPD	30004	PPD	30045	PPD	30086	PPD	30127	PPD	30168
	29923		29964		30005		30046		30087		30128		30169
	29924		29965		30006		30047		30088		30129		30170
	29925		29966		30007		30048		30089		30130		30171
	29926		29967		30008		30049		30090		30131		30172
	29927		29968		30009		30050		30091		30132		30173
	29928		29969		30010		30051		30092		30133		30174
	29929		29970		30011		30052		30093		30134		30175
	29930		29971		30012		30053		30094		30135		30176
	29931		29972		30013		30054		30095		30136		30177
	29932		29973		30014		30055		30096		30137		30178
	29933		29974		30015		30056		30097		30138		30179
	29934		29975		30016		30057		30098		30139		30180
	29935		29976		30017		30058		30099		30140		30181
	29936		29977		30018		30059		30100		30141		30182
	29937		29978		30019		30060		30101		30142		30183
	29938		29979		30020		30061		30102		30143		30184
	29939		29980		30021		30062		30103		30144		30185
	29940		29981		30022		30063		30104		30145		30186
	29941		29982		30023		30064		30105		30146		30187
	29942		29983		30024		30065		30106		30147		30188
	29943		29984		30025		30066		30107		30148		30189
	29944		29985		30026		30067		30108		30149		30190
	29945		29986		30027		30068		30109		30150		30191
	29946		29987		30028		30069		30110		30151		30192
	29947		29988		30029		30070		30111		30152		30193
	29948		29989		30030		30071		30112		30153		30194
	29949		29990		30031		30072		30113		30154		30195
	29950		29991		30032		30073		30114		30155		30196
	29951		29992		30033		30074		30115		30156		30197
	29952		29993		30034		30075		30116		30157		30198
	29953		29994		30035		30076		30117		30158		30199
	29954		29995		30036		30077		30118		30159		30200
	29955		29996		30037		30078		30119		30160		30201
	29956		29997		30038		30079		30120		30161		30202
	29957		29998		30039		30080		30121		30162		30203
	29958		29999		30040		30081		30122		30163		30204
	29959		30000		30041		30082		30123		30164		30205
	29960		30001		30042		30083		30124		30165		30206
	29961		30002		30043		30084		30125		30166		30207
	29962		30003		30044		30085		30126		30167		30208

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	30209	PPD	30250	PPD	30291	PPD	30332	PPD	30373	PPD	30414	PPD	30455
	30210		30251		30292		30333		30374		30415		30456
	30211		30252		30293		30334		30375		30416		30457
	30212		30253		30294		30335		30376		30417		30458
	30213		30254		30295		30336		30377		30418		30459
	30214		30255		30296		30337		30378		30419		30460
	30215		30256		30297		30338		30379		30420		30461
	30216		30257		30298		30339		30380		30421		30462
	30217		30258		30299		30340		30381		30422		30463
	30218		30259		30300		30341		30382		30423		30464
	30219		30260		30301		30342		30383		30424		30465
	30220		30261		30302		30343		30384		30425		30466
	30221		30262		30303		30344		30385		30426		30467
	30222		30263		30304		30345		30386		30427		30468
	30223		30264		30305		30346		30387		30428		30469
	30224		30265		30306		30347		30388		30429		30470
	30225		30266		30307		30348		30389		30430		30471
	30226		30267		30308		30349		30390		30431		30472
	30227		30268		30309		30350		30391		30432		30473
	30228		30269		30310		30351		30392		30433		30474
	30229		30270		30311		30352		30393		30434		30475
	30230		30271		30312		30353		30394		30435		30476
	30231		30272		30313		30354		30395		30436		30477
	30232		30273		30314		30355		30396		30437		30478
	30233		30274		30315		30356		30397		30438		30479
	30234		30275		30316		30357		30398		30439		30480
	30235		30276		30317		30358		30399		30440		30481
	30236		30277		30318		30359		30400		30441		30482
	30237		30278		30319		30360		30401		30442		30483
	30238		30279		30320		30361		30402		30443		30484
	30239		30280		30321		30362		30403		30444		30485
	30240		30281		30322		30363		30404		30445		30486
	30241		30282		30323		30364		30405		30446		30487
	30242		30283		30324		30365		30406		30447		30488
	30243		30284		30325		30366		30407		30448		30489
	30244		30285		30326		30367		30408		30449		30490
	30245		30286		30327		30368		30409		30450		30491
	30246		30287		30328		30369		30410		30451		30492
	30247		30288		30329		30370		30411		30452		30493
	30248		30289		30330		30371		30412		30453		30494
	30249		30290		30331		30372		30413		30454		30495

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt.	Bl. No	nb
PPD		30496
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		30498
		30499
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		30533
		30534
		30535
		30536

Trt.	Bl. No	nb
PPD		30537
		30538
		30539
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		30542
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		30574
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		30576
		30577

Trt.	Bl. No	nb
PPD		30578
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		30618

Trt.	Bl. No	nb
PPD		30619
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		30659

Trt.	Bl. No	nb
PPD		30660
		30661
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		30696
		30697
		30698
		30699
		30700

Trt.	Bl. No	nb
PPD		30701
		30702
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		30738
		30739
		30740
		30741

Trt.	Bl. No	nb
PPD		30742
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		30781
		30782

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	30783	PPD	30824	PPD	30865	PPD	30906	PPD	30947	PPD	30988	PPD	31029
	30784		30825		30866		30907		30948		30989		31030
	30785		30826		30867		30908		30949		30990		31031
	30786		30827		30868		30909		30950		30991		31032
	30787		30828		30869		30910		30951		30992		31033
	30788		30829		30870		30911		30952		30993		31034
	30789		30830		30871		30912		30953		30994		31035
	30790		30831		30872		30913		30954		30995		31036
	30791		30832		30873		30914		30955		30996		31037
	30792		30833		30874		30915		30956		30997		31038
	30793		30834		30875		30916		30957		30998		31039
	30794		30835		30876		30917		30958		30999		31040
	30795		30836		30877		30918		30959		31000		31041
	30796		30837		30878		30919		30960		31001		31042
	30797		30838		30879		30920		30961		31002		31043
	30798		30839		30880		30921		30962		31003		31044
	30799		30840		30881		30922		30963		31004		31045
	30800		30841		30882		30923		30964		31005		31046
	30801		30842		30883		30924		30965		31006		31047
	30802		30843		30884		30925		30966		31007		31048
	30803		30844		30885		30926		30967		31008		31049
	30804		30845		30886		30927		30968		31009		31050
	30805		30846		30887		30928		30969		31010		31051
	30806		30847		30888		30929		30970		31011		31052
	30807		30848		30889		30930		30971		31012		31053
	30808		30849		30890		30931		30972		31013		31054
	30809		30850		30891		30932		30973		31014		31055
	30810		30851		30892		30933		30974		31015		31056
	30811		30852		30893		30934		30975		31016		31057
	30812		30853		30894		30935		30976		31017		31058
	30813		30854		30895		30936		30977		31018		31059
	30814		30855		30896		30937		30978		31019		31060
	30815		30856		30897		30938		30979		31020		31061
	30816		30857		30898		30939		30980		31021		31062
	30817		30858		30899		30940		30981		31022		31063
	30818		30859		30900		30941		30982		31023		31064
	30819		30860		30901		30942		30983		31024		31065
	30820		30861		30902		30943		30984		31025		31066
	30821		30862		30903		30944		30985		31026		31067
	30822		30863		30904		30945		30986		31027		31068
	30823		30864		30905		30946		30987		31028		31069

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	31070	PPD	31111	PPD	31152	PPD	31193	PPD	31234	PPD	31275	PPD	31316
	31071		31112		31153		31194		31235		31276		31317
	31072		31113		31154		31195		31236		31277		31318
	31073		31114		31155		31196		31237		31278		31319
	31074		31115		31156		31197		31238		31279		31320
	31075		31116		31157		31198		31239		31280		31321
	31076		31117		31158		31199		31240		31281		31322
	31077		31118		31159		31200		31241		31282		31323
	31078		31119		31160		31201		31242		31283		31324
	31079		31120		31161		31202		31243		31284		31325
	31080		31121		31162		31203		31244		31285		31326
	31081		31122		31163		31204		31245		31286		31327
	31082		31123		31164		31205		31246		31287		31328
	31083		31124		31165		31206		31247		31288		31329
	31084		31125		31166		31207		31248		31289		31330
	31085		31126		31167		31208		31249		31290		31331
	31086		31127		31168		31209		31250		31291		31332
	31087		31128		31169		31210		31251		31292		31333
	31088		31129		31170		31211		31252		31293		31334
	31089		31130		31171		31212		31253		31294		31335
	31090		31131		31172		31213		31254		31295		31336
	31091		31132		31173		31214		31255		31296		31337
	31092		31133		31174		31215		31256		31297		31338
	31093		31134		31175		31216		31257		31298		31339
	31094		31135		31176		31217		31258		31299		31340
	31095		31136		31177		31218		31259		31300		31341
	31096		31137		31178		31219		31260		31301		31342
	31097		31138		31179		31220		31261		31302		31343
	31098		31139		31180		31221		31262		31303		31344
	31099		31140		31181		31222		31263		31304		31345
	31100		31141		31182		31223		31264		31305		31346
	31101		31142		31183		31224		31265		31306		31347
	31102		31143		31184		31225		31266		31307		31348
	31103		31144		31185		31226		31267		31308		31349
	31104		31145		31186		31227		31268		31309		31350
	31105		31146		31187		31228		31269		31310		31351
	31106		31147		31188		31229		31270		31311		31352
	31107		31148		31189		31230		31271		31312		31353
	31108		31149		31190		31231		31272		31313		31354
	31109		31150		31191		31232		31273		31314		31355
	31110		31151		31192		31233		31274		31315		31356

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	31357	PPD	31398	PPD	31439	PPD	31480	PPD	31521	PPD	31562	PPD	31603
	31358		31399		31440		31481		31522		31563		31604
	31359		31400		31441		31482		31523		31564		31605
	31360		31401		31442		31483		31524		31565		31606
	31361		31402		31443		31484		31525		31566		31607
	31362		31403		31444		31485		31526		31567		31608
	31363		31404		31445		31486		31527		31568		31609
	31364		31405		31446		31487		31528		31569		31610
	31365		31406		31447		31488		31529		31570		31611
	31366		31407		31448		31489		31530		31571		31612
	31367		31408		31449		31490		31531		31572		31613
	31368		31409		31450		31491		31532		31573		31614
	31369		31410		31451		31492		31533		31574		31615
	31370		31411		31452		31493		31534		31575		31616
	31371		31412		31453		31494		31535		31576		31617
	31372		31413		31454		31495		31536		31577		31618
	31373		31414		31455		31496		31537		31578		31619
	31374		31415		31456		31497		31538		31579		31620
	31375		31416		31457		31498		31539		31580		31621
	31376		31417		31458		31499		31540		31581		31622
	31377		31418		31459		31500		31541		31582		31623
	31378		31419		31460		31501		31542		31583		31624
	31379		31420		31461		31502		31543		31584		31625
	31380		31421		31462		31503		31544		31585		31626
	31381		31422		31463		31504		31545		31586		31627
	31382		31423		31464		31505		31546		31587		31628
	31383		31424		31465		31506		31547		31588		31629
	31384		31425		31466		31507		31548		31589		31630
	31385		31426		31467		31508		31549		31590		31631
	31386		31427		31468		31509		31550		31591		31632
	31387		31428		31469		31510		31551		31592		31633
	31388		31429		31470		31511		31552		31593		31634
	31389		31430		31471		31512		31553		31594		31635
	31390		31431		31472		31513		31554		31595		31636
	31391		31432		31473		31514		31555		31596		31637
	31392		31433		31474		31515		31556		31597		31638
	31393		31434		31475		31516		31557		31598		31639
	31394		31435		31476		31517		31558		31599		31640
	31395		31436		31477		31518		31559		31600		31641
	31396		31437		31478		31519		31560		31601		31642
	31397		31438		31479		31520		31561		31602		31643

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	31644	PPD	31685	PPD	31726	PPD	31767	PPD	31808	PPD	31849	PPD	31890
	31645		31686		31727		31768		31809		31850		31891
	31646		31687		31728		31769		31810		31851		31892
	31647		31688		31729		31770		31811		31852		31893
	31648		31689		31730		31771		31812		31853		31894
	31649		31690		31731		31772		31813		31854		31895
	31650		31691		31732		31773		31814		31855		31896
	31651		31692		31733		31774		31815		31856		31897
	31652		31693		31734		31775		31816		31857		31898
	31653		31694		31735		31776		31817		31858		31899
	31654		31695		31736		31777		31818		31859		31900
	31655		31696		31737		31778		31819		31860		31901
	31656		31697		31738		31779		31820		31861		31902
	31657		31698		31739		31780		31821		31862		31903
	31658		31699		31740		31781		31822		31863		31904
	31659		31700		31741		31782		31823		31864		31905
	31660		31701		31742		31783		31824		31865		31906
	31661		31702		31743		31784		31825		31866		31907
	31662		31703		31744		31785		31826		31867		31908
	31663		31704		31745		31786		31827		31868		31909
	31664		31705		31746		31787		31828		31869		31910
	31665		31706		31747		31788		31829		31870		31911
	31666		31707		31748		31789		31830		31871		31912
	31667		31708		31749		31790		31831		31872		31913
	31668		31709		31750		31791		31832		31873		31914
	31669		31710		31751		31792		31833		31874		31915
	31670		31711		31752		31793		31834		31875		31916
	31671		31712		31753		31794		31835		31876		31917
	31672		31713		31754		31795		31836		31877		31918
	31673		31714		31755		31796		31837		31878		31919
	31674		31715		31756		31797		31838		31879		31920
	31675		31716		31757		31798		31839		31880		31921
	31676		31717		31758		31799		31840		31881		31922
	31677		31718		31759		31800		31841		31882		31923
	31678		31719		31760		31801		31842		31883		31924
	31679		31720		31761		31802		31843		31884		31925
	31680		31721		31762		31803		31844		31885		31926
	31681		31722		31763		31804		31845		31886		31927
	31682		31723		31764		31805		31846		31887		31928
	31683		31724		31765		31806		31847		31888		31929
	31684		31725		31766		31807		31848		31889		31930

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	31931	PPD	31972	PPD	32013	PPD	32054	PPD	32095	PPD	32136	PPD	32177
	31932		31973		32014		32055		32096		32137		32178
	31933		31974		32015		32056		32097		32138		32179
	31934		31975		32016		32057		32098		32139		32180
	31935		31976		32017		32058		32099		32140		32181
	31936		31977		32018		32059		32100		32141		32182
	31937		31978		32019		32060		32101		32142		32183
	31938		31979		32020		32061		32102		32143		32184
	31939		31980		32021		32062		32103		32144		32185
	31940		31981		32022		32063		32104		32145		32186
	31941		31982		32023		32064		32105		32146		32187
	31942		31983		32024		32065		32106		32147		32188
	31943		31984		32025		32066		32107		32148		32189
	31944		31985		32026		32067		32108		32149		32190
	31945		31986		32027		32068		32109		32150		32191
	31946		31987		32028		32069		32110		32151		32192
	31947		31988		32029		32070		32111		32152		32193
	31948		31989		32030		32071		32112		32153		32194
	31949		31990		32031		32072		32113		32154		32195
	31950		31991		32032		32073		32114		32155		32196
	31951		31992		32033		32074		32115		32156		32197
	31952		31993		32034		32075		32116		32157		32198
	31953		31994		32035		32076		32117		32158		32199
	31954		31995		32036		32077		32118		32159		32200
	31955		31996		32037		32078		32119		32160		32201
	31956		31997		32038		32079		32120		32161		32202
	31957		31998		32039		32080		32121		32162		32203
	31958		31999		32040		32081		32122		32163		32204
	31959		32000		32041		32082		32123		32164		32205
	31960		32001		32042		32083		32124		32165		32206
	31961		32002		32043		32084		32125		32166		32207
	31962		32003		32044		32085		32126		32167		32208
	31963		32004		32045		32086		32127		32168		32209
	31964		32005		32046		32087		32128		32169		32210
	31965		32006		32047		32088		32129		32170		32211
	31966		32007		32048		32089		32130		32171		32212
	31967		32008		32049		32090		32131		32172		32213
	31968		32009		32050		32091		32132		32173		32214
	31969		32010		32051		32092		32133		32174		32215
	31970		32011		32052		32093		32134		32175		32216
	31971		32012		32053		32094		32135		32176		32217

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	32218	PPD	32259	PPD	32300	PPD	32341	PPD	32382	PPD	32423	PPD	32464
	32219		32260		32301		32342		32383		32424		32465
	32220		32261		32302		32343		32384		32425		32466
	32221		32262		32303		32344		32385		32426		32467
	32222		32263		32304		32345		32386		32427		32468
	32223		32264		32305		32346		32387		32428		32469
	32224		32265		32306		32347		32388		32429		32470
	32225		32266		32307		32348		32389		32430		32471
	32226		32267		32308		32349		32390		32431		32472
	32227		32268		32309		32350		32391		32432		32473
	32228		32269		32310		32351		32392		32433		32474
	32229		32270		32311		32352		32393		32434		32475
	32230		32271		32312		32353		32394		32435		32476
	32231		32272		32313		32354		32395		32436		32477
	32232		32273		32314		32355		32396		32437		32478
	32233		32274		32315		32356		32397		32438		32479
	32234		32275		32316		32357		32398		32439		32480
	32235		32276		32317		32358		32399		32440		32481
	32236		32277		32318		32359		32400		32441		32482
	32237		32278		32319		32360		32401		32442		32483
	32238		32279		32320		32361		32402		32443		32484
	32239		32280		32321		32362		32403		32444		32485
	32240		32281		32322		32363		32404		32445		32486
	32241		32282		32323		32364		32405		32446		32487
	32242		32283		32324		32365		32406		32447		32488
	32243		32284		32325		32366		32407		32448		32489
	32244		32285		32326		32367		32408		32449		32490
	32245		32286		32327		32368		32409		32450		32491
	32246		32287		32328		32369		32410		32451		32492
	32247		32288		32329		32370		32411		32452		32493
	32248		32289		32330		32371		32412		32453		32494
	32249		32290		32331		32372		32413		32454		32495
	32250		32291		32332		32373		32414		32455		32496
	32251		32292		32333		32374		32415		32456		32497
	32252		32293		32334		32375		32416		32457		32498
	32253		32294		32335		32376		32417		32458		32499
	32254		32295		32336		32377		32418		32459		32500
	32255		32296		32337		32378		32419		32460		32501
	32256		32297		32338		32379		32420		32461		32502
	32257		32298		32339		32380		32421		32462		32503
	32258		32299		32340		32381		32422		32463		32504

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	32505	PPD	32546	PPD	32587	PPD	32628	PPD	32669	PPD	32710	PPD	32751
	32506		32547		32588		32629		32670		32711		32752
	32507		32548		32589		32630		32671		32712		32753
	32508		32549		32590		32631		32672		32713		32754
	32509		32550		32591		32632		32673		32714		32755
	32510		32551		32592		32633		32674		32715		32756
	32511		32552		32593		32634		32675		32716		32757
	32512		32553		32594		32635		32676		32717		32758
	32513		32554		32595		32636		32677		32718		32759
	32514		32555		32596		32637		32678		32719		32760
	32515		32556		32597		32638		32679		32720		32761
	32516		32557		32598		32639		32680		32721		32762
	32517		32558		32599		32640		32681		32722		32763
	32518		32559		32600		32641		32682		32723		32764
	32519		32560		32601		32642		32683		32724		32765
	32520		32561		32602		32643		32684		32725		32766
	32521		32562		32603		32644		32685		32726		32767
	32522		32563		32604		32645		32686		32727		32768
	32523		32564		32605		32646		32687		32728		32769
	32524		32565		32606		32647		32688		32729		32770
	32525		32566		32607		32648		32689		32730		32771
	32526		32567		32608		32649		32690		32731		32772
	32527		32568		32609		32650		32691		32732		32773
	32528		32569		32610		32651		32692		32733		32774
	32529		32570		32611		32652		32693		32734		32775
	32530		32571		32612		32653		32694		32735		32776
	32531		32572		32613		32654		32695		32736		32777
	32532		32573		32614		32655		32696		32737		32778
	32533		32574		32615		32656		32697		32738		32779
	32534		32575		32616		32657		32698		32739		32780
	32535		32576		32617		32658		32699		32740		32781
	32536		32577		32618		32659		32700		32741		32782
	32537		32578		32619		32660		32701		32742		32783
	32538		32579		32620		32661		32702		32743		32784
	32539		32580		32621		32662		32703		32744		32785
	32540		32581		32622		32663		32704		32745		32786
	32541		32582		32623		32664		32705		32746		32787
	32542		32583		32624		32665		32706		32747		32788
	32543		32584		32625		32666		32707		32748		32789
	32544		32585		32626		32667		32708		32749		32790
	32545		32586		32627		32668		32709		32750		32791

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	32792	PPD	32833	PPD	32874	PPD	32915	PPD	32956	PPD	32997	PPD	33038
	32793		32834		32875		32916		32957		32998		33039
	32794		32835		32876		32917		32958		32999		33040
	32795		32836		32877		32918		32959		33000		33041
	32796		32837		32878		32919		32960		33001		33042
	32797		32838		32879		32920		32961		33002		33043
	32798		32839		32880		32921		32962		33003		33044
	32799		32840		32881		32922		32963		33004		33045
	32800		32841		32882		32923		32964		33005		33046
	32801		32842		32883		32924		32965		33006		33047
	32802		32843		32884		32925		32966		33007		33048
	32803		32844		32885		32926		32967		33008		33049
	32804		32845		32886		32927		32968		33009		33050
	32805		32846		32887		32928		32969		33010		33051
	32806		32847		32888		32929		32970		33011		33052
	32807		32848		32889		32930		32971		33012		33053
	32808		32849		32890		32931		32972		33013		33054
	32809		32850		32891		32932		32973		33014		33055
	32810		32851		32892		32933		32974		33015		33056
	32811		32852		32893		32934		32975		33016		33057
	32812		32853		32894		32935		32976		33017		33058
	32813		32854		32895		32936		32977		33018		33059
	32814		32855		32896		32937		32978		33019		33060
	32815		32856		32897		32938		32979		33020		33061
	32816		32857		32898		32939		32980		33021		33062
	32817		32858		32899		32940		32981		33022		33063
	32818		32859		32900		32941		32982		33023		33064
	32819		32860		32901		32942		32983		33024		33065
	32820		32861		32902		32943		32984		33025		33066
	32821		32862		32903		32944		32985		33026		33067
	32822		32863		32904		32945		32986		33027		33068
	32823		32864		32905		32946		32987		33028		33069
	32824		32865		32906		32947		32988		33029		33070
	32825		32866		32907		32948		32989		33030		33071
	32826		32867		32908		32949		32990		33031		33072
	32827		32868		32909		32950		32991		33032		33073
	32828		32869		32910		32951		32992		33033		33074
	32829		32870		32911		32952		32993		33034		33075
	32830		32871		32912		32953		32994		33035		33076
	32831		32872		32913		32954		32995		33036		33077
	32832		32873		32914		32955		32996		33037		33078

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	33079	PPD	33120	PPD	33161	PPD	33202	PPD	33243	PPD	33284	PPD	33325
	33080		33121		33162		33203		33244		33285		33326
	33081		33122		33163		33204		33245		33286		33327
	33082		33123		33164		33205		33246		33287		33328
	33083		33124		33165		33206		33247		33288		33329
	33084		33125		33166		33207		33248		33289		33330
	33085		33126		33167		33208		33249		33290		33331
	33086		33127		33168		33209		33250		33291		33332
	33087		33128		33169		33210		33251		33292		33333
	33088		33129		33170		33211		33252		33293		33334
	33089		33130		33171		33212		33253		33294		33335
	33090		33131		33172		33213		33254		33295		33336
	33091		33132		33173		33214		33255		33296		33337
	33092		33133		33174		33215		33256		33297		33338
	33093		33134		33175		33216		33257		33298		33339
	33094		33135		33176		33217		33258		33299		33340
	33095		33136		33177		33218		33259		33300		33341
	33096		33137		33178		33219		33260		33301		33342
	33097		33138		33179		33220		33261		33302		33343
	33098		33139		33180		33221		33262		33303		33344
	33099		33140		33181		33222		33263		33304		33345
	33100		33141		33182		33223		33264		33305		33346
	33101		33142		33183		33224		33265		33306		33347
	33102		33143		33184		33225		33266		33307		33348
	33103		33144		33185		33226		33267		33308		33349
	33104		33145		33186		33227		33268		33309		33350
	33105		33146		33187		33228		33269		33310		33351
	33106		33147		33188		33229		33270		33311		33352
	33107		33148		33189		33230		33271		33312		33353
	33108		33149		33190		33231		33272		33313		33354
	33109		33150		33191		33232		33273		33314		33355
	33110		33151		33192		33233		33274		33315		33356
	33111		33152		33193		33234		33275		33316		33357
	33112		33153		33194		33235		33276		33317		33358
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	33114		33155		33196		33237		33278		33319		33360
	33115		33156		33197		33238		33279		33320		33361
	33116		33157		33198		33239		33280		33321		33362
	33117		33158		33199		33240		33281		33322		33363
	33118		33159		33200		33241		33282		33323		33364
	33119		33160		33201		33242		33283		33324		33365

SD4\RDE\ENABLE

Randomisation list

MMR-160 (A.18JAN2018)

Treatment number associated to material : Prevnar vaccine

Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb	Trt. No	Bl. nb
PPD	33366	PPD	33407	PPD	33448	PPD	33489	PPD	33530	PPD	33571	PPD	33612
	33367		33408		33449		33490		33531		33572		33613
	33368		33409		33450		33491		33532		33573		33614
	33369		33410		33451		33492		33533		33574		33615
	33370		33411		33452		33493		33534		33575		33616
	33371		33412		33453		33494		33535		33576		33617
	33372		33413		33454		33495		33536		33577		33618
	33373		33414		33455		33496		33537		33578		33619
	33374		33415		33456		33497		33538		33579		33620
	33375		33416		33457		33498		33539		33580		33621
	33376		33417		33458		33499		33540		33581		33622
	33377		33418		33459		33500		33541		33582		33623
	33378		33419		33460		33501		33542		33583		33624
	33379		33420		33461		33502		33543		33584		33625
	33380		33421		33462		33503		33544		33585		
	33381		33422		33463		33504		33545		33586		
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	33383		33424		33465		33506		33547		33588		
	33384		33425		33466		33507		33548		33589		
	33385		33426		33467		33508		33549		33590		
	33386		33427		33468		33509		33550		33591		
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	33388		33429		33470		33511		33552		33593		
	33389		33430		33471		33512		33553		33594		
	33390		33431		33472		33513		33554		33595		
	33391		33432		33473		33514		33555		33596		
	33392		33433		33474		33515		33556		33597		
	33393		33434		33475		33516		33557		33598		
	33394		33435		33476		33517		33558		33599		
	33395		33436		33477		33518		33559		33600		
	33396		33437		33478		33519		33560		33601		
	33397		33438		33479		33520		33561		33602		
	33398		33439		33480		33521		33562		33603		
	33399		33440		33481		33522		33563		33604		
	33400		33441		33482		33523		33564		33605		
	33401		33442		33483		33524		33565		33606		
	33402		33443		33484		33525		33566		33607		
	33403		33444		33485		33526		33567		33608		
	33404		33445		33486		33527		33568		33609		
	33405		33446		33487		33528		33569		33610		
	33406		33447		33488		33529		33570		33611		

Audit Certificates

AUDIT CERTIFICATE

Study Number: 115648

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Clinical studies are conducted by or on behalf of GlaxoSmithKline in accordance with Standard Operating Procedures, which conform to the requirements of international GCP guidelines (ICH Harmonised Tripartite Guidelines E6 for Good Clinical Practice, FDA 21CFR parts 50, 56 and 312).

During the conduct and reporting of this study, the following independent audits were performed by or on behalf of GlaxoSmithKline.

Study Number	Type	Conducted by	Centre number	Country	Audit Date
115648	Investigator Site	Falcon-US	PPD	Estonia	14-15 August 2013
115648	Investigator Site	GSK-CDQA-US	PPD	USA	14-16 August 2013
115648	Investigator Site	GSK-CDQA-UK	PPD	Finland	21-23 August 2013
115648	Investigator Site	GSK-CDQA-US	PPD	USA	6-8 August 2014
115648	Investigator Site	GSK-CDQA-US	PPD	USA	13-15 August 2014

Clinical Development Quality Assurance hereby confirm that the audits detailed above were carried out in accordance with appropriate regulatory requirements and guidelines in order to assess compliance with the study protocol, ICH GCP, FDA 21CFR parts 314.50 and 601.2, appropriate standard operating procedures and policies.

Name: PPD **Date:** 30 November 2016

Role: Manager

Clinical Development Quality Assurance
GlaxoSmithKline Research and Development

Documentation of statistical methods

Statistical Analysis Plan

Study alias & e-track number(s): MMR-160 (115648)

Detailed Title:	A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.
SAP version	Version 2
SAP date	13-NOV-2015
Scope:	All data pertaining to the above study.
Co-ordinating author:	PPD
Other author(s):	PPD
Adhoc reviewers:	PPD (Regulatory Affairs)
	PPD (Safety Physician)
Approved by:	PPD (CRDL)
	PPD (Lead Statistician)
	PPD (Scientific Writer Manager)

Statistical Analysis Plan	
Study alias & e-track number(s): MMR-160 (115648)	

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Statistical Analysis Plan	
Study alias & e-track number(s): MMR-160 (115648)	

The complete statistical analysis plan and results presentation is divided into 2 parts: the first part detailing the analyses to be performed (known as SAP, current document) and a second part, annexes (called TFLs) describing the flow and format of tables, figures and listings to be annexed to the study report.

LIST OF ABBREVIATIONS

AE	Adverse event
ATP	According-To-Protocol
CI	Confidence Interval
CRF	Case Report Form
CTRS	Clinical Trial Registry
EL.U/ml	ELISA unit per milliliter
ELISA	Enzyme-linked immunosorbent assay
Eli Type	Internal GSK database code for type of elimination code
GMC(T)	Geometric mean antibody concentration (titer)
GSK	GlaxoSmithKline
IU/ml	International units per milliliter
LL	Lower Limit of the confidence interval
MedDRA	Medical Dictionary for Regulatory Activities
N.A.	Not Applicable
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SBIR	GSK Biological's Internet Randomization System
SD	Standard Deviation
TFL	Tables Figures and Listing template annexed to SAP
UL	Upper Limit of the confidence interval

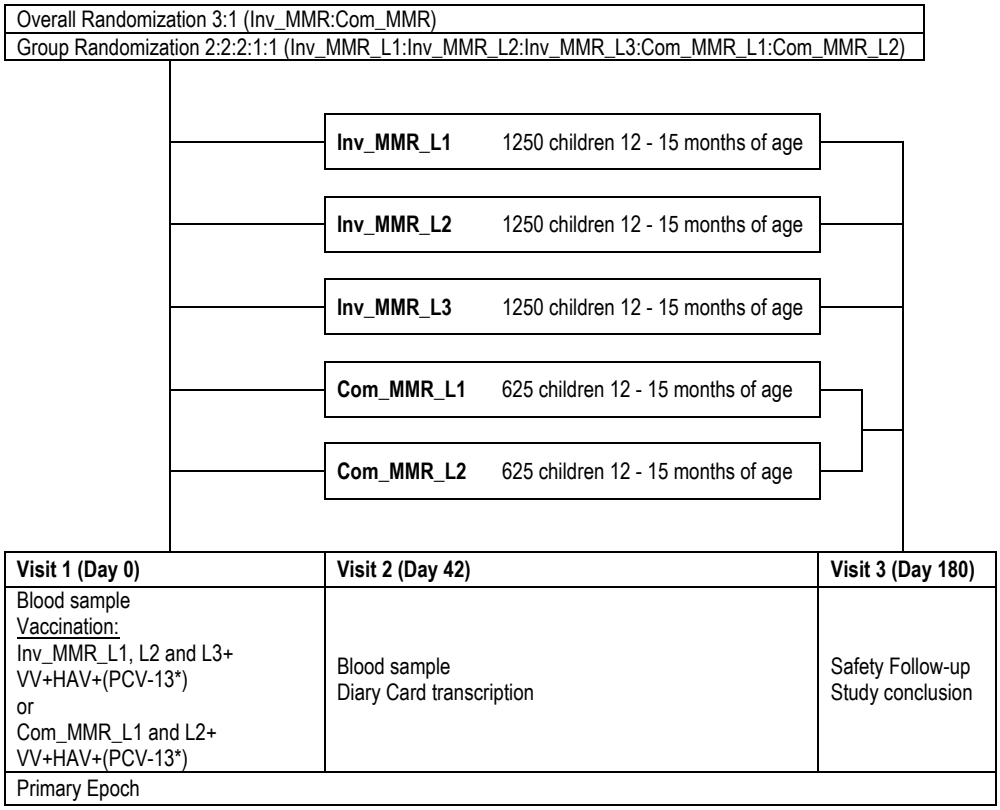
Statistical Analysis Plan	
Study alias & e-track number(s): MMR-160 (115648)	

1. DOCUMENT HISTORY

Date	Description	Protocol Version
29-MAY-2015	Version 1	Amendment 2 - 26-FEB-2015
13-NOV-2015	Version 2 – Minor updates to add subsets in section 2, clarify model in section 6.2.2, and add analysis disclosure details in section 8.1.	Amendment 2 - 26-FEB-2015

2. STUDY DESIGN

Figure 1 Study design



L= Lot; VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* PCV-13 is only administered to children in the US

Statistical Analysis Plan	
Study alias & e-track number(s): MMR-160 (115648)	

- **Experimental design:** Phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with five parallel groups.
- **Duration of the study:**
  - Primary Epoch: The study period is approximately 6 months starting at Visit 1 (Day 0) and ending with Visit 3 (Day 180).

Table 1 Study groups and epochs foreseen in the study

Study groups	Number of children	Age (Min/Max)	Primary Epoch
Inv_MMR_L1	1250	12 – 15 months	●
Inv_MMR_L2	1250	12 – 15 months	●
Inv_MMR_L3	1250	12 – 15 months	●
Com_MMR_L1	625	12 – 15 months	●
Com_MMR_L2	625	12 – 15 months	●

L = Lot

- **Control:** active control, Com_MMR_L1 and Com_MMR_L2 vaccine.
- **Co-administered vaccines:** All children will receive *Varivax* and *Havrix* as study vaccines, concomitantly with MMR vaccine at 12 to 15 months of age. *Prevnar 13* will be administered only to US children. At the end of the study ***or shortly after the study, depending on vaccine availabilit***y, GSK will provide a second dose of *Havrix* and/or varicella vaccine to participants enrolled in selected non-US countries if local health departments do not routinely provide hepatitis A and varicella vaccination. The second dose of *Havrix* and varicella vaccine is not part of the study procedures.
- **Vaccination schedule:** A single vaccination, with either one of the three Inv_MMR lots or one of two Com_MMR active control lots, along with the co-administered vaccines *Varivax*, *Havrix* (to all children) and *Prevnar 13*, (only to children enrolled in the US) will be administered at Visit 1 (12-15 months of age).

The following group names will be used for the statistical analyses:

Group order in tables	Group label in tables	Group definition for footnote	Pooled group order	Pooled Groups label in tables	Pooled definition for footnote
1	INV_MMR_L1	GSK MMR Lot 1	1	INV_MMR	GSK MMR
2	INV_MMR_L2	GSK MMR Lot 2			
3	INV_MMR_L3	GSK MMR Lot 3			
4	COM_MMR (combination of COM_MMR_L1 and COM_MMR_L2)	Merck MMR	2	COM_MMR	Merck MMR

Statistical Analysis Plan	
Study alias & e-track number(s): MMR-160 (115648)	

- **Immunogenicity subset:** All subjects will be tested for measles, mumps, and rubella immune response, but only specific subsets of subjects will be tested for immune response to the co-administered vaccines. Subset A is planned to include the first 1250 subjects enrolled in the US. Subset B is planned to include the next 1250 subjects enrolled in the US. Subset C is planned to include all other subjects.

Subset name	Planned number of subjects	Components
Subset A	1250	Mumps Virus Jeryl Lynn 135 Ab.IgG Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG Hepatitis A Virus Ab
Subset B	1250	Mumps Virus Jeryl Lynn 135 Ab.IgG Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG
Subset C	2500	Mumps Virus Jeryl Lynn 135 Ab.IgG Measles Virus Ab.IgG Rubella Virus Ab.IgG

Statistical Analysis Plan	
Study alias & e-track number(s): MMR-160 (115648)	

3. OBJECTIVES

3.1. Primary objectives

The co-primary objectives will be assessed in a hierarchical manner according to the order presented below. A co-primary objective can only be met if the statistical criteria for that objective are met as well as the statistical criteria for all previous co-primary objectives.

All primary and secondary immunogenicity endpoints will be tested with an ELISA.

Note: all criteria will be assessed for each assay separately. With the exception of anti-pneumococcal antibodies, the criteria will be specific to children seronegative for the assay at pre-vaccination.

1. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates (see Section 10.5 for definition) to measles, mumps and rubella viruses at Day 42.

   Criteria:

- For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for measles, mumps, and rubella viruses.

2. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.

   Criteria:

- For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses.

3. To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates for measles, mumps and rubella viruses at Day 42.

   Criteria:

- The lower limit of the two-sided 95% CI on the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses.

4. To demonstrate non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.

   Criteria:

- The lower limit of the two-sided 95% CI on GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.

5. To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates for measles, mumps and rubella viruses at Day 42.

   Criteria:

- The lower limit of the two-sided 95% CI for the seroresponse rate for the pooled Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.

Refer to Section 4.1 for the definition of the primary endpoint.

3.2. Secondary objectives

1. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of seroresponse rate and GMC for varicella zoster virus (VZV) antibodies at Day 42 (in a subset of children enrolled in the US).

   Criteria:

- The lower limit of the two-sided 95% CI on the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rate is ≥-10% for antibodies to VZV.
- The lower limit of the two-sided 95% CI on the GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to VZV.

2. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of GMC for hepatitis A virus (HAV) antibodies at Day 42 (in a subset of children enrolled in the US).

   Criteria:

- The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) of HAV antibodies (post-dose 1) is ≥0.5.

3. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of antibodies to S. pneumoniae (PS) (13 serotypes), at Day 42 (in a subset of children administered Prevnar 13 in the US).

Criteria:

- The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.

4. To assess the immunogenicity of Havrix with respect to the seroresponse rates for HAV antibodies in the pooled Inv_MMR groups in contrast to the pooled Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).
5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with Varivax, Havrix (to all children) and Prevnar 13 (only to children enrolled in the US).

Refer to Section 4.2 for the definition of the secondary endpoints.

4. ENDPOINTS

4.1. Primary endpoint

- Immunogenicity of the MMR vaccines at Day 42.
  - Seroresponse to measles, mumps and rubella viruses (see Section 7.1.3.1 for definition).
  - Measles, mumps and rubella virus antibody concentrations.

4.2. Secondary endpoints

- Immunogenicity of the Varivax, Havrix and Prevnar 13 vaccines in a subset of children at Day 42.
  - Seroresponse to VZV (see Section 7.1.3.1 for definition).
  - VZV antibody concentrations.
  - HAV antibody concentrations.
  - Seroresponse to HAV (see Section 7.1.3.1 for definition).
  - Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.
- Complementary read-out for immunogenicity of the MMR vaccines at Day 42.
  - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
  - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms.

  - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
  - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
  - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest.
  - Occurrence of new onset chronic disease (NOCD) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting emergency room (ER) visits from Day 0 through the end of study.
- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 through the end of study.

5. STUDY POPULATION

5.1.1. Total vaccinated cohort

The **Total Vaccinated cohort** will include all vaccinated children.

- An immunogenicity analysis based on the Total Vaccinated cohort will include all vaccinated children for whom immunogenicity data are available.
- A safety analysis based on the Total Vaccinated cohort will include all vaccinated children with at least one vaccine administration of either Inv_MMR or Com_MMR lots documented.

5.1.2. According-to-protocol cohort for analysis of safety

The **ATP cohort for analysis of safety** will include eligible children:

- who have received at least one MMR study vaccine/comparator and all planned country-appropriate co-administered vaccines as per protocol
- who have not received a vaccine leading to exclusion from the ATP cohort in the protocol up to Visit 2 as described in Section 6.7.1 of the protocol.
- for whom the randomization code has not been broken
- for whom the administration route of study vaccine(s) is known/correct.

5.1.3. According-to-protocol cohort for analysis of immunogenicity

The **ATP cohort for analysis of immunogenicity** will include all eligible children from the ATP cohort for safety:

- with pre-vaccination and post-dose serology results available for at least one antigen of measles, mumps, or rubella
- who are below the assay cut-off for at least one vaccine antigen for MMR at pre-vaccination
- who do not meet any elimination criteria up to the Visit 2 blood sample (see Sections 6.7.1 and 6.8 of the protocol)
- who complied with the post dose blood sample schedule, i.e., 35-77 days between vaccination at Visit 1 and the blood draw at Visit 2.

The list of applicable elimination codes for each cohort can be found in the study specific form FORM-BIO-CLIN-9004-05 Criteria for eliminating subjects from the analyses.

Cohort	Elimination codes	Eli Type
ATP cohort for analysis for safety	1030-1500	MA
ATP cohort for analysis for immunogenicity	1030-2120	MA

6. STATISTICAL METHODS

6.1. Analysis of demographics/baseline characteristics

Demographic characteristics (age at Visit 1 in months, geographic ancestry (race), ethnicity and gender) will be tabulated as a whole, for each Inv_MMR group, for the pooled Inv_MMR groups, and for the pooled Com_MMR groups.

The distribution of children enrolled among the study sites/countries will be tabulated as a whole, for each Inv_MMR group, for the pooled Inv_MMR groups, and for the pooled Com_MMR groups.

6.2. Analysis of immunogenicity

The analysis of immunogenicity will be based on the ATP cohort for immunogenicity. If, for any vaccine group, the percentage of enrolled children with serological results excluded from this ATP cohort is higher than 5%, a second analysis based on the Total Vaccinated cohort will be performed to complement the ATP analysis.

Except for anti-PS, and unless otherwise stated, the analysis post-vaccination of an assay described below will be based on the children seronegative for the assay at pre-vaccination.

6.2.1. Within groups assessment

The following descriptive analyses will be performed for each Inv_MMR group, for the pooled Inv_MMR groups, and for the pooled Com_MMR groups at each blood sampling time point for which a serological result is available:

- Percentage of children above each specific cut-off and their exact 95% CIs will be tabulated. The specific cut-offs will be 150 and 200 mIU/mL for measles, 5 and 10 EU/mL for mumps and 4 and 10 IU/mL for rubella, respectively.
- Antibody concentrations will also be summarized by GMCs with their 95% CIs after vaccination.
- Antibody concentration distributions will be displayed as reverse cumulative curves for each antigen and each treatment group after vaccination.

6.2.2. Between Inv_MMR lots analysis

At the day 42 post-vaccination blood sampling, for measles, mumps and rubella:

- The 95% CI for the GMC ratio of each pair of Inv_MMR lots will be computed using an ANOVA model on the logarithm-transformed concentrations. The ANOVA model will include the three Inv_MMR lot groups and the country as fixed effects. Only the three Inv_MMR lot groups will be included in the model.
- The asymptotic standardized 95% CIs for the pair-wise differences in seroresponse across the three Inv_MMR lots will be computed.

6.2.3. Between Inv_MMR and Com_MMR group analysis

At the day 42 post-vaccination blood sampling, for each antibody for which results are available:

- The asymptotic standardized 95% CIs for the difference in seroresponse rate and percentage of children with concentration/titer above each specific cut-off [pooled Inv_MMR lot group minus the pooled Com_MMR lot group] will be computed.

- The 95% CI for each group GMC/T group ratio [pooled Inv_MMR lot group over the pooled Com_MMR lot group] will be computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group and the country (only for measles, mumps & rubella) as fixed effects and, for pneumococcal immunogenicity, the pre-vaccination log-transformed concentration as the regressor. The vaccine groups will be the pooled Inv_MMR lot group and the pooled Com_MMR lot group.

6.2.4. Subgroup analysis of immunogencity

All descriptive analyses for anti-measles, anti-mumps, and anti-rubella antibodies will be repeated for the following subgroups:

- By country, provided that the country has at least 50 subjects per treatment group (pooled Inv_MMR or pooled Com_MMR)
- By gender, provided that each gender has at least 50 subjects per treatment group (pooled Inv_MMR or pooled Com_MMR)
- By geographic ancestry (race) category, provided that the category has at least 50 subjects per treatment group (pooled Inv_MMR or pooled Com_MMR). Subjects from the ‘other’ category will be split into two sub-categories: ‘Other: American Hispanic or Latino’ and ‘Other: Not American Hispanic or Latino’.

6.2.5. Interpretation of analyses

Except for analyses addressing criteria specified in the objectives, comparative analyses will be exploratory with the aim to characterize the difference between groups in immunogenicity. These exploratory analyses should be interpreted with caution since there is no adjustment for multiplicity of endpoints.

With respect to primary and secondary objectives involving pre-specified criteria, the interpretation must be done according to a hierarchical procedure described in Section 10.3.1 of the protocol. For instance, the primary objective 3 can only be reached if all the associated criteria are met and the previous primary objectives have been reached. If an objective is not met, all subsequent comparisons will be purely descriptive.

6.3. Analysis of safety

The analysis of safety will be based on the Total Vaccinated cohort. If more than 5% of the vaccinated children are excluded from the ATP cohort for the analysis of safety, a second analysis based on the ATP cohort will be performed to complement the Total Vaccinated cohort analysis.

For each group (each Inv_MMR lot group, the pooled Inv_MMR lot group and the pooled Com_MMR lot group), the following results will be tabulated by Inv_MMR lot, pooled for the three Inv_MMR lots, and pooled for the two Com_MMR lots:

- the number and percentage of children (with exact 95% CIs) with at least one local, general, and any adverse event (solicited or unsolicited) during the 43-day follow-up period after vaccination (Day 0-42);
- the number and percentage of children (with exact 95% CIs) reporting each local solicited symptom during Days 0-3 for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically attended visit;
- the number and percentage of children (with exact 95% CIs) reporting general symptom (drowsiness, irritability and loss of appetite) during the 15-day follow-up period after vaccination (Days 0-14) for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically-attended visit;

- the number and percentage of children reporting fever by half degree (°C) cumulative increments from Days 0-14, from Days 5-12 and from Days 0-42 after vaccination. Similar tabulations will be performed for any fever with a causal relationship to vaccination and for any fever resulting in a medically attended visit. In addition, the prevalence of any and grade 3 fever will be presented graphically over time after vaccination.
- the number and percentage of children (with exact 95% CIs) reporting measles/rubella-like rash and varicella-like rash (Days 0-42, according to number of lesions), any rash (Days 0-42), parotid/salivary gland swelling (Days 0-42, according to intensity) and any sign of meningism/febrile convulsions (Days 0-42, according to intensity), after vaccination. Similar tabulations will be performed for general solicited adverse events with a causal relationship to vaccination and for solicited AEs resulting in a medically-attended visit;
- the number and percentage of children (with exact 95% CIs) for whom unsolicited adverse events are reported from Days 0-42. The verbatim reports of unsolicited symptoms will be reviewed by a physician and the signs and symptoms will be coded according to MedDRA, the Medical Dictionary for Regulatory Activities. Every verbatim term will be matched with the appropriate Preferred Term. Similar tabulations will be done for grade 3 unsolicited adverse events, for unsolicited adverse events related to vaccination and for unsolicited adverse events resulting in a medically attended visit;
- the number and percentage of children who received at least one concomitant medication from Days 0-14 and from Days 0-42 after vaccination. Additionally, the number and percentage of children receiving antipyretic drugs will also be calculated by group from Days 0-14 and from Days 0-42 after vaccination.
- Discontinuations due to AEs will be described in detail.
- The percentages of children who experienced at least one serious adverse event or who reported a NOCD (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies), or an AE leading to an ER visit, or an AE leading to a medically attended visit from Day 0 to study end, will be calculated.
- Descriptive listing of SAEs, any related SAEs to study participation, study withdrawals and deaths post-vaccination(s) for the entire study.

All safety results will also be produced by country.

6.3.1. Subgroup analysis of safety

All safety analyses on the pooled treatment groups will be repeated for the following subgroups:

- By country, provided that the country has at least 50 subjects per treatment group (pooled Inv_MMR or pooled Com_MMR)
- By gender, provided that each gender has at least 50 subjects per treatment group (pooled Inv_MMR or pooled Com_MMR)
- By geographic ancestry (race) category, provided that the category has at least 50 subjects per treatment group (pooled Inv_MMR or pooled Com_MMR). Subjects from the 'other' category will be split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

7. STATISTICAL CALCULATIONS

7.1. Derived and transformed variables

7.1.1. General

7.1.1.1. Study group

The study group is the treatment associated to the administered treatment number.

7.1.2. Demography

7.1.2.1. Age at vaccination

Age will be calculated as the number of complete months between the date of birth and the date of vaccination. If the year and month of birth is recorded, but the day is missing, the 15th of the month will be used. For example:

- DOB = 10JUN2013, Date of vaccination = 09JUL2014 -> Age = 12 months
- DOB = 10JUN2013, Date of vaccination = 10JUL2014 -> Age = 13 months

7.1.2.2. Height and weight

Weight will be presented in kilograms. Weights reported in pounds will be converted as follows: Weight in kilograms = Weight in pounds / 2.2 (rounded to 2 decimal places)

Height will be presented in centimeters. Heights reported in feet and inches will be converted as follows: Height in centimeters = Height in inches * 2.54 (rounded to the unit - no decimal places)

7.1.3. Immunogenicity

For the analysis of immunogenicity, the following definitions will be applied.

7.1.3.1. Seroresponse

Seroresponses for MMR, VZV, and HAV are defined as follows:

- For measles virus, a seroresponse is defined as a post-vaccination anti-measles virus antibody concentration ≥200 mIU/mL (ELISA, Enzygnost) for a child who was seronegative (antibody concentration <150 mIU/mL) before vaccination.
- For mumps virus, a seroresponse is defined as a post-vaccination anti-mumps virus antibody concentration ≥10 EU/mL (ELISA, PPD) for a child who was seronegative (antibody concentration <5 EU/mL) before vaccination.
- For rubella virus, a seroresponse is defined as a post-vaccination anti-rubella virus antibody concentration ≥10 IU/mL (ELISA, Enzygnost) for a child who was seronegative (antibody concentration <4 IU/mL) before vaccination.
- For VV, a seroresponse is defined as a post-vaccination anti-VZV antibody concentration ≥75 mIU/mL for a child who was seronegative (antibody concentration <25 mIU/mL) before vaccination.
- For HAV, a seroresponse is defined as a post-vaccination concentration equal to or above the cut-off of 15 mIU/mL for a child with a concentration below the assay cut-off of 15 mIU/mL before vaccination, or a ≥ 2-fold increase in antibody concentration for a child ≥ 15 mIU/mL before vaccination.

7.1.3.2. GMC/T calculation

The GMC calculation for antibodies to varicella virus will be performed by taking the anti-log of the mean of the log concentration transformations of all values equal to or above Limit of Quantitation (LOQ) (40 mIU/mL), with anti-VZV antibody concentrations between LOQ and Limit of Detection (LOD) (25 mIU/mL) given a value of 25 mIU/mL. By convention, values <25 mIU/mL will be given an arbitrary value of 12.5 mIU/mL.

For the other assays, the GMC calculation will be performed by taking the anti-log of the mean of the log concentration transformations. Antibody concentrations below the cut-off of the assay will be given an arbitrary value of half the cut-off for the purpose of GMC calculation.

7.1.3.3. Numerical immuno results

Numerical immuno results (the NUM_RES variable in SAS datasets) will be derived from a character field (RAWRES). For assays with a specific cut-off, the following derivations apply:

- If RAWRES ='NEG', '-', or '(-)' then NUM_RES =cut_off/2
- If RAWRES ='POS', '+', or '(+)' then NUM_RES =cut_off
- If RAWRES ='< value' and value<=cut_off then NUM_RES =cut_off/2
- If RAWRES ='< value' and value>cut_off then NUM_RES =value
- If RAWRES ='> value' and value<cut_off then NUM_RES =cut_off/2
- If RAWRES ='> value' and value>=cut_off then NUM_RES =value
- If RAWRES is a value < cut-off then NUM_RES =cut_off/2
- If RAWRES is a value >= cut-off then NUM_RES =rawres
- In all other cases, NUM_RES is considered missing.

7.1.4. Safety and Reactogenicity

7.1.4.1. Counting rules

The way the percentage of subjects will be derived will depend on the event analysed (see the following table for details). As a result, the denominator (N) will differ from one table to another.

Event	N used for deriving %	Terminology used in the tables for N
Concomitant medication	All vaccinated subjects	Number of vaccinated subjects
Solicited general symptom	All vaccinated subjects with at least one solicited general symptom documented as either present or absent	Number of subjects with general symptom screen completed
Solicited local symptom	All vaccinated subjects with at least one solicited local symptom documented as either present or absent	Number of subjects with local symptom screen completed
Unsolicited symptom from day 0 to day X	All vaccinated subjects with a solicited symptom, unsolicited symptom or SAE documented as either present or absent.	All vaccinated subjects
SAE	All vaccinated subjects with a solicited symptom, unsolicited symptom or SAE documented as either present or absent.	All vaccinated subjects
Specific event for the ESFU	All vaccinated subjects with a solicited symptom, unsolicited symptom or SAE documented as either present or absent.	All vaccinated subjects

7.1.4.2. Handling of missing daily recording

In the primary analysis of solicited symptoms, missing **daily** recordings will be replaced by the maximum value recorded for the child. For children reporting a symptom without a single daily recording (i.e., reporting fever as present in the absence of temperature measurement), missing daily recordings will be replaced by grade 1. A sensitivity analysis of the impact of missing data on the endpoints will be conducted if the percentage of children reporting a symptom without a single daily recording is above 1%.

All efforts will be made during the study database cleaning, through queries to the investigators, to keep the number of missing recordings as small as possible. For instance, if question (1) in Figure 2 ("Has the subject experienced any of the following signs/symptoms during the solicited period?") is answered 'yes', the cleaning will ensure that, for all symptoms, question (2) (Yes/No for experiencing the specified symptom) and (3) (daily recording of intensity) are completed. For ease of review, "screen shots" showing information captured in the safety database are provided.

7.1.4.3. Solicited general symptoms

The analysis of solicited general symptoms will include all subjects for whom the answer to (1) in Figure 2 is 'Yes' or 'No'. The next sections describe how each subject contributes to the analyses, depending on the endpoints.

Statistical Analysis Plan	GlaxoSmithKline
Study alias & e-track number(s): MMR-160 (115648)	

Figure 2 Information captured in the clinical database for solicited general symptoms

SOLICITED ADVERSE EVENTS – GENERAL SIGNS/SYMPTOMS

Has the subject experienced any general solicited signs/symptoms during the appropriate follow up period?

1 →
- [N] ☐ No → Please complete the **Temperature** section
- [Y] ☐ Yes, please tick No/Yes for each sign/symptom and complete further as necessary
- [U] ☐ Unknown, no information available
- [NA] ☐ Not applicable, no vaccine administered

Record daily temperature during the solicited period, regardless of signs/symptoms.
Additional information (i.e., causality, etc) is collected if the temperature is ≥ 38℃ /100.4℉ .

Fever 2 →	[N] ☐ No → [Y] ☐ Yes →	Please complete the **Temperature** section Note: daily temperatures must still be recorded regardless of whether or not fever is present
Rash / Exanthem	[N] ☐ No [Y] ☐ Yes →	Please complete the **Rash / Exanthem** section
*Parotid / Salivary gland swelling	[N] ☐ No [Y] ☐ Yes →	Please complete the **Parotid / Salivary gland swelling** section
Suspected signs of meningism including febrile convulsions/seizures	[N] ☐ No [Y] ☐ Yes →	Please complete the **Suspected signs of meningism (including febrile convulsions/seizures)** section

TEMPERATURE

Record direct temperature measurements within 42 days post-vaccination.

Unit: [CE] ☐ Celsius (℃) [FA] ☐ Fahrenheit (℉)

Route: [A] ☐ Axillary (Preferred) [O] ☐ Oral [R] ☐ Rectal [T] ☐ Tympanic [TA] ☐ Temporal

3 ↓

		Temperature		if ≥ 38.0 ℃ or 100.4 ℉	
	route if different A/O/R/T/TA		*tick if not taken* ↓	**Relationship to investigational product**	**Medically attended visit**
Day 0	|__|	|__|__|.|__| (℃) |__|__|__|.|__| (℉)	☐	☐ No ☐ Yes	NO/HO/ER/MD |__|__|
Day 1	|__|	|__|__|.|__| (℃) |__|__|__|.|__| (℉)	☐	☐ No ☐ Yes	NO/HO/ER/MD |__|__|
Day 2	|__|	|__|__|.|__| (℃) |__|__|__|.|__| (℉)	☐	☐ No ☐ Yes	NO/HO/ER/MD |__|__|
Day 3	|__|	|__|__|.|__| (℃) |__|__|__|.|__| (℉)	☐	☐ No ☐ Yes	NO/HO/ER/MD |__|__|
Day 4	|__|	|__|__|.|__| (℃) |__|__|__|.|__| (℉)	☐	☐ No ☐ Yes	NO/HO/ER/MD |__|__|

7.1.4.4. Analysis of percentage of subjects with general symptoms

For solicited general symptoms if the answer to (2) in Figure 2 is "No", the subject will be considered as not having that symptom after that dose. If the answer to (2) in Figure 2 is “Yes” for at least one symptom, the maximum intensity recording over the considered follow-up period is used for the analysis of the percentage of subjects with symptoms.

Note that subjects who documented the presence of a symptom but partially recorded daily measurement (3) over the considered solicited period will be included in the summaries and classified according to their maximum observed daily recording over the solicited period.

Subjects who have documented the presence of a symptom without having recorded any daily measurement (3) in Figure 2 from day 0 to 42 will not be counted in the summary of subjects with symptoms above a specified threshold, however they will be part of the summary corresponding to the ‘All’ category.

Subjects who have documented the presence of a symptom without having any recorded daily measurement (3) in Figure 2 in a restricted solicited period but with some temperatures recorded between day 0-42 will only be counted as having fever if they have temperature above fever threshold in the restricted solicited period.

Examples where the answer to (2) in Figure 2 is “Yes”:

- A subject has a recorded temperature of 37.5C every day (Day 0 to Day 42), with the exception of Day 18, where the temperature was 38.3C. This subject will be counted in the “All’ and “>=38C” categories during the Day 0-42 period, and will be considered to have no fever for the Day 0-14 period.
- A subject has missing daily recordings for all days (Day 0 to Day 42). This subject will be counted in the “All” fever category for both the Day 0-14 and Day 0-42 periods.
- A subject has missing daily recordings from Day 0 to Day 14 (inclusive), followed by a temperature of 38.7C on Day 15, and 37.5C every day from Day 16 to Day 42. This subject will be counted in the “All” and “>=38.5C” categories during the Day 0-42 period, and the “All” category for the Day 0-14 period.

7.1.4.5. Prevalence graph for fever

For fever prevalence graph, a missing daily recording on a specific day will not be replaced: it will be considered as a subject with unknown temperature on that day.

7.1.4.6. Solicited local symptoms

The analysis of solicited local symptoms will include all subjects for whom at least one vaccine site question (1) in Figure 3 is answered 'Yes' or 'No' at the specific dose.

Figure 3 Information captured in the clinical database for solicited local symptoms

SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS
MMR Vaccine injection site

Has the subject experienced any of the following signs/symptoms between Day 0 and Day 3?

1 [N] ☐ No
[Y] ☐ Yes, please tick No/Yes for each sign/symptom and complete further as necessary.
[U] ☐ Unknown, no information available
[NA] ☐ Not applicable, no vaccine administered.

Local Sign/Symptom	Day 0	Day 1	Day 2	Day 3
2 **Redness** [RE] ☐ No ☐ Yes → size (mm):	|___|	|___|	|___|	|___| 3
Swelling [SW] ☐ No ☐ Yes → size (mm):	|___|	|___|	|___|	|___|
Pain [PA] ☐ No ☐ Yes → intensity:	|___|	|___|	|___|	|___|

7.1.4.7. Analysis of percentage of subjects with local symptoms

For each solicited local symptom, if the answer to (2) in Figure 3 is 'No', the subject will be considered not having that local symptom at that injection site after that dose. If the answer to (2) in Figure 3 is 'Yes', the maximum intensity recording over the considered follow-up period is used for the analysis of the percentage of subjects with symptoms. Subjects who documented the presence of a symptom but partially recorded daily measurement over the solicited period will be included in the summaries and classified according to their maximum observed daily recording over the solicited period.

In the main analysis, subjects who have documented the presence of a symptom without any recorded daily measurement (3) in Figure 3 from Day 0 to Day 3 will not be counted in the summary of subjects with each grade, however they will be part of the summary corresponding to the 'Any' category.

7.1.4.8. Sensitivity analyses for solicited symptoms

If the frequency of doses with symptoms documented (answer to (2) in Figure 3 is "Yes") and without a single daily recording is more than 1%, two supplementary analyses will be performed:

- In the first supplementary analysis, subjects who have documented the presence of a symptom without any recorded daily measurement will be assigned to the highest intensity category (i.e. grade 3), while the ones without documentation will be excluded.
- In the second supplementary analysis, both subjects who have documented the presence of a symptom without any recorded daily measurement and subjects without documentation will be excluded.

For the definition of grade of all local symptoms, see the protocol.

7.1.4.9. Unsolicited symptoms

The analysis of unsolicited adverse events, including serious adverse events, consists of evaluating the percentage of subjects with at least 1 report of an unsolicited adverse event classified by the Medical Dictionary for Regulatory Activities (MedDRA).

This analysis will include all subjects who received a study vaccine and who satisfy at least one of the following conditions:

- The response to (1) on the study conclusion page (Figure 4) is 'Yes' or 'No'.
- The response to the question on the occurrence of unsolicited symptoms (Figure 5) is 'Yes' or 'No'.
- The subject is included in the analysis of local or general solicited symptoms.
- The subject reported at least one unsolicited AE or SAE.

Figure 4 Information captured in the clinical database that will determine the contribution of a subject to the analysis of unsolicited symptom including SAE.

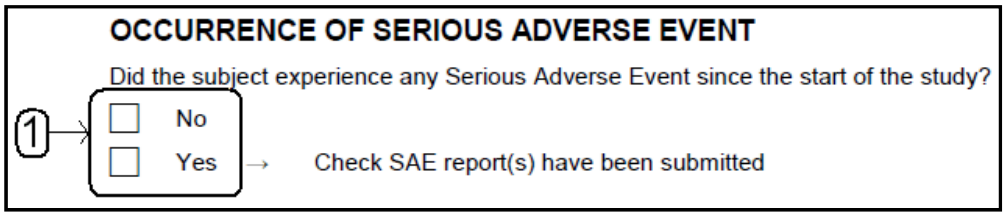


Figure 5 Information captured in the clinical database that will determine the contribution of a subject to the analysis of unsolicited symptom

NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS
(Please report *serious* adverse events only in the Serious Adverse Event report, not here)

Have any non-serious adverse events occurred during the time frame as specified in the protocol?

☐ No
☐ Yes → Please complete the following table.

7.1.4.10. Counting rules for rash

In the MMR project, rash is considered as a general symptom, however we also collect information on administration site rashes in the CRF (see Figure 6). Therefore, in rash summaries the 'General' category will include all types of rash (at the administration site or not.

Figure 6 Information captured in the clinical database on rash description

RASH / EXANTHEM

Please report any rash/exanthem event that occurred from Day 0 to Day 42 post-vaccination.

Rash No.	RA 1
Description	_____ _____
	[G]☐ Generalised [L]☐ Localised: [AS]☐ MMR administration site: [OT]☐ Other location, specify: _____

The denominator for rash summaries will be all subjects for whom (1) in Figure 2 is 'Yes' or 'No'.

The numerator for each of the categories in the rash summary will be computed as shown in Table 2.

Statistical Analysis Plan	GlaxoSmithKline
Study alias & e-track number(s): MMR-160 (115648)	

Table 2 Determination of the numerator for rash categories

Rash type	Description	CRF
Any rashes	Number of subjects with a generalized or localized rash (G) or (L)	[G]☐ Generalised [L]☐ Localised: [AS]☐ MMR administration site: [OT]☐ Other location, specify: ___
Generalized	Number of subjects with a generalized rash (G)	
Localized	Number of subjects with a localized rash (L) regardless of the site	
Localized administration site	Number of subjects with a localized rash (L) at the MMR administration site (AS)	
Localized other site	Number of subjects with a localized rash (L) at another (not administration) site (OT)	
with fever	Number of subjects with a rash (generalized, localized, or any) with fever. The definition of fever is at least one day of fever (temperature >=38.0°C by any route) during the period from three days before the start date of the rash to the end date of the rash (inclusive).	Generalized (G) checked in the above CRF section (temperature information taken from the daily solicited temperature CRF page).
varicella-like	Number of subjects with a rash (generalized, localized, or any), that is varicella like ((1) in the corresponding CRF section).	[1]☐ Varicella-like rash
measles / Rubella like	Number of subjects with a Generalized (G), measles/rubella like rash ((2) in the corresponding CRF section).	[2]☐ Measles / rubella- like rash [3]☐ Other
Grade 3 or >150 lesions	Number of subjects with a rash (generalized, localized, or any) that is either severe or has >150 lesions ((3) in the corresponding CRF section).	[1]☐ 1 – 50 lesions [2]☐ 51 – 150 lesions [3]☐ > 150 lesions [1]☐ Mild [2]☐ Moderate [3]☐ Severe
related	Number of subjects with a rash (generalized, localized, or any) that is considered related to the investigational product ((Y) in the corresponding CRF section).	**Is there a reasonable possibility that the AE may have been caused by the investigational product?** [N] ☐ No [Y] ☐ Yes
medical advice	Number of subjects with a rash (generalized, localized, or any) that led to a medical visit ((HO), (ER) or (MD) in the corresponding CRF section).	**Medically attended visit:** NO: None HO: Hospitalisation ER: Emergency Room MD: Medical Personnel NO/HO/ER/MD |__|__|

7.1.4.11. Counting rule for parotid/salivary gland swelling

The denominator for parotid/salivary gland swelling summaries will be all subjects for whom (1) in Figure 2 is 'Yes' or 'No'.

The numerator for each of the categories in the parotid/salivary gland swelling summary will be computed as shown in Table 3.

Table 3 Determination of the numerator for parotid/salivary gland swelling categories

Rash type	Description	CRF
All	Number of subjects with parotid/salivary gland swelling reported	
Grade 3	Number of subjects with parotid/salivary gland swelling at intensity (3)	[1] ☐ Swelling without difficulties to move the jaw. [2] ☐ Swelling with difficulties to move the jaw. [3] ☐ Swelling and additional general symptoms.
related	Number of subjects with parotid/salivary gland swelling that is considered related to the investigational product ((Y) in the corresponding CRF section).	**Is there a reasonable possibility that the AE may have been caused by the investigational product?** [N] ☐ No [Y] ☐ Yes
medical advice	Number of subjects with parotid/salivary gland swelling that led to a medical visit ((HO), (ER) or (MD) in the corresponding CRF section).	**Medically attended visit:** NO: None HO: Hospitalisation ER: Emergency Room MD: Medical Personnel NO/HO/ER/MD |__|__|

7.1.4.12. Counting rule for signs of meningism (including febrile convulsions/seizures)

The denominator for the summary of signs of meningism (including febrile convulsions/seizures) will be all subjects for whom (1) in Figure 2 is 'Yes' or 'No'.

The numerator for each of the categories in the signs of meningism summary will be computed as shown in Table 4.

Table 4 Determination of the numerator for signs of meningism (including febrile convulsions/seizures) categories

Rash type	Description	CRF
All	Number of subjects with signs of meningism (including febrile convulsions/seizures) reported.	
Grade 3	Number of subjects with signs of meningism (including febrile convulsions/seizures) reported at intensity 3 (severe).	[1] ☐ Mild [2] ☐ Moderate [3] ☐ Severe
related	Number of subjects with signs of meningism (including febrile convulsions/seizures) reported that is considered related to the investigational product ((Y) in the corresponding CRF section).	**Is there a reasonable possibility that the AE may have been caused by the investigational product?** [N] ☐ No [Y] ☐ Yes
medical advice	Number of subjects with signs of meningism (including febrile convulsions/seizures) reported that led to a medical visit ((HO), (ER) or (MD) in the corresponding CRF section).	**Medically attended visit:** NO: None HO: Hospitalisation ER: Emergency Room MD: Medical Personnel NO/HO/ER/MD |__|__|
febrile convulsion	Number of subjects with signs of meningism (including febrile convulsions/seizures) corresponding to a febrile convulsion ((Y) in the corresponding CRF section)	**Does this event correspond to febrile convulsion?** [N] ☐ No [Y] ☐ Yes → Intensity? [1] ☐ Simple [2] ☐ Complex
Brighton Level x	Number of subjects with signs of meningism (including febrile convulsions/seizures) corresponding to a febrile convulsion, with the corresponsding Brighton Collaboration Level of Diagnostic Certainty (x=1 to 4)	[N] ☐ No [Y] ☐ Yes → Level of diagnostic certainty (Brighton Collaboration): [1] ☐ Level 1 [2] ☐ Level 2 [3] ☐ Level 3 [4] ☐ Level 4 [5] ☐ Level 5

7.1.4.13. Counting rule for irritability/fussiness, drowsiness, and loss of appetite

The denominator for the summary of irritability/fussiness, drowsiness, and loss of appetite will be all subjects for whom (1) in Figure 2 is 'Yes' or 'No'.

For each of these symptoms, if the answer to (2) in Figure 7 is 'No', the subject will be considered not having that symptom after that dose. If the answer to (2) in Figure 7 is 'Yes', the maximum intensity recording over the considered follow-up period is used for the analysis of the percentage of subjects with symptoms. Subjects who documented the presence of a symptom but partially recorded daily recordings over the solicited period will be included in the summaries and classified according to their maximum observed daily recording over the solicited period.

In the main analysis, subjects who have documented the presence of a symptom without any recorded daily measurement (3) in Figure 7 from Day 0 to Day 14 will not be counted in the summary of subjects with each grade, however they will be part of the summary corresponding to the 'Any' category.

Figure 7 Information captured in the clinical database for solicited general symptoms

General sign / symptom	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5
(2) **Irritability / Fussiness** [IF] ☐ No ☐ Yes → intensity:	(3) |___|	|___|	|___|	|___|	|___|	|___|
Drowsiness [DR] ☐ No ☐ Yes → intensity:	|___|	|___|	|___|	|___|	|___|	|___|
Loss of appetite [LO] ☐ No ☐ Yes → intensity:	|___|	|___|	|___|	|___|	|___|	|___|

7.1.4.14. Temperature conversion

The conversion of temperature (Fahrenheit to Celsius) will be done as follows and rounded to 1 decimal place:

- Temperature (Celsius) = ((Temperature (Fahrenheit) - 32) * 5)/9

7.1.4.15. Relative dose

The relative dose for an event (AE, medication, vaccination) is the most recent study dose given before an event. In case the event takes place on the day a study dose is given, the related dose will be that of the study dose, even if the event actually took place before vaccination. For instance, if an adverse event begins on the day of the study vaccination but prior to administration of the vaccine, it will be assigned to this dose.

7.1.4.16. Onset day

The onset day for an event will be the number of days between the most recent vaccination and the start of the event. Events occurring on the day of vaccination will have an onset day of 0.

7.1.4.17. Duration of events

The duration of an event will be the number of days between the start and stop dates + 1, e.g. an event which starts on 01JUN2013 and ends on 10JUN2013 will have a duration of 10 days.

7.1.4.18. Concomitant medication

All vaccinated subjects will be considered for the analysis of concomitant medication use. Subjects who did not report the use of a concomitant medication will be considered as subjects without medication.

7.2. Methodology for computing CI

The exact CIs for a proportion within a group [Clopper 1934] and the standardized asymptotic CI for the group difference in proportions [Newcombe, 1998] will be calculated using SAS.

The CI for GMCs will be obtained within each group separately. The CI for the mean of log-transformed concentration will be first obtained assuming that log-transformed values were normally distributed with unknown variance. The CI for the GMCs will then be obtained by exponential transformation of the CI for the mean of log-transformed concentration.

The CI for GMC group ratio will be obtained using an Analysis of Variance (ANOVA) model on the logarithm-transformed titers. The ANOVA model will include the vaccine group (INV_MMR and COM_MMR) and the country effect (only for measles, mumps & rubella) as fixed effects, and, for pneumococcal immunogenicity, the pre-vaccination log-transformed titer as the regressor. The model will assume equal variance in the log concentrations post vaccination. The between group GMC ratios and their 95% CI will be derived by exponential transformation of the corresponding group contrast in the model.

7.3. Number of decimals to display

The following number of decimal digits will be displayed for demography, immunogenicity and safety/reactogenicity statistics.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	Minimum and maximum age	0
Demographic characteristics	SD (age)	1
Immunogenicity	GMC or GMT, including LL & UL	The number of decimal digits in the raw data + 1 (this may vary between assays)
Immunogenicity	Ratio of GMC/T	2
All summaries	% counts, including LL & UL of CI	1
All summaries	% differences, including LL & UL of CI	2

8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

The analysis will be performed in two steps:

- A final analysis of immunogenicity data for measles, mumps and rubella and solicited symptoms up to Day 42 will be performed as soon as all measles, mumps and rubella immunogenicity data and reactogenicity data (i.e. solicited symptoms) up to Visit 2 are available and cleaned. No clinical report will be written at this time.
- A final analysis of immunogenicity data for the co-administered vaccines (i.e. VV, HAV and PCV-13) and unsolicited AEs from Day 0 to Day 42 following vaccination, and of SAEs and specific AEs covering the period from Day 0 to study end (including the 6-months safety follow-up) will be performed at the end of the study.

These two analyses will be combined in the final clinical report.

Following unblinding for the analysis up to Day 42, accessibility to group attribution will be limited to the statisticians until all study procedures pertaining to the active phase and the 6-months safety follow-up are completed for all children.

Description	Analysis ID	Disclosure Purpose	Reference for TFL
MMR and safety analysis	E1_01	Internal and CTR tables relating to MMR immunogenicity and solicited symptoms	All output is detailed in the TFL for Analysis E1_01
Final	E1_02	Study report and full CTR tables	All output is detailed in the TFL for Analysis E1_02

9. CHANGES FROM PLANNED ANALYSES

There are no changes to the analyses detailed in the study protocol.

10. REFERENCES

Clopper CJ, Pearson E. The Use of Confidence or Fiducial Limits Illustrated in the case of Binomial. *Biometrika.* 1934;26:404-13.

Newcombe RG. Interval estimation for the difference between independent proportions: comparison of eleven methods. *Statistics in Medicine.* 1998;17:873-90.

Documentation of inter-laboratory standardization methods and quality assurance procedures

Not Applicable

Publications based on the study

Not Applicable

Important publications referenced in the report

No key references have been identified and the other ones will be available on request.

CRF /eCRFs for deaths, other SAEs and withdrawals due to adverse events

Pages 1598 to 10844 have been removed - Out of Scope of phase 1 of Policy 0070 - CRF/eCRFs

Signature of principal or coordinating investigator

GlaxoSmithKline Biologicals
Vaccines R&D
Investigator Approval Page

STUDY TITLE: A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Study: 115648 (MMR-160) Development Phase: IIIa

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Investigator:	Mercedes Macias Parra
Affiliation /investigational centre:	Instituto Nacional de Pediatria, Av. Insurgentes Sur 3700-C, Insurgentes Cuicuilco, Mexico City, Mexico, 04530 PPD
Signature of Investigator:	PPD
Date:	24-APR-2018

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GlaxoSmithKline Biologicals, SA

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age.

Clinical Study Report for Study 115648 (MMR-160)

This report provides immunogenicity results at Day 42 and safety results obtained from Dose 1 (Day 0) up to Month 6.

Development Phase: IIIa

IND Number: BB-IND 7229

EUDRACT Number: 2011-004891-12

Name of Investigational Product: GlaxoSmithKline (GSK) Biologicals' live attenuated measles, mumps, rubella vaccine (MMR, vaccine number 209762)

Indication Studied: Combined measles, mumps and rubella vaccine is indicated for active immunization against measles, mumps and rubella diseases

Study initiation date:	09-November-2012
Study completion date:	16-April-2015
Data lock point (Date of database freeze) for measles, mumps and rubella immunogenicity data and solicited safety data:	18-January-2018
Date of report amendment 1	Final: 18-September-2018
Earlier study report:	Final: 09-April-2018

Clinical Study Report Revision History: The Clinical Study Report Amendment 1 dated 18-September-2018 was prepared following the discovery of an error in a program used for CDISC conversion. One table in the body of the report (Table 43) was updated and corresponding tables in the post text tables section of the report (Table 8.15 to Table 8.21) were also updated. In addition, the name of the lab cited in the synopsis for the ELISA analysis of measles and rubella antibodies was changed from GSK to NEOMED- LABS, and the name of the lab that performed the ELISA analysis of VZV and hepatitis A antibodies was added. Finally, typographical errors were also corrected. The amendment does not impact the original conclusions of the study.

Sponsor Signatory: **(Amended: 18-September-2018)**	***Paul Gillard*** ***Clinical and Epidemiology Project Lead*** GlaxoSmithKline Biologicals, SA

This study was performed according to the principles of GCP including the archiving of essential documents.

Based on GSK Biologicals' Study Report INS-BIO-CLIN-1010 v05

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SYNOPSIS

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Study No.: 115648 (MMR-160)

Title of the study:

A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Investigators and study centers:

This was a multicenter study conducted in 5 countries: Estonia (6 sites), Finland (11 sites), Mexico (2 sites), Spain (9 sites) and the United States of America (USA) (63 sites), including Puerto Rico (1 site).

Principal investigator: Dr.PPD PPD Mexico,PPD

Publication (reference): None at the time of this report

Clinical Study Report Revision History: (Amended: 18-September-2018)

The clinical study report was amended following the discovery of an error in a program used for CDISC conversion. One table in the body of the report (*Table 43*) was updated and corresponding tables in the post text tables section of the report (Table 8.15 to Table 8.21) were also updated.
In addition, the name of the lab cited in the synopsis for the ELISA analysis of measles and rubella antibodies was changed from GSK to NEOMED- LABS, and the name of the lab that performed the ELISA analysis of VZV and hepatitis A antibodies was added.
Finally, typographical errors were also corrected.
The amendment does not impact the original conclusions of the study.

Study period: **Study initiation date:** 09-November-2012 **Study completion date:** 16-April-2015 **Data lock point (Date of database freeze):** 18-January-2018	**Phase:** IIIA

Indication: Combined measles, mumps and rubella vaccine is indicated for active immunization against measles, mumps and rubella diseases.

Objectives: There were 5 co-primary objectives for the study; a hierarchical procedure was used to analyze the primary and secondary objectives, i.e., each objective could only be reached if all the associated criteria were met and all previous objectives were reached.

Co-primary objectives: The 5 co-primary objectives were assessed in a hierarchical manner according to the order listed below:

1. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
   Criterion:
   For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for antibodies to measles, mumps, and rubella viruses.
2. To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.
   Criterion:
   For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

3. To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
   Criterion:
   The lower limit of the two-sided 95% CI on the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses.

4. To demonstrate non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.
   Criterion:
   The lower limit of the two-sided 95% CI on GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.
5. To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.
   Criterion:
   The lower limit of the two-sided 95% CI for the seroresponse rate for the pooled Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.

Secondary objectives: According to the hierarchical analysis plan, the secondary objectives to evaluate non-inferiority of the immune response to the co-administered vaccines were only assessed when all co-primary objectives were met. No hierarchy between secondary objectives was made.

1. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of seroresponse rate and GMC for antibodies to varicella zoster virus (VZV) at Day 42 (in a subset of children enrolled in the US).
   Criteria:
   The lower limit of the two-sided 95% CI for the group difference (pooled Inv_MMR minus pooled Com_MMR) in seroresponse rates for antibodies to VZV is ≥-10%.
   The lower limit of the two-sided 95% CI on the GMC ratio (pooled Inv_MMR over pooled Com_MMR) is ≥0.67 for antibodies to VZV.
2. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of GMC for antibodies to hepatitis A virus (HAV) at Day 42 (in a subset of children enrolled in the US).
   Criterion:
   The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to HAV (post-dose 1) is ≥0.5.
3. To demonstrate non-inferiority of the pooled Inv_MMR groups compared to the pooled Com_MMR groups in terms of antibodies to *S. pneumoniae* (PS) (13 serotypes), at Day 42 (in a subset of children administered *Prevnar 13* in the US).
   Criterion:
   The lower limit of the two-sided 95% CI for the group GMC ratio (pooled Inv_MMR over pooled Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.
4. To assess the immunogenicity of *Havrix* with respect to the seroresponse rates for antibodies to HAV in the pooled Inv_MMR groups in contrast to the pooled Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).
5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with *Varivax*, *Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US).

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Methodology:

Design: This was a phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with 5 parallel groups, designed to evaluate the consistency of the immune response to three different lots of GSK Biologicals' trivalent combined MMR vaccine (*Priorix*, referred to as Inv_MMR throughout this document) manufactured to target potencies. The study was designed to evaluate immunogenicity of Inv_MMR vaccine compared to the US standard of care (*M-M-R II/M-M-R VaxPro* vaccine, referred to as Com_MMR throughout this document) when both MMR vaccines were used as a first (primary) dose. Subjects 12 to 15 months of age were enrolled and randomized to the 5 study groups below:

- Group Inv_MMR_L1 received a single dose of Lot 1 of Inv_MMR vaccine;
- Group Inv_MMR_L2 received a single dose of Lot 2 of Inv_MMR vaccine;
- Group Inv_MMR_L3 received a single dose of Lot 3 of Inv_MMR vaccine;
- Group Com_MMR_L1 received a single dose of Lot 1 of Com_MMR vaccine;
- Group Com_MMR_L2 received a single dose of Lot 2 of Com_MMR vaccine.

Throughout the study, Com_MMR_L1 and Com_MMR_L2 were analyzed as pooled lots.

Co-administered vaccines: All subjects also received appropriate co-administered vaccinations. *Varivax* (VV) and *Havrix* (HAV) were administered to all subjects while *Prevnar 13* (PCV-13) was administered only to subjects enrolled in the US.

Vaccination schedule: A single vaccination with either one of three lots of Inv_MMR or one of two Com_MMR active control lots was administered at Visit 1 (12 to 15 months of age), along with the appropriate co-administered vaccines.

Treatment allocation: 5,000 healthy subjects 12 to 15 months of age were planned to be enrolled and randomized in a 2:2:2:1:1 ratio to receive either one dose of Inv_MMR_L1 (1,250 subjects), one dose of Inv_MMR_L2 (1,250 subjects), one dose of Inv_MMR_L3 (1,250 subjects), or one dose of either Com_MMR_L1 (625 subjects) or Com_MMR_L2 (625 subjects). Overall, the randomization was 3:1 (Inv_MMR: Com_MMR).

Visits: Subjects from each treatment group participated in 3 study visits: Day 0, Day 42 and Day 180.

Sampling: Two blood samples were collected from each subject; one at Visit 1/Day 0 prior to vaccination and one at Visit 2/Day 42 post-vaccination.

Immunogenicity and safety assessments (Amended: 18-September-2018):

The antibody response to MMR was measured by enzyme-linked immunosorbent assay (ELISA). For evaluation of immune response in Inv_MMR and Com_MMR groups, blood samples were collected from each subject at Visit 1 (Day 0) prior to vaccination and at Visit 2 (Day 42) post-vaccination. Antibody response to measles and rubella was measured by ***NEOMED-LABS Inc. ELISA***; antibody response to mumps was measured by Pharmaceutical Product Inc. (PPD) ELISA. The antibody response to the co-administered vaccines against VZV and hepatitis A virus was measured by ***NEOMED-LABS Inc.*** ELISA ***and GSK ELISA, respectively***. The antibody response to the co-administered vaccines against PCV was measured by electrochemiluminescence (ECL).

Occurrences of solicited local symptoms (injection site redness, pain and swelling) were recorded from Day 0 to Day 3 following vaccination. Some solicited general symptoms (drowsiness, loss of appetite and irritability) were recorded from Day 0 to Day 14, while certain other solicited general symptoms (fever [temperature ≥38.0°C / 100.4°F], rash, parotid/salivary gland swelling, any sign of meningism including

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

febrile convulsions) as well as unsolicited adverse events (AEs) were recorded from Day 0 to Day 42 after vaccination. Serious adverse events (SAEs) and AEs of specific interest (new onset chronic disease [NOCD] and AEs prompting emergency room [ER] visits) occurring at any time during the whole study period were recorded.

Study vaccine, dose, mode of administration, lot no.:

Synopsis Table 1: Vaccination schedule/site

Type of contact and time point	Dose	Treatment Group	Vaccine/Product	Route[1]	Site	Side
Visit 1 (Day 0)	1	Inv_MMR_L1	Inv_MMR_L1	SC	Triceps region	Left
	1	Inv_MMR_L2	Inv_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L3	Inv_MMR_L3	SC	Triceps region	Left
	1	Com_MMR_L1	Com_MMR_L1	SC	Triceps region	Left
	1	Com_MMR_L2	Com_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Varivax*	SC	Triceps region	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Havrix*	IM	Anterolateral thigh	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Prevnar 13**	IM	Anterolateral thigh	Left

[1] Intramuscular (IM)/ Subcutaneous (SC); * For US children only

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Synopsis Table 2: Vaccine composition, dose and lot number

Treatment name	Vaccine/product name	Formulation	Lot Numbers	Volume	Number of doses
Inv_MMR_L1	Inv_MMR_L1	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	AMJRC455A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	DD12A002A	0.5 mL	1
Inv_MMR_L2	Inv_MMR_L2	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	AMJRC456A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	DD12A003A	0.5 mL	1
Inv_MMR_L3	Inv_MMR_L3	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	AMJRC457A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	DD12A004B	0.5 mL	1
Com_MMR_L1	Com_MMR_L1	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	H004594 J006933 H017980 J006564 0682AE H015824 J015488	0.5 mL†	1

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Treatment name	Vaccine/product name	Formulation	Lot Numbers	Volume	Number of doses
	Com_MMR_L1 Diluent‡	water for injection	G004842 J003177 J015955	0.5 mL	1
Com_MMR_L2	Com_MMR_L2	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	G019547 J006564 H021002 H020866 J006933 0498AE H016132 J015222	0.5 mL†	1
	Com_MMR_L2 Diluent‡	water for injection	0184AE J002990 J015955	0.5 mL	1
Varivax	*Varivax*	A minimum of 1350 pfu of Oka/Merck varicella virus; sucrose approximately 25 mg; hydrolyzed gelatin 12.5 mg, sodium chloride 3.2 mg; monosodium L-glutamate 0.5 mg; sodium phosphate dibasic 0.45 mg; potassium phosphate monobasic 0.08 mg; potassium chloride 0.08 mg; residual components of MRC-5 cells including DNA and protein; and trace quantities of sodium phosphate monobasic; EDTA; neomycin; and fetal bovine serum	H004550; H019070 H012704 J004098 0603AE 0604AE	0.5 mL†	2§
	Varivax Diluent	water for injection	H007994 H003763	0.5 mL	2§

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Treatment name	Vaccine/product name	Formulation	Lot Numbers	Volume	Number of doses
Havrix	*Havrix*	720 EU of hepatitis A virus antigen; 0.25 mg aluminum (as hydroxide); amino acid supplement (0.3% w/v); in a phosphate-buffered saline solution and polysorbate 20 (0.05 mg/mL)	AHAVB666C AHAVB668A AHAVB573C AHAVB646BA AHAVVB738B	0.5 mL	2§
Prevnar 13	*Prevnar 13*	2.2 µg of the purified saccharides 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F; 4.4 mcg of the purified saccharide 6B; approximately 34 µg CRM_{197} carrier protein; 100 µg polysorbate 80; 295 µg succinate buffer; 125 µg aluminum as aluminum phosphate adjuvant	F94001 H17427	0.5 mL	1¥

L= Lot; CCID = Cell Culture Infectious Dose; TCID = Tissue Culture Infectious Dose; EU = ELISA Unit
ppm = Parts Per Million; pfu = Plaque Forming Unit; mL = Milliliter; mg = Milligram; mcg = Microgram; µg = Microgram
MRC = Medical Research Council; DNA = Deoxyribonucleic Acid; EDTA = Ethylenediamine-Tetraacetic Acid
CRM_{197} = Cross-Reactive Material (mutant diphtheria toxin)
† Volume after reconstitution
‡ The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
§ At the end of the study or shortly after the study, depending on vaccine availability, GSK will provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. Not applicable for subjects enrolled in US. The second dose of HAV and varicella vaccine was not part of the study procedures.
¥ PCV-13 was administered to US children with a history of 3-doses of PCV-13 at least 60 days prior to study entry.

Study Population: Male or female children aged 12 to 15 months of age whose parent(s)/legally acceptable representative(s) could and would comply with protocol requirements and for whom a written informed consent was provided. For US sites only: a child who had received all routine vaccinations as per Advisory Committee on Immunization Practices (ACIP) recommendations prior to study entry.

Duration of treatment:
The duration of the study was approximately 6 months for each subject.

Criteria for evaluations:
Primary endpoint:
- Immunogenicity of the MMR vaccines at Day 42**.**
  - Seroresponse to measles, mumps and rubella viruses.
  - Measles, mumps and rubella virus antibody concentrations.

Secondary endpoints:
- Immunogenicity of the *Varivax, Havrix* and *Prevnar 13* vaccines in a subset of children at Day 42.
  - Seroresponse to VZV.
  - VZV antibody concentrations.
  - HAV antibody concentrations.

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- Seroresponse to HAV.
- Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.

- Complementary read-out for immunogenicity of the MMR vaccines at Day 42.
  - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
  - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms.
  - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
  - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
  - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest.
  - Occurrence of new onset chronic disease (NOCD) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting emergency room (ER) visits from Day 0 through the end of study.
- Serious adverse events.
  - Occurrence of SAEs from Day 0 through the end of study.

Statistical methods:

Analysis of immunogenicity: The analysis of immunogenicity was based on the According-to-Protocol (ATP) cohort for immunogenicity. If, for any vaccine group, the percentage of enrolled children with serological results excluded from this ATP cohort was higher than 5%, a second analysis based on the Total Vaccinated cohort (TVC) would be required to complement the ATP analysis.

Except for antibody to *S.pneumoniae* (anti-PS), and unless otherwise stated, the analysis of post-vaccination samples tested by an assay described below was based on children seronegative for the assay at pre-vaccination.

Apart from the endpoints related to clinical consistency, the 3 Inv_MMR lots were pooled for analysis (referred to as Inv_MMR throughout the CSR). The 2 Com_MMR lots used in this study were pooled in all analyses (referred to as Com_MMR throughout the CSR).

Within groups assessment

The following descriptive analyses were performed for each Inv_MMR group, for the Inv_MMR groups, and for the Com_MMR groups at each blood sampling time point for which a serological result was available:

- Percentage of children above each specific cut-off and their exact 95% CIs were tabulated. The specific cut-offs were 150 and 200 mIU/mL for measles, 5 and 10 EU/mL for mumps by PPD ELISA and 4 and 10 IU/mL for rubella, respectively. For the co-administered vaccines, the specific cut-offs were 25 and 75 mIU/mL for varicella zoster, 15 mIU/mL for hepatitis A and in the range of 0.061 – 0.199 µg/mL for each of the 13 serotypes of PS.
- Antibody concentrations were summarized by GMCs with their 95% CIs after vaccination.
- Antibody concentration distributions were displayed as reverse cumulative curves for each antigen

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and each treatment group after vaccination.

Between Inv_MMR lots analysis (consistency)

At the Day 42 post-vaccination blood sampling, for measles, mumps and rubella:

- The 95% CI for the GMC ratio of each pair of Inv_MMR lots was computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations. The ANOVA model included the three Inv_MMR lot groups and the country as fixed effects. Only the three Inv_MMR lot groups were included in the model.
- The asymptomatic standardized 95% CIs for the pair-wise differences in seroresponse across the three Inv_MMR lots were computed.

Between Inv_MMR and Com_MMR group analysis (non-inferiority)

At the Day 42 post-vaccination blood sampling, for each antibody for which results were available:

- The asymptotic standardized 95% CIs for the difference in seroresponse rate and percentage of children with concentration/titer above each specific cut-off between groups [Inv_MMR lot group minus the Com_MMR lot group] were computed.
- The 95% CI for each GMC/T group ratio [Inv_MMR lot group over the Com_MMR lot group] was computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model included the vaccine group and the country (only for measles, mumps & rubella) as fixed effects and, for pneumococcal immunogenicity, the pre-vaccination log-transformed concentration as the regressor. The vaccine groups were the Inv_MMR lot group and the Com_MMR lot group.

Subgroup analysis of immunogenicity

All descriptive analyses for anti-measles, anti-mumps, and anti-rubella antibodies were repeated for the following subgroups:

- By country, provided that the country had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By gender, provided that each gender had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By geographic ancestry (race) category, provided that the category had at least 50 subjects per treatment group (Inv_MMR or Com_MMR). Subjects from the 'other' category were split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

Analysis of safety: The analysis of safety was based on the TVC. If more than 5% of the vaccinated subjects were excluded from the ATP cohort for the analysis of safety, a second analysis based on the ATP cohort would be required to complement the TVC analysis. All safety analyses were repeated by country.

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Synopsis Table 3: Study population (Total vaccinated cohort)

Number of subjects	**INV_MMR_1**	**INV_MMR_1**	**INV_MMR_1**	**COM_MMR**	**Total**
Planned, N	1250	1250	1250	1250	5000
Randomized, N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Completed, n (%)	1175 (94.8)	1162 (94.3)	1190 (95.7)	1232 (95.6)	4759 (95.1)
Demographics	**INV_MMR_1**	**INV_MMR_2**	**INV_MMR_3**	**COM_MMR**	**Total**
N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Females : Males	607:632	594:638	615:628	618:671	2434:2569
Mean Age, months (SD)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)
Median Age, months (minimum, maximum)	12 (12, 16)	12 (12, 15)	12 (12, 16)	12 (11, 15)	12 (11, 16)
White - Caucasian / European Heritage, n (%)	932 (75.2)	938 (76.1)	944 (75.9)	970 (75.3)	3784 (75.6)
Other, n (%)	170 (13.7)	155 (12.6)	162 (13.0)	163 (12.6)	650 (13.0)
African Heritage / African American, n (%)	60 (4.8)	52 (4.2)	57 (4.6)	70 (5.4)	239 (4.8)

INV_MMR_1 = GSK MMR Lot 1; INV_MMR_2 = GSK MMR Lot 2; INV_MMR_3 = GSK MMR Lot 3
COM_MMR = Merck MMR

Summary:

Immunogenicity results:

Pair-wise comparison analyses of the antibodies to measles virus (anti-measles), mumps virus (anti-mumps) and rubella virus (anti-rubella) at Day 42 showed that the co-primary objectives to demonstrate consistency of the three manufacturing lots of Inv_MMR were met (Synopsis Table 4 and Synopsis Table 5).

For the comparison of three manufacturing lots of Inv_MMR:

- For each pair-wise comparison, the two sided 95% CI for the lot difference in seroresponse rates between lots was within the [-5%; 5%] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 1.
- For each pair-wise comparison, the two sided 95% CI for the adjusted GMC ratio was within the [0.67; 1.5] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 2.

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Synopsis table 4: Consistency of INV_MMR lots in terms of seroresponse rate for measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

					Difference (First group minus Second group)		
	First group		Second group			95% CI	
Antibody	**INV_MMR Lot**	**SR rate**	**INV_MMR Lot**	**SR rate**	**%**	**LL**	**UL**
anti-Measles antibody	1	98.1	2	98.6	-0.54	-1.69	0.58
	1	98.1	3	97.8	0.25	-0.98	1.50
	2	98.6	3	97.8	0.79	-0.35	1.98
anti-Mumps (PPD) antibody	1	98.6	2	98.6	0.02	-1.05	1.09
	1	98.6	3	98.0	0.63	-0.50	1.81
	2	98.6	3	98.0	0.61	-0.53	1.79
anti-Rubella antibody	1	97.2	2	97.1	0.14	-1.30	1.58
	1	97.2	3	97.7	-0.49	-1.86	0.86
	2	97.1	3	97.7	-0.62	-2.02	0.74

INV_MMR_1 = GSK MMR LOT 1; INV_MMR_2 = GSK MMR LOT 2; INV_MMR_3 = GSK MMR LOT 3
SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay -
seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively)
PPD = Pharmaceutical Product Development Inc.
95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Synopsis table 5: Consistency of INV_MMR lots in terms of adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

					Adjusted GMC ratio (First group over Second group)		
	First group		Second group			95% CI	
Antibody	**Lot**	**Adjusted GMC**	**Lot**	**Adjusted GMC**	**Value**	**LL**	**UL**
anti-Measles antibody (mIU/mL)	INV_MMR_1	3128.5	INV_MMR_2	3174.4	0.99	0.91	1.06
	INV_MMR_1	3128.5	INV_MMR_3	3217.7	0.97	0.90	1.05
	INV_MMR_2	3174.4	INV_MMR_3	3217.7	0.99	0.91	1.06
anti-Mumps (PPD) antibody (EU/mL)	INV_MMR_1	75.2	INV_MMR_2	80.5	0.93	0.87	1.00
	INV_MMR_1	75.2	INV_MMR_3	72.3	1.04	0.97	1.11
	INV_MMR_2	80.5	INV_MMR_3	72.3	1.11	1.04	1.19
anti-Rubella antibody (IU/mL)	INV_MMR_1	54.5	INV_MMR_2	50.5	1.08	1.01	1.15
	INV_MMR_1	54.5	INV_MMR_3	54.3	1.00	0.94	1.07
	INV_MMR_2	50.5	INV_MMR_3	54.3	0.93	0.87	0.99

INV_MMR_1 = GSK MMR LOT 1; INV_MMR_2 = GSK MMR LOT 2; INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for Country
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country - pooled variance with more than 2 groups), LL = lower limit, UL = upper limit

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Between group analyses of the anti-measles, anti-mumps and anti-rubella antibodies at Day 42 showed that the co-primary objectives to demonstrate non-inferiority of Inv_MMR compared to Com_MMR were met (Synopsis Table 6 and Synopsis Table 7).

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 3.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 4.

Synopsis table 6: NI of INV_MMR vs COM_MMR in terms of seroresponse rate to measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

			Difference (INV_MMR minus COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	**SR rate**	**SR rate**	**%**	**LL**	**UL**
anti-Measles antibody	98.2	98.0	0.18	-0.68	1.25
anti-Mumps (PPD) antibody	98.4	97.6	0.81	-0.10	1.96
anti-Rubella antibody	97.3	98.5	-1.15	-2.00	-0.15

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR; SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay - seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively); 95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Synopsis table 7: NI of INV_MMR vs COM_MMR in terms of post-vaccination adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only
(ATP cohort for immunogenicity)

			Adjusted GMC ratio (INV_MMR over COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	**Adjusted GMC**	**Adjusted GMC**	**Value**	**LL**	**UL**
anti-Measles antibody (mIU/mL)	3165.2	3215.4	0.98	0.93	1.05
anti-Mumps (PPD) antibody (EU/mL)	76.4	73.0	1.05	0.99	1.11
anti-Rubella antibody (IU/mL)	52.5	60.0	0.87	0.83	0.92

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR;
Adjusted GMC = geometric mean antibody concentration adjusted for Country;
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country - pooled variance), LL = lower limit, UL = upper limit

Analyses of anti-measles, anti-mumps and anti-rubella antibodies at Day 42 in Inv_MMR group showed that the co-primary objective of acceptable immune response for Inv_MMR in terms of seroresponse rates was met (Synopsis Table 8 to Synopsis Table 10).

- The lower limit of the two sided 95% CI for the seroresponse rate for Inv_MMR lots was ≥90% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 5.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Synopsis table 8: Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 mIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3196	98.4	97.9	98.8	3188	98.2	97.6	98.6	3017.4	2923.9	3113.8
	COM_MMR	PI(D42)	1137	1115	98.1	97.1	98.8	1114	98.0	97.0	98.7	3074.4	2911.0	3246.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Synopsis table 9: Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3187	3168	99.4	99.1	99.6	3135	98.4	97.9	98.8	72.4	70.4	74.5
	COM_MMR	PI(D42)	1107	1099	99.3	98.6	99.7	1080	97.6	96.5	98.4	69.1	65.7	72.7

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Synopsis table 10: Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3245	3229	99.5	99.2	99.7	3159	97.3	96.7	97.9	55.7	54.2	57.3
	COM_MMR	PI(D42)	1135	1130	99.6	99.0	99.9	1118	98.5	97.6	99.1	64.0	61.1	67.0

INV_MMR = GSK MMR Pooled; COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Between group analyses of the anti-varicella zoster virus (anti-VZV) antibodies at Day 42 showed that secondary objective 1 to demonstrate non-inferiority of Inv_MMR compared to Com_MMR in terms of seroresponse rates and GMC ratio of anti-VZV antibodies was met (Synopsis Table 11 and Synopsis Table 12).

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies
- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies, thus meeting secondary objective 1.

Synopsis table 11: Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an VZV antibody concentration equal to or above 75 mIU/ML - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-VZV antibody	75 mIU/mL	1492	1376	92.2	540	491	90.9	1.30	-1.31	4.29

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Synopsis table 12: Ratios of Anti-VZV antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	GMC	N	GMC	Value	LL	UL
1492	169.6	540	167.2	1.01	0.95	1.08

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

Between groups analyses of the antibodies to HAV at Day 42 showed that secondary objective 2 to demonstrate non-inferiority of Inv_MMR compared to Com_MMR in terms of the GMC ratio of antibodies to HAV was met (Synopsis Table 13).

- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV, thus meeting secondary objective 2.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Synopsis table 13: Ratios of Antibodies to HAV GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	GMC	N	GMC	Value	LL	UL
748	41.8	271	42.8	0.98	0.86	1.11

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

Between group analyses of the anti-*S.pneumoniae* (anti-PS) (13 serotypes) antibodies at Day 42 showed that secondary objective 3 to demonstrate non-inferiority of Inv_MMR compared to Com_MMR in terms of the adjusted GMC ratio of anti-PS antibodies was met (Synopsis Table 14).

- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for each of the thirteen *S. pneumoniae* serotypes, thus meeting secondary objective 3.

Synopsis table 14: Adjusted Ratios of Anti-S.Pneu GMCs at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

					Adjusted GMC ratio (INV_MMR / COM_MMR)		
	INV_MMR		COM_MMR			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PnPS 1 antibody (ECL) (µg/mL)	740	2.258	256	2.392	0.94	0.85	1.05
anti-PnPS 3 antibody (ECL) (µg/mL)	739	0.499	255	0.503	0.99	0.91	1.08
anti-PnPS 4 antibody (ECL) (µg/mL)	732	1.620	255	1.844	0.88	0.79	0.98
anti-PnPS 5 antibody (ECL) (µg/mL)	738	2.092	256	2.280	0.92	0.83	1.01
anti-PnPS 6A antibody (ECL) (µg/mL)	740	5.815	256	5.761	1.01	0.92	1.11
anti-PnPS 6B antibody (ECL) (µg/mL)	739	5.812	256	5.924	0.98	0.89	1.09
anti-PnPS 7F antibody (ECL) (µg/mL)	739	3.658	256	3.887	0.94	0.86	1.03
anti-PnPS 9V antibody (ECL) (µg/mL)	740	2.295	256	2.324	0.99	0.90	1.08
anti-PnPS 14 antibody (ECL) (µg/mL)	738	6.512	256	7.151	0.91	0.81	1.02
anti-PnPS 18C antibody (ECL) (µg/mL)	740	2.082	255	2.255	0.92	0.84	1.02
anti-PnPS 19A antibody (ECL) (µg/mL)	739	4.708	255	4.876	0.97	0.87	1.07
anti-PnPS 19F antibody (ECL) (µg/mL)	740	4.186	256	4.367	0.96	0.87	1.06
anti-PnPS 23F antibody (ECL) (µg/mL)	701	2.178	240	2.301	0.95	0.85	1.06

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for baseline concentration
N = Number of subjects with both pre- and post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Ancova model: adjustment for baseline concentration - pooled variance); LL = lower limit, UL = upper limit

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Safety results:

- Overall, during the 43-day post-vaccination period, at least one solicited or unsolicited symptom was reported by ***87.1***% of subjects in the Inv_MMR group and by ***88.3***% in the Com_MMR group. General symptoms were reported by ***84.8***% and ***86.1***% of subjects in Inv_MMR and Com_MMR groups, respectively. Local symptoms were reported by 40.2% and 41.9% of subjects in the Inv_MMR and Com_MMR groups, respectively.
- Within the 4-day post-vaccination period, the most frequently reported solicited local symptoms in the Inv_MMR and Com_MMR groups were pain (25.9% and 28.1%) and redness (24.5% and 25.2%), respectively. Solicited local symptoms of grade 3 were reported in up to 1.0% of subjects in any group.
- Within the 15-day post-vaccination period, the most commonly reported general symptom in the Inv_MMR group and Com_MMR groups was irritability or fussiness reported in 63.3% and 65.9% of subjects respectively. This was followed by drowsiness (44.9% and 47.1%) and loss of appetite (45.1% and 44.1%). Solicited general AEs of grade 3 were reported in a maximum of 4.9% of subjects in the Inv_MMR and Com_MMR groups.
- Within the 43-day post-vaccination period, the following solicited general symptoms were reported in both the Inv_MMR and Com_MMR groups, respectively: fever ≥38.0°C/100.4°F (34.7% and 33.1%), rash (29.2% and 30.4%) and febrile convulsions (10 subjects [0.3%] and 3 subjects [0.2%]; 4 of these 10 events in the Inv_MMR group and 2 of the 3 events in the Com_MMR group were considered related to vaccination). No subject reported parotid gland swelling in any of the groups.
- Within the 43-day post-vaccination period, 50.0% of subjects in the Inv_MMR group and 47.9% in the Com_MMR group reported at least one unsolicited AE. The most common AE by MedDRA preferred term was upper respiratory tract infection, reported in 9.5% of subjects of both the Inv_MMR and Com_MMR groups.
- During the entire study period, 102 subjects reported one or more SAEs in this study. A total of 98 SAEs were reported in 77 subjects (2.1%) in the Inv_MMR group and 40 were reported in 25 subjects (1.9%) in the Com_MMR group. Two of these SAEs in the Inv_MMR group were considered by the investigator to be related to the study vaccination. One subject in the Inv_MMR_2 group had gastroenteritis, and another subject in the Inv_MMR_3 group had febrile convulsion. There were no fatal SAEs in the study. Safety results were consistent between the 3 lots of Inv_MMR used in this study.
- The most frequently occurring SAE during the study period was bronchitis reported by 8 subjects (0.2%) in the Inv_MMR group and by 2 subjects (0.2%) in the Com_MMR group.
- Two subjects were withdrawn from the study due to an AE.

Name of company: GlaxoSmithKline Biologicals, SA, Rixensart, Belgium	**Name of finished product:** Priorix®	**Name of active substance:** Live attenuated measles (Schwarz strain), mumps (RIT 4385 strain), and rubella (RA 27/3 strain) viruses.

Conclusion:

All co-primary study objectives were met:

- The lot-to-lot consistency of the immune response to each of the three vaccine components after one dose of *Priorix*, out of three consistency lots, was demonstrated:

All 95% CIs for the pair-wise lot differences in seroresponse rates were between -5% and +5% for anti-measles, anti-mumps, and anti-rubella antibodies.

All 95% CIs for the pair-wise adjusted GMC ratios were between 0.67 and 1.50 for anti-measles, anti-mumps, and anti-rubella antibodies.

- Non-inferiority of the immune responses of the Inv_MMR lots versus *M-M-R-II* was demonstrated:

The lower limit of the 95% CI for the group difference in seroresponse rates (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps, and anti-rubella antibodies.

The lower limit of the 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps, and anti-rubella antibodies.

- The acceptability of the immune response of the Inv_MMR lots was demonstrated:

The lower limit of the 95% CI for the seroresponse rate in the Inv_MMR group was ≥90% for anti-measles, anti-mumps, and anti-rubella antibodies.

All secondary study objectives related to immunogenicity were met.

- Non-inferiority of the immune response of the Inv_MMR lots versus the Com_MMR lots in terms of co-administered vaccines was demonstrated:

The lower limit of the two-sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies.

The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies.

The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV.

The lower limit of the two-sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to each of the thirteen *S. pneumoniae* serotypes.

An acceptable safety profile was observed for the Inv_MMR groups when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US), which was similar to that observed with *M-M-R-II*.

Date of report amendment 1: Final: 18-September-2018.

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LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
ANOVA	Analysis of Variance
Anti-HAV	Antibody to Hepatitis A Virus
Anti-measles	Antibody to Measles Virus
Anti-mumps	Antibody to Mumps Virus
Anti-PS	Antibody to *S.pneumoniae* serotypes
Anti-rubella	Antibody to Rubella Virus
Anti-VZV	Antibody to Varicella Zoster Virus
ATP	According-To-Protocol
CBER	Center for Biologics Evaluation and Research
CDC	Center for Disease Control
CI	Confidence Interval
Com_MMR_L1	Comparator MMR vaccine Lot 1
Com_MMR_L2	Comparator MMR vaccine Lot 2
CRO	Contract Research Organization
CSR	Clinical Study Report
ECL	Electrochemiluminescence
eCRF	electronic Case Report Form
ELISA	Enzyme-linked Immunosorbent Assay
ER	Emergency Room
EU	European Union
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GMC	Geometric mean concentration
GSK	GlaxoSmithKline
HAV	Hepatitis A vaccine (*Havrix*)
Hib	*Haemophilus influenzae* type b
ICF	Informed Consent Form
IEC	Independent Ethics Committee
IM	Intramuscular
IND	Investigational New Drug

Inv_MMR	Investigational MMR Vaccine
Inv_MMR_L1	Investigational MMR Vaccine Lot 1
Inv_MMR_L2	Investigational MMR Vaccine Lot 2
Inv_MMR_L3	Investigational MMR Vaccine Lot 3
IRB	Institutional Review Board
LAR(s)	Legally Acceptable Representative(s)
LOD	Limit of Detection
LOQ	Limit of Quantitation
mcg / μg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
mIU	Milli International Unit
MMR	Measles, Mumps and Rubella
NOCD	New Onset Chronic Disease
PASS	Power Analysis and Sample Size (Software)
PCV-13	Pneumococcal Conjugate Vaccine (*Prevnar 13)*
PFU	Plaque Forming Units
PPD	Pharmaceutical Product Development, Inc.
RDE	Remote Data Entry
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis Software
SBIR	Central Randomization System on the Internet
SC	Subcutaneous
SD	Standard Deviation
SOP	Standard Operating Procedures
SP/MSD	Sanofi Pasteur/Merck Sharp and Dohme
SPM	Study Procedures Manual
TVC	Total Vaccinated Cohort
USA	United States (US) of America
VV	Varicella Vaccine (*Varivax*)
VZV	Varicella Zoster Virus
WHO	World Health Organization

GLOSSARY OF TERMS

Adverse event: Any untoward medical occurrence in a patient or clinical investigation child, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also includes failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse.

Blinding: A procedure in which one or more parties to the trial are kept unaware of the treatment assignment in order to reduce the risk of biased study outcomes. The level of blinding is maintained throughout the conduct of the trial, and only when the data are cleaned to an acceptable level of quality will appropriate personnel be unblinded or when required in case of a serious adverse event. In an observer-blind study, the subject/parent(s)/Legally Acceptable Representative(s) (LAR(s)) and the site and sponsor personnel involved in the clinical evaluation of the subjects are blinded while other study personnel may be aware of the treatment assignment. In a double blind study, the subject/parent(s)/LAR(s), the investigator and sponsor staff who are involved in the treatment or clinical evaluation of the subjects and the review or analysis of data are all unaware of the treatment assignments. Partially-blind is to be used for study designs with different blinding levels between different groups, e.g., double-blinded consistency lots which are open with respect to the control group.

Child in care: A child who has been placed under the control or protection of an agency, organization, institution or entity by the courts, the government or a government body, acting in accordance with powers conferred on them by law or regulation. The definition of a child in care can include a child cared for by foster parents or living in a care home or institution, provided that the arrangement falls within the definition above. The definition of a child in care does not include a child who is adopted or has an appointed LAR/s.

Eligible: Qualified for enrollment into the study based upon strict adherence to inclusion/exclusion criteria.

Epoch:	An epoch is a well-defined part of a protocol that covers a set of consecutive time points. Generally, an epoch is self-contained and allows performance of data analysis to address some of the trial objectives (e.g., primary, booster, yearly follow-ups).
eTrack:	GSK's tracking tool for clinical trials.
Evaluable:	Meeting all eligibility criteria, complying with the procedures defined in the protocol, and, therefore, included in the according-to-protocol (ATP) analysis.
Medically Attended Adverse Event:	An event for which the subject received medical attention defined as hospitalization, an emergency room visit or a visit to or from medical personnel (e.g., nurse practitioner or physician assistant or medical doctor) for any reason.
Randomization:	Process of random attribution of treatment to subjects in order to reduce bias of selection.
SBIR:	A central Internet randomization system.
Site Monitor:	An individual assigned by the sponsor who is responsible for assuring proper conduct of clinical studies at one or more investigational sites.
Solicited adverse event:	Adverse events (AEs) to be recorded as endpoints in the clinical study. The presence/occurrence/intensity of these events is actively solicited from the subject or an observer during a specified post-vaccination follow-up period.
Subject	Term used throughout the protocol to denote an individual who has been enrolled to participate or participates in the clinical study, either as a recipient of the investigational product(s) or as a control.
Subset:	A group of subjects who have the same study procedures at a given time point, but the biological assays performed on that sample will be different, relative to the other subsets.
Treatment:	Term used throughout the clinical study to denote a set of investigational product(s) or marketed product(s) or placebo intended to be administered to a subject, identified by a unique number, according to the study randomization or treatment allocation.

Unsolicited adverse event:	Any adverse event (AE) reported in addition to those solicited during the clinical study. Also any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms will be reported as an unsolicited adverse event.

TRADEMARKS

The following trademarks are used in the present report.

Note: In the body of the Study Report, the names of the vaccines/products and/or medications are written without the superscript symbol ™ or ® and in *italics*.

Trademarks of the GSK group of companies	Generic description
Priorix®*	Measles, mumps and rubella vaccine live
Havrix®	Hepatitis A vaccine (HAV)

* *Priorix* is not licensed in the US.

Trademarks not owned by the GSK group of companies	Generic description
M-M-R®II (Merck & Co., Inc.) also called M-M-R Vax Pro® (distributed by Sanofi Pasteur/Merck Sharp and Dohme [SPMSD] in certain countries)*	Measles, mumps, and rubella virus vaccine live
Varivax® (Merck & Co., Inc.)	Varicella virus vaccine live (VV)
Prevnar 13® (Pfizer Inc.)	Pneumococcal 13-valent conjugate vaccine (diphtheria CRM_{197} protein) (PCV-13)

* The Merck & Co., Inc.'s combined measles-mumps-rubella virus vaccine live is referred to as Com_MMR (Com_MMR_L1 and Com_MMR_L2, for lots 1 and 2 respectively) for the comparator vaccine throughout the study report.

1. ETHICS

1.1. Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The study protocol, any amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational center IEC or IRB.

1.2. Ethical conduct of the study

This study was conducted in accordance with ethical principles that have their origins in the Declaration of Helsinki, the principles of "good clinical practice" (GCP) and all applicable regulatory requirements.

During the course of the study, whenever potential issues with regard to the conduct of the study were identified, either via site monitoring activities or brought to GlaxoSmithKline (GSK) Biologicals' attention by other oversight mechanisms, these issues were investigated and appropriate corrective and / preventive actions where possible were taken.

Deviations that occurred during the study are described in Section 5.11 and Section 6.3.

1.3. Subject information and consent

Written informed consent was to be obtained from each subject's parent(s) / legally acceptable representative (LAR) prior to the performance of any study-specific procedures.

2. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This multicenter study, sponsored by GSK Biologicals, was conducted in Estonia (6 sites), Finland (11 sites), Mexico (2 sites), Spain (9 sites), the United States of America (USA) (63 sites) including Puerto Rico (1 site).

Principal investigator:

- Dr. PPD PPD Mexico, PPD

The contract research organizations (CROs) involved in this study are given in Table 1. Study sites in Estonia and Mexico did not employ a CRO.

Table 1 Contract research organizations involved in the study

Country	Contract research organization	Scope
Finland	Smerud Medical Research Finland AB/Oy Jorvas High-tech Center, Hirsalantie 11 02420 Jorvas, Finland	Sample management, site monitoring and vaccine distribution
Canada	NÉOMED-LABS Inc. 525 Cartier Blvd. West, Laval, Quebec, Canada - H7V 3S8	Sample management
USA	PPD, Inc., 466 Devon Park Drive, Wayne, PA 19087-1816, USA	Sample management
USA	PPD, Inc., 929 North Front Street, Wilmington, NC 28401, USA	Site monitoring (Puerto Rico)
USA	BARC USA Inc. 5 Delaware Drive, Lake Success, NY 11042-1114, USA	Sample handling/processing

2.1. Clinical study report revision history (Amended: 18-September-2018)

The clinical study report was amended following the discovery of an error in a program used for CDISC conversion. One table in the body of the report (Table 43) was updated, and corresponding tables in the post text tables section of the report (Table 8.15 to Table 8.21) were also updated. In addition, the name of the lab cited in the synopsis for the ELISA analysis of measles and rubella antibodies was changed from GSK to NEOMED- LABS, and the name of the lab that performed the ELISA analysis of VZV and hepatitis A antibodies was added. Finally, typographical errors were also corrected. The amendment does not impact the original conclusions of the study.

3. INTRODUCTION

Measles, mumps and rubella (MMR) are common viral illnesses of childhood. These highly infectious diseases and their complications are responsible for considerable morbidity and mortality throughout the world [WHO, 2007; WHO, 2009; WHO, 2011]. Measles can cause pneumonia and encephalitis. Mumps is associated with complications including aseptic meningitis, deafness and orchitis. Rubella symptoms in subjects include fever, swollen lymph nodes and rash; while rubella infection in pregnant women can cause congenital rubella syndrome. When immunization against these diseases is routinely practiced, significant reduction in disease incidence and associated complications has been reported [MMWR, 2013]. GSK Biologicals has developed a trivalent MMR vaccine that is licensed outside the USA under the trade name of *Priorix* in over 100 countries, including Canada, Australia, and all countries in the European Union (EU).

This study was intended to support licensure of GSK Biologicals' trivalent combined measles, mumps and rubella vaccine (*Priorix,* referred to as Inv_MMR vaccine in this document) in the USA by generating safety and immunogenicity data in subjects 12 to 15 months of age. The US Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommends routine 2-dose vaccination with MMR vaccine at 12 to 15 months and at 4 to 6 years of age [MMWR, 2013].

This study evaluated the consistency of the immune response to three different lots of Inv_MMR vaccine manufactured to target potencies. In addition, the study also evaluated the immunogenicity of Inv_MMR vaccine in contrast to the US standard of care (*M-M-R-II* / *M-M-R Vax Pro*, referred to as Com_MMR vaccine throughout this document) when both were used as a first (primary) dose. In order to obtain more representative data on the comparator vaccine, the Com_MMR used in this study consisted of two lots designated Com_MMR_L1 and Com_MMR_L2. Throughout the study Com_MMR_L1 and Com_MMR_L2 were analyzed as pooled lots.

In the US, the primary dose of measles, mumps and rubella-containing vaccine is routinely co-administered with *Varivax* (VV), *Havrix* (HAV) and *Prevnar 13* (PCV-13) at 12 to 15 months of age. Hence, in the US, the study also evaluated the safety and immunogenicity of both Inv_MMR and Com_MMR vaccines when both were co-administered with these three vaccines. In other countries the study evaluated the safety and immunogenicity of Inv_MMR and Com_MMR vaccines when co-administered with *Varivax* and *Havrix*. Note: Given the heterogeneity in the use of pediatric pneumococcal vaccines globally, and administration of these vaccines generally begins in infancy, *Prevnar 13* was administered only to children enrolled in the US.

At the end of the study or shortly after the study, depending on vaccine availability, GSK provided a second dose of *Havrix* and/or varicella vaccine to participants enrolled in non-US countries where local health departments did not provide hepatitis A and varicella vaccinations.

4. STUDY OBJECTIVES

4.1. Primary objectives

The co-primary objectives were assessed in a hierarchical manner according to the order presented below. A co-primary objective can only be met if the statistical criteria for that objective were met as well as the statistical criteria for all previous co-primary objectives (see Section 5.10.3.1 for details).

All primary and secondary immunogenicity endpoints were tested with an ELISA.

Note: all criteria were assessed for each assay separately. With the exception of the anti-pneumococcal antibodies, the criteria were specific to children seronegative for the assay at pre-vaccination.

- To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

***Criterion**: For each pair-wise comparison, the two-sided 95% confidence interval (CI) on the lot difference in seroresponse rates is within the [-5%; 5%] margin for antibodies to measles, mumps, and rubella viruses.*

- To demonstrate the consistency of three manufacturing lots of Inv_MMR vaccine in terms of geometric mean concentrations (GMCs) for antibodies to measles, mumps and rubella viruses at Day 42.

  ***Criterion**: For each pair-wise comparison, the two-sided 95% CI on the lot ratio is within the [0.67; 1.5] margin for antibodies to measles, mumps and rubella viruses.*

- To demonstrate the non-inferiority of Inv_MMR (for the three pooled lots) compared to Com_MMR (for the two pooled lots) vaccine in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

  ***Criterion**: The lower limit of the two-sided 95% CI on the group difference (Inv_MMR minus Com_MMR) in seroresponse rate is ≥-5% for antibodies to measles, mumps and rubella viruses.*

- To demonstrate non-inferiority of Inv_MMR (for the three lots) compared to Com_MMR (for the two lots) vaccine in terms of GMCs for antibodies to measles, mumps and rubella viruses at Day 42.

  ***Criterion**: The lower limit of the two-sided 95% CI on GMC ratio (Inv_MMR over Com_MMR) is ≥0.67 for antibodies to measles, mumps and rubella viruses.*

- To demonstrate an acceptable immune response for Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses at Day 42.

  ***Criterion:** The lower limit of the two-sided 95% CI for the seroresponse rate for the Inv_MMR lots is ≥90% for antibodies to measles, mumps, and rubella viruses.*

Refer to Section 5.10.1 for the definition of the primary endpoint.

4.2. Secondary objectives

1. To demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of seroresponse rate and GMC for antibodies to varicella zoster virus (VZV) at Day 42 (in a subset of children enrolled in the US).

   ***Criteria**: The lower limit of the two-sided 95% CI for the group difference (Inv_MMR minus Com_MMR) in seroresponse rates for antibodies to VZV is ≥-10%.*

   The lower limit of the two-sided 95% CI on the GMC ratio (Inv_MMR over Com_MMR) is ≥0.67 for antibodies to VZV.

2. To demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of GMC for antibodies to hepatitis A virus (HAV) at Day 42 (in a subset of children enrolled in the US).

   ***Criterion**: The lower limit of the two-sided 95% CI for the group GMC ratio (Inv_MMR over Com_MMR) for antibodies to HAV (post-dose 1) is ≥0.5.*

3. To demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of GMCs for antibodies to *S. pneumoniae* (PS) (13 serotypes), at Day 42 (in a subset of children administered *Prevnar 13* in the US).

   Criterion*: The lower limit of the two-sided 95% CI for the group GMC ratio (Inv_MMR over Com_MMR) for antibodies to PS serotypes (13 endpoints) is ≥0.5.*

4. To assess the immunogenicity of *Havrix* with respect to the seroresponse rates for antibodies to HAV in the Inv_MMR group in contrast to the Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US).
5. To assess safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US).

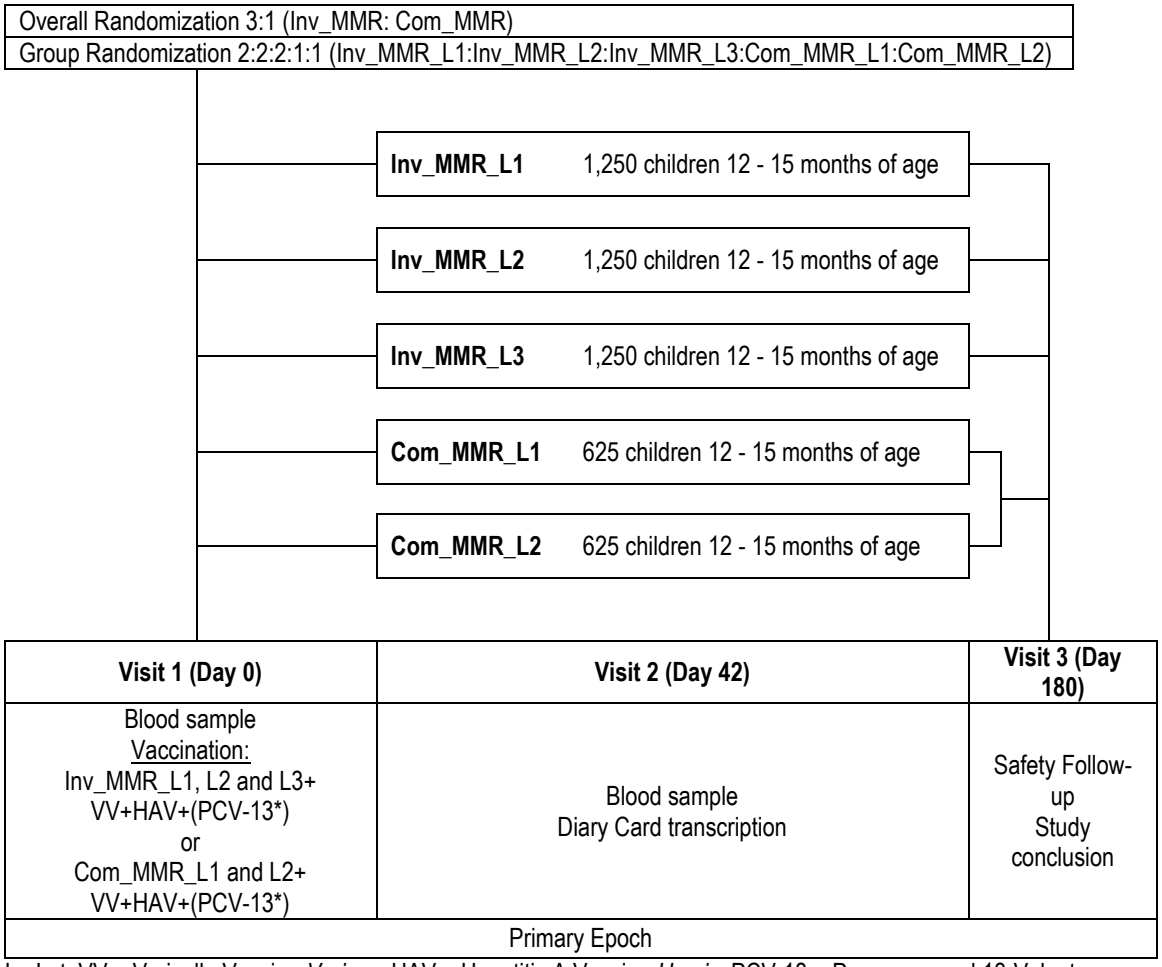
Refer to Section 5.10.2 for the definition of the secondary endpoints.

5. INVESTIGATIONAL PLAN

5.1. Study design

5.1.1. Overall study design – Description

Figure 1 Study design



L= Lot; VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* PCV-13 was only administered to children in the US

- **Experimental design**: Phase IIIA, observer-blind, randomized, controlled, multicenter, multi-country, consistency study with 5 parallel groups.
- **Duration of the study**: The study period was approximately 6 months for each subject, starting at Visit 1 (Day 0) and ending with Visit 3 (Day 180).

Table 2 Study groups

Study groups	Number of subjects	Age (Min/Max)
Inv_MMR_L1	1,250	12 – 15 months
Inv_MMR_L2	1,250	12 – 15 months
Inv_MMR_L3	1,250	12 – 15 months
Com_MMR_L1	625	12 – 15 months
Com_MMR_L2	625	12 – 15 months

L = Lot

- **Control:** active control: Com_MMR_L1 and Com_MMR_L2 vaccines.
- **Co-administered vaccines:** All subjects received *Varivax* (VV) and *Havrix* (HAV) vaccines, concomitantly with MMR vaccine at 12 to 15 months of age. *Prevnar 13* (PCV-13) was co-administered only to US subjects. At the end of the study, GSK provided a second dose of HAV and/or VV vaccine to subjects enrolled in selected non-US countries if local health departments did not routinely provide hepatitis A and varicella vaccinations. The second dose of HAV and VV was not part of the study procedures.
- **Vaccination schedule:** A single vaccination, with either 1 of three lots of Inv_MMR or one of 2 Com_MMR active control lots was administered at Visit 1 (12-15 months of age), along with the appropriate co-administered vaccines. The VV and HAV vaccines were administered to all subjects while PCV-13 was administered only to subjects enrolled in the US.

Table 3 Treatment groups

Treatment name	Vaccine / Product name	Treatment Groups				
		Inv_MMR_L1 (active)	Inv_MMR_L2 (active)	Inv_MMR_L3 (active)	Com_MMR_L1 (control)	Com_MMR_L2 (control)
Inv_MMR_L1	Inv_MMR_L1	X				
	Inv_MMR Diluent	X				
Inv_MMR_L2	Inv_MMR_L2		X			
	Inv_MMR Diluent		X			
Inv_MMR_L3	Inv_MMR_L3			X		
	Inv_MMR Diluent			X		
Com_MMR_L1	Com_MMR_L1				X	
	Com_MMR_L1 Diluent†				X	
Com_MMR_L2	Com_MMR_L2					X
	Com_MMR_L2 Diluent†					X
Varivax	*Varivax*	X	X	X	X	X
	Varivax Diluent	X	X	X	X	X
Havrix	*Havrix*	X	X	X	X	X
*Prevnar 13**	*Prevnar 13*	X	X	X	X	X

L= Lot
† The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
* *Prevnar-13* was only given to children enrolled in the US

- **Treatment allocation:** 5,000 healthy children 12 to 15 months of age were planned to be enrolled and randomized in a 2:2:2:1:1 ratio to receive either one dose of Inv_MMR_L1 (1,250 subjects), one dose of Inv_MMR_L2 (1,250 subjects), one dose of Inv_MMR_L3 (1,250 subjects), or one dose of either Com_MMR_L1 (625 subjects) or Com_MMR_L2 (625 subjects). The vaccines *Havrix*, *Varivax* and *Prevnar 13* were co-administered according to the protocol) with Inv_MMR vaccine or Com_MMR vaccine. The treatment allocation at the investigator site was performed using a central randomization system on the Internet (SBIR). Overall, the randomization was 3:1 (Inv_MMR: Com_MMR).
- **Blinding:** observer-blind.
  - The study was conducted in a double-blind fashion with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots, and in an observer-blind fashion for the comparison of the Inv_MMR vaccine versus the Com_MMR vaccine.
- **Visits:** Children from each treatment group participated in three study visits (Day 0, Day 42 and Day 180).
- **Sampling:** Blood samples were to be collected from each child; one at Day 0 and one at Day 42.
- **Type of study:** self-contained.
- **Data collection:** Electronic Case Report Form (eCRF) encoded using remote data entry (RDE).

5.1.2. Discussion of study design

The MMR-160 study was designed to evaluate the consistency of the immune response to three different lots of Inv_MMR vaccine manufactured to target potencies. In addition, the study was designed to evaluate the immunogenicity of Inv_MMR vaccine in contrast to the US standard of care (*M-M-R II/ M-M-R VaxPro* vaccine) when both are used as a first (primary) dose. In order to obtain more representative data on the comparator vaccine, the Com_MMR used in this study consisted of two lots designated Com_MMR_L1 and Com_MMR_L2. Throughout the study Com_MMR_L1 and Com_MMR_L2 were analyzed as pooled lots.

In the US, the primary dose of measles, mumps and rubella-containing vaccine is routinely co-administered with VV, HAV and PCV-13 vaccines at 12 to 15 months of age. Hence, in the US, the study also evaluated the safety and immunogenicity of both Inv_MMR and Com_MMR vaccines when both are co-administered with these 3 vaccines. In other countries the study evaluated safety and immunogenicity of Inv_MMR and Com_MMR vaccines when co-administered only with VV and HAV. Given the heterogeneity in the use of pediatric pneumococcal vaccines globally, and administration of these vaccines generally begins in infancy, PCV-13 was to be administered only to subjects enrolled in the US who previously received a 3-dose series of *Prevnar 13* only (i.e., no doses given as *Prevnar/Prevenar*), at least 60 days prior to study entry.

At the end of the study, GSK provided a second dose of HAV and/or VV vaccine to subjects enrolled in non-US countries if local health departments did not routinely provide hepatitis A and varicella vaccinations.

5.2. Study procedures

An overview of the study procedures performed on each group is provided in Table 4.

Table 4 List of study procedures

Age at enrollment	12-15 months		
Epoch	*Primary Epoch*		
Type of contact	Visit 1	Visit 2	Visit 3
Time points	Day 0	Day 42	Day 180
Sampling time points	Pre-Vacc	Post-Vacc	
Informed consent	●		
Check inclusion/exclusion criteria	●		
Check contraindications, warnings and precautions	O		O [1]
Collect demography data	●		
Medical history	●		
Physical examination	●	O [2]	O [2]
Measure/record height and weight	●		
Vaccination history (protocol specific vaccines) [3]	●		
Pre-vaccination body temperature	●		
Randomization and recording of treatment number	●		
Blood sampling for antibody determination (~5 mL)	●	●	
Study vaccinations	●		
Second dose of *Havrix* and/or varicella vaccine			x [1]
Distribution of Diary Cards	O	O	
Daily post-vaccination recording of solicited local adverse events by children's parent(s)/LAR(s) on Diary Cards (Day 0-3)	●		
Daily post-vaccination recording of solicited general adverse events by children's parent(s)/LAR(s) on Diary Cards for drowsiness, loss of appetite, and irritability (Day 0-14) and for fever, rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42) [4]	●		
Recording of the occurrence of any post-vaccination unsolicited symptoms by children's parent(s)/LAR(s) on Diary Cards (Day 0-42)	●		
Recording of concomitant medication/vaccination by children's parent(s)/LAR(s) on Diary Cards (Day 0-through study end)	●	O	O
Investigator/designee medical evaluation of any measles/rubella or varicella-like rash, parotid/salivary gland swelling and suspected signs of meningism, including febrile convulsions (Day 0-42)	●		
Recording of any medications/vaccinations through Visit 2	●	●	
Recording of any forbidden investigational product (through study end)	●	●	●
Return of Diary Cards by parent(s)/LAR(s) and transcription by investigator/designee		●	● [5]
Recording of any intercurrent medical condition	●	●	
Recording of all Serious Adverse Events (Day 0 through study end)	●	●	●
Recording of NOCD(s) and AEs prompting medically attended visits including ER visits (Day 0 through study end) [6]	●	●	●
Visit 2 investigator sign-off on data for the Day 42 analysis		●	
Study Conclusion			●
Final investigator signature			●

● is used to indicate a study procedure that required documentation in the individual eCRF
x is used to indicate a procedure (that was not part of the study) that required documentation in the individual eCRF
O is used to indicate a study procedure that did not require documentation in the individual eCRF
[1] At the end of the study or shortly after the study, depending on vaccine availability, GSK was to provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. The second dose of HAV and varicella vaccine was not part of the study procedures.
[2] Physical exam at Visit 2 and Visit 3 only required if deemed necessary based on child's interim medical history. Findings were to be recorded only if symptom/abnormality was present.
[3] For US children only, child that previously received a 3-dose series of PCV-13 at least 60 days prior to study entry
[4] Parent(s)/LAR(s) were to contact the investigator immediately for any suspected measles/rubella, varicella-like rash, parotid/salivary gland swelling or suspected signs of meningism, including febrile convulsions occurring between Day 0 and Day 42 and were to schedule a visit for evaluation by the investigator).
[5] Return of Diary Card for contraindicated medication / vaccination, any specific Adverse Events (AEs), and AEs prompting medically attended visits including Emergency Room (ER) visits until study end.
[6] Events recorded were new onset chronic disease(s) (NOCD(s)) (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting medically attended visits including Emergency Room (ER) visits.

Table 5 Intervals between study visits

Visit	Optimal Visit Day*	Interval	Allowed interval
Visit 1	Day 0	---	---
Visit 2	Day 42	Visit 1 → Visit 2	35 - 77 days†
Visit 3	Day 180	Visit 1 → Visit 3	180 - 210 days

* Whenever possible, the investigator had to arrange study visits on this optimal visit day.
† Subjects were not eligible for inclusion in the ATP immunogenicity analyses if study visits were outside the allowed interval.

5.3. Selection of study population

5.3.1. Inclusion criteria for enrollment

All subjects had to satisfy all the following criteria at study entry:

- Male or female child between 12 and 15 months of age (e.g., from the 1 year birthday until the day before age 16 months) at the time of vaccination.
- Subjects' parent(s)/LARs who, in the opinion of the investigator, could and would comply, with the requirements of the protocol (e.g., completion of the diary cards, return for follow-up visits, respects intervals between visits).
- Written informed consent obtained from the parent(s)/LAR(s) of the child.
- Child was in stable health as determined by investigator's clinical examination and assessment of child's medical history.
- **For US subjects only:** a child who previously received a 3-dose series of *Prevnar 13* only (i.e., no doses given as *Prevnar/Prevenar*), with the last dose at least 60 days prior to study entry.

5.3.2. Exclusion criteria

The following criteria were to be checked at the time of study entry. If any exclusion criterion applied, the child was not to be included in the study:

- Child in care (refer to the glossary of terms for the definition of child in care).
- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the period starting 30 days before the day of study vaccination (i.e., 30 days prior to Day 0) or planned use during the entire study period.
- Concurrently participating in another clinical study, in which the child had been or would have been exposed to an investigational or a non-investigational product (pharmaceutical product or device).
- Chronic administration (defined as 14 or more consecutive days) of immunosuppressants, or other immune-modifying drugs during the period starting 180 days prior to the first vaccine dose or any planned administration of immunosuppressive and immune-modifying drugs during the entire study.
  - For corticosteroids, this will mean prednisone, ≥0.5 mg/kg/day or equivalent.
  - Inhaled and topical steroids are allowed.
- Planned administration/ administration of a vaccine not foreseen by the study protocol during the period starting 30 days prior to study vaccination at Visit 1 and ending at Visit 2. Please Note:
  - **Inactivated** influenza (Flu) vaccine and *Haemophilus influenzae* type b conjugate vaccine (Hib) could be given at any time, including the day of study vaccination (administered at a different location than the study vaccine/s).
  - Any other age appropriate vaccine could be given starting at Visit 2 and anytime thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting 180 days prior to study vaccination at Visit 1 or planned administration from the date of vaccination through the immunogenicity evaluation at Visit 2.
- History of measles, mumps, rubella, varicella/zoster and/or hepatitis A disease.
- Known exposure to measles, mumps, rubella and/or varicella/zoster during the period starting within 30 days prior to first study vaccination.
- Previous vaccination against measles, mumps, rubella, hepatitis A and/or varicella virus.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
- A family history of congenital or hereditary immunodeficiency.
- History of allergic disease or reactions likely to be exacerbated by any component of the vaccines, including hypersensitivity to neomycin, latex or gelatin.

- Blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- Acute disease at the time of enrollment (Acute disease was defined as the presence of a moderate or severe illness with or without fever). Fever was defined as temperature ≥38.0°C/100.4°F by any age appropriate route. All vaccines could be administered to persons with a minor illness such as diarrhea, mild upper respiratory infection without fever.
- Active untreated tuberculosis based on medical history.
- Any other condition which, in the opinion of the investigator, prevented the child from participating in the study.
- **For US subjects only:** a child that previously received a vaccination with heptavalent *Prevnar/Prevenar* (prior vaccination should have been with 3 doses of *Prevnar 13* only) and a child that previously received a fourth dose of any pneumococcal conjugate vaccine.

A list of criteria that may eliminate children from ATP analyses can be found in Sections 5.6.1, 5.6.2 and 5.10.5.

5.3.3. Withdrawal criteria

5.3.3.1. Subject completion

A subject who returned for the concluding Visit 3 (Day 180) was considered to have completed the study.

5.3.3.2. Subject withdrawal from the study

From an analysis perspective, a ‘withdrawal’ from the study referred to any subject who did not return for the concluding visit (Visit 3) or was not available for the concluding contact foreseen in the protocol.

All data collected until the date of withdrawal or last contact with the subject was used for analysis.

A child was considered a ‘withdrawal’ from the study when no study procedure had occurred, no follow-up had been performed and no further information had been collected for this subject from the date of withdrawal or last contact.

Investigators were to make an attempt to contact the parent(s)/LAR(s) of those subjects who did not return for scheduled visits or follow-up.

Information relative to the withdrawal was to be documented in the eCRF. The investigator was to document whether the decision to withdraw a subject from the study was made by the subject's parent(s) or LAR(s), or by the investigator, as well as which of the following possible reasons was responsible for withdrawal:

- Serious adverse event,
- Non-serious adverse event,
- Protocol violation (specify),
- Consent withdrawal, not due to an adverse event,
- Moved from the study area,
- Lost to follow-up,
- Other (specify).

5.3.3.3. Subject withdrawal from investigational vaccine

Not applicable in this study.

5.4. Composition and administration of vaccine(s)

5.4.1. Description of vaccine(s)

The candidate live, attenuated Inv_MMR vaccine was developed and manufactured by GSK Biologicals. The control vaccines Com_MMR_L1 and Com_MMR_L2 were manufactured by Sanofi Pasteur/Merck Sharp and Dohme (SPMSD).

The vaccines were labeled and packed according to applicable regulatory requirements. Commercial vaccines were assumed to comply with the specifications given in the manufacturer's Product Information. The formulation and lot numbers for the different study vaccines are given in Table 6.

Table 6 Study Vaccines

Treatment name	Vaccine/product name	Formulation	Presentation	Lot number	Volume	Number of doses
Inv_MMR_L1	Inv_MMR_L1	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	AMJRC455A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	DD12A002A	0.5 mL	1
Inv_MMR_L2	Inv_MMR_L2	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	AMJRC456A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	DD12A003A	0.5 mL	1
Inv_MMR_L3	Inv_MMR_L3	Measles virus (Schwarz strain) ≥$10^{3.0}$ $CCID_{50}$; Mumps virus (RIT4385 strain) ≥$10^{4.3}$ $CCID_{50}$; Rubella virus (Wistar RA 27/3 strain) ≥$10^{3.0}$ $CCID_{50}$; anhydrous lactose; sorbitol; mannitol; amino acids; neomycin	Lyophilized pellet in a vial for reconstitution with water for injection	AMJRC457A	0.5 mL†	1
	Inv_MMR Diluent	water for injection	Vial	DD12A004B	0.5 mL	1

Treatment name	Vaccine/product name	Formulation	Presentation	Lot number	Volume	Number of doses
Com_MMR_L1	Com_MMR_L1	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	Lyophilized pellet in a vial for reconstitution with water for injection	H004594 J006933 H017980 J006564 0682AE H015824 J015488	0.5 mL†	1
	Com_MMR_L1 Diluent‡	water for injection	Vial or a Syringe (depending on the country)	G004842 J003177 J015955	0.5 mL	1
Com_MMR_L2	Com_MMR_L2	Measles virus ≥1,000 $TCID_{50}$; Mumps virus ≥12,500 $TCID_{50}$; Rubella virus ≥1,000 $TCID_{50}$; sorbitol 14.5 mg; sodium phosphate, sucrose 1.9 mg; sodium chloride; hydrolyzed gelatin 14.5 mg; recombinant human albumin ≤0.3 mg; fetal bovine serum <1 ppm; other buffer and media ingredients; neomycin approximately 25 mcg	Lyophilized pellet in a vial for reconstitution with water for injection	G019547 J006564 H021002 H020866 J006933 0498AE H016132 J015222	0.5 mL†	1
	Com_MMR_L2 Diluent‡	water for injection	Vial or a Syringe (depending on the country)	0184AE J002990 J015955	0.5 mL	1

Treatment name	Vaccine/product name	Formulation	Presentation	Lot number	Volume	Number of doses
Varivax	*Varivax*	A minimum of 1350 pfu of Oka/Merck varicella virus; sucrose approximately 25 mg; hydrolyzed gelatin 12.5 mg, sodium chloride 3.2 mg; monosodium L-glutamate 0.5 mg; sodium phosphate dibasic 0.45 mg; potassium phosphate monobasic 0.08 mg; potassium chloride 0.08 mg; residual components of MRC-5 cells including DNA and protein; and trace quantities of sodium phosphate monobasic; EDTA; neomycin; and fetal bovine serum	Lyophilized pellet in a vial for reconstitution with water for injection	H004550; H019070 H012704 J004098 0603AE 0604AE	0.5 mL†	2§
	Varivax Diluent	water for injection	Vial or Syringe (depending on the country)	H007994 H003763	0.5 mL	2§
Havrix	*Havrix*	720 EU of hepatitis A virus antigen; 0.25 mg aluminum (as hydroxide); amino acid supplement (0.3% w/v); in a phosphate-buffered saline solution and polysorbate 20 (0.05 mg/mL)	Suspension in vial/ pre-filled syringe	AHAVB666C AHAVB668A AHAVB573C AHAVB646BA AHAVVB738B	0.5 mL	2§
Prevnar 13	*Prevnar 13*	2.2 µg of the purified saccharides 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F; 4.4 mcg of the purified saccharide 6B; approximately 34 µg CRM_{197} carrier protein; 100 µg polysorbate 80; 295 µg succinate buffer; 125 µg aluminum as aluminum phosphate adjuvant	Suspension in vial/ pre-filled syringe	F94001; H17427	0.5 mL	1¥

L= Lot; CCID = Cell Culture Infectious Dose; TCID = Tissue Culture Infectious Dose; EU = ELISA Unit

ppm = Parts Per Million; pfu = Plaque Forming Unit; mL = Milliliter; mg = Milligram; mcg = Microgram; µg = Microgram
MRC = Medical Research Council; DNA = Deoxyribonucleic Acid; EDTA = Ethylenediamine-Tetraacetic Acid
CRM_{197} = Cross-Reactive Material (mutant diphtheria toxin)
† Volume after reconstitution
‡ The Com_MMR_L1 Diluent may be distinct from the Com_MMR_L2 Diluent
§ At the end of the study or shortly after the study, depending on vaccine availability, GSK was to provide a second dose of HAV and/or varicella vaccine in countries where they are not routinely provided. Not applicable for subjects enrolled in US. The second dose of HAV and varicella vaccine was not part of the study procedures.
¥ PCV-13 was administered to US children with a history of 3-doses of PCV-13 at least 60 days prior to study entry.

5.4.2. Dosage and administration of study vaccines

The dosage and administration of all the study vaccines is described in Table 7.

Table 7 Dosage and administration

Type of contact and time point	Dose	Treatment Group	Vaccine/Product	Route[1]	Site	Side
Visit 1 (Day 0)	1	Inv_MMR_L1	Inv_MMR_L1	SC	Triceps region	Left
	1	Inv_MMR_L2	Inv_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L3	Inv_MMR_L3	SC	Triceps region	Left
	1	Com_MMR_L1	Com_MMR_L1	SC	Triceps region	Left
	1	Com_MMR_L2	Com_MMR_L2	SC	Triceps region	Left
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Varivax*	SC	Triceps region	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Havrix*	IM	Anterolateral thigh	Right
	1	Inv_MMR_L1 Inv_MMR_L2 Inv_MMR_L3 Com_MMR_L1 Com_MMR_L2	*Prevnar 13**	IM	Anterolateral thigh	Left

[1] Intramuscular (IM)/ Subcutaneous (SC)
* For US children only.

The dose of Inv_MMR, Com_MMR was 0.5 mL administered subcutaneously in the upper regions ("Triceps") of the left arm. After reconstitution, the MMR vaccines were injected promptly (within 30 minutes).

Due to potential color differences between the reconstituted Inv_MMR and Com_MMR, dedicated unblinded staff in each investigational site was accountable for reconstitution and administration to each child.

Varivax was also administered subcutaneously in the Triceps region of the right arm. The dosage of this co-administered vaccine was 0.5 mL.

Havrix and *Prevnar 13* were administered by intramuscular injection in the right and left thigh, respectively. The dosage for these co-administered vaccines was 0.5 mL.

All vaccine recipients were to be observed closely for at least 30 minutes following the administration of vaccines with appropriate medical treatment readily available in case of a rare anaphylactic reaction. The contraindications and warnings/precautions to vaccination were specified in the protocol.

5.4.3. Treatment allocation and randomization

5.4.3.1. Randomization

Subjects:

At Visit 1, subject numbers were assigned sequentially to subjects participating in the study, according to the range of subject numbers allocated to each study center. Subjects were enrolled in a 2:2:2:1:1 ratio, with twice the number in the Inv_MMR vaccine lot groups (1250 subjects each) as in the active control Com_MMR vaccine lot groups, Com_MMR_L1 and Com_MMR_L2 (625 subjects each). Overall, the randomization was to be 3:1 (Inv_MMR: Com_MMR).

Supplies:

A first list based on a randomization blocking scheme using a 2:2:21:1 (Inv_MMR_L1: Inv_MMR_L2: Inv_MMR_L3: Com_MMR_L1: Com_MMR_L2) randomization ratio was to be used to number the MMR vaccines. The vaccines from this list were distributed to the study center while respecting the randomization block size. The co-administered vaccines were to be numbered separately using sequential lists.

To allow GSK Biologicals to take advantage of greater rates of recruitment than anticipated at individual centers in this multicenter study and to thus reduce the overall study recruitment period, a surplus of at least 20% of supplies was to be prepared.

5.4.3.2. Treatment allocation

The treatment allocation at the investigator site was to be performed using SBIR. The treatment numbers were to be allocated by MMR dose. The randomization algorithm used was stratified by country and within each country a minimization procedure accounting for center was be used. When SBIR was not available, the study staff was to refer to the SBIR user guide or the study procedures manual (SPM) for specific instructions.

After having checked the eligibility of the subject and obtaining the Informed Consent Form (ICF), the site staff accessed SBIR. Upon providing the child identification number, the randomization system used the randomization algorithm to determine the group allocation and the treatment number(s) to be used for the subject for MMR vaccination (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 or Com_MMR_L2). For replacement dose, the system would allocate a new treatment number according to the treatment initially allocated.

For allocation of co-administered vaccines (*Havrix* and *Varivax* to all subjects, and *Prevnar 13* to the subjects in the US), the site staff were to select a treatment number available for the vaccine dose to be used for the subject. See the SPM for further details. All treatment numbers had to be recorded in the eCRF on the 'Vaccine Administration' screen.

5.5. Blinding

The study was conducted in a double-blind fashion with regard to the lot-to-lot consistency evaluation of the three Inv_MMR vaccine lots (Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3) and in an observer-blind fashion for the comparison of the Inv_MMR vaccine versus the Com_MMR vaccine.

Data was collected in an observer-blind manner with the subjects and those responsible for the evaluation of any study endpoint (e.g., safety, reactogenicity, and immunogenicity) all unaware of which vaccine was administered. Vaccine preparation and administration was done by authorized medical personnel who did not participate in any of the clinical evaluations of the study.

The laboratory in charge of the laboratory testing was blinded to the treatment, and codes were used to link the subject and study (without any link to the treatment attributed to the child) to each sample.

Unblinding of a subject's individual treatment code was to occur only in the case of a medical emergency, or in the event of a serious medical condition, when knowledge of the study treatment would be essential for the clinical management or welfare of the subject, as judged by the investigator.

The emergency unblinding process was enabled by SBIR, which allowed the investigator to have unrestricted, immediate and direct access to the subject's individual study treatment.

Any emergency unblinding had to be fully documented by the investigator using the Emergency Unblinding Documentation Form and sent within 24 hours to GSK Biologicals.

Furthermore, GSK Biologicals' policy is to unblind the report of any SAE which was unexpected and attributable or suspected to be attributable to the investigational product, prior to regulatory reporting. The GSK Biologicals' Central Safety Physician was responsible for unblinding the treatment assignment in accordance with the specified timeframes for expedited reporting of SAEs (see Section 5.9.2).

5.6. Prior and concomitant medication/vaccinations

At each study visit, the investigator was to question the subjects' parent(s)/LAR(s) about any medication taken and vaccination received by the subject. All concomitant medications and vaccinations, with the exception of vitamins and/or dietary supplements, were to be recorded in the eCRF, within the window defined by the protocol (see protocol

Section 6.7.2). This also applied to concomitant medication administered prophylactically in anticipation of reaction to the vaccination and any medication intended to treat an AE.

Similarly, concomitant medication administered for the treatment of a SAE, at any time, was recorded on the SAE Report / SAE screens in the eCRF, as applicable. Refer to protocol Section 8.1.2 for the definition of an SAE.

5.6.1. Medications/products that may lead to the elimination from ATP analyses

The following criteria were checked at each visit:

- Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) during the entire study period.
- Chronic administration (defined as 14 or more consecutive days) of immunosuppressants, or other immune-modifying drugs, during the period starting at vaccination and ending at the immunogenicity evaluation at Visit 2.
  - For corticosteroids, this will mean prednisone ≥0.5 mg/kg/day, or equivalent.
  - Inhaled and topical steroids are allowed.
- Planned administration/ administration of a vaccine not foreseen by the study protocol during the study period starting at vaccination and ending at Visit 2. Please Note:
  - **Inactivated** Flu and Hib vaccines could be given at any time, including the day of study vaccination (administered at a different location than the study vaccine/s).
  - Any ***other*** age appropriate vaccine could be given starting at Visit 2 and any time thereafter.
- Administration of immunoglobulins and/or any blood products during the period starting at vaccination through the immunogenicity evaluation at Visit 2.

If any became applicable during the study, it did not require withdrawal of the subject from the study but could have determined a subject's evaluability in the according-to-protocol (ATP) analysis. See Section 5.10.5 for definition of study cohorts to be evaluated.

5.6.2. Intercurrent medical conditions that may lead to elimination from the ATP cohort

Children were eliminated from the ATP cohort if they were confirmed as having an immunodeficiency condition, or if they developed measles, mumps, or rubella, in the interval between vaccination and the collection of the blood specimen for immunogenicity at the blood draw at Visit 2.

5.7. Assessment of efficacy variables

Not applicable as there were no efficacy assessments performed in this study.

5.8. Assessment of immunogenicity variables

Biological samples collected during the study consisted of 2 blood draws of approximately 5 mL each, at Visit 1 and Visit 2 respectively.

Serological assays for the determination of antibodies against measles, mumps and rubella viruses were performed by enzyme-linked immunosorbent assay (ELISA).

All testing was done at GSK Biologicals' laboratory or in a validated laboratory designated by GSK Biologicals using standardized and validated procedures (refer to Table 8).

Table 8 Summary of immunogenicity assessments

System	Component	Method	Kit / Manufacturer	Unit	Cut-off	Assay performed at
Serum	Measles Virus Ab.IgG	ELISA	Dade Behring Enzygnost	mIU/mL	150	NÉOMED-LABS Inc.
Serum	Rubella Virus Ab.IgG	ELISA	Dade Behring Enzygnost	IU/mL	4	NÉOMED-LABS Inc.
Serum	Mumps Virus Jeryl Lynn 135 Ab.IgG	ELISA	PPD	EU/mL	5	PPD
Serum	Varicella Zoster Virus Ab.IgG	ELISA	Dade Behring Enzygnost	mIU/mL	25	NÉOMED-LABS Inc.
Serum	Hepatitis A Virus Ab	ELISA	In-house	mIU/mL	15	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 01 Ab.IgG	ECL	In-house	μg/mL	0.08	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 03 Ab.IgG	ECL	In-house	μg/mL	0.075	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 04 Ab.IgG	ECL	In-house	μg/mL	0.061	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 05 Ab.IgG	ECL	In-house	μg/mL	0.198	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 06A Ab.IgG	ECL	In-house	μg/mL	0.111	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 06B Ab.IgG	ECL	In-house	μg/mL	0.102	GSK Biologicals

System	Component	Method	Kit / Manufacturer	Unit	Cut-off	Assay performed at
Serum	*Streptococcus pneumoniae*. Polysaccharide 07F Ab.IgG	ECL	In-house	μg/mL	0.063	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 09V Ab.IgG	ECL	In-house	μg/mL	0.066	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 14 Ab.IgG	ECL	In-house	μg/mL	0.16	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 18C Ab.IgG	ECL	In-house	μg/mL	0.111	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 19A Ab.IgG	ECL	In-house	μg/mL	0.199	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 19F Ab.IgG	ECL	In-house	μg/mL	0.163	GSK Biologicals
Serum	*Streptococcus pneumoniae*. Polysaccharide 23F Ab.IgG	ECL	In-house	μg/mL	0.073	GSK Biologicals

Ab = Antibody; IgG = Immunoglobulin class G
ELISA = Enzyme Linked Immunosorbent Assay
ECL = ElectroChemiLuminescence
PPD = Pharmaceutical Product Development
IU = International Unit; mIU = Milli International Unit; EU = ELISA Unit; mL = Milliliter; μg = micro-gram

The addresses of the clinical laboratories for sample analysis in this study are:

GlaxoSmithKline Biologicals
Clinical Immunology
Rue de l'Institut, 89
B-1330 Rixensart – Belgium

NÉOMED-LABS Inc.
Clinical Serology
525 Cartier Blvd West - Laval - Quebec - Canada - H7V 3S8

PPD, Inc.
466 Devon Park Drive
Wayne, PA 19087-1816 – USA

The central laboratory responsible for sample handling/processing for sites in the USA (including Puerto Rico) was BARC.

BARC USA Inc.
5 Delaware Drive
Lake Success, NY 11042-1114 - USA

For Estonia, Finland, Mexico and Spain, the sites shipped the samples directly to GlaxoSmithKline Biologicals, Global, Rue de l'Institut, 89 - B-1330 Rixensart, Belgium.

In case of insufficient blood sample volume to perform assays for all antibodies, the samples were analyzed according to priority ranking provided in Table 9.

Table 9 Immunological read outs

Blood sampling time point		Subset Name	Actual No. of children	Components	Priority rank
Type of contact and time point	Sampling time point				
Visit 1 (Day 0)	Pre-Vacc	Subset A	1234	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				Hepatitis A Virus Ab	3
		Subset B	1193	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG	3
		Subset C	2495	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG	2
Visit 2 (Day 42)	Post-Vacc	Subset A	1136	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				Hepatitis A Virus Ab	3
		Subset B	1113	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG Varicella Zoster Virus Ab.IgG	2
				S. pneumoniae Polysaccharide 01, 03, 04, 05, 06A, 06B, 07F, 09V, 14, 18C, 19A, 19F and 23F Ab.IgG	3
		Subset C	2479	Mumps Virus Jeryl Lynn 135 Ab.IgG	1
				Measles Virus Ab.IgG Rubella Virus Ab.IgG	2

Vacc = vaccination; Ab = Antibody; IgG = Immunoglobulin class G
Subset A: the first 1250 children enrolled in the US
Subset B: the next 1250 children enrolled in the US
Subset C: the other 2500 children enrolled

5.8.1. Immunological correlates of protection

The following antibody thresholds for seroresponse are accepted by the Food and Drug Administration (FDA) as endpoints defining clinically meaningful change in antibody titer:

- Measles ≥200 mIU/mL
- Mumps ≥10 EU/mL
- Rubella ≥10 IU/mL

The blood sample taken at Visit 2 was the time point used to determine sub-optimal responders, i.e., an individual immunological assay result which is below the threshold accepted by the FDA.

The investigator, even though remaining blinded with respect to each subject's group attribution, was to be told which child had a sub-optimal response as confirmed by the results of blood samples. A list of sub-optimal responders was to be communicated to the investigators in a timely manner (no later than 12 months after the last sampling date of the last child enrolled).

The investigator was to share the immunological assay results for non-responders with the subjects' parent(s)/LAR(s). For the study subjects identified as non-responders**,** a rescue plan was to be implemented and re-vaccination with *M-M-R-II* (or *Priorix* in ex-US settings where the vaccine is licensed) was to be offered to subjects that fail to serorespond to measles, mumps or rubella virus components.

Children that received only one dose of varicella vaccine as part of this study (e.g., children enrolled in the US) and who failed to serorespond to the varicella virus (i.e. achieve a post-vaccination titer ≥75 mIU/mL) were offered re-vaccination with *Varivax.* Children in non-US countries that were provided with a second dose of varicella vaccine, because they were enrolled in countries where it is not routinely provided (see Table 4), were not considered sub-optimal responders based on their post dose immune response.

5.8.2. Sequence of analyses

The analysis was performed in 2 steps:

- A final analysis of immunogenicity data for measles, mumps and rubella and solicited symptoms up to Day 42 was performed as soon as all measles, mumps and rubella immunogenicity data and reactogenicity data (i.e. solicited symptoms) up to Visit 2 were available and cleaned. No clinical study report (CSR) was written at this time.
- A final analysis of immunogenicity data for the co-administered vaccines (i.e. VV, HAV and PCV-13) and unsolicited AEs from Day 0 to Day 42 following vaccination, and of SAEs and specific AEs covering the period from Day 0 to study end (including the 6-months safety follow-up) was performed at the end of the study.

These two analyses were combined in this final CSR.

Following unblinding for the analysis up to Day 42, accessibility to group attribution was limited to the statisticians until all study procedures pertaining to the active phase and the 6-months safety follow-up were completed for all subjects.

5.9. Assessment of safety variables

The investigator or site staff was/were responsible during the study for the detection and documentation of events meeting the criteria and definition of an AE or an SAE.

Each subject's parent(s)/LAR(s) were to be instructed to contact the investigator immediately should the subject manifest any signs or symptoms they perceived as serious.

5.9.1. Adverse events

5.9.1.1. Definition of adverse events and serious adverse events

An AE was any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For marketed medicinal products, this also included failure to produce expected benefits (i.e., lack of efficacy), abuse or misuse. Examples of possible AEs are given in protocol Section 8.1.1

AEs to be recorded as endpoints (solicited AEs) are described in Section 5.9.1.2, while all other AEs were to be recorded as unsolicited AEs.

An SAE was any untoward medical occurrence that:

- Resulted in death,
- Was life-threatening,
- Required hospitalization or prolongation of existing hospitalization,
- Resulted in disability/incapacity.

Further details are provided in protocol Section 8.1.2.

5.9.1.2. Solicited adverse events

The following local (injection-site) AE were solicited (Table 10):

Table 10 Solicited local adverse events at Inv_MMR and Com_MMR injection sites

Adverse Event	Solicited follow-up period
Pain at injection site	from Day 0 to Day 3 after vaccination
Redness at injection site	
Swelling at injection site	

These local AEs were recorded from Day 0 to Day 3 on the Diary Cards following vaccinations in both groups. Redness and swelling were measured in millimeters and the greatest surface diameter was recorded. Solicited local symptoms at the co-administration site were not assessed.

The solicited general AEs are shown in Table 11.

Table 11 Solicited general adverse events

Adverse Event	Solicited follow-up period
Drowsiness	from Day 0 to Day 14 after vaccination
Loss of appetite	
Irritability	
Varicella-like rash*	from Day 0 to Day 42 after vaccination
Measles/rubella-like rash*	
Other rash (not measles/rubella-like nor varicella-like)	
Fever (defined as temperature ≥38°C/100.4°F)**	
Parotid gland / Salivary gland swelling*	
Meningism including febrile convulsions*	

* To be confirmed by a physician.

** Fever is defined as temperature ≥38°C/100.4°F [Marcy, 2004]. The preferred route for recording temperature in this study was axillary. Temperature was recorded daily from Day 0 to Day 42 after vaccination. The child's parent(s)/LAR(s) were requested to record the child's body temperature each evening at bedtime. Should additional temperature measurements be performed at other times of day, the highest temperature was recorded.

Intensity of the following AEs was assessed as described in Table 12.

Table 12 Intensity scales for solicited adverse events

Adverse Event	Intensity Grade	Parameter
Pain at injection site	0	None
	1	Minor reaction to touch (digital pressure)
	2	Cries/protests on touch (digital pressure)
	3	Cries when limb is moved/spontaneously painful
Local injection site redness (Record greatest surface diameter in mm)	0	None
	1	> 0-≤ 5mm
	2	> 5-≤ 20mm
	3	>20mm
Local injection site swelling (Record greatest surface diameter in mm)	0	None
	1	> 0-≤ 5mm
	2	> 5-≤ 20mm
	3	>20mm
Fever* body temperature in °C or °F, (axillary route preferred)	Temperature will be analyzed in 0.5°C increments from ≥38°C (≥100.4°F) Grade 3 fever is defined as >39.5°C. (103.1°F)	
Measles/rubella-like rash and varicella-like rash	1	1-50 lesions
	2	51-150 lesions
	3	>150 lesions
Other rash	1	Rash which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities
	2	Rash which is sufficiently discomforting to interfere with normal everyday activities
	3	Rash which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day care and would cause the parent(s)/LAR(s) to seek medical advice)
Parotid/salivary gland swelling	1	Swelling without difficulty moving the jaw
	2	Swelling with difficulty moving the jaw
	3	Swelling with accompanying general symptoms
Irritability/Fussiness	0	Behavior as usual
	1	Crying more than usual/ no effect on normal activity
	2	Crying more than usual/ interferes with normal activity
	3	Crying that cannot be comforted/ prevents normal activity
Drowsiness	0	Behavior as usual
	1	Drowsiness easily tolerated
	2	Drowsiness that interferes with normal activity
	3	Drowsiness that prevents normal activity
Loss of appetite	0	Appetite as usual
	1	Eating less than usual/ no effect on normal activity
	2	Eating less than usual/ interferes with normal activity
	3	Not eating at all
Meningism (any suspected signs including febrile convulsions)	1	An event which is easily tolerated by the child, causing minimal discomfort and not interfering with everyday activities
	2	An event which is sufficiently discomforting to interfere with normal everyday activities
	3	An event which prevents normal, everyday activities (in a young child, such an AE would, for example, prevent attendance at school/day care and would cause the parent(s)/LAR(s) to seek medical advice)

*Fever is defined as temperature ≥38°C/100.4°F.
mm = Millimeter; °C = Degree Celsius;°F = Degree Fahrenheit

The maximum intensity of local injection site redness/swelling was graded based on subject's parent(s)/LAR(s) measurements recorded on the Diary Card.

Temperature/ fever: Temperature was to be recorded daily, from Day 0 through Day 42. Parent(s)/LAR(s) were requested to record on the diary card the subject's body temperature measured each evening at bedtime (while at home ONLY one temperature route [axillary preferred] was to be used consistently for all measurements on a given subject). Should additional temperature measurements be performed at other times of day, the highest temperature was to be recorded.

Rash and parotid/salivary gland swelling and signs of meningism including febrile convulsions:

If any of the following symptoms below were suspected during the follow-up period after vaccination (Day 0-42), the parent(s)/LAR(s) had to perform daily post-vaccination recording on the Diary Card and contact the investigator's center.

- ***Rash/ exanthema:***

Parent(s)/LAR(s) were to be provided with a description of rashes and asked to contact the study site immediately if the subject developed a rash that could be a measles/rubella or varicella-like rash (Day 0-42). If the investigator/designee also suspected that the rash could possibly be a measles/rubella-like rash or varicella-like rash, a visit should be arranged as soon as possible; ideally within 48 hours after rash onset, or as soon as possible thereafter.

The investigator's assessment of the rash was recorded in the eCRF. If the investigator had not seen the rash, and other medically qualified person had assessed the rash during a medically attended visit, then this assessment was to be recorded in eCRF. If the subject was not seen by the investigator or other medically qualified person, the information about rash entered in eCRF was to be recorded by the parent in the diary card.

The investigator classified cases of the rash as follows:

- Measles/ rubella rashes (macular or maculopapular rashes): presence of macules, discolored small patches or spots of the skin, neither elevated nor depressed below the skin's surface and/or papules, raised bumps on the skin usually <1 cm in diameter.
- Varicella-like rash (papulo-vesicular): simultaneous presence of papules and vesicles raised above the skin's surface.
- Or other types of rash (heat rash, etc.).

Duration of rash episode was to be indicated, as well as the locality of the rash:

- Measles/rubella-like or varicella-like rash:
  - rash onset, i.e., date when the first lesion appears
  - rash ended, i.e., date of the first day when no new lesion appears.

- Other rash:
  - start date, i.e., date when first symptom appears
  - end date, i.e., date when the rash disappears/resolves.

Intensity of measles/rubella-like, or varicella-like rash was assessed according to the maximum number of overall lesions (Table 12).

The outcome of each rash was to be assessed as: recovered/resolved, recovering/resolving, not recovered/not resolved, recovered with sequelae/resolved with sequelae. The investigator was to assess the causality of rash episode.

- ***Parotid/salivary gland swelling:***

If parotitis was clinically suspected (swelling / tenderness in the mandibular / submandibular region) during Day 0 to Day 42 after vaccination, the child was to be seen by the investigator as soon as possible for an additional visit.

Only those cases diagnosed by the investigator/designee as parotitis were to be recorded as a solicited symptom in the eCRF. Other cases of swelling/tenderness in the mandibular/submandibular region that did not meet the criteria for parotitis clinically were to be reported as an unsolicited AE in the eCRF. Intensity was recorded as described in Table 12 and the outcome of each case was assessed as described in Section 5.9.1.5.

- ***Any suspected signs of meningism including febrile convulsions/seizures:***

If the subject experienced febrile convulsions or presented any other neurological signs or symptoms indicative of meningism (i.e., neck stiffness with or without light intolerance (photophobia) and headache; or convulsion/seizure) during Day 0 to Day 42 follow-up after vaccination, the parent(s)/LAR(s) had to contact the investigator immediately for follow-up. The investigator was requested to write a descriptive assessment of the case and evaluate the relationship to the study vaccination.

The investigator was requested to document full case details and to provide a diagnosis. In the case of all seizures, including febrile seizures, the investigator had to classify the level of diagnostic certainty regarding the seizure as guided by The Brighton Collaboration Seizure Working Group's case definitions of generalized convulsive seizure as an adverse event following immunization, as described in Table 13 [Bonhoeffer, 2004].

Table 13 Brighton Collaborative levels of diagnostic certainty

Level 1 of diagnostic certainty
witnessed sudden loss of consciousness AND generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations
Level 2 of diagnostic certainty
history of unconsciousness AND generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations
Level 3 of diagnostic certainty
history of unconsciousness AND other generalized motor manifestations
Level 4 of diagnostic certainty
reported generalized convulsive seizure with insufficient evidence to meet the case definitions for Level 1, 2 or 3 of diagnostic certainty above
Level 5 of diagnostic certainty
Not a case of generalized convulsive seizure

For any case of febrile convulsion, the investigator was also asked to classify the event based on the definitions below [American Academy of Pediatrics , 2008]:

- *Simple Febrile Convulsion/Seizure*: defined as a brief (<15 minutes in duration) generalized tonic-clonic seizure that occurs once during a 24 hour period in a febrile subject who does not have intracranial infection, metabolic disturbance or history of febrile seizures. The neurologic examination in the post-ictal period should be no different from baseline, i.e., there should be no newly acquired neurologic deficits.
- *Complex Febrile Convulsion/Seizure*: defined as a generalized tonic-clonic seizure that is not a simple febrile seizure. For instance, any seizure that has at least one of the following characteristics should be defined as a complex seizure:
  - lasts 15 minutes or longer, or
  - has a focal/localized component, or
  - recurs within 24 hours, or
  - is associated with an abnormal post-ictal neurologic examination.

5.9.1.3. Unsolicited adverse events and serious adverse events

All AEs starting from Day 0 through Visit 2 after the administration of study vaccine were recorded on the Adverse Event screen in the subject's eCRF, irrespective of intensity or whether or not they were considered vaccination-related. The standard time period for collecting and recording SAEs began at the first receipt of study vaccines and was collected throughout the entire study. See Section 5.9.2 for instructions on reporting of SAEs. SAEs that were related to the study vaccine(s) were collected and recorded from the time of the first study vaccination until the subject was discharged.

When an AE/SAE occurred, it was the responsibility of the investigator to review all documentation (e.g., hospital progress notes, laboratory, and diagnostics reports) relative to the event. The investigator would then record all relevant information regarding an AE/SAE on the eCRF or SAE Report screens as applicable. It was not acceptable for the investigator to send photocopies of the subject's medical records to GSK Biologicals

instead of the appropriate completed AE/SAE screens in the eCRF. However, there could be instances when copies of medical records for certain cases were requested by GSK Biologicals. In this instance, all subject identifiers were to be blinded on the copies of the medical records prior to submission to GSK Biologicals.

The investigator would attempt to establish a diagnosis pertaining to the event based on signs, symptoms, and/or other clinical information. In such cases, the diagnosis was to be documented as the AE/SAE and not the individual signs/symptoms. Treatment of any AE was at the sole discretion of the investigator and according to current good medical practices. Any medication administered for the treatment of an AE was recorded in the subject's eCRF.

In addition to the above-mentioned reporting requirements and in order to fulfill international reporting obligations, SAEs that were related to study participation (i.e., protocol-mandated procedures, invasive tests, a change from existing therapy) or were related to a concurrent GSK medication/vaccine or any fatal SAE were collected and recorded from the time the parent(s)/LAR(s) consented to have the subject participate in the study until she/he was discharged. The standard time period for collecting and recording AEs of specific interest, including NOCDs and AEs prompting emergency room (ER) visits, started at the first receipt of study vaccine and ended at the last study visit or contact. The standard time period for collecting and recording of AEs prompting a medically attended visit(s) started at the first receipt of study vaccine and ended at the last study visit or contact through study end. An overview of the protocol-required reporting periods for AEs, and SAEs is given in Table 14.

Table 14 Reporting periods and methods for adverse events and serious adverse events

	Visit 1 Vaccination			Visit 2 Follow-up	Visit 3 Conclusion
Optimal Visit Day	**Day 0**			**Day 42**	**Day 180**
Solicitation period	Day 0-3	Day 4-14	Day 15-42		
Study activity					
Reporting solicited local AEs	DC/RDE				
Reporting solicited drowsiness, loss of appetite or irritability	DC/RDE				
Reporting solicited fever, rash (measles / rubella or varicella-like rash, other rash), parotid/salivary gland swelling and any sign of meningism including febrile convulsions	DC/RDE				
Reporting unsolicited AEs	DC/RDE			DC	DC
Reporting NOCD(s) and AEs prompting a medically attended visit(s) (including ER visits)	DC/RDE			DC/RDE	DC/RDE
Reporting ALL SAEs	DC/RDE			DC/RDE	DC/RDE

AEs = Adverse Events; DC = Diary Card; RDE = Remote Data Entry; SAEs = Serious Adverse Events
NOCD = New Onset Chronic Disease; ER = Emergency Room.

A post-study AE/SAE was defined as any event that occurred outside of the AE/SAE reporting period defined in Table 14. Investigators were not obligated to actively seek AEs or SAEs in former study subjects. However, if the investigator learned of any SAE at any time after a subject had been discharged from the study, and he/she considered the event reasonably related to the investigational product, the investigator would promptly notify the Study Contact for reporting SAEs.

The investigator/designee would assess the maximum intensity that occurred over the duration of the event for all AEs and SAEs reported during the study, with the assessment based on the investigator's clinical judgment. The intensity of each AE and SAE recorded in the eCRF or SAE Report screens, as applicable, had to be assigned to one of the following categories:

1 (mild)	=	An AE which was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
2 (moderate)	=	An AE which was sufficiently discomforting to interfere with normal everyday activities.
3 (severe)	=	An AE which prevented normal, everyday activities (in a young subject, such an AE would, for example, prevent attendance at school/day-care and would cause the parent(s)/LAR(s) to seek medical advice.)

An AE that was assessed as Grade 3 (severe) was not to be confused with an SAE. Grade 3 is a category utilized for rating the intensity of an event; and both AEs and SAEs could be assessed as Grade 3. An event was defined as 'serious' when it met one of the pre-defined outcomes as described in protocol Section 8.1.2.

5.9.1.4. Assessment of causality

The investigator was also obligated to assess the relationship between study vaccine(s) and the occurrence of each AE/SAE, using his/her clinical judgment to determine the relationship. Alternative plausible causes based on natural history of the underlying diseases, concomitant therapy, other risk factors and the temporal relationship of the event to the investigational product were considered and investigated. The investigator would also consult the Investigator Brochure and/or Product Information for marketed products, in the determination of his/her assessment.

There may have been situations when an SAE had occurred and the investigator had minimal information to include in the initial report to GSK Biologicals. However, it was very important that the investigator always made an assessment of causality for every event prior to submission of the SAE to GSK Biologicals. The investigator could change his/her opinion of causality in light of follow-up information, amending the SAE information accordingly. The causality assessment was one of the criteria used when determining regulatory reporting requirements.

In case of concomitant administration of multiple vaccines, it might not have been possible to determine the causal relationship of general AEs to the individual vaccines administered. The investigator had to, therefore, assess whether the AE could be causally related to vaccination rather than to the individual vaccines/products.

All solicited local (injection site) AEs would be considered causally related to vaccination. Causality of all other AEs had to be assessed by the investigator using the following question:

Is there a reasonable possibility that the AE may have been caused by the investigational product?

NO	:	The AE was not causally related to administration of the study vaccine(s). There were other, more likely causes and administration of the study vaccine(s) was not suspected to have contributed to the AE.
YES	:	There was a reasonable possibility that the vaccine(s) contributed to the AE.

Non-serious and serious AEs were evaluated as two distinct events. If an event met criteria to be determined 'serious' (see protocol Section 8.1.2 for definition of an SAE), additional examinations/tests were performed by the investigator in order to determine all possible contributing factors applicable to each SAE.

Possible contributing factors included:

- Medical history;
- Concomitant medication;
- Protocol required procedure;
- Other procedure not required by the protocol;
- Lack of efficacy of the vaccine(s), if applicable;
- Erroneous administration;
- Other cause (specify).

5.9.1.5. Assessment of Outcomes

Outcome of any non-serious AE occurring within 42 days post-vaccination (i.e., unsolicited AE) or any SAE reported during the entire study were assessed as:

- Recovered/resolved.
- Recovering/resolving.
- Not recovered/not resolved.
- Recovered with sequelae/resolved with sequelae.
- Fatal (SAEs only).

5.9.2. Reporting of serious adverse events

SAEs that occurred in the time period defined in Table 14 were to be reported promptly to GSK within the timeframes described in Table 15, once the investigator determined that the event met the protocol definition of an SAE.

Table 15 Timeframes for submitting serious adverse event reports to GSK Biologicals

Type of Event	Initial Reports		Follow-up of Relevant Information on a Previous Report	
	Timeframe	Documents	Timeframe	Documents
All SAEs	24 hours*	SAE report/SAE screen	24 hours*	SAE report/SAE screen

* Timeframe allowed after receipt or awareness of the information.

5.9.2.1. Completion and transmission of SAE reports to GSK Biologicals

As soon as an investigator became aware of the occurrence of an SAE in a subject, the investigator (or designate) had to complete the information in the SAE screens of the eCRF within 24 hours. The SAE screens were always to be completed as thoroughly as possible with all available details of the event. Even if the investigator did not have all information regarding a SAE, the SAE screens had to be completed within 24 hours. Once additional relevant information was received, the SAE screens in the eCRF were to be updated, again within 24 hours.

The investigator would always provide an assessment of causality at the time of the initial report (see Section 5.9.1.4). The contact information for reporting SAEs to GSK Biologicals is provided in study protocol Section 8.3.2, with details on the back-up system to be used if the electronic SAE reporting system did not work are in protocol Section 8.3.3.1.

5.9.2.2. Updating of SAE information after freezing of the subjects' eCRF

When additional information was received on a SAE after freezing of the subject's eCRF, new or updated information had to be recorded on a SAE Report Form, with all changes signed and dated by the investigator. The updated form had to be faxed to the GSK Biologicals Clinical Safety and Pharmacovigilance department or to the Study Contact for Reporting SAEs within 24 hours of receipt of the follow-up information.

5.9.2.3. Regulatory reporting requirements for SAEs

The investigator would promptly report all SAEs to GSK in accordance with the procedures detailed above in Section 5.9.2.1. GSK Biologicals has a legal responsibility to promptly notify, as appropriate, both the local regulatory authority and other regulatory agencies about the safety of a product under clinical investigation. Prompt notification of SAEs by the investigator to the Study Contact for Reporting SAEs was essential so that legal obligations and ethical responsibilities towards the safety of other subjects are met.

Investigator safety reports were prepared according to the current GSK policy and were forwarded to investigators as necessary. An investigator safety report was prepared for a SAE(s) that was both attributable to the investigational product and unexpected. The purpose of the report was to fulfill specific regulatory and GCP requirements, regarding the product under investigation.

5.9.3. Medically attended visits

For each solicited and unsolicited AE the subject experienced, the parent(s)/LAR(s) were asked if the subject received medical attention defined as hospitalization, an ER visit or a visit to or from medical personnel (e.g., medical doctor) for any reason. This information was recorded in the eCRF; routine 'well child' visit information however was not to be recorded in the eCRF.

5.9.4. Clinical laboratory parameters and other abnormal assessments qualifying as adverse events or serious adverse events

Abnormal laboratory findings (e.g., clinical chemistry, hematology, urinalysis) or other abnormal assessments that were judged by the investigator to be clinically significant were recorded as AEs or SAEs if they met the definition of an AE, as defined in protocol Section 8.1.1 and Section 8.1.2. Clinically significant abnormal laboratory findings or other abnormal assessments that a) were detected during the study or b) were present at baseline and significantly worsened following the start of the study, were reported as AEs or SAEs. The investigator was to exercise his or her medical and scientific judgment in deciding whether an abnormal laboratory finding or other abnormal assessment was clinically significant.

5.9.5. Adverse events of specific interest

AEs of specific interest for safety monitoring included NOCDs (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting ER visits. Occurrences of AEs of specific interest, including NOCDs and AEs prompting ER visits, were reported throughout the study, through a minimum of six months post-vaccination, whether or not they were considered to be possibly related to the treatment administration. Medical documentation of the events was reported in appropriate places in the eCRF. These events also had to be reported as AEs or SAEs as appropriate in the eCRF.

5.9.6. Follow-up of adverse events and serious adverse events

After the initial AE/SAE report, the investigator was required to proactively follow each subject within the study and provide further information on the subject's condition to GSK Biologicals.

All AEs, SAEs, AEs of specific interest (including NOCDs such as autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies, and AEs prompting ER visits) documented at a previous visit and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until the end of the study.

Investigators would follow-up subjects:

- With SAEs or subjects withdrawn from the study as a result of an AE, until the event had resolved, subsided, stabilized, disappeared, or until the event was otherwise explained, or the subject was lost to follow-up.
- Or, in the case of other non-serious AEs, until resolution or study end or the subject was lost to follow-up.

Clinically significant laboratory abnormalities were followed up until they had returned to normal, or a satisfactory explanation had been provided. Additional information (including but not limited to laboratory results) relative to the subsequent course of such abnormalities noted for any subject was to be made available to the Site Monitor.

GSK Biologicals could request that the investigator performed or arranged for the conduct of additional clinical tests or evaluations to elucidate as fully as possible the nature and/or causality of the AE or SAE. The investigator was obliged to assist. If a subject died during participation in the study or during a recognized follow-up period, GSK Biologicals was to be provided with a copy of any available post-mortem findings, including histopathology.

5.10. Statistical methods

The statistical analyses were performed using the Statistical Analysis Systems (SAS) version 9.3 on SAS Drug Development 4.3.

Throughout this section, endpoints for the 2 lots of comparator Com_MMR vaccine (Com_MMR_L1 and Com_MMR_L2) were analyzed as pooled lots. In addition, apart from the endpoints related to clinical consistency, the 3 Inv_MMR lots (Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3) were analyzed as pooled lots and referred to as Inv_MMR throughout the report.

5.10.1. Primary endpoint

- Immunogenicity of the MMR vaccines at Day 42:
  - Seroresponse to measles, mumps and rubella viruses.
  - Measles, mumps and rubella virus antibody concentrations.

5.10.2. Secondary endpoints

- Immunogenicity of the *Varivax*, *Havrix* and *Prevnar 13* vaccines in a subset of children at Day 42:
  - Seroresponse to VZV.
  - VZV antibody concentrations.
  - HAV antibody concentrations.
  - Seroresponse to HAV.
  - Pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) antibody concentrations.
- Complementary read-out for immunogenicity of the MMR vaccines at Day 42:
  - Measles virus antibody concentration equal to or above the cut-off of 150 mIU/mL.
  - Rubella virus antibody concentration equal to or above the cut-off of 4 IU/mL.
- Solicited local and general symptoms:
  - Occurrence of solicited local symptoms in terms of injection site redness, pain and swelling from Day 0 to Day 3 after vaccination.
  - Occurrence of solicited general symptoms in terms of drowsiness, loss of appetite and irritability from Day 0 to Day 14 after vaccination.
  - Occurrence of solicited general symptoms in terms of fever (temperature ≥38.0°C / 100.4°F), rash, parotid/salivary gland swelling, any sign of meningism (including febrile convulsions) from Day 0 to Day 42 after vaccination.
- Unsolicited adverse events:
  - Occurrence of unsolicited symptoms, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, from Day 0 to Day 42 after vaccination.
- Adverse events of specific interest:
  - Occurrence of NOCD (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies) and AEs prompting ER visits from Day 0 through the end of study.
- Serious adverse events:
  - Occurrence of serious adverse events from Day 0 through the end of study.

5.10.3. Determination of sample size

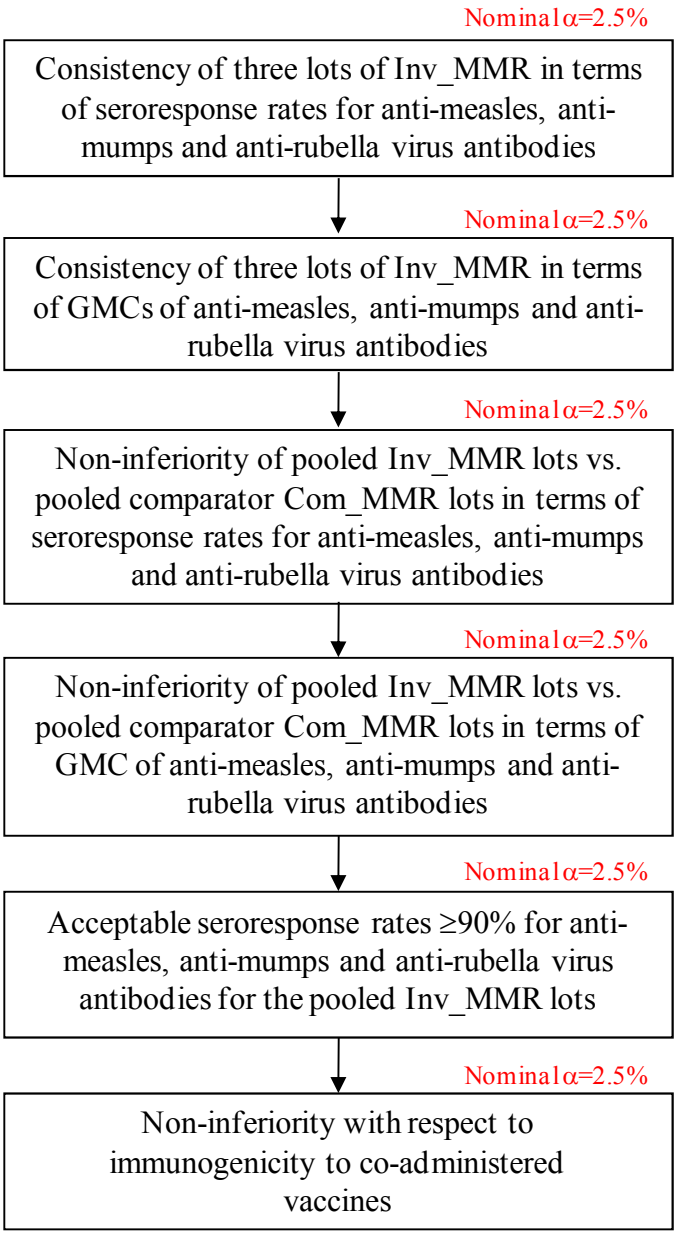
The target was to enroll 5000 subjects to be randomly assigned to 5 study groups (Inv_MMR_L1, Inv_MMR_L2, Inv_MMR_L3, Com_MMR_L1 and Com_MMR_L2) in a 2:2:2:1:1 ratio. There would be approximately 1250 children in each Inv_MMR lot group; and approximately 625 children in each Com_MMR lot group. Assuming a 20% non-evaluable rate, the planned enrollment would result in 4000 evaluable children (1000 per Inv_MMR lot group; and 500 in each Com_MMR lot group).

5.10.3.1. Control on type I error

To control the type I error below 2.5%, a hierarchical procedure was used for the primary and secondary objectives, i.e., each co-primary objective could only be reached if all the associated criteria were met and all previous co-primary objectives were reached, and the secondary objectives (to evaluate non-inferiority of the immune response to the co-administered vaccines) were only assessed when all co-primary objectives were met. No hierarchy between secondary objectives was made (see Figure 2).

Figure 2 Sequence for evaluating the primary study objectives in order to control the overall type I error below 2.5%

An objective was reached if its associated criterion was met and the previous objectives were reached



5.10.3.2. Power for lot-to-lot consistency

The lot-to-lot consistency of the Inv_MMR groups was demonstrated if the lot-to-lot consistency criteria specific to each MMR antigen were met simultaneously (p-value <2.5%). Table 16 and Table 17 show that the probability to reach the lot-to-lot consistency criterion was at least 97.46% [=100%-sum of type II errors].

Table 16 Probability to meet the consistency criteria with respect to seroresponse rates for antibodies to measles, mumps and rubella viruses among the three Inv_MMR groups

Vaccine component	Endpoints	Reference values*	Clinically acceptable bounds for consistency	Power N= 1000 vs. 1000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98%	[-5%,5%]	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94%	[-5%,5%]	99.58%	2.54%
Rubella	Seroresponse (≥ 10 IU/mL)	98%	[-5%,5%]	>99.99%	<0.01%
			Total	97.46%	2.54%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** Power obtained using the Power Analysis and Sample Size software (PASS 2005) (Likelihood Score [Miettinen and Nurminen approach [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value for the 3 lots & alpha=2.5%; the type II error was multiplied by 6 to account for the 6 pairwise lot comparisons.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

Table 17 Probability to meet the consistency criteria with respect to GMCs of antibodies to measles, mumps and rubella viruses among the three Inv_MMR lot groups

Vaccine component	Endpoints	Reference SD*	Clinically acceptable bounds for consistency	Power N= 1000 vs. 1000**	Type II error
Measles	GMC	0.50	[0.67,1.50]	>99.99%	<0.01%
Mumps	GMC	0.50	[0.67,1.50]	>99.99%	<0.01%
Rubella	GMC	0.44	[0.67,1.50]	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
SD = Standard Deviation (of the $\log_{10}$ transformed titer); GMC = Geometric Mean Concentration
Observed SDs for measles for the three lots of *Priorix* were 0.33, 0.34, and 0.34
Observed SDs for mumps for the three lots of *Priorix* were 0.41, 0.40, and 0.44
Observed SDs for rubella for the three lots of *Priorix* were 0.33, 0.34, and 0.34
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of equal means & alpha=2.5%; the type II error was multiplied by 6 to account for the 6 pairwise lot comparisons.

5.10.3.3. Power for Non-inferiority to Com_MMR

The non-inferiority of the Inv_MMR groups compared to Com_MMR was demonstrated if the non-inferiority criteria specific to each MMR antigen were met simultaneously (p-value <2.5%) and lot-to-lot consistency was demonstrated. Table 18 and Table 19 show that the probability to reach the non-inferiority criteria was at least 97.46% [= 100% - sum of type II error from Table 16, Table 17, Table 18 and Table 19

Table 18 Probability to meet the non-inferiority criteria with respect to seroresponse rate for antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups compared to the pooled Com_MMR lot groups

Vaccine component	Endpoints	Reference values* Pooled Inv_MMR vs. Com_MMR	Clinically acceptable limit for non-inferiority	Power N= 3000 vs. 1000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98% vs. 98%	-5%	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94% vs. 94%	-5%	>99.99%	<0.01%
Rubella	Seroresponse (≥ 10 IU/mL)	98% vs. 98%	-5%	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** Power obtained using PASS 2005 (Likelihood Score [Miettinen and Nurminen approach, [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value & alpha=2.5%.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

Table 19 Probability to meet the non-inferiority criteria with respect to GMCs of antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups compared to the pooled Com_MMR lot groups

Vaccine component	Endpoints	Reference ratio (Com_MMR over Inv_MMR lots)*	Reference SD*	Clinically acceptable limit for non-inferiority	Power N= 3000 vs. 1000**	Type II error
Measles	GMC	1	0.50	0.67	>99.99%	<0.01%
Mumps	GMC	1	0.53	0.67	>99.99%	<0.01%
Rubella	GMC	1	0.44	0.67	>99.99%	<0.01%
				Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
SD = Standard Deviation (of the log10 transformed titer); GMC = Geometric Mean Concentration
Observed SDs for measles for three lots of *Priorix* were 0.33, 0.34, and 0.34
Observed SDs for mumps (PPD ELISA) for the three lots of *Priorix* were 0.41, 0.40, and 0.44
Observed SDs for rubella for three lots of *Priorix* were 0.33, 0.34, and 0.34
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of a 1.2-fold difference in means & alpha=2.5%.

5.10.3.4. Power for a minimal seroresponse rate of pooled Inv_MMR lots

Assuming 20% of children were non-evaluable, an estimated 3000 children were to be evaluable in the Inv_MMR groups. Table 20 shows the probability to reach the immunogenicity criterion that the MMR seroresponse rate was at least 90% for measles, mumps and rubella.

Considering this was conditional to previous primary objectives the power to conclude on minimal MMR-seroresponse rate was at least 97.46% [= 100% - sum of type II error from Table 16, Table 17, Table 18, Table 19 and Table 20].

Table 20 Probability to meet the minimum level of seroresponse rate for antibodies to measles, mumps and rubella viruses in the pooled Inv_MMR groups

Vaccine component	Endpoints	Reference values*	Acceptable lower limit	Power N= 3000**	Type II error
Measles	Seroresponse (≥ 200 mIU/mL)	98%	90%	>99.99%	<0.01%
Mumps	Seroresponse (≥ 10 EU/mL)	94%	90%	>99.99%	<0.01%
Rubella	Seroresponse (≥ 10 IU/mL)	98%	90%	>99.99%	<0.01%
			Total	>99.99%	<0.01%

* Reference for sample size calculation: Study MMR-157
Measles seroresponse rates for three lots of *Priorix* were 99.2% (95% CI: 97.1%; 99.9%), 98.3% (95% CI: 95.8%; 99.5%), and 98.3% (95% CI: 95.8%; 99.5%)
Mumps seroresponse rate for three lots of *Priorix* were 95.5% (95% CI: 92.1%; 97.7%), 94.1% (95% CI: 90.2%; 96.7%), and 90.8% (95% CI: 86.5%; 94.2%)
Rubella seroresponse rates for three lots of *Priorix* were 98.8% (95% CI: 96.5%; 99.7%), 98.7% (95% CI: 96.4%; 99.7%), and 97.5% (95% CI: 94.6%; 99.1%)
** PASS 2005, 1-sided non-inferiority test on one proportion alpha = 2.5%, H0: p ≤ margin, Ha: p = reference value. The type II error was multiplied by 3 to account for the 3 lots.
mIU = Milli International Unit; mL = Milliliter; EU = ELISA Unit; IU = International Unit.

5.10.4. Power for the secondary objectives

Anti-VZV antibodies were to be tested in a subset of 2500 children enrolled in the US (subsets A and B). Assuming 20% were non-evaluable, this analysis would be based on 1500 children in the Inv_MMR groups and 500 children in the Com_MMR groups. Antibodies to HAV (subset A only) and anti-PS antibodies (subset B only) were to be tested in subsets of 1250 children enrolled in the US. Assuming 20% were non-evaluable, the analysis would be based on 750 children in the Inv_MMR groups and 250 children in the Com_MMR groups.

The probability to meet the non-inferiority criteria associated to immunogenicity to co-administered vaccine is shown in Table 21and Table 22 and would be demonstrated if the non-inferiority criteria specific to each antigen are met (p-value <2.5%) and non-inferiority and acceptability for MMR responses and lot-to-lot consistency have been demonstrated.

Table 21 Probability to meet the non-inferiority criteria with respect to VZV seroresponse rate

Vaccine component	Endpoints	Reference values*	Clinically acceptable limit for non-inferiority	Power N= 1500 vs. 500**	Type II error
VV	Seroresponse (≥ 75 mIU/mL)	95%	- 10%	>99.9%	<0.01%

VV = Varicella Vaccine *Varivax*
* Reference for sample size calculation: Study MMR-157 where the lowest observed seroresponse rate was 95% [92.5%; 98.0%]
** Power obtained using PASS 2005 (Likelihood Score [Miettinen and Nurminen approach, [Miettinen, 1985]), one-sided non-inferiority test for the difference of two independent proportions, under the alternative associated to the reference value for the 2 groups; N is based on the immuno subsets.
mIU = Milli International Unit; mL = Milliliter.

Table 22 Probability to meet the non-inferiority criteria with respect to GMC for antibodies associated to co-administered vaccines

Vaccine component	Reference SD*	Clinically acceptable limit for non-inferiority	N Inv_MMR lots vs. Com_MMR	Power**	Type II error
VV	0.4	1.5	1500 vs. 500	>99.99%	<0.01%
HAV	0.6	2	750 vs. 250	>99.99%	<0.01%

VV = Varicella Vaccine *Varivax*; HAV = Hepatitis A Vaccine *Havrix*; PCV-13 = Pneumococcal 13-Valent Conjugate Vaccine *Prevnar 13*
* Reference for sample size calculation: Study MMR-157
** Type II error is obtained using PASS 2005, one-sided non-inferiority test for 2 means, under the alternative of equal means & alpha=2.5%, N is based on the immuno subsets.
SD = Standard Deviation (of the $\log_{10}$ transformed titer)
Observed SDs for VZV for three lots of *Priorix* were 0.24, 0.26, and 0.27
Observed SDs for HAV for the three lots of *Priorix* were 0.38, 0.39, and 0.43

5.10.5. Study cohorts /data sets analyzed

5.10.5.1. Total vaccinated cohort

The TVC cohort included all vaccinated subjects.

- An immunogenicity analysis based on the Total Vaccinated cohort included all vaccinated subjects for whom immunogenicity data were available.
- A safety analysis based on the TVC included all vaccinated subjects with at least one vaccine administration of either Inv_MMR or Com_MMR lots documented.

5.10.5.2. According-to-protocol cohort for analysis of safety

The ATP cohort for analysis of safety included eligible subjects:

- who had received at least one MMR study vaccine/comparator as per protocol

- who had not received a vaccine leading to exclusion from the ATP cohort in the protocol as described in Section 6.7.1 up to Visit 2
- for whom the randomization code had not been broken
- for whom the administration route of study vaccine(s) was known and correct.

5.10.5.3. According-to-protocol cohort for analysis of immunogenicity

The ATP cohort for analysis of immunogenicity included all eligible subjects from the ATP cohort for safety:

- with pre-vaccination and post-dose serology results available for at least one antigen of measles, mumps, or rubella
- who were below the assay cut-off for at least one vaccine antigen for MMR at pre-vaccination
- who did not meet any elimination criteria up to the Visit 2 blood sample (see protocol Sections 6.7.1 and 6.8)
- who complied with the post-vaccination blood sample schedule, i.e., 35-77 days between vaccination at Visit 1 and the blood draw at Visit 2

5.10.6. Derived and transformed data

For the analysis of immunogenicity, the following definitions were applied:

- **Seroresponse for MMR vaccine was defined as follows**:
  - For measles virus, a seroresponse was defined as post-vaccination anti-measles virus antibody concentration ≥200 mIU/mL (ELISA, Enzygnost) among subjects who were seronegative (antibody concentration <150 mIU/mL) before vaccination.
  - For mumps virus, a seroresponse was defined as post-vaccination anti-mumps virus antibody concentration ≥10 EU/mL (ELISA, PPD) among subjects who were seronegative (antibody concentration <5 EU/mL) before vaccination.
  - For rubella virus, a seroresponse was defined as post-vaccination anti-rubella virus antibody concentration ≥10 IU/mL (ELISA, Enzygnost) among subjects who were seronegative (antibody concentration <4 IU/mL) before vaccination.
- **Seroresponse for *Varivax* was defined as follows**:
  - For VV, a seroresponse was defined as post-vaccination anti-VZV antibody concentration ≥75 mIU/mL among children who were seronegative (antibody concentration <25 mIU/mL) before vaccination.

- **Antibody response for *Havrix* was defined as follows**:
  - For HAV, an antibody response was defined as post-vaccination concentration equal to or above the cut-off of 15 mIU/mL in children below the assay cut-off of 15 mIU/mL before vaccination, or ≥ 2-fold increase in antibody concentration in children ≥ 15 mIU/mL before vaccination.
- **Antibody response for *Prevnar 13* is defined as follows**:
  - For each *S. Pneumoniae* serotype, an antibody response was defined as post-vaccination concentration equal to or above the ECL assay cut-off for the respective serotype. The ECL assay cut-off for each serotype is:
    - anti-PnPS 1 antibody =0.08 µg/mL
    - anti-PnPS 3 antibody =0.075 µg/mL
    - anti-PnPS 4 antibody =0.061 µg/mL
    - anti-PnPS 5 antibody =0.198 µg/mL
    - anti-PnPS 6A antibody =0.111 µg/mL
    - anti-PnPS 6B antibody =0.102 µg/mL
    - anti-PnPS 7F antibody =0.063 µg/mL
    - anti-PnPS 9V antibody =0.066 µg/mL
    - anti-PnPS 14 antibody =0.16 µg/mL
    - anti-PnPS 18C antibody =0.111 µg/mL
    - anti-PnPS 19A antibody =0.199 µg/mL
    - anti-PnPS 19F antibody =0.163 µg/mL
    - anti-PnPS 23F antibody =0.073 µg/mL
- **GMC/T calculation**:

  The GMC calculation for antibody to varicella virus was performed by taking the anti-log of the mean of the log concentration transformations of all values equal to or above Limit of Quantitation (LOQ) (40 mIU/mL), with anti-VZV antibody concentrations between LOQ and Limit of Detection (LOD) (25 mIU/mL) given a value of 25 mIU/mL. By convention, values <25 mIU/mL were given an arbitrary value of 12.5 mIU/mL.

  For the other assays, the GMC calculation was performed by taking the anti-log of the mean of the log concentration transformations. Antibody concentrations below the cut-off of the assay were given an arbitrary value of half the cut-off for the purpose of GMC calculation.
- **Handling of missing results or recordings**

  For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements were not replaced. Therefore, the analyses excluded subjects with missing or non-evaluable measurements.

  For the analysis of solicited symptoms, only subjects with a completed solicited AE section of the eCRF were considered.

Missing or non-evaluable measurements were not replaced. Therefore the analysis of the solicited symptoms based on the TVC cohort included only subjects/doses with documented safety data (i.e., symptom screen/sheet completed).

In the primary analysis of solicited symptoms, missing daily recordings were replaced by the maximum value recorded for the subject. For subjects reporting a symptom without a single daily recording (i.e., reporting fever as present in the absence of temperature measurement), missing daily recordings were replaced by grade 1. A sensitivity analysis of the impact of missing data on the endpoints was to be conducted if the percentage of children reporting a symptom without a single daily recording is above 1%.

For the analyses of unsolicited AEs, SAEs and concomitant medication, all vaccinated subjects were considered, with those not reporting an event being considered as subjects without an event.

- **Methodology for computing CI**

  All CIs were 95% CI. The exact 95% CIs for a proportion within a group was calculated using SAS 9.3 [Clopper, 1934]. SAS 9.3 was also used to derive the standardized asymptotic 95% CI for the group difference in proportions (method 6 in [Newcombe, 1998]).

  The 95% CI for GMCs was obtained within each group separately. The 95% CI for the mean of log-transformed titer/concentration were first obtained assuming that log-transformed values were normally distributed with unknown variance. The 95% CI for the GMCs were then obtained by exponential-transformation of the 95% CI for the mean of log-transformed titer/concentration.

  The 95% CI for GMC group ratio was obtained using an ANOVA model on the logarithm-transformed titers. The ANOVA model included the vaccine group as the fixed effect, the country effect (only for measles, mumps & rubella) and, for pneumococcal immunogenicity, the pre-vaccination log-transformed titer as the regressor. The model assumed equal variance in the log concentrations post vaccination. The between group GMC ratios and their 95% CI were derived by exponential transformation of the corresponding group contrast in the model.

5.10.7. Analysis of demographics and other baseline characteristics

Demographic characteristics (age at Visit 1 in months, geographic ancestry (race), ethnicity and gender) were tabulated as a whole, for the Inv_MMR group and for the Com_MMR groups.

The distribution of subjects enrolled among the study sites/countries was tabulated as a whole, for each Inv_MMR group, for the Inv_MMR groups and for the Com_MMR groups.

5.10.8. Analysis of immunogenicity

The analysis of immunogenicity was based on the ATP cohort for immunogenicity. If, for any vaccine group, the percentage of enrolled children with serological results excluded from this ATP cohort was higher than 5%, a second analysis based on the TVC was required to complement the ATP analysis.

Except for anti-PS, and unless otherwise stated, the analysis post-vaccination of an assay described below was based on the children seronegative for the assay at pre-vaccination. The following descriptive analyses were performed for each Inv_MMR group, for the Inv_MMR groups, and for the Com_MMR groups at each blood sampling time point for which a serological result was available:

- Percentage of subjects above each specific cut-off and their exact 95% CIs were tabulated. See Section 5.10.6. for thresholds of all antigens evaluated for seroresponse.
- Antibody concentrations were also summarized by GMCs with their 95% CIs after vaccination.
- Antibody concentration distributions were displayed as reverse cumulative curves for each antigen and each treatment group after vaccination.

5.10.8.1. Between Inv_MMR lots analysis

At the Day 42 post-vaccination blood sampling, for measles, mumps and rubella:

- The 95% CIs for the GMC ratio of each pair of Inv_MMR lots were computed using an ANOVA model on the logarithm-transformed concentrations. The ANOVA model included the three Inv_MMR lot groups and the country as fixed effects.
- The asymptotic standardized 95% CIs for the pair-wise differences in seroresponse across the three Inv_MMR lots were computed.

5.10.8.2. Between Inv_MMR and Com_MMR group analysis

At the Day 42 post-vaccination blood sampling, for each antibody for which results were available:

- The asymptotic standardized 95% CIs for the difference in seroresponse rate and percentage of subjects with concentration/titer above each specific cut-off [Inv_MMR lot group minus the Com_MMR lot group] were computed.
- The 95% CIs for each GMC/T group ratio [Inv_MMR lot group over the Com_MMR lot group] were computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model included the vaccine group and the country (only for measles, mumps & rubella) as fixed effects and, for pneumococcal immunogenicity, the pre-vaccination log-transformed concentration as the regressor. The vaccine groups were the Inv_MMR lot group and the Com_MMR lot group.

5.10.8.2.1. Subgroup analysis of immunogenicity

All descriptive analyses for anti-measles, anti-mumps, and anti-rubella antibodies were repeated for the following subgroups:

- By country, provided that the country had at least 50 subjects per treatment group (Inv_MMR or Com_MMR)
- By gender, provided that each gender had at least 50 subjects per treatment group (Inv_MMR or Com_MMR)
- By geographic ancestry (race) category, provided that the category had at least 50 subjects per treatment group (Inv_MMR or Com_MMR). Subjects from the 'other' category were split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

5.10.8.2.2. Interpretation of analyses

Except for analyses addressing criteria specified in the objectives, comparative analyses were exploratory with the aim to characterize the difference between groups in immunogenicity. These exploratory analyses should be interpreted with caution since there is no adjustment for multiplicity of endpoints.

With respect to primary and secondary objectives involving pre-specified criteria, the interpretation was done according to a hierarchical procedure described in Section 10.3.1 of the protocol and Section 5.10.3.1 of this report. For instance, the primary objective 3 could only be reached if all the associated criteria were met and the previous primary objectives had been reached. If an objective was not met, all subsequent comparisons would be purely descriptive.

5.10.9. Analysis of safety

The analysis of safety was based on the TVC. If more than 5% of the vaccinated subjects were excluded from the ATP cohort for the analysis of safety, a second analysis based on the ATP cohort was to be performed to complement the TVC analysis. All safety analyses were repeated by country.

5.10.9.1. Between groups assessment

For each group (each Inv_MMR lot group, the Inv_MMR lot group and the Com_MMR lot group), the following results were tabulated:

- the number and percentage of subjects (with exact 95% CIs) with at least one local, general, and any AE (solicited or unsolicited) during the 43-day follow-up period after vaccination (Day 0-42);
- the number and percentage of subjects (with exact 95% CIs) reporting each local solicited symptom during Days 0-3 for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically attended visit;

- the number and percentage of subjects (with exact 95% CIs) reporting general symptom (drowsiness, irritability and loss of appetite) during the 15-day follow-up period after vaccination (Days 0-14) for the following categories: any grade, grade 2 or 3, grade 3, and resulting in a medically-attended visit;
- the number and percentage of subjects reporting fever by half degree (°C) cumulative increments from Days 0-14, from Days 5-12 and from Days 0-42 after vaccination. Similar tabulations were performed for any fever with a causal relationship to vaccination and for any fever resulting in a medically attended visit. In addition, the prevalence of any and grade 3 fevers was presented graphically over time after vaccination. The distribution of maximum temperature recorded over 43 days after vaccination was displayed as reverse cumulative curves for the Inv_MMR lots and Com_MMR lots;
- the number and percentage of subjects (with exact 95% CIs) reporting measles/rubella-like rash and varicella-like rash (Days 0-42, according to number of lesions), any rash (Days 0-42), parotid/salivary gland swelling (Days 0-42, according to intensity) and any sign of meningism/febrile convulsions (Days 0-42, according to intensity), after vaccination. Similar tabulations were performed for general solicited adverse events with a causal relationship to vaccination and for solicited AEs resulting in a medically-attended visit;
- the number and percentage of subjects (with exact 95% CIs) for whom unsolicited adverse events were reported from Days 0-42. The verbatim reports of unsolicited symptoms were reviewed by a physician and the signs and symptoms were coded according to MedDRA, the Medical Dictionary for Regulatory Activities. Every verbatim term was matched with the appropriate Preferred Term. Similar tabulations were done for grade 3 unsolicited AEs, for unsolicited AEs related to vaccination and for unsolicited AEs resulting in a medically attended visit;
- the number and percentage of subjects who received at least one concomitant medication from Days 0-14 and from Days 0-42 after vaccination. Additionally, the number and percentage of children receiving antipyretic drugs was also calculated by group from Days 0-14 and from Days 0-42 after vaccination.
- Discontinuations due to AEs were described in detail.
- The percentages of subjects who experienced at least one serious adverse event or who reported a NOCD (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, conditions associated with sub-acute or chronic thrombocytopenia and allergies), or an AE leading to an ER visit, or an AE leading to a medically attended visit from Day 0 to study end, were calculated.
- Descriptive listing of SAEs, any related SAEs to study participation, study withdrawals and deaths post-vaccination(s) for the entire study.
- All safety results will also be produced by country.

5.10.9.2. Subgroup analysis of safety

All safety analyses on the treatment groups were repeated for the following subgroups:

- By country, provided that the country had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By gender, provided that each gender had at least 50 subjects per treatment group (Inv_MMR or Com_MMR).
- By geographic ancestry (race) category, provided that the category had at least 50 subjects per treatment group (Inv_MMR or Com_MMR). Subjects from the 'other' category were split into two sub-categories: 'Other: American Hispanic or Latino' and 'Other: Not American Hispanic or Latino'.

5.10.10. Interim analysis

No interim analyses were performed.

5.11. Data quality assurance at study level

To ensure that the study procedures conformed across all investigator sites, the protocol, CRF/eCRF and safety reporting were reviewed with the investigator(s) and his/her/their personnel responsible for the conduct of the study by the Company representative(s) prior to study start**.** A multi-investigator meeting or a site initiation visit was held prior to the study start.

Adherence to the protocol requirements and verification of data generation accuracy were achieved through monitoring visits to each investigator site. Computer checks and blinded review of subject tabulations were performed to ensure consistency of CRF/eCRF completion. All procedures were performed according to methodologies detailed in GlaxoSmithKline Biologicals Standard Operating Procedures (SOPs).

Between April and May 2013, two technical problems were identified in the Electronic Data Capture system (e-N@ble Web system) used in this study. The first technical issue was related to the incorrect display of the investigator's signature on the electronic screens in the system. The second technical issue was that the reasons for change of the data noted in the audit trail were overwritten; the author, date and time of original entry as well as data changes were not affected. These technical issues were corrected in December 2013. This does not change the validity of the data collected nor have any impact on the data reported.

All protocol deviations collected during the study were reviewed by the GSK study team in order to identify important protocol deviations. Consistent with ICH E3 guidance, important deviations are defined as deviations that were likely to affect the interpretation of the results and/or led to exclusion of any subject data from an analysis. Important deviations include, but are not limited to, those related to study inclusion or exclusion criteria, adherence to the protocol, conduct of the study, subject management or subject assessment**.**

The following issues with regard to the conduct of the study were identified, either via site monitoring activities or were brought to GSK Biologicals' attention by other oversight mechanisms. These issues were investigated and where possible corrective and / preventive actions were taken as described in Section 6.3.2.

CROs were employed to perform the activities listed in Table 1 according to an agreed contract. The CRO responsibilities were conducted according to GSK's SOPs.

Independent Audit statement: This study was subject to audit by GlaxoSmithKline's R&D Global Quality Compliance (GQC) - Clinical Development Quality Assurance (CDQA) department.

5.12. Changes in the conduct of the study or planned analyses

5.12.1. Protocol amendments

There were two amendments to the study protocol issued on 14 May 2014 and 26 February 2015 respectively. Both were issued after study initiation (09 November 2012) but prior to completion (16 April 2015). The main changes incorporated in these amendments are listed below:

Protocol Amendment 1 (14 May 2014)

- Vaccination against influenza (with inactivated influenza vaccine) and Haemophilus influenzae type b can be given at any time before, during, or after the study, including the day of study vaccination. This was to correct a prior exclusion criterion which stated that it could be given at any time during the study. The intent has always been to allow these vaccinations at any time regardless of whether or not it was before, during or after the study period.
- For other MMR US Phase III studies, the Center for Biologics Evaluation and Research (CBER) requested that all conditions leading to non-routine medically attended visits be collected for the entire study in the eCRF. It has been clarified throughout the protocol that from Visit 1 (Day 0) to study end (Day 180), all medically attended events will be recorded in the eCRF. Subjects' routine 'well child' doctor visits will not be recorded in the eCRF.
- Other minor corrections were implemented.

Protocol Amendment 2 (26 February 2015)

- Based on comments from CBER, the *Streptococcus pneumoniae* testing will not be the 22F ELISA currently listed but a validated assay accepted by CBER. The assessment of this assay is ongoing. As such, the secondary endpoint related to assessment of the percentage of subjects with *Streptococcus pneumoniae* antibody concentrations ≥0.05, 0.2, 0.5, and 1.0 µg/mL with the 22F ELISA has been removed. The need for any additional endpoints related to *Streptococcus pneumoniae* antibody testing will be reassessed once a CBER validated assay is selected.

- Serological assays for the determination of antibodies against measles, rubella and varicella viruses now will be performed by GSK Biologicals' laboratory in Laval, Canada. Note: In the future, the GSK Laval Clinical Serology group will integrate/join a new 3rd party CRO.
- Serological testing for the co-administered vaccines (i.e. VV, HAV and PCV-13) will be completed much later than the antibody determination for measles, mumps and rubella. Therefore, the immunogenicity data analysis for the co-administered vaccines will be included in the final analysis performed at the end of the study.
- Other minor corrections were implemented.

5.12.2. Other changes

This study was conducted according to the protocol and all analyses were performed as planned in the protocol and the statistical analysis plan (SAP).

In accordance with other studies conducted with *Priorix* (Inv_MMR), subjects enrolled in Puerto Rico were analyzed together with the US subjects.

6. STUDY POPULATION RESULTS

6.1. Study dates

The first subject was enrolled in the study on 09 November 2012 and the last study visit was on 16 April 2015.

6.2. Subject disposition

A total of 5003 subjects were vaccinated in the study: 1239 subjects in the Inv_MMR_Lot 1 group, 1232 subjects in the Inv_MMR_Lot 2 group, 1243 subjects in the Inv_MMR_Lot 3 group and 1289 subjects in the Com_MMR group (Table 23).

The most common reasons for withdrawal were lost to follow-up subjects with complete vaccination course (133 subjects) and consent withdrawal (68 subjects). Two subjects were withdrawn due to experiencing an AE, and four subjects due to protocol violations.

Table 23 Number of subjects vaccinated, completed and withdrawn with reason for withdrawal (Total vaccinated cohort)

	INV_MMR_1	INV_MMR_2	INV_MMR_3	COM_MMR	Total
Number of subjects vaccinated	1239	1232	1243	1289	5003
Number of subjects completed	1175	1162	1190	1232	4759
Number of subjects withdrawn	64	70	53	57	244
Reasons for withdrawal					
Serious Adverse Event	0	0	0	0	0
Non-Serious Adverse Event	2	0	0	0	2
Protocol violation	3	0	1	0	4
Consent withdrawal (not due to an adverse event)	21	23	14	10	68
Migrated/moved from study area	7	3	6	6	22
Lost to follow-up (subjects with incomplete vaccination course)	0	0	0	0	0
Lost to follow-up (subjects with complete vaccination course)	26	38	31	38	133
Sponsor study termination	0	0	0	0	0
Others	5	6	1	3	15

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Vaccinated = number of subjects who were vaccinated in the study
Completed = number of subjects who completed last study visit
Withdrawn = number of subjects who did not come back for the last visit

The number of subjects enrolled in each study center is given in Table 6.1. The number of subjects at each visit and a list of withdrawn subjects are given in Table 6.2.

6.3. Important protocol deviations at subject level

6.3.1. Protocol deviations leading to elimination from ATP analyses

The total number of subjects included in each data cohort and the deviations leading to elimination from a particular cohort are shown in Table 24. A total of 5016 subjects were enrolled, with 5003 receiving a study vaccination and eligible to be included in the TVC.

A total of 4958 subjects (99.1%) were included in the ATP cohort for safety. The most common reason for exclusion from the safety analysis was administration of vaccines forbidden in the protocol (22 subjects).

A total of 4498 subjects (89.9%) were included in the ATP cohort for immunogenicity. The primary reason for exclusion from the ATP immunogenicity analysis was due to ‘essential serological data missing’ (276 subjects).

Note: On 21 May 2014, it was noted that a total of 17 blood samples were collected using expired “Vacutainer tubes”. Subjects impacted by the use of this material were excluded from the ATP analyses and were part of those eliminated due to ‘essential serological data missing’.

Table 24 Number of subjects enrolled into the study as well as the number excluded from ATP analyses with reasons for exclusion

	Total			INV_MMR_1		INV_MMR_2		INV_MMR_3		COM_MMR		NOGRP	
Title	**n**	**s**	**%**	**n**	**s**	**n**	**s**	**n**	**s**	**n**	**s**	**n**	**s**
Total cohort	**5016**			**1239**		**1234**		**1246**		**1291**		**6**	
Study vaccine dose not administrated but subject number allocated (code 1030)	13	13		0	0	2	2	3	3	2	2	6	6
Total vaccinated cohort	**5003**		**100**	**1239**		**1232**		**1243**		**1289**		**0**	
Administration of vaccine(s) forbidden in the protocol (code 1040)	22	22		8	8	4	4	5	5	5	5	0	0
Randomization code broken at the investigator site (code 1060)	1	1		0	0	1	1	0	0	0	0	0	0
Study vaccine dose not administered according to protocol (code 1070)	4	4		1	1	1	1	2	2	0	0	0	0
Vaccine temperature deviation (code 1080)	12	12		2	2	3	3	2	2	5	5	0	0
Expired vaccine administered (code 1090)	3	3		1	1	1	1	0	0	1	1	0	0
Others (reacto) (code 1500)	3	3		1	1	0	0	1	1	1	1	0	0
ATP cohort for safety	**4958**		**99.1**	**1226**		**1222**		**1233**		**1277**		**0**	
Protocol violation (inclusion/exclusion criteria) (code 2010)	4	5		1	1	1	1	2	3	0	0	0	0
Initially seropositive or initially unknown antibody status (code 2020)	139	144		40	42	34	35	28	30	37	37	0	0
Administration of any medication forbidden by the protocol (code 2040)	1	1		0	0	0	0	0	0	1	1	0	0
Underlying medical condition forbidden by the protocol (code 2050)	1	1		1	1	0	0	0	0	0	0	0	0
Non-compliance with blood sampling schedule (including wrong and unknown dates (code 2090)	39	42		8	8	10	10	11	11	10	13	0	0
Essential serological data missing (code 2100)	276	312		68	79	79	83	62	69	67	81	0	0
ATP cohort for immunogenicity	**4498**		**89.9**	**1108**		**1098**		**1130**		**1162**		**0**	

NOGRP = No assigned group
INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Note: Subjects may have more than one elimination code assigned
n = number of subjects with the elimination code assigned excluding subjects who have been assigned a lower elimination code number
s = number of subjects with the elimination code assigned
% = percentage of subjects in the considered ATP cohort relative to the Total vaccinated cohort

6.3.2. Protocol deviations not leading to elimination from ATP analyses

Deviations from specifications for subject age and intervals between study visits are provided for each treatment group in Table 6.3.

Deviations related to study vaccines

The *Varivax* vaccine was stored at a temperature colder than advised by the manufacturer at a US site, and administered to five study subjects. The affected subjects were notified, and one consenting subject was re-vaccinated at the site.

Deviations related to randomization process

Two subjects from a site in the US were entered and/or randomized in the Randomization System on Internet (SBIR) before the subject's parent(s)/ LAR signed or thumb-printed the ICF. No other study procedure was performed on these subjects until a signed Informed Consent/thumb impression was obtained for them. After acquiring a valid ICF, the subjects were included in the study, and data from the impacted subjects were used for the analysis(es) of the study.

6.4. Demographic characteristics and other baseline characteristics

Demographic and other baseline characteristics of the ATP cohort for immunogenicity cohort are presented by treatment group and overall in Table 25.

The mean age of subjects included in the ATP cohort for immunogenicity was 12.3 months at the time of the first study vaccination. Overall, majority of the subjects were White/Caucasian (76.6%) and male (51.5%); this distribution was reflected in the study groups. Overall, all demographic and baseline characteristics were similar among the study groups.

Summary of demographic characteristics of the TVC are given in Table 6.5, and reflected what was observed for the ATP cohort for immunogenicity.

Table 25 Summary of demographic characteristics (ATP cohort for immunogenicity

		INV_MMR_1 N = 1108		INV_MMR_2 N = 1098		INV_MMR_3 N = 1130		INV_MMR N = 3336		COM_MMR N = 1162		Total N = 4498	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	542	48.9	529	48.2	550	48.7	1621	48.6	562	48.4	2183	48.5
	Male	566	51.1	569	51.8	580	51.3	1715	51.4	600	51.6	2315	51.5
Ethnicity	American Hispanic or Latino	184	16.6	215	19.6	210	18.6	609	18.3	209	18.0	818	18.2
	Not American Hispanic or Latino	924	83.4	883	80.4	920	81.4	2727	81.7	953	82.0	3680	81.8
Geographic Ancestry	African Heritage / African American	49	4.4	36	3.3	44	3.9	129	3.9	56	4.8	185	4.1
	American Indian or Alaskan Native	21	1.9	32	2.9	27	2.4	80	2.4	23	2.0	103	2.3
	Asian - Central/South Asian Heritage	12	1.1	6	0.5	7	0.6	25	0.7	8	0.7	33	0.7
	Asian - East Asian Heritage	7	0.6	8	0.7	8	0.7	23	0.7	9	0.8	32	0.7
	Asian - Japanese Heritage	1	0.1	2	0.2	2	0.2	5	0.1	1	0.1	6	0.1
	Asian - South East Asian Heritage	18	1.6	23	2.1	18	1.6	59	1.8	22	1.9	81	1.8
	Native Hawaiian or Other Pacific Islander	2	0.2	0	0.0	4	0.4	6	0.2	1	0.1	7	0.2
	White - Arabic / North African Heritage	3	0.3	6	0.5	2	0.2	11	0.3	7	0.6	18	0.4
	White - Caucasian / European Heritage	847	76.4	841	76.6	869	76.9	2557	76.6	889	76.5	3446	76.6
	Other	148	13.4	144	13.1	149	13.2	441	13.2	146	12.6	587	13.1
Country	Estonia	115	10.4	115	10.5	119	10.5	349	10.5	119	10.2	468	10.4
	Spain	56	5.1	56	5.1	55	4.9	167	5.0	61	5.2	228	5.1
	Finland	326	29.4	318	29.0	330	29.2	974	29.2	330	28.4	1304	29.0
	Mexico	86	7.8	93	8.5	94	8.3	273	8.2	93	8.0	366	8.1
	United States	525	47.4	516	47.0	532	47.1	1573	47.2	559	48.1	2132	47.4
Subset	VZV and HAV subset	265	23.9	263	24.0	267	23.6	795	23.8	286	24.6	1081	24.0
	VZV and PCV subset	257	23.2	249	22.7	263	23.3	769	23.1	270	23.2	1039	23.1
	Not in subset	586	52.9	586	53.4	600	53.1	1772	53.1	606	52.2	2378	52.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

7. IMMUNOGENICITY RESULTS

The primary analysis of immunogenicity was performed on the ATP cohort for immunogenicity. A second analysis based on the TVC was not performed because less than 5% of subjects were eliminated from each group in the ATP cohort.

Co-primary objectives 1 and 2 of the study were to demonstrate the consistency of 3 manufacturing lots of Inv_MMR vaccine in terms of seroresponse rates and GMCs of anti-measles, anti-mumps and anti-rubella antibodies at Day 42.

Co-primary objectives 3 and 4 were to demonstrate the non-inferiority of Inv_MMR (for the 3 pooled lots) compared to Com_MMR (for the 2 pooled lots) vaccine in terms of seroresponse rates and GMCs of anti-measles, anti-mumps and anti-rubella antibodies at Day 42.

Co-primary objective 5 was to demonstrate acceptable immune response for Inv_MMR in terms of seroresponse rates to anti-measles, anti-mumps and anti-rubella antibodies at Day 42.

The secondary objectives 1, 2 and 3 were to demonstrate the non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of seroresponse rates and GMC ratio of antibodies to the VZV at Day 42 (in a subset of subjects enrolled in the US), to demonstrate non-inferiority of the Inv_MMR groups compared to the Com_MMR groups in terms of GMC for antibodies to hepatitis A virus at Day 42 (in a subset of subjects enrolled in the US), and to demonstrate the non-inferiority of the Inv_MMR groups compared to Com_MMR groups in terms of antibodies to *S.pneumoniae* (13 serotypes) at Day 42 (in a subset of subjects administered *Prevnar 13* in the US), respectively.

Secondary objective 4 was to assess the immunogenicity of *Havrix* with respect to the seroresponse rates for antibodies to HAV in the Inv_MMR groups in contrast to the Com_MMR vaccine groups at Day 42 (in a subset of children enrolled in the US). Finally, secondary objective 5 was to assess the safety and reactogenicity of Inv_MMR and Com_MMR when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to subjects enrolled in the US).

7.1. According-to-protocol analysis

The ATP cohort for immunogenicity consisted of 4498 subjects; 1108 subjects in the Inv_MMR_1 group, 1098 subjects in the Inv_MMR_2 group, 1130 subjects in the Inv_MMR_3 group and 1162 subjects in the Com_MMR group.

The co-primary objectives of the study were to demonstrate the consistency of three manufacturing lots of Inv_MMR, to demonstrate the non-inferiority of the Inv_MMR vaccine compared to the Com_MMR, and to demonstrate acceptable immune response of Inv_MMR in terms of seroresponse rates to measles, mumps and rubella viruses. To control the risk of erroneous conclusions, a hierarchical procedure (Figure 2) was used for the primary and secondary objectives. Thus, each objective could only be reached if all the associated criteria were met and all previous objectives were reached.
The pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies in the study groups is given in Table 7.1. The majority of subjects in both groups (≥95%) were seronegative at baseline prior to vaccination, against anti-measles, anti-mumps and anti-rubella antibodies.

7.1.1. Consistency of the three manufacturing lots of Inv_MMR (Co-primary objectives 1 and 2)

Consistency of the immune response after one dose of GSK MMR was demonstrated (See Table 26 and Table 27):

- For each pair-wise comparison, the two sided 95% CI for the difference in lots seroresponse rates was within the [-5%; 5%] margin for anti-measles, anti-mumps and anti-rubella antibodies.
- For each pair-wise comparison, the two sided 95% CI for the adjusted GMC ratio was between 0.67 and 1.5 for anti-measles, anti-mumps and anti-rubella antibodies.

Table 26 Consistency of INV_MMR lots in terms of seroresponse rate for measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

					Difference (First group minus Second group)		
	First group		Second group			95% CI	
Antibody	INV_MMR Lot	SR rate	INV_MMR Lot	SR rate	%	LL	UL
anti-Measles antibody	1	98.1	2	98.6	-0.54	-1.69	0.58
	1	98.1	3	97.8	0.25	-0.98	1.50
	2	98.6	3	97.8	0.79	-0.35	1.98
anti-Mumps (PPD) antibody	1	98.6	2	98.6	0.02	-1.05	1.09
	1	98.6	3	98.0	0.63	-0.50	1.81
	2	98.6	3	98.0	0.61	-0.53	1.79
anti-Rubella antibody	1	97.2	2	97.1	0.14	-1.30	1.58
	1	97.2	3	97.7	-0.49	-1.86	0.86
	2	97.1	3	97.7	-0.62	-2.02	0.74

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay -
seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively)
95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Table 27 Consistency of INV_MMR lots in terms of adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

					Adjusted GMC ratio (First group over Second group)		
	First group		Second group			95% CI	
Antibody	Lot	Adjusted GMC	Lot	Adjusted GMC	Value	LL	UL
anti-Measles antibody (mIU/mL)	INV_MMR_1	3128.5	INV_MMR_2	3174.4	0.99	0.91	1.06
	INV_MMR_1	3128.5	INV_MMR_3	3217.7	0.97	0.90	1.05
	INV_MMR_2	3174.4	INV_MMR_3	3217.7	0.99	0.91	1.06
anti-Mumps (PPD) antibody (EU/mL)	INV_MMR_1	75.2	INV_MMR_2	80.5	0.93	0.87	1.00
	INV_MMR_1	75.2	INV_MMR_3	72.3	1.04	0.97	1.11
	INV_MMR_2	80.5	INV_MMR_3	72.3	1.11	1.04	1.19
anti-Rubella antibody (IU/mL)	INV_MMR_1	54.5	INV_MMR_2	50.5	1.08	1.01	1.15
	INV_MMR_1	54.5	INV_MMR_3	54.3	1.00	0.94	1.07
	INV_MMR_2	50.5	INV_MMR_3	54.3	0.93	0.87	0.99

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for Country
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country - pooled variance with more than 2 groups), LL = lower limit, UL = upper limit

7.1.2. Non-inferiority of the immune response of Inv_MMR vs. Com_MMR (Co-primary objectives 3 and 4)

Since co-primary objectives 1 and 2 were met, this allowed for the hierarchical analyses to continue evaluating the subsequent co-primary objectives. The acceptance criteria for both co-primary objectives 3 and 4 for Inv_MMR i.e. demonstrating the non-inferiority of Inv_MMR vaccines compared to Com_MMR in terms of seroresponse rates and GMCs of anti-measles, anti-mumps and anti-rubella antibodies at Day 42 (see Table 28 and Table 29) were met:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps and anti-rubella antibodies.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps and anti-rubella antibodies.

Table 28 NI of INV_MMR vs COM_MMR in terms of seroresponse rate to measles, mumps and rubella viruses at Day 42 (ATP cohort for immunogenicity)

			Difference (INV_MMR minus COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	SR rate	SR rate	%	LL	UL
anti-Measles antibody	98.2	98.0	0.18	-0.68	1.25
anti-Mumps (PPD) antibody	98.4	97.6	0.81	-0.10	1.96
anti-Rubella antibody	97.3	98.5	-1.15	-2.00	-0.15

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SR = Seroresponse rate (percentage of initially seronegative subjects with concentration above seroresponse threshold for each assay -
seroresponse thresholds are 200 mIU/mL, 10 ELU/mL, and 10 IU/mL for anti-measles, anti-mumps, and anti-rubella antibodies respectively)
95% CI = Standardized asymptotic 95% confidence interval LL = lower limit, UL = upper limit

Table 29 NI of INV_MMR vs COM_MMR in terms of post-vaccination adjusted GMC ratios for antibodies to measles, mumps and rubella viruses at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

			Adjusted GMC ratio (INV_MMR over COM_MMR)		
	INV_MMR	COM_MMR		95% CI	
Antibody	Adjusted GMC	Adjusted GMC	Value	LL	UL
anti-Measles antibody (mIU/mL)	3165.2	3215.4	0.98	0.93	1.05
anti-Mumps (PPD) antibody (EU/mL)	76.4	73.0	1.05	0.99	1.11
anti-Rubella antibody (IU/mL)	52.5	60.0	0.87	0.83	0.92

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for Country
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for Country – pooled variance), LL = lower limit, UL = upper limit

7.1.3. Acceptable Immune response of Inv_MMR to measles, mumps and rubella viruses (Co-primary objective 5)

The final co-primary objective was to demonstrate an acceptable immune response of Inv_MMR in terms of seroresponse rates for anti-MMR virus antibodies at Day 42 (Table 30, Table 31 and Table 32) and this objective was met:

- The lower limit of the two sided 95% CI for the seroresponse rate for the Inv_MMR lots was ≥90% for anti-measles, anti-mumps and anti-rubella antibodies.

Table 30 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 mIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3196	98.4	97.9	98.8	3188	98.2	97.6	98.6	3017.4	2923.9	3113.8
	COM_MMR	PI(D42)	1137	1115	98.1	97.1	98.8	1114	98.0	97.0	98.7	3074.4	2911.0	3246.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 31 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 EU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 5 EU/ml				≥ 10 EU/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3187	3168	99.4	99.1	99.6	3135	98.4	97.9	98.8	72.4	70.4	74.5
	COM_MMR	PI(D42)	1107	1099	99.3	98.6	99.7	1080	97.6	96.5	98.4	69.1	65.7	72.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 32 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 4 IU/ml				≥ 10 IU/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3245	3229	99.5	99.2	99.7	3159	97.3	96.7	97.9	55.7	54.2	57.3
	COM_MMR	PI(D42)	1135	1130	99.6	99.0	99.9	1118	98.5	97.6	99.1	64.0	61.1	67.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

7.1.4. Antibody responses against each of the vaccine components

7.1.4.1. Anti-measles antibody responses

The percentages of subjects with concentrations equal to or above thresholds of 150 and 200 mIU/mL and GMCs of anti-measles antibodies in initially seronegative subjects are given in Table 30.

The percentages of subjects with anti-measles virus antibody concentrations ≥ 150 and concentrations ≥200 mIU/mL were ≥98% of subjects in both Inv_MMR and Com_MMR groups.

At Day 42, GMCs were 3017.4 mIU/mL in Inv_MMR group and 3074.4 mIU/mL in Com_MMR group.

The distribution of anti-measles antibody concentrations in initially seronegative subjects is given in Table 7.14. Figure 7.1 depicts the reverse cumulative distribution curve of anti-measles antibody concentrations.

7.1.4.2. Anti-mumps antibody response

The percentages of subjects with concentrations equal to or above thresholds of 5 and 10 EU/mL and GMCs of anti-mumps antibodies in initially seronegative subjects are given in Table 31.

The percentages of subjects with anti-mumps virus antibody concentrations ≥ 5 EU/mL and concentrations ≥ 10 EU/mL were ≥97.6% of subjects in both Inv_MMR and Com_MMR.

At Day 42, GMCs were 72.4 EU/mL in Inv_MMR group and 69.1 EU/mL in Com_MMR group.

The distribution of anti-mumps antibody concentrations in initially seronegative subjects is given in Table 7.20. Figure 7.2 depicts the reverse cumulative distribution curve of anti-mumps antibody concentrations.

7.1.4.3. Anti-rubella antibody response

The percentages of subjects with concentrations equal to or above thresholds of 4 and 1 IU/ml and GMCs of anti-rubella antibodies in initially seronegative subjects are given in Table 32.

The percentages of subjects with anti-rubella virus antibody concentrations ≥ 4 IU/mL and concentrations ≥ 10 IU/mL were ≥97.3% of subjects in both Inv_MMR and Com_MMR groups.

At Day 42, GMCs were 55.7 IU/mL in Inv_MMR group and 64.0 IU/mL in Com_MMR group.

The distribution of anti-rubella antibody concentrations in initially seronegative subjects is given in Table 7.26. Figure 7.3 depicts the reverse cumulative distribution curve of anti-rubella antibody concentrations.

7.1.5. Non-inferiority of the immune response to varicella virus in terms of seroresponse rates and GMCs for anti-VZV antibodies (Secondary objective 1)

Since co-primary objectives 1 to 5 were met, this allowed for the hierarchical analyses to continue evaluating the subsequent secondary objectives i.e. to assess non-inferiority of the immune response to the co-administered vaccines.

The percentages of subjects with anti-VZV antibodies equal to or above the thresholds were at least 92.2% of subjects in the Inv_MMR group and at least ***90.9%*** in the Com_MMR group. The GMCs were 169.6 in the Inv_MMR group and 167.2 in the Com_MMR group (See Table 33).

The acceptance criteria for secondary objective 1, demonstrating non-inferiority of the Inv_MMR groups to the Com_MMR groups in terms of the seroresponse rates and GMC of anti-VZV antibodies in a subset of children enrolled in the US (subsets A and B) were met (See Table 34 and Table 35):

- The lower limit of the two-sided 95% CI for the group difference (Inv_MMR minus Com_MMR) in seroresponse rates for anti-VZV antibodies was ≥-10%.
- The lower limit of the two-sided 95% CI on the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies.

Table 33 Number and percentage of subjects with an Anti-VZV antibody concentration equal to or above 25 and 75 mIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				≥ 25 mIU/mL				≥ 75 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-VZV antibody	INV_MMR	PI(D42)	1492	1488	99.7	99.3	99.9	1376	92.2	90.7	93.5	169.6	164.3	175.0
	COM_MMR	PI(D42)	540	538	99.6	98.7	100	491	90.9	88.2	93.2	167.2	158.2	176.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 34 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an VZV antibody concentration equal to or above 75 mIU/ML - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-VZV antibody	75 mIU/mL	1492	1376	92.2	540	491	90.9	1.30	-1.31	4.29

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 35 Ratios of Anti-VZV antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	GMC	N	GMC	Value	LL	UL
1492	169.6	540	167.2	1.01	0.95	1.08

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

7.1.6. Non-inferiority of the immune response to Hepatitis A Virus in terms of antibodies to HAV GMCs (Secondary objective 2)

The percentages of subjects with antibodies to HAV equal to or above the threshold of 15 mIU/mL were ≥91.4% of seropositive subjects on Day 42 for both the Inv_MMR and Com_MMR groups, and >87.1% in seronegative subjects on Day 42 for both the Inv_MMR and Com_MMR groups. The corresponding GMCs for each group are 42.0 for Inv_MMR and 42.4 for Com_MMR, respectively (see Table 36).

The acceptance criterion for secondary objective 2, demonstrating non-inferiority of Inv_MMR groups to Com_MMR groups in terms of the GMC of antibodies to HAV in a subset of children enrolled in the US (subset A) was met (see Table 37):

- The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was >0.5 for antibodies to HAV.

Table 36 Number and percentage of subjects with an Anti-HAV concentration equal to or above 15 mIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset)

					≥ 15 mIU/mL				GMC		
							95% CI			95% CI	
Antibody	**Group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-HAV	INV_MMR	S-	PI(D42)	748	664	88.8	86.3	90.9	41.8	39.2	44.7
		S+	PI(D42)	35	32	91.4	76.9	98.2	44.9	32.7	61.6
		Total	PI(D42)	783	696	88.9	86.5	91.0	42.0	39.3	44.8
	COM_MMR	S-	PI(D42)	271	236	87.1	82.5	90.8	42.8	38.3	47.9
		S+	PI(D42)	14	13	92.9	66.1	99.8	35.2	23.9	51.9
		Total	PI(D42)	285	249	87.4	82.9	91.0	42.4	38.1	47.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 15 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL) prior to vaccination
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 37 Ratios of Anti-HAV GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)

				GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		**COM_MMR**			**95% CI**	
N	**GMC**	**N**	**GMC**	**Value**	**LL**	**UL**
748	41.8	271	42.8	0.98	0.86	1.11

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the GMC ratio (Anova model - pooled variance); LL = lower limit, UL = upper limit

7.1.7. Non-inferiority of the immune response to PCV-13 in terms of anti-PS GMCs (Secondary objective 3)

The acceptance criterion for secondary objective 3, demonstrating non-inferiority of the Inv_MMR groups to Com_MMR groups in terms of GMCs for anti-PS antibodies (13 serotypes) at Day 42 in a subset of children administered *Prevnar 13* in the US (subset B) was met (see Table 38):

- The lower limit of the two-sided 95% CI for the group GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for each of the 13 PS serotypes.

The percentages of subjects with anti-PS antibodies equal to or above the respective assay cut offs for each of the 13 serotypes were at least 82.5% in the Inv_MMR group and at least 80.8% in the Com_MMR group at pre-vaccination, while the percentages of subjects with anti-PS antibodies equal to or above the threshold of 0.35 µg/mL were at least 70.1% and 69.4% for Inv_MMR and Com_MMR groups, respectively on Day 42 (see Table 39). The corresponding lower limit of the 95% CI of the adjusted GMC ratio ranged from 0.79 to 0.92 on Day 42 (see Table 38). Antibody GMCs were within the same ranges for both groups thus meeting objective 3.

Table 38 Adjusted Ratios of Anti-S.Pneu GMCs at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

					Adjusted GMC ratio (INV_MMR / COM_MMR)		
	INV_MMR		COM_MMR			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PnPS 1 antibody (ECL) (µg/mL)	740	2.258	256	2.392	0.94	0.85	1.05
anti-PnPS 3 antibody (ECL) (µg/mL)	739	0.499	255	0.503	0.99	0.91	1.08
anti-PnPS 4 antibody (ECL) (µg/mL)	732	1.620	255	1.844	0.88	0.79	0.98
anti-PnPS 5 antibody (ECL) (µg/mL)	738	2.092	256	2.280	0.92	0.83	1.01
anti-PnPS 6A antibody (ECL) (µg/mL)	740	5.815	256	5.761	1.01	0.92	1.11
anti-PnPS 6B antibody (ECL) (µg/mL)	739	5.812	256	5.924	0.98	0.89	1.09
anti-PnPS 7F antibody (ECL) (µg/mL)	739	3.658	256	3.887	0.94	0.86	1.03
anti-PnPS 9V antibody (ECL) (µg/mL)	740	2.295	256	2.324	0.99	0.90	1.08
anti-PnPS 14 antibody (ECL) (µg/mL)	738	6.512	256	7.151	0.91	0.81	1.02
anti-PnPS 18C antibody (ECL) (µg/mL)	740	2.082	255	2.255	0.92	0.84	1.02
anti-PnPS 19A antibody (ECL) (µg/mL)	739	4.708	255	4.876	0.97	0.87	1.07
anti-PnPS 19F antibody (ECL) (µg/mL)	740	4.186	256	4.367	0.96	0.87	1.06
anti-PnPS 23F antibody (ECL) (µg/mL)	701	2.178	240	2.301	0.95	0.85	1.06

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for baseline concentration
N = Number of subjects with both pre- and post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Ancova model: adjustment for baseline concentration - pooled variance); LL = lower limit, UL = upper limit

Table 39 Number and percentage of subjects with an Anti-S.Pneu antibody concentration equal to or above the specified assay cut-off and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**Value**	**LL**	**UL**
anti-PnPS 1 antibody(ECL)(assay cut-off=0.08 µg/ml)	INV_MMR	PRE	750	743	99.1	98.1	99.6	469	62.5	59.0	66.0	0.476	0.449	0.505
		PI(D42)	759	755	99.5	98.7	99.9	751	98.9	97.9	99.5	2.257	2.121	2.402
	COM_MMR	PRE	260	260	100	98.6	100	173	66.5	60.4	72.2	0.491	0.450	0.535
		PI(D42)	266	266	100	98.6	100	264	99.2	97.3	99.9	2.425	2.195	2.679
anti-PnPS 3 antibody(ECL)(assay cut-off=0.075 µg/ml)	INV_MMR	PRE	750	619	82.5	79.6	85.2	116	15.5	13.0	18.3	0.151	0.141	0.162
		PI(D42)	758	754	99.5	98.7	99.9	531	70.1	66.7	73.3	0.506	0.481	0.533
	COM_MMR	PRE	260	210	80.8	75.4	85.4	35	13.5	9.6	18.2	0.143	0.127	0.161
		PI(D42)	265	264	99.6	97.9	100	184	69.4	63.5	74.9	0.496	0.454	0.542
anti-PnPS 4 antibody(ECL)(assay cut-off=0.061 µg/ml)	INV_MMR	PRE	748	726	97.1	95.6	98.1	292	39.0	35.5	42.6	0.272	0.256	0.289
		PI(D42)	753	749	99.5	98.6	99.9	738	98.0	96.7	98.9	1.618	1.518	1.725
	COM_MMR	PRE	259	255	98.5	96.1	99.6	98	37.8	31.9	44.0	0.279	0.253	0.308
		PI(D42)	266	266	100	98.6	100	258	97.0	94.2	98.7	1.872	1.676	2.091
anti-PnPS 5 antibody(ECL)(assay cut-off=0.198 µg/ml)	INV_MMR	PRE	750	677	90.3	87.9	92.3	510	68.0	64.5	71.3	0.490	0.462	0.520
		PI(D42)	757	753	99.5	98.7	99.9	748	98.8	97.8	99.5	2.106	1.991	2.228
	COM_MMR	PRE	260	239	91.9	87.9	94.9	182	70.0	64.0	75.5	0.485	0.443	0.532
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	2.280	2.085	2.493
anti-PnPS 6A antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	750	737	98.3	97.1	99.1	619	82.5	79.6	85.2	0.719	0.677	0.764
		PI(D42)	759	755	99.5	98.7	99.9	755	99.5	98.7	99.9	5.840	5.508	6.192
	COM_MMR	PRE	260	257	98.8	96.7	99.8	214	82.3	77.1	86.7	0.710	0.643	0.783
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	5.743	5.233	6.304
anti-PnPS 6B antibody(ECL)(assay cut-off=0.102 µg/ml)	INV_MMR	PRE	750	695	92.7	90.6	94.4	495	66.0	62.5	69.4	0.534	0.493	0.577
		PI(D42)	758	754	99.5	98.7	99.9	754	99.5	98.7	99.9	5.872	5.504	6.265
	COM_MMR	PRE	260	240	92.3	88.4	95.2	171	65.8	59.7	71.5	0.507	0.442	0.580
		PI(D42)	266	266	100	98.6	100	265	99.6	97.9	100	5.838	5.239	6.505
anti-PnPS 7F antibody(ECL)(assay cut-off=0.063 µg/ml)	INV_MMR	PRE	750	750	100	99.5	100	671	89.5	87.0	91.6	0.862	0.819	0.907
		PI(D42)	758	754	99.5	98.7	99.9	754	99.5	98.7	99.9	3.691	3.489	3.905
	COM_MMR	PRE	260	260	100	98.6	100	236	90.8	86.6	94.0	0.813	0.749	0.882
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	3.814	3.484	4.176

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**Value**	**LL**	**UL**
anti-PnPS 9V antibody(ECL)(assay cut-off=0.066 µg/ml)	INV_MMR	PRE	750	734	97.9	96.6	98.8	378	50.4	46.8	54.0	0.359	0.336	0.383
		PI(D42)	759	755	99.5	98.7	99.9	748	98.6	97.4	99.3	2.318	2.183	2.461
	COM_MMR	PRE	260	256	98.5	96.1	99.6	126	48.5	42.2	54.7	0.343	0.310	0.378
		PI(D42)	266	266	100	98.6	100	264	99.2	97.3	99.9	2.282	2.065	2.521
anti-PnPS 14 antibody(ECL)(assay cut-off=0.16 µg/ml)	INV_MMR	PRE	750	740	98.7	97.6	99.4	704	93.9	91.9	95.5	1.702	1.589	1.823
		PI(D42)	757	753	99.5	98.7	99.9	752	99.3	98.5	99.8	6.578	6.155	7.029
	COM_MMR	PRE	260	255	98.1	95.6	99.4	249	95.8	92.6	97.9	1.668	1.490	1.867
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	7.053	6.368	7.811
anti-PnPS 18C antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	750	675	90.0	87.6	92.1	307	40.9	37.4	44.5	0.286	0.268	0.304
		PI(D42)	759	755	99.5	98.7	99.9	749	98.7	97.6	99.4	2.102	1.973	2.241
	COM_MMR	PRE	260	230	88.5	83.9	92.1	108	41.5	35.5	47.8	0.274	0.247	0.304
		PI(D42)	265	265	100	98.6	100	262	98.9	96.7	99.8	2.217	1.990	2.470
anti-PnPS 19A antibody(ECL)(assay cut-off=0.199 µg/ml)	INV_MMR	PRE	749	652	87.0	84.4	89.4	475	63.4	59.9	66.9	0.511	0.475	0.550
		PI(D42)	759	755	99.5	98.7	99.9	753	99.2	98.3	99.7	4.731	4.461	5.017
	COM_MMR	PRE	260	224	86.2	81.3	90.1	168	64.6	58.5	70.4	0.475	0.423	0.534
		PI(D42)	265	265	100	98.6	100	265	100	98.6	100	4.821	4.372	5.317
anti-PnPS 19F antibody(ECL)(assay cut-off=0.163 µg/ml)	INV_MMR	PRE	750	724	96.5	95.0	97.7	577	76.9	73.7	79.9	0.654	0.612	0.699
		PI(D42)	759	755	99.5	98.7	99.9	754	99.3	98.5	99.8	4.251	4.013	4.504
	COM_MMR	PRE	260	251	96.5	93.5	98.4	189	72.7	66.8	78.0	0.591	0.533	0.656
		PI(D42)	266	266	100	98.6	100	266	100	98.6	100	4.260	3.872	4.687
anti-PnPS 23F antibody(ECL)(assay cut-off=0.073 µg/ml)	INV_MMR	PRE	728	644	88.5	85.9	90.7	266	36.5	33.0	40.2	0.251	0.231	0.273
		PI(D42)	742	738	99.5	98.6	99.9	730	98.4	97.2	99.2	2.198	2.051	2.355
	COM_MMR	PRE	254	223	87.8	83.1	91.6	91	35.8	29.9	42.1	0.244	0.212	0.281
		PI(D42)	256	255	99.6	97.8	100	251	98.0	95.5	99.4	2.291	2.025	2.592

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

7.1.8. Immune response to HAV in terms of seroresponse rates (Secondary objective 4)

For secondary objective 4, the immunogenicity of HAV with respect to the seroresponse rate for antibodies to HAV was assessed in the Inv_MMR groups and Com_MMR groups at Day 42 in a subset of children enrolled in the US. The results show that the percentages of subjects with antibodies to HAV equal to or above the threshold of 15 mIU/mL were 86.5% and 84.9% of subjects in the Inv_MMR and Com_MMR groups respectively (see Table 40).

Table 40 Vaccine response for Anti-HAV at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset)

			Vaccine response			
					95% CI	
Group	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR	S-	748	664	88.8	86.3	90.9
	S+	35	13	37.1	21.5	55.1
	Total	783	677	86.5	83.9	88.8
COM_MMR	S-	271	236	87.1	82.5	90.8
	S+	14	6	42.9	17.7	71.1
	Total	285	242	84.9	80.2	88.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 15 mIU/mL for anti-HAV antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL for anti-HAV antibody) prior to vaccination
Total = subjects either seropositive or seronegative at pre-vaccination
Vaccine response defined as:
For initially seronegative subjects, antibody concentration ≥ 15 mIU/mL at PI(D42)
For initially seropositive subjects: antibody concentration at PI(D42) ≥ 2 fold the pre-vaccination antibody concentration
N = number of subjects with both pre- and post-vaccination results available
n/% = number/percentage of responders
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

7.2. Analysis by sub-groups

The analyses of immunogenicity were also repeated for subjects in each country, by gender and by geographic ancestry. These results can be found in Table 7.29 through Table 7.35. The immune responses in these categories were generally similar to what has been reported above for the overall groups.

7.3. Immunogenicity summary

Primary analyses of anti-measles, anti-mumps, and anti-rubella antibody responses at Day 42 showed that all 5 co-primary objectives were met.

The consistency of three manufacturing lots of Inv_MMR was demonstrated. For the comparison of Inv_MMR_L1, Inv_MMR_L2 and Inv_MMR_L3:

- For each pair-wise comparison, the two sided 95% CI for the difference in lots seroresponse rates was within the [-5%; 5%] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 1.
- For each pair-wise comparison, the two sided 95% CI for the adjusted GMC ratio was within the [0.67; 1.5] margin for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 2.

The co-primary objectives of the non-inferiority of Inv_MMR compared to Com_MMR were met.

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 3.
- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 4.

The co-primary objective of acceptable immune response for Inv_MMR in terms of seroresponse rates to anti-measles, anti-mumps and anti-rubella antibodies was met.

- The lower limit of the two sided 95% CI for the seroresponse rate for the Inv_MMR lots was ≥90% for anti-measles, anti-mumps and anti-rubella antibodies, thus meeting co-primary objective 5.

With respect to secondary objectives, analyses of anti-VZV, anti-HAV and anti-PS responses at Day 42 showed that all secondary objectives related to the non-inferiority of Inv_MMR compared to Com_MMR in terms of co-administered vaccines were met.

For the comparison of Inv_MMR to Com_MMR:

- The lower limit of the two sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies, and
- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies, thus meeting secondary objective 1.
- The lower limit of the two sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV, thus meeting secondary objective 2.

- The lower limit of the two sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to each of the 13 *S. pneumoniae* serotypes, thus meeting secondary objective 3.

Assessment of the immunogenicity of *Havrix* with respect to the seroresponse rates of antibodies to HAV showed a comparable vaccine response in both the Inv_MMR and Com_MMR groups (secondary objective 4).

8. SAFETY RESULTS

The analysis of safety was performed on the TVC. See Section 5.10.5 for the definition of the cohorts identified for analyses. A second analysis was not performed on the ATP cohort to complement the TVC analysis because less than 5% of subjects were eliminated from each group in the ATP cohort for the analysis of safety.

8.1. Total vaccinated cohort analysis

A total of 1239 subjects in the Inv_MMR_1 group, 1232 subjects in the Inv_MMR_2 group, 1243 subjects in the Inv_MMR_3 group and 1289 subjects in the Com_MMR group received study vaccine. At least 99.6% of the subjects in the 4 groups received HAV and VV but only about 50% of subjects received PCV-13 concomitantly, as the latter was administered only to subjects enrolled in US study sites (Table 41).

Compliance was ≥ 95.4% in returning symptom sheets for collection of local and general solicited AEs with regard to administered doses (Table 42).

Table 41 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort)

	INV_MMR_1 HAVRIX N = 1239		INV_MMR_1 MEMURU N = 1239		INV_MMR_1 PREVENAR 13 N = 1239		INV_MMR_1 VARIVAX VACCINE N = 1239		INV_MMR_2 HAVRIX N = 1234		INV_MMR_2 MEMURU N = 1234		INV_MMR_2 PREVENAR 13 N = 1234		INV_MMR_2 VARIVAX VACCINE N = 1234		INV_MMR_3 HAVRIX N = 1246		INV_MMR_3 MEMURU N = 1246	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	1	0.1	0	0.0	621	50.1	0	0.0	2	0.2	2	0.2	622	50.4	2	0.2	5	0.4	3	0.2
1	1238	99.9	1239	100	618	49.9	1239	100	1232	99.8	1232	99.8	612	49.6	1232	99.8	1241	99.6	1243	99.8

	INV_MMR_3 PREVENAR 13 N = 1246		INV_MMR_3 VARIVAX VACCINE N = 1246		INV_MMR HAVRIX N = 3719		INV_MMR MEMURU N = 3719		INV_MMR PREVENAR 13 N = 3719		INV_MMR VARIVAX VACCINE N = 3719		COM_MMR HAVRIX N = 1291		COM_MMR MMR II VACCINE N = 1291		COM_MMR PREVENAR 13 N = 1291		COM_MMR VARIVAX VACCINE N = 1291	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	629	50.5	4	0.3	8	0.2	5	0.1	1872	50.3	6	0.2	2	0.2	2	0.2	637	49.3	2	0.2
1	617	49.5	1242	99.7	3711	99.8	3714	99.9	1847	49.7	3713	99.8	1289	99.8	1289	99.8	654	50.7	1289	99.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose
Note: A second dose of HAV or VV was provided by GSK in Finland, Estonia and Mexico at the end of the study or shortly after the study.

Table 42 Compliance in returning symptom information (Total vaccinated cohort)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	1239	5	1190	96.0	1186	95.7
INV_MMR_2	1232	5	1176	95.5	1175	95.4
INV_MMR_3	1243	6	1200	96.5	1194	96.1
INV_MMR	3714	16	3566	96.0	3555	95.7
COM_MMR	1289	5	1243	96.4	1242	96.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

8.1.1. Overall incidence of adverse events (Amended: 18-September-2018)

The incidence and nature of solicited and unsolicited symptoms reported by subjects from Day 0 to Day 42 following the study vaccination is presented in Table 43.

Overall, at least one solicited or unsolicited symptom was reported by ***87.1***% of subjects in the Inv_MMR group and by ***88.3***% in the Com_MMR group.

General symptoms were reported by ***84.8***% of subjects in Inv_MMR and ***86.1***% in Com_MMR groups. Local symptoms were reported by 40.2% and 41.9% of subjects in the Inv_MMR and Com_MMR groups, respectively.

Table 43 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort) (Amended: 18-September-2018)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	1239	***1090***	***88.0***	***86.0***	***89.7***	1239	***1060***	***85.6***	***83.5***	***87.5***	1239	513	41.4	38.6	44.2
INV_MMR_2	1232	***1054***	***85.6***	***83.5***	***87.5***	1232	***1030***	***83.6***	***81.4***	***85.6***	1232	487	39.5	36.8	42.3
INV_MMR_3	1243	***1090***	***87.7***	***85.7***	***89.5***	1243	***1058***	***85.1***	***83.0***	***87.1***	1243	493	39.7	36.9	42.4
INV_MMR	3714	***3234***	***87.1***	***86.0***	***88.1***	3714	***3148***	***84.8***	***83.6***	***85.9***	3714	1493	40.2	38.6	41.8
COM_MMR	1289	***1138***	***88.3***	***86.4***	***90.0***	1289	***1110***	***86.1***	***84.1***	***88.0***	1289	540	41.9	39.2	44.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.1.2. Solicited local adverse events

The percentages of subjects reporting solicited local symptoms within 4 days post-vaccination are presented in Table 44.

The incidences of solicited local symptoms were comparable among the groups. The most frequently reported solicited local symptoms post vaccination in the Inv_MMR and Com_MMR groups were pain and redness. Overall, 25.9% of subjects in the Inv_MMR group reported pain compared to 28.1% in the Com_MMR group, and 24.5% of the Inv_MMR group reported redness compared to the 25.2% of subjects in the Com_MMR group.

Redness >20 mm was reported in 0.4% of subjects in the Inv_MMR group, and 0.6% in the Com_MMR group, while pain (grade 3) was experienced by 0.7% and 1.0% of subjects in the Inv_MMR and Com_MMR groups, respectively. In addition, medical advice for pain and redness was sought by up to 0.2% of subjects in the Inv_MMR group and Com_MMR group.

Table 44 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	1186	331	27.9	25.4	30.6	1175	315	26.8	24.3	29.4	1194	273	22.9	20.5	25.4	3555	919	25.9	24.4	27.3	1242	349	28.1	25.6	30.7
	Grade 2 or 3	1186	76	6.4	5.1	8.0	1175	71	6.0	4.7	7.6	1194	73	6.1	4.8	7.6	3555	220	6.2	5.4	7.0	1242	89	7.2	5.8	8.7
	Grade 3	1186	6	0.5	0.2	1.1	1175	9	0.8	0.4	1.4	1194	9	0.8	0.3	1.4	3555	24	0.7	0.4	1.0	1242	12	1.0	0.5	1.7
	Medical advice	1186	1	0.1	0.0	0.5	1175	0	0.0	0.0	0.3	1194	1	0.1	0.0	0.5	3555	2	0.1	0.0	0.2	1242	2	0.2	0.0	0.6
Redness (mm)	All	1186	296	25.0	22.5	27.5	1175	273	23.2	20.8	25.8	1194	301	25.2	22.8	27.8	3555	870	24.5	23.1	25.9	1242	313	25.2	22.8	27.7
	>5	1186	46	3.9	2.9	5.1	1175	45	3.8	2.8	5.1	1194	49	4.1	3.1	5.4	3555	140	3.9	3.3	4.6	1242	41	3.3	2.4	4.5
	>20	1186	6	0.5	0.2	1.1	1175	2	0.2	0.0	0.6	1194	6	0.5	0.2	1.1	3555	14	0.4	0.2	0.7	1242	8	0.6	0.3	1.3
	Medical advice	1186	2	0.2	0.0	0.6	1175	1	0.1	0.0	0.5	1194	0	0.0	0.0	0.3	3555	3	0.1	0.0	0.2	1242	0	0.0	0.0	0.3
Swelling (mm)	All	1186	116	9.8	8.1	11.6	1175	99	8.4	6.9	10.2	1194	103	8.6	7.1	10.4	3555	318	8.9	8.0	9.9	1242	133	10.7	9.0	12.6
	>5	1186	16	1.3	0.8	2.2	1175	19	1.6	1.0	2.5	1194	19	1.6	1.0	2.5	3555	54	1.5	1.1	2.0	1242	25	2.0	1.3	3.0
	>20	1186	1	0.1	0.0	0.5	1175	5	0.4	0.1	1.0	1194	6	0.5	0.2	1.1	3555	12	0.3	0.2	0.6	1242	5	0.4	0.1	0.9
	Medical advice	1186	1	0.1	0.0	0.5	1175	0	0.0	0.0	0.3	1194	0	0.0	0.0	0.3	3555	1	0.0	0.0	0.2	1242	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

8.1.3. Solicited general adverse events

The percentages of subjects reporting solicited general symptoms within 15 days post-vaccination only are presented in Table 45.

Overall, the incidences of solicited general symptoms were similar between the groups. The most commonly reported general symptom post vaccination was irritability or fussiness, reported in 63.3% in the Inv_MMR group compared to 65.9% in Com_MMR group.

Drowsiness (44.9% and 47.1%) and loss of appetite (45.1% and 44.1%) were the next most commonly reported general symptoms in the Inv_MMR and Com_MMR groups, respectively.

Severe irritability or fussiness (grade 3) was reported in up to 4.9% of subjects in the Inv_MMR and Com_MMR groups. Grade 3 drowsiness and loss of appetite occurred in up to 2.5% of subjects in the Inv_MMR and Com_MMR groups, with overall medical advice being sought by a maximum of 3.0 and 3.4% of subjects in the Inv_MMR and Com_MMR groups, respectively for any solicited general symptom.

Table 45 Incidence of solicited general symptoms reported during the 15-day (Days 0-14) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	1190	533	44.8	41.9	47.7	1176	535	45.5	42.6	48.4	1200	533	44.4	41.6	47.3	3566	1601	44.9	43.3	46.5	1243	586	47.1	44.3	50.0
	Grade 2 or 3	1190	161	13.5	11.6	15.6	1176	181	15.4	13.4	17.6	1200	169	14.1	12.2	16.2	3566	511	14.3	13.2	15.5	1243	175	14.1	12.2	16.1
	Grade 3	1190	23	1.9	1.2	2.9	1176	39	3.3	2.4	4.5	1200	23	1.9	1.2	2.9	3566	85	2.4	1.9	2.9	1243	22	1.8	1.1	2.7
	Medical advice	1190	19	1.6	1.0	2.5	1176	15	1.3	0.7	2.1	1200	23	1.9	1.2	2.9	3566	57	1.6	1.2	2.1	1243	17	1.4	0.8	2.2
Irritability / fussiness	All	1190	764	64.2	61.4	66.9	1176	729	62.0	59.1	64.8	1200	765	63.8	61.0	66.5	3566	2258	63.3	61.7	64.9	1243	819	65.9	63.2	68.5
	Grade 2 or 3	1190	326	27.4	24.9	30.0	1176	324	27.6	25.0	30.2	1200	338	28.2	25.6	30.8	3566	988	27.7	26.2	29.2	1243	371	29.8	27.3	32.5
	Grade 3	1190	56	4.7	3.6	6.1	1176	63	5.4	4.1	6.8	1200	57	4.8	3.6	6.1	3566	176	4.9	4.2	5.7	1243	58	4.7	3.6	6.0
	Medical advice	1190	35	2.9	2.1	4.1	1176	32	2.7	1.9	3.8	1200	40	3.3	2.4	4.5	3566	107	3.0	2.5	3.6	1243	42	3.4	2.4	4.5
Loss of appetite	All	1190	546	45.9	43.0	48.8	1176	536	45.6	42.7	48.5	1200	526	43.8	41.0	46.7	3566	1608	45.1	43.4	46.7	1243	548	44.1	41.3	46.9
	Grade 2 or 3	1190	164	13.8	11.9	15.9	1176	168	14.3	12.3	16.4	1200	146	12.2	10.4	14.2	3566	478	13.4	12.3	14.6	1243	164	13.2	11.4	15.2
	Grade 3	1190	24	2.0	1.3	3.0	1176	29	2.5	1.7	3.5	1200	19	1.6	1.0	2.5	3566	72	2.0	1.6	2.5	1243	31	2.5	1.7	3.5
	Medical advice	1190	27	2.3	1.5	3.3	1176	22	1.9	1.2	2.8	1200	33	2.8	1.9	3.8	3566	82	2.3	1.8	2.8	1243	24	1.9	1.2	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

The percentages of subjects reporting fever (temperature ≥38.0°C/100.4°F) during the period from Day 5 to Day 12 post vaccination are given in Table 46.

In both the Inv_MMR and Com_MMR groups, up to 24.3% of subjects reported fever post dose. Medical advice for fever was sought by 4.6% of subjects in the Inv_MMR group and 4.4% in Com_MMR group.

Incidences of grade 3 fever (temperature >39.5°C) were reported in 1.4% and 1.1% of subjects in the Inv_MMR and Com_MMR groups, respectively.

The percentages of subjects reporting grade 3 fever (temperature >39.5°C), that was considered related to the study vaccination, were 1.0% and 0.7% of subjects in the Inv_MMR and Com_MMR groups, respectively.

The daily prevalence of any fever and grade 3 fever between Day 0 and Day 42 after vaccination are represented graphically in Figure 8.2 and Figure 8.3, respectively. As seen in the graphs, the peak prevalence of fever was observed approximately from Day 5 to Day 12 after vaccination, with the sharpest peak from Day 8 to Day 10.

Percentages of subjects reporting fever in the 43 days post-vaccination period are given in Table 8.44. Occurrences of fever ≥38.0°C/100.4°F in the 43-day post-vaccination period were reported by 34.7% and 33.1% of subjects in the Inv_MMR and Com_MMR groups, respectively. Occurrences of fever ≥39.5°C in the 43-day post-vaccination period were reported by 2.9% and 2.6% of subjects in the Inv_MMR and Com_MMR groups, respectively.

Table 46 Incidence of fever reported during the day 5 to day 12 post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1190	281	23.6	21.2	26.1	1176	287	24.4	22.0	27.0	1200	297	24.8	22.3	27.3	3566	865	24.3	22.9	25.7	1243	284	22.8	20.5	25.3
	≥38	1190	226	19.0	16.8	21.3	1176	242	20.6	18.3	23.0	1200	236	19.7	17.5	22.0	3566	704	19.7	18.4	21.1	1243	226	18.2	16.1	20.4
	>38.5	1190	103	8.7	7.1	10.4	1176	116	9.9	8.2	11.7	1200	114	9.5	7.9	11.3	3566	333	9.3	8.4	10.3	1243	103	8.3	6.8	10.0
	>39.0	1190	44	3.7	2.7	4.9	1176	47	4.0	3.0	5.3	1200	48	4.0	3.0	5.3	3566	139	3.9	3.3	4.6	1243	39	3.1	2.2	4.3
	>39.5	1190	16	1.3	0.8	2.2	1176	16	1.4	0.8	2.2	1200	17	1.4	0.8	2.3	3566	49	1.4	1.0	1.8	1243	14	1.1	0.6	1.9
	>40.0	1190	2	0.2	0.0	0.6	1176	6	0.5	0.2	1.1	1200	4	0.3	0.1	0.9	3566	12	0.3	0.2	0.6	1243	5	0.4	0.1	0.9
	≥38 Related	1190	164	13.8	11.9	15.9	1176	167	14.2	12.3	16.3	1200	165	13.8	11.9	15.8	3566	496	13.9	12.8	15.1	1243	159	12.8	11.0	14.8
	>38.5 Related	1190	71	6.0	4.7	7.5	1176	78	6.6	5.3	8.2	1200	87	7.3	5.8	8.9	3566	236	6.6	5.8	7.5	1243	73	5.9	4.6	7.3
	>39.0 Related	1190	29	2.4	1.6	3.5	1176	28	2.4	1.6	3.4	1200	37	3.1	2.2	4.2	3566	94	2.6	2.1	3.2	1243	23	1.9	1.2	2.8
	>39.5 Related	1190	11	0.9	0.5	1.6	1176	9	0.8	0.4	1.4	1200	14	1.2	0.6	1.9	3566	34	1.0	0.7	1.3	1243	9	0.7	0.3	1.4
	>40.0 Related	1190	1	0.1	0.0	0.5	1176	3	0.3	0.1	0.7	1200	4	0.3	0.1	0.9	3566	8	0.2	0.1	0.4	1243	4	0.3	0.1	0.8
	Medical advice	1190	49	4.1	3.1	5.4	1176	53	4.5	3.4	5.9	1200	62	5.2	4.0	6.6	3566	164	4.6	3.9	5.3	1243	55	4.4	3.4	5.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Solicited general symptoms specific to MMR vaccination were also collected from subjects. The percentages of subjects reporting the occurrence of febrile convulsion and parotid gland swelling during the 43-day post-vaccination period are presented in Table 47.

A total of 10 subjects (0.3%) in the Inv_MMR group and 3 (0.2%) in the Com_MMR group reported febrile convulsions within the 43-day reporting period post-vaccination. Nine out of 10 in the Inv_MMR group and 1 out of 3 in the Com_MMR group sought medical advice. Four of the 10 events in the Inv_MMR group and 2 of the 3 events in the Com_MMR group were considered related to vaccination.

No subject reported parotid gland swelling in any of the groups.

Table 47 Incidence of MMR specific solicited general symptoms reported during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**N**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	1190	4	0.3	0.1	0.9	1176	1	0.1	0.0	0.5	1200	5	0.4	0.1	1.0	3566	10	0.3	0.1	0.5	1243	3	0.2	0.0	0.7
	Grade 2 or 3	1190	3	0.3	0.1	0.7	1176	1	0.1	0.0	0.5	1200	3	0.3	0.1	0.7	3566	7	0.2	0.1	0.4	1243	1	0.1	0.0	0.4
	Grade 3	1190	2	0.2	0.0	0.6	1176	0	0.0	0.0	0.3	1200	2	0.2	0.0	0.6	3566	4	0.1	0.0	0.3	1243	0	0.0	0.0	0.3
	Related	1190	1	0.1	0.0	0.5	1176	1	0.1	0.0	0.5	1200	2	0.2	0.0	0.6	3566	4	0.1	0.0	0.3	1243	2	0.2	0.0	0.6
	Medical advice	1190	4	0.3	0.1	0.9	1176	1	0.1	0.0	0.5	1200	4	0.3	0.1	0.9	3566	9	0.3	0.1	0.5	1243	1	0.1	0.0	0.4
Parotid gland	All	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Grade 2 or 3	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Grade 3	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Related	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3
	Medical advice	1190	0	0.0	0.0	0.3	1176	0	0.0	0.0	0.3	1200	0	0.0	0.0	0.3	3566	0	0.0	0.0	0.1	1243	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

The percentages of subjects with any incidence of rash post vaccination, regardless of whether localized or generalized, were similar among the groups: 29.2% in Inv_MMR and 30.4% in Com_MMR groups. Fever along with rash was reported in up to 9.7% of subjects across the Inv_MMR and Com_MMR groups. Measles/rubella-like rash was seen in 6.6% of the Inv_MMR and 6.2% in Com_MMR groups (Table 48).

Medical advice for any rash post vaccination was sought by 12.5% and 13.2% of subjects in the Inv_MMR and Com_MMR groups, respectively, and a maximum of 13.7% of subjects had a rash considered by the investigator to be related to the study vaccination across the Inv_MMR and Com_MMR groups. A severe (grade 3) rash was reported in up to 3.0% of subjects across the Inv_MMR and Com_MMR groups.

Table 48 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95% CI					95% CI					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	1190	352	29.6	27.0	32.3	1176	331	28.1	25.6	30.8	1200	360	30.0	27.4	32.7	3566	1043	29.2	27.8	30.8	1243	378	30.4	27.9	33.1
	With fever	1190	106	8.9	7.4	10.7	1176	123	10.5	8.8	12.4	1200	118	9.8	8.2	11.7	3566	347	9.7	8.8	10.8	1243	104	8.4	6.9	10.1
	Varicella like	1190	87	7.3	5.9	8.9	1176	78	6.6	5.3	8.2	1200	85	7.1	5.7	8.7	3566	250	7.0	6.2	7.9	1243	85	6.8	5.5	8.4
	Measles/Rubella like	1190	71	6.0	4.7	7.5	1176	88	7.5	6.0	9.1	1200	76	6.3	5.0	7.9	3566	235	6.6	5.8	7.5	1243	77	6.2	4.9	7.7
	Grade 3	1190	33	2.8	1.9	3.9	1176	37	3.1	2.2	4.3	1200	36	3.0	2.1	4.1	3566	106	3.0	2.4	3.6	1243	25	2.0	1.3	3.0
	Related	1190	153	12.9	11.0	14.9	1176	165	14.0	12.1	16.2	1200	171	14.3	12.3	16.4	3566	489	13.7	12.6	14.9	1243	162	13.0	11.2	15.0
	Med adv	1190	160	13.4	11.6	15.5	1176	136	11.6	9.8	13.5	1200	150	12.5	10.7	14.5	3566	446	12.5	11.4	13.6	1243	164	13.2	11.4	15.2
Localized	Any	1190	230	19.3	17.1	21.7	1176	224	19.0	16.8	21.4	1200	251	20.9	18.7	23.3	3566	705	19.8	18.5	21.1	1243	266	21.4	19.2	23.8
	Administration site	1190	10	0.8	0.4	1.5	1176	16	1.4	0.8	2.2	1200	12	1.0	0.5	1.7	3566	38	1.1	0.8	1.5	1243	16	1.3	0.7	2.1
	Other site	1190	225	18.9	16.7	21.3	1176	213	18.1	16.0	20.4	1200	242	20.2	17.9	22.6	3566	680	19.1	17.8	20.4	1243	252	20.3	18.1	22.6
	With fever	1190	48	4.0	3.0	5.3	1176	67	5.7	4.4	7.2	1200	67	5.6	4.4	7.0	3566	182	5.1	4.4	5.9	1243	54	4.3	3.3	5.6
	Varicella like	1190	68	5.7	4.5	7.2	1176	57	4.8	3.7	6.2	1200	55	4.6	3.5	5.9	3566	180	5.0	4.4	5.8	1243	61	4.9	3.8	6.3
	Measles/Rubella like	1190	25	2.1	1.4	3.1	1176	34	2.9	2.0	4.0	1200	34	2.8	2.0	3.9	3566	93	2.6	2.1	3.2	1243	35	2.8	2.0	3.9
	Grade 3	1190	6	0.5	0.2	1.1	1176	10	0.9	0.4	1.6	1200	9	0.8	0.3	1.4	3566	25	0.7	0.5	1.0	1243	5	0.4	0.1	0.9
	Related	1190	87	7.3	5.9	8.9	1176	101	8.6	7.1	10.3	1200	101	8.4	6.9	10.1	3566	289	8.1	7.2	9.1	1243	103	8.3	6.8	10.0
	Med adv	1190	84	7.1	5.7	8.7	1176	77	6.5	5.2	8.1	1200	80	6.7	5.3	8.2	3566	241	6.8	6.0	7.6	1243	95	7.6	6.2	9.3
Generalized	Any	1190	143	12.0	10.2	14.0	1176	138	11.7	10.0	13.7	1200	133	11.1	9.4	13.0	3566	414	11.6	10.6	12.7	1243	143	11.5	9.8	13.4
	With fever	1190	66	5.5	4.3	7.0	1176	65	5.5	4.3	7.0	1200	55	4.6	3.5	5.9	3566	186	5.2	4.5	6.0	1243	55	4.4	3.4	5.7
	Varicella like	1190	20	1.7	1.0	2.6	1176	23	2.0	1.2	2.9	1200	31	2.6	1.8	3.7	3566	74	2.1	1.6	2.6	1243	25	2.0	1.3	3.0
	Measles/Rubella like	1190	47	3.9	2.9	5.2	1176	55	4.7	3.5	6.0	1200	44	3.7	2.7	4.9	3566	146	4.1	3.5	4.8	1243	42	3.4	2.5	4.5
	Grade 3	1190	29	2.4	1.6	3.5	1176	27	2.3	1.5	3.3	1200	27	2.3	1.5	3.3	3566	83	2.3	1.9	2.9	1243	20	1.6	1.0	2.5
	Related	1190	74	6.2	4.9	7.7	1176	74	6.3	5.0	7.8	1200	75	6.3	5.0	7.8	3566	223	6.3	5.5	7.1	1243	69	5.6	4.3	7.0
	Med adv	1190	83	7.0	5.6	8.6	1176	68	5.8	4.5	7.3	1200	76	6.3	5.0	7.9	3566	227	6.4	5.6	7.2	1243	80	6.4	5.1	8.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.1.4. Unsolicited adverse events

The percentages of subjects with the most frequently occurring unsolicited AEs reported during the 43-day reporting period post-vaccination are listed in Table 49. All unsolicited AEs reported by subjects in this period in each system organ class by preferred term are given in Table 8.81.

Overall, 50.0% of subjects in the Inv_MMR group and 47.9% in the Com_MMR group reported at least one unsolicited AE. The most commonly occurring MedDRA system organ class of AEs was 'infections and infestations', followed by 'gastrointestinal disorders' (Table 49). The most common AE by MedDRA preferred term was upper respiratory tract infection, reported in 9.5% of subjects in the Inv_MMR and 9.5% in Com_MMR groups, respectively (Table 49).

Table 49 Number (%) of subjects with adverse events during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

System Organ Class	Most frequent adverse events - On-Therapy (occurring within day 0-42 following vaccination)	INV_MMR_1 N = 1239	INV_MMR_2 N = 1232	INV_MMR_3 N = 1243	INV_MMR N = 3714	COM_MMR N = 1289
	Subjects with any AE(s), n (%)	615 (49.6)	633 (51.4)	609 (49.0)	1857 (50.0)	618 (47.9)
Infections and infestations	Upper respiratory tract infection	106 (8.6)	124 (10.1)	122 (9.8)	352 (9.5)	122 (9.5)
Gastrointestinal disorders	Teething	91 (7.3)	92 (7.5)	77 (6.2)	260 (7.0)	95 (7.4)
Infections and infestations	Otitis media	80 (6.5)	75 (6.1)	63 (5.1)	218 (5.9)	87 (6.7)
Infections and infestations	Nasopharyngitis	74 (6.0)	75 (6.1)	74 (6.0)	223 (6.0)	65 (5.0)
Gastrointestinal disorders	Diarrhea	64 (5.2)	58 (4.7)	49 (3.9)	171 (4.6)	64 (5.0)

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

8.2. Serious adverse events

All SAEs were collected throughout the entire study period (Days 0 to 180). The listing of SAEs for the TVC can be found in Table 8.136, and the SAE clinical narratives are in Section 12.

8.2.1. Fatal events

There were no fatal events reported.

8.2.2. Non-fatal events

The number and percentages of subjects that experienced an SAE during the study period are given in Table 50.

A total of 102 subjects reported one or more SAEs in this study. A total of 98 SAEs were reported in 77 subjects (2.1%) in the Inv_MMR group and 40 were reported in 25 subjects (1.9%) in the Com_MMR group.

Two of these SAEs in the Inv_MMR group were considered by the investigator to be related to the study vaccination. One subject in the Inv_MMR_2 group had gastroenteritis, occurring on the day of vaccination, for a duration of 14 days, and one subject in the Inv_MMR_3 group had febrile convulsion on Day 9 post dose lasting one day.

The most frequently occurring SAE during the study period was bronchitis reported by 8 subjects (0.2%) in the Inv_MMR group and by 2 subjects (0.2%) in the Com_MMR group. Overall, the safety results were consistent between the 3 lots of Inv_MMR used in this study

Table 50 Number (%) of subjects with serious adverse events including number of events reported during the study period (Total vaccinated cohort)

			INV_MMR_1 N = 1239			INV_MMR_2 N = 1232			INV_MMR_3 N = 1243			INV_MMR N = 3714			COM_MMR N = 1289		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**
SAE	At least one symptom		26	21	1.7	34	28	2.3	38	28	2.3	98	77	2.1	40	25	1.9
	Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	2	2	0.2
	Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	1	1	0.1
		Enterocolitis (10014893)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Gastritis (10017853)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
	General disorders and administration site conditions (10018065)	Pyrexia (10037660)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
	Immune system disorders (10021428)	Milk allergy (10027633)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
	Infections and infestations (10021881)	Abscess (10000269)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Bronchiolitis (10006448)	1	1	0.1	2	2	0.2	1	1	0.1	4	4	0.1	2	2	0.2
		Bronchitis (10006451)	3	3	0.2	2	2	0.2	3	3	0.2	8	8	0.2	3	2	0.2
		Cellulitis (10007882)	1	1	0.1	0	0	0.0	2	2	0.2	3	3	0.1	0	0	0.0
		Conjunctivitis (10010741)	1	1	0.1	0	0	0.0	1	1	0.1	2	2	0.1	1	1	0.1
		Croup infectious (10011416)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Escherichia urinary tract infection (10052238)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Gastroenteritis (10017888)	1	1	0.1	1	1	0.1	2	2	0.2	4	4	0.1	2	2	0.2
		Gastroenteritis adenovirus (10017889)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	1	1	0.1
		Gastroenteritis rotavirus (10017913)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	1	1	0.1
		Gastroenteritis viral (10017918)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Herpangina (10019936)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Laryngitis (10023874)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Mycoplasma infection (10061300)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Nasopharyngitis (10028810)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Neutropenic infection (10059482)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
		Otitis media (10033078)	0	0	0.0	0	0	0.0	4	4	0.3	4	4	0.1	2	2	0.2
		Otitis media acute (10033079)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
		Pharyngitis (10034835)	1	1	0.1	1	1	0.1	0	0	0.0	2	2	0.1	0	0	0.0
		Pneumococcal sepsis (10054047)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Pneumonia (10035664)	2	2	0.2	1	1	0.1	3	3	0.2	6	6	0.2	0	0	0.0

			INV_MMR_1 N = 1239			INV_MMR_2 N = 1232			INV_MMR_3 N = 1243			INV_MMR N = 3714			COM_MMR N = 1289		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**
		Pneumonia bacterial (10060946)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Pneumonia respiratory syncytial viral (10035732)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	1	1	0.1
		Pneumonia viral (10035737)	1	1	0.1	2	2	0.2	1	1	0.1	4	4	0.1	0	0	0.0
		Pyelonephritis acute (10037597)	1	1	0.1	0	0	0.0	1	1	0.1	2	2	0.1	0	0	0.0
		Respiratory syncytial virus bronchiolitis (10038718)	1	1	0.1	1	1	0.1	1	1	0.1	3	3	0.1	1	1	0.1
		Respiratory tract infection viral (10062106)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Rotavirus infection (10067470)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Subcutaneous abscess (10042343)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Tonsillitis (10044008)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	1	1	0.1
		Upper respiratory tract infection (10046306)	1	1	0.1	1	1	0.1	0	0	0.0	2	2	0.1	0	0	0.0
		Viral infection (10047461)	0	0	0.0	0	0	0.0	2	2	0.2	2	2	0.1	3	3	0.2
		Viral pharyngitis (10047473)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Viral upper respiratory tract infection (10047482)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
	Injury, poisoning and procedural complications (10022117)	Burns second degree (10006802)	0	0	0.0	1	1	0.1	1	1	0.1	2	2	0.1	0	0	0.0
		Concussion (10010254)	1	1	0.1	1	1	0.1	0	0	0.0	2	2	0.1	0	0	0.0
		Femur fracture (10016454)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Foot fracture (10016970)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
		Head injury (10019196)	2	2	0.2	0	0	0.0	0	0	0.0	2	2	0.1	0	0	0.0
	Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0	0.0	2	2	0.2	3	3	0.2	5	5	0.1	3	3	0.2
		Hypoglycaemia (10020993)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	1	1	0.1
		Type 1 diabetes mellitus (10067584)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
	Nervous system disorders (10029205)	Epilepsy (10015037)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0
		Febrile convulsion (10016284)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	5	5	0.4
		Loss of consciousness (10024855)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
		Seizure (10039906)	0	0	0.0	0	0	0.0	2	2	0.2	2	2	0.1	0	0	0.0
	Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	2	0.2	2	2	0.2	0	0	0.0	4	4	0.1	2	2	0.2
		Bronchial hyperreactivity (10066091)	0	0	0.0	3	3	0.2	0	0	0.0	3	3	0.1	3	3	0.2
		Hypoxia (10021143)	1	1	0.1	0	0	0.0	0	0	0.0	1	1	0.0	0	0	0.0

			INV_MMR_1 N = 1239			INV_MMR_2 N = 1232			INV_MMR_3 N = 1243			INV_MMR N = 3714			COM_MMR N = 1289		
Type of Event	**Primary System Organ Class**	**Preferred Term (CODE)**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**	**n***	**n**	**%**
	Skin and subcutaneous tissue disorders (10040785)	Urticaria (10046735)	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	2	2	0.2
	Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
Related SAE	At least one symptom		0	0	0.0	1	1	0.1	1	1	0.1	2	2	0.1	0	0	0.0
	Infections and infestations (10021881)	Gastroenteritis (10017888)	0	0	0.0	1	1	0.1	0	0	0.0	1	1	0.0	0	0	0.0
	Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0	0.0	0	0	0.0	1	1	0.1	1	1	0.0	0	0	0.0
Fatal SAE	At least one symptom		0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0
Related fatal SAE	At least one symptom		0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n* = number of events reported
n/% = number/percentage of subjects reporting the symptom at least once

8.3. Adverse events leading to premature discontinuation of study

Two AEs occurred that led to subjects prematurely discontinuing the study (Table 6.2). Both subjects belonged to the Inv_MMR_1 group, and their cases were reported as non-serious adverse events.

8.4. Other significant adverse events

8.4.1. New Onset of Chronic Disease

The percentages of subjects reporting NOCDs during the entire study period are given in Table 51. At least one NOCD was reported in 3.4% of subjects in the Inv_MMR group and 3.7% in the Com_MMR group. The most frequent NOCD reported in 33 subjects was dermatitis atopic (0.7% in Inv_MMR and 0.5% in Com_MMR).

Table 51 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		40	3.2	2.3	4.4	39	3.2	2.3	4.3	49	3.9	2.9	5.2	128	3.4	2.9	4.1	48	3.7	2.8	4.9
Blood and lymphatic system disorders (10005329)	Thrombocytopenia (10043554)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Coeliac disease (10009839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Immune system disorders (10021428)	Allergy to animal (10001742)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	6	0.5	0.2	1.0	9	0.2	0.1	0.5	6	0.5	0.2	1.0
	Food allergy (10016946)	5	0.4	0.1	0.9	3	0.2	0.1	0.7	8	0.6	0.3	1.3	16	0.4	0.2	0.7	7	0.5	0.2	1.1
	Hypersensitivity (10020751)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Milk allergy (10027633)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Multiple allergies (10028164)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Seasonal allergy (10048908)	2	0.2	0.0	0.6	5	0.4	0.1	0.9	0	0.0	0.0	0.3	7	0.2	0.1	0.4	2	0.2	0.0	0.6
Infections and infestations (10021881)	Viral rash (10047476)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Metabolism and nutrition disorders (10027433)	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	3	0.2	0.0	0.7	4	0.3	0.1	0.8	7	0.6	0.2	1.2	14	0.4	0.2	0.6	8	0.6	0.3	1.2
	Bronchial hyperreactivity (10066091)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinitis allergic (10039085)	10	0.8	0.4	1.5	5	0.4	0.1	0.9	4	0.3	0.1	0.8	19	0.5	0.3	0.8	7	0.5	0.2	1.1
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	3	0.2	0.0	0.7	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Dermatitis atopic (10012438)	5	0.4	0.1	0.9	10	0.8	0.4	1.5	11	0.9	0.4	1.6	26	0.7	0.5	1.0	7	0.5	0.2	1.1
	Dermatitis contact (10012442)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug eruption (10013687)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eczema (10014184)	4	0.3	0.1	0.8	5	0.4	0.1	0.9	7	0.6	0.2	1.2	16	0.4	0.2	0.7	10	0.8	0.4	1.4
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Henoch-schonlein purpura (10019617)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urticaria (10046735)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled

COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

8.4.2. Emergency Room Visit

The percentage of subjects reporting AEs that required an ER visit throughout the study is given in Table 52. Overall, 10.1% in the Inv_MMR and 10.4% in Com_MMR groups experienced an AE that required an ER visit. The most frequent AEs that required an ER visit were otitis media reported in 80 subjects (1.6% in Inv_MMR and 1.5% in Com_MMR); upper respiratory tract infection reported in 60 subjects (1.1% in Inv_MMR and 1.4% in Com_MMR); and pyrexia reported in 45 subjects (0.8% in Inv_MMR and 1.3% in Com_MMR).

Table 52 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		123	9.9	8.3	11.7	116	9.4	7.8	11.2	136	10.9	9.3	12.8	375	10.1	9.1	11.1	134	10.4	8.8	12.2
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
Eye disorders (10015919)	Eyelid oedema (10015993)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Colitis (10009887)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Constipation (10010774)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Diarrhoea (10012735)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	12	0.9	0.5	1.6
	Gastritis (10017853)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Stomatitis (10042128)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Teething (10043183)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	3	0.2	0.0	0.7
	Vomiting (10047700)	7	0.6	0.2	1.2	2	0.2	0.0	0.6	6	0.5	0.2	1.0	15	0.4	0.2	0.7	9	0.7	0.3	1.3
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gait disturbance (10017577)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyrexia (10037660)	15	1.2	0.7	2.0	5	0.4	0.1	0.9	8	0.6	0.3	1.3	28	0.8	0.5	1.1	17	1.3	0.8	2.1
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Food allergy (10016946)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Hypersensitivity (10020751)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.2	0.0	0.7	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Seasonal allergy (10048908)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abscess neck (10053576)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchiolitis (10006448)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	1	0.1	0.0	0.4	9	0.2	0.1	0.5	2	0.2	0.0	0.6
	Bronchitis (10006451)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	6	0.5	0.2	1.0	13	0.4	0.2	0.6	5	0.4	0.1	0.9
	Burn infection (10051548)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Candida nappy rash (10007135)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cellulitis (10007882)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cellulitis orbital (10007918)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Conjunctivitis (10010741)	3	0.2	0.0	0.7	5	0.4	0.1	0.9	6	0.5	0.2	1.0	14	0.4	0.2	0.6	4	0.3	0.1	0.8
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Croup infectious (10011416)	3	0.2	0.0	0.7	12	1.0	0.5	1.7	5	0.4	0.1	0.9	20	0.5	0.3	0.8	8	0.6	0.3	1.2
	Ear infection (10014011)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	2	0.2	0.0	0.6	7	0.2	0.1	0.4	5	0.4	0.1	0.9
	Enterovirus infection (10014909)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Exanthema subitum (10015586)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Fungal skin infection (10017543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis (10017888)	3	0.2	0.0	0.7	5	0.4	0.1	0.9	7	0.6	0.2	1.2	15	0.4	0.2	0.7	9	0.7	0.3	1.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hand-foot-and-mouth disease (10019113)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	1	0.1	0.0	0.4	7	0.2	0.1	0.4	4	0.3	0.1	0.8
	Herpangina (10019936)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Herpes simplex (10019948)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Impetigo (10021531)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Influenza (10022000)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Laryngitis (10023874)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	4	0.3	0.1	0.8	14	0.4	0.2	0.6	3	0.2	0.0	0.7
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	3	0.2	0.0	0.7	6	0.5	0.2	1.1	5	0.4	0.1	0.9	14	0.4	0.2	0.6	3	0.2	0.0	0.7
	Oral herpes (10067152)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Otitis externa (10033072)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	17	1.4	0.8	2.2	23	1.9	1.2	2.8	21	1.7	1.0	2.6	61	1.6	1.3	2.1	19	1.5	0.9	2.3
	Otitis media acute (10033079)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	4	0.3	0.1	0.8	14	0.4	0.2	0.6	5	0.4	0.1	0.9
	Pharyngitis (10034835)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	4	0.3	0.1	0.8	14	0.4	0.2	0.6	4	0.3	0.1	0.8

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngitis streptococcal (10034839)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Pharyngotonsillitis (10049140)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pneumonia (10035664)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	5	0.4	0.1	0.9	11	0.3	0.1	0.5	0	0.0	0.0	0.3
	Pyelonephritis (10037596)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory tract infection (10062352)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Rhinitis (10039083)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Sinusitis (10040753)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Skin candida (10054152)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Streptococcal infection (10061372)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tonsillitis (10044008)	4	0.3	0.1	0.8	1	0.1	0.0	0.5	3	0.2	0.0	0.7	8	0.2	0.1	0.4	4	0.3	0.1	0.8
	Upper respiratory tract infection (10046306)	14	1.1	0.6	1.9	15	1.2	0.7	2.0	13	1.0	0.6	1.8	42	1.1	0.8	1.5	18	1.4	0.8	2.2
	Urinary tract infection (10046571)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral infection (10047461)	1	0.1	0.0	0.4	4	0.3	0.1	0.8	6	0.5	0.2	1.0	11	0.3	0.1	0.5	7	0.5	0.2	1.1
	Viral rash (10047476)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Animal bite (10002515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Arthropod bite (10003399)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	5	0.4	0.1	0.9	9	0.2	0.1	0.5	2	0.2	0.0	0.6
	Arthropod sting (10003402)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical eye injury (10055116)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Concussion (10010254)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Contusion (10050584)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	6	0.5	0.2	1.0
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Craniocerebral injury (10070976)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Eye injury (10061128)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eyelid injury (10069200)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Fall (10016173)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Foreign body in eye (10017012)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Head injury (10019196)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	6	0.5	0.2	1.0	10	0.3	0.1	0.5	2	0.2	0.0	0.6
	Humerus fracture (10020462)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Joint dislocation (10023204)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Laceration (10023572)	7	0.6	0.2	1.2	2	0.2	0.0	0.6	7	0.6	0.2	1.2	16	0.4	0.2	0.7	3	0.2	0.0	0.7
	Limb injury (10061225)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Lip injury (10055082)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Mouth injury (10049294)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Poisoning (10061355)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Wound (10052428)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	3	0.2	0.0	0.7
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pain in extremity (10033425)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Pyogenic granuloma (10037649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Nervous system disorders (10029205)	Febrile convulsion (10016284)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	3	0.2	0.0	0.7	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tremor (10044565)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Breath holding (10006322)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Irritability (10022998)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Renal and urinary disorders (10038359)	Pollakiuria (10036018)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Perineal cyst (10066058)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Aspiration (10003504)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Asthma (10003553)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Bronchospasm (10006482)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.2	0.0	0.7	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Catarrh (10007774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cough (10011224)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	3	0.2	0.0	0.7	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Dyspnoea (10013968)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rhinitis allergic (10039085)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinorrhoea (10039101)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Stridor (10042241)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	2	0.2	0.0	0.6	5	0.1	0.0	0.3	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dermatitis allergic (10012434)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dermatitis contact (10012442)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Miliaria (10027627)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pityriasis (10035110)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash (10037844)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	5	0.4	0.1	0.9	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Rash generalised (10037858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rash scarlatiniform (10037890)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin burning sensation (10054786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Urticaria (10046735)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	4	0.3	0.1	0.8	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Urticaria vesiculosa (10046755)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Vascular disorders (10047065)	Haematoma (10018852)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

8.4.3. Medically Attended Visits

The percentage of subjects reporting AEs that led to a medically attended visit throughout the study period are given in Table 53. A total of 59.4% of subjects in the Inv_MMR group and 60.4% in Com_MMR group had 1 or more symptoms that required medical attention; the most commonly reported AEs with a medically attended visit in both the Inv_MMR and Com_MMR groups were: otitis media (17.0% and 19.2%), upper respiratory tract infection (13.4% and 13.5%), nasopharyngitis (8.4% and 7.6%) and conjunctivitis (6.6% and 7.2%).

Table 53 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		743	60.0	57.2	62.7	736	59.7	56.9	62.5	727	58.5	55.7	61.2	2206	59.4	57.8	61.0	779	60.4	57.7	63.1
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	7	0.6	0.2	1.2	9	0.2	0.1	0.5	3	0.2	0.0	0.7
	Iron deficiency anaemia (10022972)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.8
	Leukocytosis (10024378)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	5	0.4	0.1	0.9
	Leukopenia (10024384)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	4	0.3	0.1	0.8
	Thrombocytopenia (10043554)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Supraventricular extrasystoles (10042602)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Congenital, familial and genetic disorders (10010331)	Ankyloglossia congenital (10049244)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Atrial septal defect (10003664)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cerebral palsy (10008129)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Cleft uvula (10053507)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Congenital cardiovascular anomaly (10061054)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cryptorchism (10011498)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Imperforate hymen (10021529)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Microcephaly (10027534)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Phimosis (10034878)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Supernumerary nipple (10042571)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Talipes (10043101)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Tibial torsion (10064515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Ear and labyrinth disorders (10013993)	Auricular swelling (10003800)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cerumen impaction (10050337)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Conductive deafness (10010280)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Deafness (10011878)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Ear pain (10014020)	13	1.0	0.6	1.8	4	0.3	0.1	0.8	13	1.0	0.6	1.8	30	0.8	0.5	1.2	10	0.8	0.4	1.4
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Excessive cerumen production (10076897)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Middle ear effusion (10062545)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otorrhoea (10033101)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Endocrine disorders (10014698)	Hypothyroidism (10021114)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Eye disorders (10015919)	Astigmatism (10003569)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Blepharitis (10005148)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Conjunctivitis allergic (10010744)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Dacryostenosis acquired (10053990)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Entropion (10061842)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye discharge (10015915)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye swelling (10015967)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eyelid oedema (10015993)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Hypermetropia (10020675)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Lacrimation increased (10023644)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Panophthalmitis (10033683)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pseudostrabismus (10072123)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Scleral haemorrhage (10050508)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Strabismus (10042159)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abdominal distension (10000060)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.2	0.0	0.7	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Abdominal pain upper (10000087)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Anal fissure (10002153)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Anal skin tags (10002172)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Aphthous ulcer (10002959)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Chapped lips (10049047)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chronic gastritis (10008882)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Coeliac disease (10009839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Colitis (10009887)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Constipation (10010774)	11	0.9	0.4	1.6	8	0.6	0.3	1.3	15	1.2	0.7	2.0	34	0.9	0.6	1.3	14	1.1	0.6	1.8
	Dental caries (10012318)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Diarrhoea (10012735)	59	4.8	3.6	6.1	45	3.7	2.7	4.9	51	4.1	3.1	5.4	155	4.2	3.6	4.9	62	4.8	3.7	6.1
	Dyspepsia (10013946)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Dysphagia (10013950)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Enterocolitis (10014893)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastritis (10017853)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastrooesophageal reflux disease (10017885)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	1	0.1	0.0	0.4	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Gingival hypertrophy (10018284)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gingival pain (10018286)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Haematochezia (10018836)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Inguinal hernia (10022016)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Melaena (10027141)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mouth cyst (10028020)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mucous stools (10028140)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Oral disorder (10067621)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Proctitis (10036774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ranula (10037838)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Stomatitis (10042128)	1	0.1	0.0	0.4	13	1.1	0.6	1.8	6	0.5	0.2	1.0	20	0.5	0.3	0.8	2	0.2	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Teething (10043183)	12	1.0	0.5	1.7	17	1.4	0.8	2.2	14	1.1	0.6	1.9	43	1.2	0.8	1.6	14	1.1	0.6	1.8
	Tongue ulceration (10043991)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tooth discolouration (10044032)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Toothache (10044055)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Umbilical hernia (10045458)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Vomiting (10047700)	29	2.3	1.6	3.3	17	1.4	0.8	2.2	20	1.6	1.0	2.5	66	1.8	1.4	2.3	29	2.2	1.5	3.2
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Asthenia (10003549)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Developmental delay (10012559)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Fatigue (10016256)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Feeling hot (10016334)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gait disturbance (10017577)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Gait inability (10017581)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ill-defined disorder (10061520)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza like illness (10022004)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Injection site erythema (10022061)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	0	0.0	0.0	0.3	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Injection site rash (10022094)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site swelling (10053425)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mucosal inflammation (10028116)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain (10033371)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pyrexia (10037660)	55	4.4	3.4	5.7	54	4.4	3.3	5.7	41	3.3	2.4	4.4	150	4.0	3.4	4.7	52	4.0	3.0	5.3
Immune system disorders (10021428)	Allergy to animal (10001742)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Allergy to arthropod bite (10058285)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	5	0.4	0.1	0.9	9	0.2	0.1	0.5	6	0.5	0.2	1.0
	Food allergy (10016946)	6	0.5	0.2	1.1	6	0.5	0.2	1.1	8	0.6	0.3	1.3	20	0.5	0.3	0.8	7	0.5	0.2	1.1
	Hypersensitivity (10020751)	2	0.2	0.0	0.6	5	0.4	0.1	0.9	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Immunisation reaction (10021432)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Milk allergy (10027633)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	2	0.2	0.0	0.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Multiple allergies (10028164)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Seasonal allergy (10048908)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	0	0.0	0.0	0.3	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Selective iga immunodeficiency (10039915)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Abscess limb (10050473)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Abscess neck (10053576)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acarodermatitis (10063409)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Acute sinusitis (10001076)	7	0.6	0.2	1.2	3	0.2	0.1	0.7	6	0.5	0.2	1.0	16	0.4	0.2	0.7	2	0.2	0.0	0.6
	Adenoiditis (10051223)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Adenovirus infection (10060931)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body tinea (10005913)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	2	0.2	0.0	0.6	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Borrelia infection (10061591)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Bronchiolitis (10006448)	22	1.8	1.1	2.7	30	2.4	1.6	3.5	19	1.5	0.9	2.4	71	1.9	1.5	2.4	27	2.1	1.4	3.0
	Bronchitis (10006451)	30	2.4	1.6	3.4	37	3.0	2.1	4.1	43	3.5	2.5	4.6	110	3.0	2.4	3.6	42	3.3	2.4	4.4
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchitis viral (10053160)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bullous impetigo (10006563)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Burn infection (10051548)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	10	0.8	0.4	1.5	5	0.4	0.1	0.9	3	0.2	0.0	0.7	18	0.5	0.3	0.8	12	0.9	0.5	1.6
	Candida nappy rash (10007135)	12	1.0	0.5	1.7	8	0.6	0.3	1.3	4	0.3	0.1	0.8	24	0.6	0.4	1.0	9	0.7	0.3	1.3
	Cellulitis (10007882)	5	0.4	0.1	0.9	4	0.3	0.1	0.8	8	0.6	0.3	1.3	17	0.5	0.3	0.7	3	0.2	0.0	0.7
	Cellulitis orbital (10007918)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clostridium difficile infection (10054236)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	71	5.7	4.5	7.2	88	7.1	5.8	8.7	86	6.9	5.6	8.5	245	6.6	5.8	7.4	93	7.2	5.9	8.8
	Conjunctivitis bacterial (10061784)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Coxsackie viral infection (10011261)	8	0.6	0.3	1.3	6	0.5	0.2	1.1	5	0.4	0.1	0.9	19	0.5	0.3	0.8	4	0.3	0.1	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Croup infectious (10011416)	28	2.3	1.5	3.2	37	3.0	2.1	4.1	31	2.5	1.7	3.5	96	2.6	2.1	3.1	33	2.6	1.8	3.6
	Cutaneous larva migrans (10059547)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cystitis (10011781)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Diarrhoea infectious (10012742)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Ear infection (10014011)	30	2.4	1.6	3.4	34	2.8	1.9	3.8	18	1.4	0.9	2.3	82	2.2	1.8	2.7	35	2.7	1.9	3.8
	Eczema herpeticum (10014197)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eczema infected (10014199)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Enteritis infectious (10058839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Enterovirus infection (10014909)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	2	0.2	0.0	0.6	7	0.2	0.1	0.4	5	0.4	0.1	0.9
	Epstein-barr virus infection (10015108)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Erythema infectiosum (10015214)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Escherichia urinary tract infection (10052238)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exanthema subitum (10015586)	8	0.6	0.3	1.3	7	0.6	0.2	1.2	4	0.3	0.1	0.8	19	0.5	0.3	0.8	7	0.5	0.2	1.1
	External ear cellulitis (10015729)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye infection (10015929)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	1	0.1	0.0	0.4	6	0.2	0.1	0.4	4	0.3	0.1	0.8
	Folliculitis (10016936)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	5	0.4	0.1	0.9	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Fungal infection (10017533)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Fungal skin infection (10017543)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	5	0.4	0.1	0.9
	Gastroenteritis (10017888)	68	5.5	4.3	6.9	57	4.6	3.5	6.0	61	4.9	3.8	6.3	186	5.0	4.3	5.8	58	4.5	3.4	5.8
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis enteroviral (10017901)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Gastroenteritis viral (10017918)	8	0.6	0.3	1.3	5	0.4	0.1	0.9	4	0.3	0.1	0.8	17	0.5	0.3	0.7	5	0.4	0.1	0.9

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gingivitis (10018292)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Hand-foot-and-mouth disease (10019113)	19	1.5	0.9	2.4	24	1.9	1.3	2.9	20	1.6	1.0	2.5	63	1.7	1.3	2.2	24	1.9	1.2	2.8
	Herpangina (10019936)	8	0.6	0.3	1.3	8	0.6	0.3	1.3	8	0.6	0.3	1.3	24	0.6	0.4	1.0	6	0.5	0.2	1.0
	Herpes dermatitis (10062639)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Herpes simplex (10019948)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Herpes zoster (10019974)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hordeolum (10020377)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Impetigo (10021531)	14	1.1	0.6	1.9	8	0.6	0.3	1.3	5	0.4	0.1	0.9	27	0.7	0.5	1.1	12	0.9	0.5	1.6
	Infected bite (10076911)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Influenza (10022000)	5	0.4	0.1	0.9	12	1.0	0.5	1.7	4	0.3	0.1	0.8	21	0.6	0.4	0.9	8	0.6	0.3	1.2
	Laryngitis (10023874)	14	1.1	0.6	1.9	23	1.9	1.2	2.8	20	1.6	1.0	2.5	57	1.5	1.2	2.0	19	1.5	0.9	2.3
	Lice infestation (10024424)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Localised infection (10024774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Lower respiratory tract infection (10024968)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Lyme disease (10025169)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	3	0.2	0.0	0.7	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Mycoplasma infection (10061300)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Nasopharyngitis (10028810)	105	8.5	7.0	10.2	101	8.2	6.7	9.9	106	8.5	7.0	10.2	312	8.4	7.5	9.3	98	7.6	6.2	9.2
	Neonatal candida infection (10028924)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Neutropenic infection (10059482)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Onychomycosis (10030338)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Oral candidiasis (10030963)	1	0.1	0.0	0.4	4	0.3	0.1	0.8	3	0.2	0.0	0.7	8	0.2	0.1	0.4	6	0.5	0.2	1.0
	Oral herpes (10067152)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	1	0.1	0.0	0.4	7	0.2	0.1	0.4	4	0.3	0.1	0.8
	Oral infection (10048685)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis externa (10033072)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	6	0.5	0.2	1.0
	Otitis media (10033078)	216	17.4	15.4	19.7	220	17.9	15.8	20.1	195	15.7	13.7	17.8	631	17.0	15.8	18.2	247	19.2	17.0	21.4

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Otitis media acute (10033079)	28	2.3	1.5	3.2	18	1.5	0.9	2.3	38	3.1	2.2	4.2	84	2.3	1.8	2.8	42	3.3	2.4	4.4
	Otitis media chronic (10033081)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Otosalpingitis (10033102)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Parasitic gastroenteritis (10067720)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Paronychia (10034016)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Parotitis (10034038)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Periorbital cellulitis (10057182)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Pertussis (10034738)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pharyngitis (10034835)	65	5.2	4.1	6.6	72	5.8	4.6	7.3	65	5.2	4.1	6.6	202	5.4	4.7	6.2	68	5.3	4.1	6.6
	Pharyngitis bacterial (10057869)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pharyngitis streptococcal (10034839)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	8	0.6	0.3	1.3	16	0.4	0.2	0.7	6	0.5	0.2	1.0
	Pharyngotonsillitis (10049140)	7	0.6	0.2	1.2	5	0.4	0.1	0.9	4	0.3	0.1	0.8	16	0.4	0.2	0.7	7	0.5	0.2	1.1
	Pneumococcal sepsis (10054047)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	12	1.0	0.5	1.7	20	1.6	1.0	2.5	10	0.8	0.4	1.5	42	1.1	0.8	1.5	9	0.7	0.3	1.3
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia viral (10035737)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pyelonephritis (10037596)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pyelonephritis acute (10037597)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pyoderma (10037632)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	2	0.2	0.0	0.6	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Respiratory syncytial virus infection (10061603)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Respiratory tract infection (10062352)	13	1.0	0.6	1.8	16	1.3	0.7	2.1	15	1.2	0.7	2.0	44	1.2	0.9	1.6	16	1.2	0.7	2.0
	Respiratory tract infection viral (10062106)	5	0.4	0.1	0.9	1	0.1	0.0	0.5	1	0.1	0.0	0.4	7	0.2	0.1	0.4	6	0.5	0.2	1.0
	Rhinitis (10039083)	26	2.1	1.4	3.1	20	1.6	1.0	2.5	19	1.5	0.9	2.4	65	1.8	1.4	2.2	33	2.6	1.8	3.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Roseola (10039222)	5	0.4	0.1	0.9	6	0.5	0.2	1.1	6	0.5	0.2	1.0	17	0.5	0.3	0.7	2	0.2	0.0	0.6
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Scarlet fever (10039587)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	4	0.3	0.1	0.8	8	0.2	0.1	0.4	4	0.3	0.1	0.8
	Sinusitis (10040753)	23	1.9	1.2	2.8	11	0.9	0.4	1.6	12	1.0	0.5	1.7	46	1.2	0.9	1.6	17	1.3	0.8	2.1
	Skin bacterial infection (10052891)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin candida (10054152)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	3	0.2	0.0	0.7	9	0.2	0.1	0.5	1	0.1	0.0	0.4
	Skin infection (10040872)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Staphylococcal infection (10058080)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Streptococcal infection (10061372)	2	0.2	0.0	0.6	8	0.6	0.3	1.3	5	0.4	0.1	0.9	15	0.4	0.2	0.7	9	0.7	0.3	1.3
	Subcutaneous abscess (10042343)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Tinea capitis (10043866)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tinea cruris (10043868)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tinea infection (10060889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tinea nigra (10043871)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillitis (10044008)	42	3.4	2.5	4.6	31	2.5	1.7	3.6	32	2.6	1.8	3.6	105	2.8	2.3	3.4	42	3.3	2.4	4.4
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tracheitis (10044302)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Upper respiratory tract infection (10046306)	155	12.5	10.7	14.5	174	14.1	12.2	16.2	169	13.6	11.7	15.6	498	13.4	12.3	14.5	174	13.5	11.7	15.5
	Urethritis (10046480)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary tract infection (10046571)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.4	0.1	0.9	9	0.2	0.1	0.5	7	0.5	0.2	1.1
	Vaginal infection (10046914)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Varicella (10046980)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.2	0.0	0.6	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	3	0.2	0.0	0.7
	Viral infection (10047461)	53	4.3	3.2	5.6	48	3.9	2.9	5.1	55	4.4	3.4	5.7	156	4.2	3.6	4.9	47	3.6	2.7	4.8
	Viral pharyngitis (10047473)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	1	0.1	0.0	0.4	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Viral rash (10047476)	11	0.9	0.4	1.6	13	1.1	0.6	1.8	15	1.2	0.7	2.0	39	1.1	0.7	1.4	12	0.9	0.5	1.6

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral tonsillitis (10047480)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	7	0.6	0.2	1.2	8	0.6	0.3	1.3	9	0.7	0.3	1.4	24	0.6	0.4	1.0	8	0.6	0.3	1.2
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vulvovaginitis (10047794)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	3	0.2	0.0	0.7	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Animal bite (10002515)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	3	0.2	0.0	0.7	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Arthropod bite (10003399)	9	0.7	0.3	1.4	11	0.9	0.4	1.6	16	1.3	0.7	2.1	36	1.0	0.7	1.3	11	0.9	0.4	1.5
	Arthropod sting (10003402)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Bite (10004966)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Burns first degree (10006797)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Burns second degree (10006802)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Chemical eye injury (10055116)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Concussion (10010254)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Contusion (10050584)	8	0.6	0.3	1.3	4	0.3	0.1	0.8	6	0.5	0.2	1.0	18	0.5	0.3	0.8	13	1.0	0.5	1.7
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	3	0.2	0.0	0.7
	Craniocerebral injury (10070976)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Ear canal injury (10056319)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear injury (10057446)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye burns (10015911)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye contusion (10073354)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye injury (10061128)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eyelid injury (10069200)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Face injury (10050392)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Fall (10016173)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Foot fracture (10016970)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in eye (10017012)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Gingival injury (10049300)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Head injury (10019196)	10	0.8	0.4	1.5	14	1.1	0.6	1.9	12	1.0	0.5	1.7	36	1.0	0.7	1.3	10	0.8	0.4	1.4
	Heat stroke (10019345)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Humerus fracture (10020462)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injury (10022116)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Joint dislocation (10023204)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Joint injury (10060820)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Laceration (10023572)	8	0.6	0.3	1.3	2	0.2	0.0	0.6	9	0.7	0.3	1.4	19	0.5	0.3	0.8	10	0.8	0.4	1.4
	Ligament sprain (10024453)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Limb crushing injury (10064031)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Limb injury (10061225)	4	0.3	0.1	0.8	2	0.2	0.0	0.6	4	0.3	0.1	0.8	10	0.3	0.1	0.5	3	0.2	0.0	0.7
	Lip injury (10055082)	4	0.3	0.1	0.8	1	0.1	0.0	0.5	5	0.4	0.1	0.9	10	0.3	0.1	0.5	3	0.2	0.0	0.7
	Mouth injury (10049294)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Nail avulsion (10028686)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Poisoning (10061355)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Post vaccination syndrome (10036242)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Procedural pain (10064882)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	3	0.2	0.0	0.7	8	0.2	0.1	0.4	5	0.4	0.1	0.9
	Radius fracture (10037802)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	5	0.4	0.1	0.9	1	0.1	0.0	0.4	6	0.2	0.1	0.4	3	0.2	0.0	0.7
	Skin wound (10072170)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skull fracture (10061365)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Splinter (10041662)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Sunburn (10042496)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	6	0.5	0.2	1.0	11	0.3	0.1	0.5	2	0.2	0.0	0.6
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Upper limb fracture (10061394)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wound (10052428)	1	0.1	0.0	0.4	4	0.3	0.1	0.8	1	0.1	0.0	0.4	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Wrist fracture (10048049)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Investigations (10022891)	Blood lead increased (10005642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body height below normal (10056811)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cardiac murmur (10007586)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Cardiac murmur functional (10007587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight decreased (10047895)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	3	0.2	0.0	0.7
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.2	0.0	0.7	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Dehydration (10012174)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	3	0.2	0.0	0.7	8	0.2	0.1	0.4	6	0.5	0.2	1.0
	Failure to thrive (10016165)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Hypoglycaemia (10020993)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Iron deficiency (10022970)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Lactose intolerance (10023681)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Malnutrition (10061273)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Overweight (10033307)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight gain poor (10047897)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Foot deformity (10061159)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Knee deformity (10062061)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Limb asymmetry (10070670)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain in extremity (10033425)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	1	0.1	0.0	0.4
	Synovial cyst (10042858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Synovitis (10042868)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Toe walking (10068872)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Trigger finger (10044654)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma of skin (10018823)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphangioma (10025219)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mycosis fungoides (10028483)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Skin papilloma (10040907)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Epilepsy (10015037)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Exaggerated startle response (10066482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Febrile convulsion (10016284)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	5	0.4	0.1	0.9	10	0.3	0.1	0.5	8	0.6	0.3	1.2
	Gross motor delay (10069118)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Headache (10019211)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lethargy (10024264)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Loss of consciousness (10024855)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Motor developmental delay (10070302)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Nystagmus (10029864)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Seizure (10039906)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Speech disorder (10041466)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Speech disorder developmental (10041467)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	5	0.4	0.1	0.9	12	0.3	0.2	0.6	2	0.2	0.0	0.6
	Tremor (10044565)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Psychiatric disorders (10037175)	Breath holding (10006322)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Insomnia (10022437)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Irritability (10022998)	7	0.6	0.2	1.2	4	0.3	0.1	0.8	3	0.2	0.0	0.7	14	0.4	0.2	0.6	2	0.2	0.0	0.6
	Pica (10035001)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Sleep disorder (10040984)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Sleep terror (10041010)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
Renal and urinary disorders (10038359)	Dysuria (10013990)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	4	0.3	0.1	0.8	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Haematuria (10018867)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pollakiuria (10036018)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Urinary tract disorder (10046566)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Balanoposthitis (10004078)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	5	0.4	0.1	0.9	12	0.3	0.2	0.6	3	0.2	0.0	0.7
	Bilateral breast buds (10004557)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Genital labial adhesions (10064162)	4	0.3	0.1	0.8	2	0.2	0.0	0.6	1	0.1	0.0	0.4	7	0.2	0.1	0.4	1	0.1	0.0	0.4
	Oedema genital (10030104)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Penile adhesion (10059636)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Perineal cyst (10066058)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prepuce redundant (10036624)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3

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	Testicular retraction (10043348)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vulval disorder (10047754)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vulvovaginal discomfort (10047786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Respiratory, thoracic and mediastinal disorders (10038738)	Adenoidal hypertrophy (10001229)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Apnoea (10002974)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Aspiration (10003504)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Asthma (10003553)	5	0.4	0.1	0.9	6	0.5	0.2	1.1	12	1.0	0.5	1.7	23	0.6	0.4	0.9	12	0.9	0.5	1.6
	Bronchial hyperreactivity (10066091)	8	0.6	0.3	1.3	8	0.6	0.3	1.3	9	0.7	0.3	1.4	25	0.7	0.4	1.0	11	0.9	0.4	1.5
	Bronchitis chronic (10006458)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Bronchospasm (10006482)	4	0.3	0.1	0.8	9	0.7	0.3	1.4	7	0.6	0.2	1.2	20	0.5	0.3	0.8	7	0.5	0.2	1.1
	Catarrh (10007774)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	4	0.3	0.1	0.8
	Cough (10011224)	44	3.6	2.6	4.7	38	3.1	2.2	4.2	37	3.0	2.1	4.1	119	3.2	2.7	3.8	55	4.3	3.2	5.5
	Dyspnoea (10013968)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	1	0.1	0.0	0.4	6	0.2	0.1	0.4	3	0.2	0.0	0.7
	Epistaxis (10015090)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Increased bronchial secretion (10062530)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	4	0.3	0.1	0.8	4	0.3	0.1	0.8	6	0.5	0.2	1.0	14	0.4	0.2	0.6	5	0.4	0.1	0.9
	Nasal discomfort (10052437)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Nasal obstruction (10028748)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Oropharyngeal pain (10068319)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Productive cough (10036790)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory disorder (10038683)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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	Rhinitis allergic (10039085)	14	1.1	0.6	1.9	10	0.8	0.4	1.5	10	0.8	0.4	1.5	34	0.9	0.6	1.3	12	0.9	0.5	1.6
	Rhinorrhoea (10039101)	3	0.2	0.0	0.7	5	0.4	0.1	0.9	3	0.2	0.0	0.7	11	0.3	0.1	0.5	2	0.2	0.0	0.6
	Stridor (10042241)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tachypnoea (10043089)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillar hypertrophy (10044003)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Upper respiratory tract congestion (10052252)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vasomotor rhinitis (10047145)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	5	0.4	0.1	0.9	19	1.5	0.9	2.4	9	0.7	0.3	1.4	33	0.9	0.6	1.2	6	0.5	0.2	1.0
Skin and subcutaneous tissue disorders (10040785)	Blister (10005191)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dermatitis (10012431)	15	1.2	0.7	2.0	10	0.8	0.4	1.5	7	0.6	0.2	1.2	32	0.9	0.6	1.2	10	0.8	0.4	1.4
	Dermatitis allergic (10012434)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	3	0.2	0.0	0.7
	Dermatitis atopic (10012438)	11	0.9	0.4	1.6	19	1.5	0.9	2.4	29	2.3	1.6	3.3	59	1.6	1.2	2.0	16	1.2	0.7	2.0
	Dermatitis contact (10012442)	4	0.3	0.1	0.8	8	0.6	0.3	1.3	6	0.5	0.2	1.0	18	0.5	0.3	0.8	6	0.5	0.2	1.0
	Dermatitis diaper (10012444)	28	2.3	1.5	3.2	29	2.4	1.6	3.4	35	2.8	2.0	3.9	92	2.5	2.0	3.0	43	3.3	2.4	4.5
	Drug eruption (10013687)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dry skin (10013786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dyshidrotic eczema (10013913)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ecchymosis (10014080)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eczema (10014184)	9	0.7	0.3	1.4	4	0.3	0.1	0.8	9	0.7	0.3	1.4	22	0.6	0.4	0.9	19	1.5	0.9	2.3
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Erythema (10015150)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Erythema multiforme (10015218)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Granuloma annulare (10018692)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hair disorder (10019037)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Henoch-schonlein purpura (10019617)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hyperkeratosis (10020649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ingrowing nail (10022013)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Keratosis pilaris (10066295)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Lichen sclerosus (10024434)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Lichen striatus (10066945)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Miliaria (10027627)	6	0.5	0.2	1.1	2	0.2	0.0	0.6	1	0.1	0.0	0.4	9	0.2	0.1	0.5	2	0.2	0.0	0.6
	Nail disorder (10028694)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Onychomalacia (10058673)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pityriasis (10035110)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pityriasis rosea (10035114)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prurigo (10037083)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash (10037844)	17	1.4	0.8	2.2	14	1.1	0.6	1.9	20	1.6	1.0	2.5	51	1.4	1.0	1.8	14	1.1	0.6	1.8
	Rash erythematous (10037855)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rash generalised (10037858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash macular (10037867)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rash maculo-papular (10037868)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash papular (10037876)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash scarlatiniform (10037890)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rash vesicular (10037898)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seborrhoea (10039792)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Seborrhoeic dermatitis (10039793)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Skin burning sensation (10054786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Skin disorder (10040831)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin fissures (10040849)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin hypopigmentation (10040868)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin irritation (10040880)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Skin lesion (10040882)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin mass (10067868)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urticaria (10046735)	13	1.0	0.6	1.8	5	0.4	0.1	0.9	6	0.5	0.2	1.0	24	0.6	0.4	1.0	13	1.0	0.5	1.7
	Urticaria vesiculosa (10046755)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Vitiligo (10047642)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	1	0.1	0.0	0.4
Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Myringotomy (10028662)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Vascular disorders (10047065)	Haematoma (10018852)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

8.5. Concomitant medications /vaccinations

The number and percentage of subjects who were given a concomitant medication during the 43-day and 15-day post-vaccination reporting periods are given in Table 8.105 and Table 8.113, respectively. Incidences of subjects that were given antipyretics are depicted graphically in Figure 8.4. The highest percentages of antipyretic use were reported on the day of vaccination and within 6-12 days post-vaccination.

8.6. Clinical laboratory evaluations

No clinical laboratory evaluations with regard to safety were performed in this study.

8.7. Analysis by sub-groups

Analysis of safety was based on the TVC. No safety analyses were performed for subjects by gender or geographic ancestry.

8.8. Safety summary

The study results are supportive of an acceptable safety profile of the Inv_MMR study vaccine that is similar to the US standard of care (Com_MMR vaccine) in healthy subjects aged 12 to 15 months of age. Safety results were consistent between the 3 lots of Inv_MMR used in this study. Reactogenicity and safety of the study vaccine was found to be acceptable when co-administered with VV, HAV and PCV-13 (in the US), and also in line with what has been previously reported for Inv_MMR globally.

- Overall, during the 43-day post-vaccination period, at least one solicited or unsolicited symptom was reported by ***87.1%***% of subjects in the Inv_MMR group and by ***88.3***% in the Com_MMR group. General symptoms were reported by ***84.8%*** and ***86.1%*** of subjects in Inv_MMR and Com_MMR groups, respectively. Local symptoms were reported by 40.2% and 41.9% of subjects in the Inv_MMR and Com_MMR groups, respectively.
- Within the 4-day post-vaccination period, the most frequently reported solicited local symptoms in the Inv_MMR and Com_MMR groups were pain (25.9% and 28.1%) and redness (24.5% and 25.2%), respectively. Solicited local symptoms of grade 3 were reported in up to 1.0% of subjects in any group.
- Within the 15-day post-vaccination period, the most commonly reported general symptom in the Inv_MMR group and Com_MMR groups was irritability or fussiness reported in 63.3% and 65.9% of subjects respectively. This was followed by drowsiness (44.9% and 47.1%) and loss of appetite (45.1% and 44.1%). Solicited general AEs of grade 3 were reported in a maximum of 4.9% of subjects in the Inv_MMR and Com_MMR groups.
- Within the 43-day post-vaccination period, the following solicited general symptoms were reported in both the Inv_MMR and Com_MMR groups, respectively: fever ≥ 38.0°C/100.4°F (34.7% and 33.1%), rash (29.2% and 30.4%) and febrile convulsions

(10 subjects [0.3%] and 3 subjects [0.2%]; 4 of these 10 events in the Inv_MMR group and 2 of the 3 events in the Com_MMR group were considered related to vaccination). No subject reported parotid gland swelling in any of the groups.

- Within the 43-day post-vaccination period, 50.0% of subjects in the Inv_MMR group and 47.9% in the Com_MMR group reported at least one unsolicited AE. The most common AE by MedDRA preferred term was upper respiratory tract infection, reported in 9.5% of subjects in both the Inv_MMR and Com_MMR groups.
- During the entire study period, 102 subjects reported one or more SAEs in this study. A total of 98 SAEs were reported in 77 subjects (2.1%) in the Inv_MMR group and 40 were reported in 25 subjects (1.9%) in the Com_MMR group. Two of these SAEs in the Inv_MMR group were considered by the investigator to be related to the study vaccination. One subject in the Inv_MMR_2 group had gastroenteritis, and another subject in the Inv_MMR_3 group had febrile convulsion. There were no fatal SAEs in the study.
- The most frequently occurring SAE during the study period was bronchitis reported by 8 subjects (0.2%) in the Inv_MMR group and by 2 subjects (0.2%) in the Com_MMR group.
- Two subjects were withdrawn from the study due to an AE.

9. OVERALL CONCLUSIONS

All co-primary study objectives were met.

The lot-to-lot consistency of the immune response to each of the three vaccine components after one dose of *Priorix*, out of three consistency lots, was demonstrated:

- All 95% CIs for the pair-wise lot differences in seroresponse rates were between -5% and +5% for anti-measles, anti-mumps, and anti-rubella antibodies.
- All 95% CIs for the pair-wise adjusted GMC ratios were between 0.67 and 1.50 for anti-measles, anti-mumps, and anti-rubella antibodies.

Non-inferiority of the immune response of the Inv_MMR lots versus *M-M-R-II* was demonstrated:

- The lower limit of the 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-5% for anti-measles, anti-mumps, and anti-rubella antibodies.
- The lower limit of the 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-measles, anti-mumps, and anti-rubella antibodies.

The acceptability of the immune response of the Inv_MMR lots was demonstrated:

- The lower limit of the 95% CI for the seroresponse rate in the Inv_MMR group was ≥90% for anti-measles, anti-mumps, and anti-rubella antibodies.

All secondary study objectives related to immunogenicity were met.

Non-inferiority of the immune response of the Inv_MMR lots versus Com_MMR lots, in terms of co-administered vaccines, was demonstrated:

- The lower limit of the two-sided 95% CI for the group difference in seroresponse rate (Inv_MMR minus Com_MMR) was ≥-10% for anti-VZV antibodies.
- The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.67 for anti-VZV antibodies.
- The lower limit of the two-sided 95% CI for the GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to HAV.
- The lower limit of the two-sided 95% CI for the adjusted GMC ratio (Inv_MMR over Com_MMR) was ≥0.5 for antibodies to each of the 13 *S. pneumoniae* serotypes.

An acceptable safety profile was observed for the Inv_MMR groups when co-administered with *Varivax, Havrix* (to all children) and *Prevnar 13* (only to children enrolled in the US) which was similar to that observed with Com_MMR.

10. REFERENCES

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11. STUDY REPORT AUTHORS /CONTRIBUTING AUTHORS

(Amended: 18-September-2018)

Scientific Writers: PPD PPD PPD

Statistician(s): PPD

Study Delivery Lead/Study Delivery Manager: PPD PPD PPD ***(for Report Amendment 1)***

Central Safety Contact: PPD PPD ***(for Report Amendment 1);***

Clinical Research and Development Lead: PPD PPD ***(for Report Amendment 1);***

Regulatory Affairs representative: PPD

N + 1 of Clinical Research and Development Lead: PPD PPD ***(for Report Amendment 1)***

12. SERIOUS ADVERSE EVENTS / OTHER SIGNIFICANT ADVERSE EVENTS

12.1. SAE Listing(s)

The listing of individual SAEs that were reported during the course of this study is found in Table 8.136.

12.2. Clinical narratives for SAEs

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Seizure, Loss of consciousness

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 19th June 2014, for prophylaxis.

On PPD 162 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 seizure. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included severe - grade 3 loss of consciousness on 28th November 2014 with serious criteria of hospitalization and GSK medically significant. The subject was treated with lorazepam (Ativan) and propofol. The outcome of seizure was recovered/resolved on 29th November 2014. The outcome(s) of the additional event(s) included loss of consciousness (recovered/resolved on 29th November 2014).

The investigator considered that there was no reasonable possibility that the seizure and loss of consciousness may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments : 17 month old child that on morning of admission child began crying and passed out. He did not return to normal base line after regaining consciousness. Eyes deviated for 10 minutes and had twitching of arms. Emergency services were called and child was intubated and transported to local hospital were child was examined for seizure. Child was then transport to specialty hospital via air.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 162 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Cellulitis, Conjunctivitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 13-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 27th May 2014, for prophylaxis.

On PPD 3 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed moderate - grade 2 cellulitis. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included moderate - grade 2 conjunctivitis on 30th May 2014 with serious criteria of hospitalization. The subject was treated with amoxicillin trihydrate, clavulanate potassium (Augmentin), polymyxin B sulfate, trimethoprim (Polytrim) and ampicillin. The outcome of cellulitis was recovered/resolved on 23rd June 2014. The outcome(s) of the additional event(s) included conjunctivitis (recovered/resolved on 23rd June 2014).

The investigator considered that there was no reasonable possibility that the cellulitis and conjunctivitis may have been caused by Priorix vs MMR II+Havrix+Varivax. Diagnostic results (unless otherwise stated, normal values were not provided): On 3rd June 2014, BLOOD BASOPHILS result was 0.0 unknown, BLOOD EOSINOPHILS result was 0.08 unknown (normal low: 0.10, normal high: 0.80), BLOOD HEMATOCRIT result was 34.3 unknown, BLOOD HEMOGLOBIN result was 11.6 unknown, BLOOD LYMPHOCYTES result was 0.08 unknown, BLOOD MCH result was 33.8 unknown, BLOOD MCV result was 80 unknown, BLOOD PLATELETS result was 310 unknown, Red blood cell count result was 4.31 unknown and White blood cell count result was 7.9 unknown.

Relevant Risk Factors : sibling with abscess after spider bite in remote past
Investigator Comments : Study coordinator became aware of participantPPD previours visits to ED and admission on 6/3/2014. PPD was brought into the ED by mother on 6/1/2014 with a complaint of 2 days of pink eye. ED diagnosis was mild preseptal conjuncitivits/cellulitis.PPD discharged home with Polytrim eye drops on 6/1/2014. ED has recorded temp of 98.4F rectally and weight of 9.1kg. PPD returned to ED by mother on 6/2/2014 with increased Left eye swelling. ED diagnosis left eye conjuncitivitis. ED recorded temp pf 98.2F axillary and weight of 9.1kg.PPD discharged home on 6/2/2014 with Augmentin medication. PPD returned to ED with mother on 6/3/2014 with complaint of worsening left eye redness and swelling and admitted to the hospital on 6/3/2014. Temp 97.8 rectal and weight 9kg.PPD upon admission recieved ampicillin. CBC +differential ordered and completed by ED with unremarkable

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Clinical Narrative report with Both Serious & Non-Serious Events

results.Study coordinator informed the PI. PI examed PPD to be in stable health and left eye swelling was secondary to pre-septal cellulitis receiving adequate treatment. Mother was educated to continue daily temps and to call coordinator for further concerns. Follow up by study coordinator completed on 6/4/2014. PPD in good spirits with decreased swelling. PPD discharged on 6/4/2014 with antibiotics and final diagnosis pre-septal cellulitis of the left eye. 2nd follow up completed on 6/23/2014. Left eye swelling resolved with no further hospitalizations.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported events has no causal association to the administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchial hyperreactivity

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 28 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

The subject's past medical history included possible pneumonia and rarely little wheeze.

On PPD 22 days after the 1st dose of Blinded vaccine, 22 days after the 1st dose of Havrix 720 Junior, 22 days after the 1st dose of Varivax, 22 days after the 1st dose of Prevnar 13, this 12-month-old subject developed reactive airway disease. The subject was hospitalised. The subject was treated with salbutamol sulphate, paracetamol and prednisolone. The event resolved on 23 June 2013. The investigator considered that there was no reasonable possibility that the reactive airway disease may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the event was possibly due to reactive airway disease secondary to viral illness and his medical condition of rare intermittent audible wheeze.

Investigator Comments:
12 month old male enrolled in MMR 160 study on 28may2013.Sub-investigator noted Rare intermittent Audible Wheeze upon exam. No other symptoms present. The only significant medical history that has

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Clinical Narrative report with Both Serious & Non-Serious Events

since come to light is a previous hospitalization at 3 1/2 mos for possible pneumonia. No medications noted at time of enrollment. Family was on vacation out of town on 19jun13 when subject started having breathing problems and was fussy. Admitted to hospital for Acute respiratory distress, most likely secondary to viral etiology. Treated with Xopenex 0.63 mg every 2 hours prn for shortness of breath and wheezing. Received Oxygen prn to keep oxygen saturations above 92%. Received Tylenol 150 mg po q 4 hours prn for fever and irritability. RSV test was negative. He was discharged on 21jun2013 on Albuterol prn and Prednisolone 3 cc po BID for three more days. The medical records received from the hospital do not indicate any oral steroids given while hospitalized. The parent notified the research site on 22jul2013 of this hospitalization. She indicated at the time all symptoms were resolved by 23jun2013. Subject came in for visit 2 for the study on PPD and Principle Investigator assessed his lungs and they were normal. Principle Investigator thinks that this illness is not related to the study drug or any other vaccines. The illness was most likely Reactive Airway Disease secondary to a viral illness.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 22 days. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Asthma

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 28 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

Medical condition at the time of the event included asthma.

On PPD 92 days after the dose of Blinded vaccine, 92 days after the dose of Havrix 720 Junior, 92 days after the dose of Varivax, 92 days after the dose of Prevnar 13, this 15-month-old subject developed asthma exacerbation. The subject was hospitalised. The subject was treated with prednisolone, Albuterol/atrovent, magnesium sulfate and beclomethasone dipropionate. The event resolved on 05 September 2013. The investigator considered that there was no reasonable possibility that the asthma exacerbation may have been caused by investigational product, Havrix 720 Junior, Varivax

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Clinical Narrative report with Both Serious & Non-Serious Events

and Prevnar 13 and that the event was possibly due to a viral infection and his medical condition of asthma.

Investigator Comments :
15 month old infant with history of Asthma/reactive Airway disease presented to clinic on 30AUG2013 with several day history of runny nose and congestion and then not sleeping well and having trouble breathing overnight. Was receiving Albuterol inhaler every two hours overnight but he was working very hard to breathe. He improved slightly after receiving 1.5 cc of Prednisolone in the clinic and an Albuterol/Atrovent nebulization but was still wheezing and working hard. He was then admitted to the hospital overnight and was monitored with pulse oximetry, nebulization treatments, magnesium sulfate IV.
He was discharged in the afternoon the next day with a prescription for Prednisolone BID for the next five days. Since this was his third hospitalization (second while in the study) he was started on a controller medication, QVAR 80 mg QD.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 92 days Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Cellulitis, Dehydration, Otitis media, Conjunctivitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 14-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received priorix vs mmr ii+havrix+varivax (subcutaneous) from 12th March 2014 to 12th March 2014, for prophylaxis.

On PPD 57 days after the first dose and 57 days after the most recent dose of priorix vs mmr ii+havrix+varivax, the subject developed moderate - grade 2 cellulitis. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included moderate - grade 2 conjunctivitis on 8th May 2014 with serious criteria of hospitalization, moderate - grade 2 otitis media on 10th May 2014 with serious criteria of hospitalization and moderate - grade 2 dehydration on 11th May 2014 with serious criteria of hospitalization. The subject was treated with ceftriaxone, amoxicillin

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Clinical Narrative report with Both Serious & Non-Serious Events

trihydrate, clavulanate potassium (Augmentin), paracetamol (Acetaminophen), cetirizine hydrochloride (Zyrtec), benadryl (nos) (Benadryl), IBUPROFEN and LORATADINE, LORATADINE, LORATADINE, LORATADINE (CLARITINE). Priorix vs mmr ii+havrix+varivax was continued with no change. The outcome of cellulitis was recovered/resolved on 17th May 2014. The outcome(s) of the additional event(s) included dehydration (recovered/resolved on 12th May 2014), conjunctivitis (recovered/resolved on 12th May 2014) and otitis media (recovered/resolved on 18th May 2014).

The investigator considered that there was no reasonable possibility that the cellulitis, conjunctivitis, otitis media and dehydration may have been caused by priorix vs mmr ii+havrix+varivax.

Investigator Comments :
Subject developed URI symptoms and yellow left eye drainage on 08May2014. Treated with Claritin with some improvement. The subject was doing well until the night of 09May2014 when developed fever to 101. The subject saw pediatrician on 10May2014 and was diagnosed with left otitis and left conjunctivitis; started on Augment BID dosing. Had received three doses prior to arrival in ER. On 11May2014 parents noted increased redness and swelling around left eye, occasionally rubbing at eye. Does not seem to have pain or discomfort or drainage. Patient received ibuprofen, acetaminophen, and Augmentin prior to arrival at the ER on 11May2014. Patient was given Benedryl upon arrival at the ER and a CBC was done. Swelling improved after Benedryl, still with mild erythema. CBC without elevated WBCs. Patient started refusing PO's so and IV was placed for NS Bolus and Ceftriaxone was given for OM. Patient was then admitted for dehydration, OM, and monitoring of periorbital swelling and redness. Patient received IV Ceftriaxone for 2 days and was discharged home with 7 days of Augmentin to complete treatment of OM. Patient received standing Zyrtec and Benadryl and was rehydrated with IV D5W NS, then the IV was saline locked and the patient was able to tolerate a normal diet and was well hydrated. On 13May2014 the subject was dischared. Patent was afebrile, vital signs normal for age, and area around left eye was dramatically improved with essentially resolved erythema and edema.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 57 days. Reported events has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Herpangina

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

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Clinical Narrative report with Both Serious & Non-Serious Events

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 19 June 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD 24 days after the 1st dose of Blinded vaccine, 24 days after the 1st dose of Varivax, 24 days after the 1st dose of Havrix 720 Junior, 24 days after the 1st dose of Prevnar 13, this 12-month-old subject developed herpangina. The subject was hospitalised. The subject was treated with paracetamol, Dextrose + normal saline + potassium chloride, ibuprofen, diphenhydramine and Maalox. The event resolved on 08 August 2013. The investigator considered that there was no reasonable possibility that the herpangina may have been caused by investigational product, Varivax, Havrix 720 Junior and Prevnar 13.

Investigator Comments :
Parent presented subject to emergency department on 7/27/2013 for histroy of fever times 1 day. Temperature maximum 104.0 degrees F. Tylenol and advil were given in the emergency department and fever reduced to 100.3 degrees F. Subject transferred to inpatient. Subjects history significant for pneumonia 1 month ago and treated with amoxicillin for 10 days. Subject remains inpatient and is being treated with IV fluids 5 percent dextrose with one third normal saline and potassium chloride at 32mL per hour. Assessment on date of this report reveals erythematous lesion in the posterior palate at the the 11 o clock position and red papules present on her hands and legs. 16Aug2013 Discharge records recieved and reviewed with PI. Changes made to SAE screens and all queries answered. Final diagnoses was Herpangina and fever and pneumonia were not relevant conditions.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 24 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Respiratory syncytial virus bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 15-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR

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Clinical Narrative report with Both Serious & Non-Serious Events

vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 21st August 2014, for prophylaxis.

The subject's past medical history included respiratory syncytial virus bronchiolitis. Previously administered products included HIB. Concomitant products included influenza vaccine (Influenza).

On PPD 111 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 respiratory syncytial virus bronchiolitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with salbutamol (Albuterol 0.083% Inhalation), ambiguous medication nos and paracetamol (Tylenol). The outcome of respiratory syncytial virus bronchiolitis was recovered/resolved on 18th December 2014.

The investigator considered that there was no reasonable possibility that the respiratory syncytial virus bronchiolitis may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the respiratory syncytial virus bronchiolitis included medical condition. Diagnostic results (unless otherwise stated, normal values were not provided): On 14th December 2014, Influenza A virus test result was NOT DECTECT unknown and Influenza B virus test result was NOT DECTECT unknown. On an unknown date, Respiratory syncytial virus test result was DECTECTED unknown.

Relevant Risk Factors : Mother has a positive family history of asthma.

Investigator Comments : This 15 month old female began having cough and runny nose on 10Dec2014. Symptoms worsened over the next couple of days and onset of fever by 13Dec2014. Mother took subject to outside facility for fever of 104 degrees farenheit on 13Dec2014. Subject was then hospitalized for fever, cough, runny nose and labored breathing (per mother). Per mother, testing revealed diagnosis of RSV and bronchiolitis. Mother states that chest xray, nasal wash and blood work were all performed to confirm diagnosis. 15Apr2015 Follow Up: Received records from outside facility: Subject was admitted due to increased work of breathing and fever up to 104. Subject was originally treated empirically for community acquired pneumonia withAmoxicillin and Azithromycin and place on 1 Liter nasal canula. Subject was weaned to room air on hospital day 3. Antibiotics were discontinued after RSV PCR became positive and clinical exam was consistent with bronchiolitis. The chest xray performed on 13Dec2014 impression: Lung volumes are not increased. Prominent perihilar markings are seen which may relect underlying reactive airwas disease or viarl process. No significant focal airspace disease. No effusion. The cardiac silhouette is within normal limits. Bony structures are intact. Pertinent Lab results on PCR Influenza A and B not dectected; RSV detected. Subject was in good condition at the subjects final study visit on 26Feb2015 and no further follow up will be conducted.

Additional Details: Other possible cause of the respiratory syncytial virus bronchiolitis included her medical condition of respiratory syncytial virus bronchiolitis.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to respiratory syncytial virus, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Respiratory syncytial virus bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 22nd August 2014, for prophylaxis.

Concurrent medical conditions included influenza. Concomitant products included diphtheria toxoid, haemophilus influenzae, pertussis toxoid, poliomyelitis vaccine, tetanus toxoid (Pentacel).

On PPD 128 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 respiratory syncytial virus bronchiolitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with amoxicillin, clavulanate potassium (Augmentin), lactobacillus nos (Lactobacillus), paracetamol (Acetaminophen) and salbutamol (Albuterol). The outcome of respiratory syncytial virus bronchiolitis was recovered/resolved on 7th January 2015.

The investigator considered that there was no reasonable possibility that the respiratory syncytial virus bronchiolitis may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the respiratory syncytial virus bronchiolitis included medical condition. Diagnostic results (unless otherwise stated, normal values were not provided): On 1st January 2015, Respiratory syncytial virus test result was POSITIVE unknown.

Investigator Comments:
Child was seen on 29Dec2014 for hypoxia with upper respiratory symptom. On 01Jan2015 child was see again for symptoms and was hospitalized. Diagnosed with Bronchiolitis due to respiratory syncytial virus. Child was seen for visit 3 on PPD at exit interview parents denied any hospitalization. Coordinator review of medical records on 12Mar2015 revealed that participant was hospitalized on 01Mar2015. Coordinator reported immediately upon discovery.

Additional Comments:
Other possible cause of the respiratory syncytial virus bronchiolitis included her medical condition of influenza with upper respiratory symptoms.

Case unblinded due to the end of study.

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Clinical Narrative report with Both Serious & Non-Serious Events

Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Leukocytosis, Dehydration

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 27 March 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD 19 days after the 1st dose of Blinded vaccine, 19 days after the 1st dose of Havrix 720 Junior, 19 days after the 1st dose of Varivax, 19 days after the 1st dose of Prevnar 13, this 12-month-old subject developed leukocytosis. On 17 April 2013, he developed dehydration. The subject was hospitalized. The subject was treated with ceftriaxone sodium, ibuprofen and paracetamol. The events resolved on 18 April 2013. The investigator considered that there was no reasonable possibility that the leukocytosis and dehydration may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13.

Investigator Comments:
Subject was seen in provider office on 15Apr2013 with fever and tonsillities, rapid strep was negative. Gever continued up to 104* F at times, Tylenols and ibuprofen used for fever control, however fever still continued. Pateint returned to clinic on 17Apr2013 when labs were collected indicating dehydration, patient was admitted to the hospital at the that time admit temp was 104.4 at provider office, CBC white blood count of 22, 000 indicated leukocytosis on 17apr2013 on 18 Apr2013 CBC was within normal range. Blood Culture was drawn on 17Apr2013 and was negative for growth at 24 hours. Urine culture from 17 Apr2013 was normal. BMP was normal. IV fluids were given, bolus and then maintenance plus IV Fluides, fluids were lowered as oral intake and urine output improved. Rocephin was given 500mg 2 doses IV, Ibuprofen (3.5cc) and Tylenol (3.5cc) given as needed. Patient was discharged on 18Apr2013, well hydrated sent with a script for Omicef for 8 days bu was later advised by provider not to fill or give. Final doase of Rocephin 500 mg IM was given on 19Apr2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

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Clinical Narrative report with Both Serious & Non-Serious Events

Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Mycoplasma infection

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 29 August 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD five months after the dose of Blinded vaccine, five months after the dose of Havrix 720 Junior, five months after the dose of Varivax, five months after the dose of Prevnar 13, this 17-month-old subject developed mycoplasma pneumoniae. The subject was hospitalised. The subject was treated with oxygen, ibuprofen, paracetamol, azithromycin, salbutamol sulphate and ipratropium bromide. The event resolved on 07 February 2014. The investigator considered that there was no reasonable possibility that the mycoplasma pneumoniae may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the event was possibly due to a bacterial lung infection.

Investigator Comments :
Cough started on the 23 Jan 2014. Mother took child to the clinic on the 29 Jan 2014. Was diagnosed with Bronchiolitis. The child s condition continued to decrease. Mother took the child to the ER where she was found to have a decrease in oxygen saturation into the 80 s.Suction treatment was given. Also albuterol and Atrovent treatment was given. The oxygen levels still remained in the 86-88 percent range. Child was admitted to the hospital. Oxygen at 0.5 liters was started and oxygen saturations were monitored constantly.Child was placed on droplet precautions. No IV fluid were given. No current fevers noted at that time. Child was found to have mycoplasma pneumonia Child was started on Azithromycin for a 5 day course. Weaned off the oxygen on 04 Feb 2014. Oxygen saturation remained within the okay range. Child was discharged to home on the 05 Feb 2014.With a follow up with primary care doctor as needed.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 147 days post vaccination. Reported event is due to Mycoplasma infection. which has no causal relationship to administered vaccines.

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchial hyperreactivity

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 18-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 1st August 2014, for prophylaxis.

Previously administered products included DTAP. Concurrent medical conditions included reactive airways disease.

On PPD 190 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 reactive airways disease. Serious criteria included hospitalization. The subject was treated with salbutamol (Albuterol), amoxicillin (Amoxicillin Trihydrate) and prednisolone. The outcome of reactive airways disease was recovered/resolved on 14th February 2015.

The investigator considered that there was no reasonable possibility that the reactive airways disease may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the reactive airways disease included medical condition.

Relevant Risk Factors : Patient s mother notes that she herself has exercise-induced asthma. Maternal grandmother has asthma. Mom s brother has asthma.

Investigator comments:
Patient started with cough 07FEB2015 and showed signs of respiratory distress 12FEB2015. Presented to urgent care 12Feb2015 at which time an x-ray was obtained and was assessed as normal. Inititially diagnosed as bronchiolitis. Elected to hospitalize for further observation. Diagnosis changed to reactive airways disease exacerbation secondary to viral illness at time of initial hospital evaluation. Patient put on continuous pulse oxygen. Patient's mother notes that she herself has exercise-induced asthma. Maternal grandmother has asthma. Mom's brother has asthma. Patient also diagnosed with otitis media at time of admission.

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Additional details:
Other possible cause of the reactive airways disease included medical condition of reactive airways disease.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 190 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Febrile convulsion

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 18-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 22nd August 2014, for prophylaxis.

Concurrent medical conditions included bronchiolitis, acute gastroenteritis, community acquired pneumonia and otitis media. Concomitant products included DIPHTHERIA TOXOID, PERTUSSIS TOXOID ACELLULAR, TETANUS TOXOID (DTAP), HAEMOPHILUS INFLUENZA B VACCINE (HIB) and INFLUENZA VACCINE.

On PPD 171 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 febrile seizure. Serious criteria included hospitalization and GSK medically significant. The subject was treated with ibuprofen, ceftriaxone sodium (Rocephine) and amoxicillin + clavulanate potassium (Augmentin). The outcome of febrile seizure was recovered/resolved on 9th February 2015.

The investigator considered that there was no reasonable possibility that the febrile seizure may have been caused by Priorix vs MMR II+Havrix+Varivax. Diagnostic results (unless otherwise stated, normal values were not provided): On 10th February 2015, Respiratory viral panel result was Positive unknown.

Invesigator comments:
6 hours prior to admission, patient developed her first tonic-clonic seizure for 30-45 seconds, post ictal

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episode noted for 6 minutes. Paramedics were called and while on the gourney, patient developed her second seizure for 45 secondsfolllowed by post ictal period for 6 mins. No medications were given. Patient and family has no history of seizure disorder. While on ED, patient was started on Ceftriaxone for possible pneumonia after CXR showed bilateral intrahilar pneumonia.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 15 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the dose of Blinded vaccine, five months after the dose of Havrix 720 Junior, five months after the dose of Varivax, this 17-month-old subject developed pneumonia. The subject was hospitalised. The subject was treated with salbutamol sulphate, benzylpenicillin, amoxicillin trihydrate, paracetamol and naproxen. The event resolved on 26 October 2013. The investigator considered that there was no reasonable possibility that the pneumonia may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an incidental illness.

Investigator Comments :
The subject came ot the visit 3 on PPD And the parent told that the subject had been hospitalized on 17Oct-19Oct2013, because of Pneumonia. The disease had started with respiratory symptoms on 14Oct2013. The child was hospitalized on 17Oct2013. At the hospital the child received i.v. antibiotics. The fever of the child was at maximum 40.2 C. The child started to recover and at home continued antibiotics tratment: Amorion 100mg/ml 2.4 ml three times per day on 19Oct2013-26Oct2013. The child is recovered on 26Oct2013 and is now feeling fine. No more information expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months post vaccination. Reported event has no causal relationship to administered vaccines.

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Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 11 June 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the dose of Blinded vaccine, five months after the dose of Havrix 720 Junior, five months after the dose of Varivax, this 17-month-old subject developed obstructive bronchitis. The subject was hospitalised. The subject was treated with salbutamol sulphate, paracetamol, prednisolone, naproxen and amoxicillin trihydrate. The event resolved on 10 November 2013. The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to incidental illness.

Investigator Comments :
The subject came to the visit 3 in the study on PPD The mother tells that the child has been hospitalized on 04Nov2013-05Nov2013, because of obstructive bronchitis. The disease started with normal upper respiratory tract infection symptoms on 02Nov2013. On 05Nov2013 at the hospital an otitis media (Non-SAE) has been diagnosed. The subject received Amorion comp 3ml twice a day medication for it on 05Nov-10Nov2013. The subject has recovered on 10Nov2013. No more information expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Serious Events: Concussion

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 22 July 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 91 days after the 1st dose of Blinded vaccine, 91 days after the 1st dose of Havrix 720 Junior, 91 days after the 1st dose of Varivax, this 15-month-old subject experienced brain concussion. The subject was hospitalised. The subject was treated with naproxen and timolol maleate. The event resolved on 24 October 2013. The investigator considered that there was no reasonable possibility that the brain concussion may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to accident.
Investigator Comments : Initial report on 23Jan2014. On the study visit 3 on PPD the mother tells that the subject has been hospitalized because of concussion, one night in October 2013. The mother does not remeber the exact date. The mother had fallen down with the child in the lap. The child had hit his forehead to the metal wheelbarrow. The mother could not take a contact to the child for a moment. And then the child had started to moan. The child was taken to the hospital emergency. There the child had vomited once. And a CT to head was taken. It was normal. But the child was taken to the pediatric surgery ward for observation. The child was discharged home next day. And was then feelig better. More information follows after receiving the medical records. Follow-up information from the mediacal records on 06Mar2014: After the accident had happened the child was about half a minute poorly reacting. The child was tired at the emergency. The CT from the head on 21Oct2013 showed no trauma in the brain, but on forehead was subcutaneous hematoma. The child was under observation at the pediatric surgery ward on 21Oct2013-22Oct2013. The child is estimated to be recovered on 24Oct2013. No more information expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 91 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Febrile convulsion

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 24 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

Medical conditions at the time of the event included affect cramps (temper tantrum cramps).

On PPD nine days after the dose of Blinded vaccine, nine days after the dose of Havrix 720 Junior, nine days after the dose of Varivax, this 13-month-old subject experienced febrile seizure. The event was clinically significant (or requiring intervention). The event resolved on 02 August 2013 and lasted about 1 to 1.5 minutes. The investigator considered that there was a reasonable possibility that the febrile seizure may have been caused by the investigational product and Varivax. The investigator also considered that there was no reasonable possibility that the febrile seizure may have been caused by Havrix 720 Junior and that the event was possibly due to an incidental illness and the subject's medical condition of affect cramps (temper tantrum cramps).

Investigator Comments :
On 05Aug2013 the subject visited the study clinic: The mother told that the child had had affect cramps (temper tantrum cramps) from the 6 months of age. The 3 last cramps were big ones and the child had lost consciousness during these cramps. On 02Aug2013 the mother and the child had been in cafeteria and the child started to have convulsions. The convulsions had lasted for about 1 minute - 1.5 minutes. During these the child's arms and chin had continuous twitching movements. Somebody called the ambulance and the ambulance took the child to the Hospital's Pediatric emergency. At the emergency the child was OK. And the laboratory tests were also normal. The temperature of the child was 37.5 C (normal). But the child was scheduled a time to the Pediatric Neurologic outpatient clinic later. Then is going to be made EEG. The causality has been put positive for MMR and Varivax vaccines, because the time when the reactions from these vaccines usually occur matches the time of the convulsions. The MMR and Varivax vaccines might have triggered the convulsions. The Havrix vaccine usually makes reactions at the first or second day after vaccination, so the causality to the Havrix vaccine, given on 24Jul2013 is not related.
Follow-up information from the medical records on 08Aug2013: At the hospital emergency the child had been crying. Movements of the limbs were normal. No neck stiffness. Pupils of the eyes were normal and symmetric. The condition of the child was good. The child was followed for 4 hours at the emergency and then sent home. Later will come time to the EEG- examination. The diagnosis was seizure symptom (temper tantrum attack suspected).

Follow-up information on 12Aug2013: There is no convulsions or epilepsy in the family history. There was no fever during the convulsions. The diagnosis is changed to the seizure symptom.

Follow-up information from the mother on 13Aug2013 by phone: The mother was asked a more precise description of the seizure. The mother told that the seizure started with crying of the child and was at first like a starting temper tantrum attack. But then the child went stiff and started to have cramping of hands and chin. This cramping had never happened before. When the ambulance men had arrived the temperature was 38.0 C from the ear. And the temperature at the hospital was 37.5 C. The child is going

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to EEG examination on 22Aug2013.

Follow up: Diagnose has been changed to febrile seizure, because temperature 38.0 degrees of celcius was measured once from the ear. Diagnosis will be updated later after neurology examinations if needed .

Follow-up information from the mother on 10Sep2013: The subject came to the visit 2 in the study with her mother. The mother told that the child had been in the EEG examination at the hospital. Only the EEG was made. And a letter came to the mother from the EEG-examination. It said that the EEG examination was normal. And that no time for the pediatric neurology outpatient clinic will come. The child continues in the study.

Follow-up information from the medical records on 23Sep2013: The final medical records have arrived. The child was in EEG examination on 22Aug2013. It was normal. There was no general abnormalities in it. No epilepsy. And no time to the pediatric outpatient clinic was scheduled. Because of the mild fever during the seizure, the episode can be considered as febrile seizure. No more information expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17
Causality cannot be excluded

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Asthma

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 14-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 17th July 2013, for prophylaxis.

The subject's past medical history included obstructive bronchitis.

On PPD 33 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 asthma. Serious criteria included hospitalization. The subject was treated with salbutamol (Ventoline), fluticasone propionate (Flixotide), ipratropium bromide (Atrovent), epinephrine

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(Racepinephrine), panadol (nos) (Panadol), theophylline (Theophyllin) and prednisolone (Prednisolon). The outcome of asthma was recovered/resolved on 6th September 2013.

The investigator considered that there was no reasonable possibility that the asthma may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the asthma included medical condition.

Investigator Comments:
The 1 year 2 months old boy, previously had obstructive bronchitis started to have dyspnea and fever on 19Aug2013. Hospitalized on 19Aug2013, diagnosed Asthma. In hospital treated with oxygen therapy and IV prednisolone, salbutamol, Flexotide inhalations.
Discharged from hospital in a better condition with medication, doctor's follow-up visit ordered on 01Oct2013. The subject has new onset of chronic disease: asthma.

Additional details:
Other possible cause of the asthma included medical condition of obstructive bronchitis.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 33 days. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Hypoglycaemia, Diarrhoea

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 18 September 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD six months after the dose of Blinded vaccine, six months after the dose of Havrix 720 Junior, six months after the dose of Varivax, this 18-month-old subject developed diarrhea. On 30 March 2014, he developed hypoglycemia. The subject was hospitalised. The subject was treated with Glucose + electrolytes and dextrose. Diarrhea resolved on 31 March 2014. Hypoglycemia resolved on 03 April 2014. The investigator considered that there was no reasonable possibility that the hypoglycemia and diarrhea may have been caused by investigational product, Havrix 720 Junior and Varivax and that the

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events were possibly due to an incidental illness.

Investigator Comments:
According to the mother child was admitted to hospital 30Mar2014 due to diarrhoea. Child is still in the hospital. More information will follow. Follow-up information from the medical records on 21May2014: On 29Mar2014 the child had 3 loose stools and was tired. The night went normally, but the child slept longer than normally.
On 30Mar2014 the child did not wake himself but had to be woken up by the parents. He was in cold sweat. Parents gave fast him 1.5 dl porridge and 2 dl milk. The child was still tired, calm and did not react to speaking. Eyes had twisted and the conscious went down. No cramps in exremities. Ambulance was called. The blood glucose was 2.1, temperature 35.0. The child got glucose solution orally and the blood glucose rose to 11.1. At the hospital the child was still not reacting properly.
The child was hospitalized on 30Mar-03Apr2014. During the hospitalization the child started to feel normally. He got glucose infusion. And the parents told that the child had started to have deviations and abnormal movements in eyes for one month time. And the EEG examination was taken.
During the EEG there was also some these attacs during eating. But the EEG was according to age. A control EEG was proposed. The child was discharged home on 03Apr2014 with normal condition. Some more laboratory tests were ordered. According the hospital papers the diagnosis was hypoglycaemia.
Follow-up information on 07Jul2014 from the medical records: The child had 3 loose stools on 29Mar2014 and was tired. The reason for hypoglycaemia according to the medical records might be the 3 loose stools on 29Mar2014 and that the food that had not absorbed from the bowel.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 02 October 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the dose of Blinded vaccine, five months after the dose of Havrix 720 Junior, five months after the dose of Varivax, this 17-month-old subject developed obstructive bronchitis.

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The subject was hospitalised. The subject was treated with salbutamol sulphate, paracetamol, ibuprofen and naproxen. The event resolved on 27 March 2014. The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to a viral infection.

Investigator Comments :
Initial on 25mar2014: parent of the subject contacted clinic and informed that subject has been on hospital 13-14Mar2014 due obstructive bronchitis.More information is coming when the hospital records arrive.SAE follow up on 09Apr2014:According to medical Records on 10Mar14 fever had started.On 13Mar14 child had fever 39,1 C,he was very tired and he used his accessory respiratory muscles.On 13Mar14 in the hospital emergency room he was treated with inhaled Ventolin.After that expiratory stridor was heard.On 13Mar14 child was admitted to hospital due to obstructive bronchitis.On 13Mar14 chest x-ray was normal.On 14Mar14 child was discharged from the hospital in good condition with inhaled Ventolin.On 18Mar14 Ventolin was stopped.Since 27Mar14 child has been symptomless.No more information is expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 159 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 14-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 8th September 2014, for prophylaxis.

On PPD 80 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 obstructive bronchitis. Serious criteria included hospitalization. The subject was treated with salbutamol (Ventoline). Priorix vs MMR II+Havrix+Varivax was continued with no change. The outcome of obstructive bronchitis was recovered/resolved on 2nd December 2014.

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The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by Priorix vs MMR II+Havrix+Varivax. Diagnostic results (unless otherwise stated, normal values were not provided): On 27th November 2014, Chest X-ray result was normal unknown and Oxygen saturation result was 86 %.

Investigator Comments;
Initial report on 08Apr2015: The mother phoned to the study clinic and told that the child had been hospitalized on Nov2014. The start and stop dates of the hospitalization is unknown at the moment. The diagnosis is Obstructive bronchitis. The child is recovered. The date is unknown. More information follows later.
Follow-up information on 16Apr2015 from the medical records and the subjects mother: The child had been hospitalized on 27Nov-29Nov2014, because of Obstructive bronchitis. The disease started on 27Nov2014 with breathing difficulties. At the hospital the child was treated with Ventoline inhalations. The outcome is recovered on 02Dec2014. No more information expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 18-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 8th September 2014, for prophylaxis.

The subject's past medical history included obstructive bronchitis.

On PPD 189 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 obstructive bronchitis. Serious criteria included hospitalization. The subject was treated with salbutamol (Ventoline), prednisolone (Prednisolon) and epinephrine (Adrenalin). Priorix vs MMR II+Havrix+Varivax was continued with no change. The outcome of obstructive bronchitis was recovered/resolved on 30th March 2015.

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The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the obstructive bronchitis included medical condition.
Diagnostic results (unless otherwise stated, normal values were not provided): In March 2015, Respiratory syncytial virus test result was negative unknown.

investigator Comments:
Initial report on 08Apr2015: The subjects mother phoned to the study clinic and told that the subject has been hospitalized on 18Mar2015-21Mar2015. The diagnosis is Obstructive bronchitis. The subject is already recovered. But the exact date is not available yet. More information follows later.
Follow-up information on 16Apr2015 from the medical records and from the subjects mother: The child was hospitalized on 18Mar-21Mar2015, because of Obstructive bronchitis. The disease started on 16Mar2015 with cough and rhinitis. The subject was treated with Ventoline inhalations and oral Prednisolon medication (dose unknown). The ventoline continues at home for 4 days. The subject is recovered on 30Mar2015. No more information expected.

Other possible cause of the obstructive bronchitis included medical condition of obstructive bronchitis.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Otitis media

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 25 March 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD six months after the 1st dose of Blinded vaccine, six months after the 1st dose of Varivax, six months after the 1st dose of Havrix 720 Junior, this 18-month-old subject developed otitis media. The subject was hospitalised. The subject was treated with ceftriaxone and cefixime. The event resolved on 26 September 2013. The investigator considered that there was no reasonable possibility that the otitis media may have been caused by investigational product, Varivax and Havrix 720 Junior and

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that the event was possibly due to incidental illness.

Investigator Comments :
Guardian telephone contact, hospitalised in Turkey due to bronchitis, hospital records requested. More information to follow.
Hospital records received, admitted due to vomiting, fever, loss of appetite as 23SEP2013 onwards. Right sided otitis media diagnosed. discharged in good condition.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 6 months. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Asthma

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 02 April 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

Medical conditions at the time of the event included congenital hypothyreosis and infectious asthma. Concomitant medications included Thyroxin.

On PPD 27 days after the dose of Blinded vaccine, 27 days after the dose of Havrix 720 Junior, 27 days after the dose of Varivax, this 16-month-old subject developed acute asthma exacerbation. The subject was hospitalised. The subject was treated with salbutamol sulphate, fluticasone propionate and prednisolone. The event resolved on 04 May 2013. The investigator considered that there was no reasonable possibility that the acute asthma exacerbation may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an incidental viral infection and his medical condition of infectious asthma.

Investigator Comments :
Signs of upper respiratory tract infection as of 29APR2013, and worsening difficulty breathing, admitted to hospital. Received salbutamole inhalations., Discharged is good condition.

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Clinical Narrative report with Both Serious & Non-Serious Events

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 27 days. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 01 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD on the same day after the dose of Blinded vaccine, and on the same day after the dose of Havrix 720 Junior, and on the same day after the dose of Varivax, this 12-month-old subject developed gastroenteritis. The subject was hospitalised. The subject was treated with intravenous fluid(s). The event resolved on 14 July 2013. The investigator considered that there was a reasonable possibility that the gastroenteritis may have been caused by the investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an incidental illness.

Investigator Comments :
The subject received the study vaccines on 01 July 2013, later that day she was more tired than usual.
02July 2013 : Patient started crying abnormal cry, and vomited. No fever at any point.
03July 2013 : Patient came to vaccination clinic. She was crying hard, wouldn't open her eyes, neck felt tight. Got sent to emergency room. In emergency room patient was crying and tired, general condition lowered, moderate. On heart auscultation functional systolic murmur. Lung auscultation clear. Stomach palpated soft. A.fem +/+, Periferia warm. Limbs had no pain. Eyes calm. Ears had tubes, no fluids. Throat little red. Quick-CRP below 5. Leukocytes 11.9. Patient was hospitalized for possible gastroenteritis. Plan was to take stomach ultrasound if needed. i.v. canyl for samples and fluids.
At the department gastroenteritis symptoms, diarrhea and vomiting. Patient felt well enough to go home on July 4th 2013. In hospital they did not take stool or urine samples. Discharged with final diagnosis of gastroenteritis.
Diarrhea continued until July 14th 2013, since then patient had been healthy.
Information on phone from subjects mother 09AUG2013 : No one else in the family had got sick or no one around was known to have gastroenteritis.

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Case unblinded due to the end of study.
Unblinding date is 25Oct17.
The report was previously unblinded with wrong study group.
TTO < 1 day, reported events could be coincidental.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 23 January 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD six months after the dose of Blinded vaccine, six months after the dose of Havrix 720 Junior, six months after the dose of Varivax, this 20-month-old subject developed acute obstructive bronchitis. The subject was hospitalised. The subject was treated with prednisolone, paracetamol, salbutamol sulphate, ipratropium bromide and naproxen. The event resolved on 08 August 2013. The investigator considered that there was no reasonable possibility that the acute obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an incidental illness.

Investigator Comments :
Previously healthy 1year 8 months old girl started to have dyspnea and fever 38.2 on 26Jul2013, visited a doctor and was hospitalized on 26Jul2013 because acute obstructive bronchitis. Treated with prednisolon and salbutamol, atrovent by inhalation in hospital. Discharged from hospital on 28Jul2013 in a good condition with medicartion prednizolon and salbutamol. Stop dat of treatment 08Aug2013. Today girl was in a good condition, no symptoms. She is healthy now.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 6 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 02 May 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 94 days after the dose of Blinded vaccine, 94 days after the dose of Havrix 720 Junior, 94 days after the dose of Varivax, this 15-month-old subject developed acute obstructive bronchitis. The subject was hospitalised. The subject was treated with salbutamol sulphate, prednisolone, prednisone, ipratropium bromide, fluticasone propionate, racepinephrine, paracetamol and naproxen. The event resolved on 14 September 2013. The investigator considered that there was no reasonable possibility that the acute obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an incidental illness.

Investigator Comments :
The 1 year 3 months old girl, previously healthy started to have dyspnea on 04Aug2013, visited a doctor, was treated with inhalaition and went home. But in the evening had again dyspnea and went to hospital, where received Salbutamol inhalaition and went to home. On 05Aug2013 had again dyspnea and went to hospital and was hospitalized because obstructive bronchitis. Treated in hospital with salbutamol and prednizolon. In hospital was diagnosed otitis media (Non SAE). Discharged from hospital on 06Aug2013 in a better condition with medication salbutamol for obstructive bronchitis and amoxicillin 400mg for otitis media. Information about SAE received from morther by phone call. On 11Sep2013 subject s mother called about new child hospitalization because obstructive bronchitis from 08Sep2013 to 10Sep2013. In hospital child was treated with prednizolon, salbutamol, atrovent for obstructive bronchitis. Discharged from hospital with medication Flixotide 125 mgx 2 x 2 times a day by inhalaition, prednizolon orally during 2 days. Phisician control 3 months later. Mother with child were in the clinic for last visit 3 in the study. Child now is a good condition, recovered from SAE on 14Sep2013. Medication Flixotide and Ventoline inhalaition twice a day continues.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 3 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Femur fracture

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 08 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 39 days after the 1st dose of Blinded vaccine, 39 days after the 1st dose of Havrix 720 Junior, 39 days after the 1st dose of Varivax, this 14-month-old subject experienced fractured femur. The subject was hospitalised. The subject was treated with ibuprofen. The event resolved on 10 September 2013. The investigator considered that there was no reasonable possibility that the fractured femur may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an accident.

Investigator Comments :
Initial report: Child had pain in the right hip from 16AUG13, first considered hip distension. Hospitalized 23-26AUG2013, diagnosis hip fracture. Now at home with splint. More information to follow after we receive the hospital report.
FOLLOWUP 18SEP2013: 16AUG13 first squirming on mother s arms, mother holding the right leg. Later same day child found crying, probably some kind of an accident with children s rocking chair, no eye witnesses. Seen by a doctor same day, clinical evaluation only. During the following week some improvement in child s use of the right leg but on 23AUG13 parents took the child to a private paediatrician who referred the child to hospital. X-rays 23AUG13 show distal metaphyse cross fracture of right femur, no other fractures, no signs of old fractures when checked as routine for all susceptible child abuse cases. No signs of sceletal pathology, routine laboratory tests normal, no details available. While in hospital, cast for the femur until 3 weeks from trauma. Discharged in good condition with cast on 26AUG13, followup on outpatient clinic scheduled 3 weeks from trauma.
FOLLOWUP 02DEC13: outpatient followup 10SEP13 child doing well, crawls around, stands on both feet, lower extremities appear symmetric. No followup scheduled. Battered child syndrome not suspected based on hospital routine evaluations. No more information to be expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 39 days. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Urticaria

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Amorion]:[Unknown] 500 mg 1D

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 16 September 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

The subject's medical history included previous recurrent otitis infections. The subject's medical conditions at the time of the event included otitis media.

On PPD 52 days after the 1st dose of Blinded vaccine, 52 days after the dose of Havrix 720 Junior, 52 days after the dose of Varivax, and 7 days after starting the concomitant medication Amorion (amoxicillin trihydrate), this 14-month-old subject developed urticaria. The subject was hospitalised. The subject was treated with desloratadine, prednisolone, hydroxyzine and dexamethasone. The event resolved on 22 November 2013. The investigator considered that there was no reasonable possibility that the urticaria may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to the concomitant medication, Amorion (amoxicillin trihydrate) (taken for : otitis media, Orion) and due to the subject's medical condition of otitis media and due to drug allergy.

Investigator Comments :
Initial report; site aware 08NOV13 but INV not present, study nurses were not sure whether reportable as SAE. Subject hospitalized because of allergic reaction, probable cause amoxicillin. First admission 07-08NOV13 but readmitted 11NOV13. More information to follow after we receive the hospital report. FOLLOWUP 27NOV13: Subject had 3 previous otitis infections, all treated with amoxicillin without problems. Now at the end of 7-day amoxicillin treatment first one papula below the right eye on 07NOV13. During the day plenty of a few mm by diameter red papulas all over. Seen first in primary health care, hydroxizine started, dose unknown. Evening of 07NOV13 hospitalized, breathing freely, oral cafity normal, all over the trunk 1-5cm sized urticaria lesions, swelling of feet, no facial, lids or hands swelling, feet bluish when hanging freely down. Epinephrine and salbutamol inhalations advised if needed but unknown whether given or not. Discharged 08NOV13, advised hydroxyzine 2.5mg daily but unknown whether given. Hospitalized again same evening 08NOV2013, because in the evening worsening of urticaria, significant swelling of hands and feet, increased tiredness, probably itching of mouth. In hospital periorbital, hand and feet swelling. Advised to continue hydroxyzine for 3 weeks at least. Planned amoxicillin exposure and IgE test after 3 months. We aim to observe these results when available.

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Follow-up 19MAR14: new data on medication. The amoxicillin exposure test has not been done yet, neither the IgE test.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 30 September 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 37 days after the dose of Blinded vaccine, 37 days after the dose of Havrix 720 Junior, 37 days after the dose of Varivax, this 13-month-old subject developed obstructive bronchitis. The subject was hospitalised. The subject was treated with dexamethasone, salbutamol sulphate, paracetamol and amoxicillin trihydrate. The event resolved on 17 November 2013. The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to viral infection.

Investigator Comments :
Initial report: child hospitalized 11NOV13 because of fever and breathing difficulty. More information to follow as we receive the hospital report. Follow up 16DEC13: From 06NOV13 child had cough and rhinitis, some fever for less than a day at the time, thriving well. From 10NOV13 evening tight cough disturbing the sleep, hospitalized 11NOV13. At admission diagnosed with bilateral otitis media, not SAE. Whining exspirium, tachypnea but general condition good. Repeated salbutamol inhalations, dose UNK, otitis treatment dose UNK. Obstruction subsides quickly, discharged in good condition 13NOV13 with oral amoxicillin continuing, otitis follow up in outpatient care. No more information to be expected. Follow up 19MAR14: Medication corrections only.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 37 days post vaccination. Reported event has no causal relationship to administered vaccines.

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumococcal sepsis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 18 March 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 40 days after the 1st dose of Blinded vaccine, 40 days after the 1st dose of Havrix 720 Junior, 40 days after the 1st dose of Varivax, this 15-month-old subject developed streptococcus pneumoniae septicemia. The subject was hospitalised. The subject was treated with benzylpenicillin and antibiotics. The event resolved on 19 May 2013. The investigator considered that there was no reasonable possibility that the streptococcus pneumoniae septicemia may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to a bacterial infection.

Investigator Comments :
Cough and rhinitis started on 27APR2013. Otitis media started in 29APR2013. 03MAY2013 high fever started and parents took child to doctor s appointment and child was sent to hospital. Blood leucocytes were elevated and pneumococcal sepsis was suspected. Child was hospitalized and intravenous antibiotic treatment was started. Streptococcus pneumonia septicemia was found in blood bacterial culture. CRP was also elevated. Thorax x-ray was normal. Subject was feeling well and was discharged from the hospital on 05MAY2013. Oral antibiotics continued for one week, but father doas not remember name of this antibiot. Subject has still cough, but is otherwise feeling well according to father. FOLLOWUP 10DEC13: Cough end date confirmed but information on the antibiotic missing. At hospital no otitis media, no treatment for that.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 40 days post vaccines. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 28 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD (unspecified date), six months after the dose of Blinded vaccine, six months after the dose of Havrix 720 Junior, six months after the dose of Varivax, this 17-month-old subject developed obstructive bronchitis. The subject was hospitalised. The subject was treated with xylometazoline hydrochloride, salbutamol sulphate, dexamethasone and amoxicillin trihydrate. The event resolved on 21 November 2013. The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to a viral infection.

Investigator Comments :
According to mother child was hospitalized on 08Oct-09Oct2013 due to obstructive bronchitis.Also otitis media was diagnosed.Otitis media is not a SAE.Otitis media was treated with Amorion comp.Stop date of obstructive bronchitis is 15Oct2013.More information will follow.SAE follow up report on 09Jan2014:Previously it was reported that child was hospitalized on 08Oct-09Oct2013 due to obstructive bronchitis but according to medical records the correct hospitalization dates are 14Nov-15Nov2013.According to medical records on 14Nov13 dyspnea had started.Cough and rhinits had started a few days earlier.On 14Nov13 first at home he was treated with inhaled Ventolin and nasal Nasolin.But dyspnea continued and the child was admitted to hospital.In the hospital child was treated with inhaled Ventolin and oral dexamethason.Also Amorion comp was started due to otitis media.Otitis media is not a SAE.Child was discharged from the hospital on 15Nov2013.Dexamethason continued at home until 17Nov2013.Amorion comp stopped on 21Nov2013.Then child was symptomless.So the stop date of this SAE is 21Nov2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 6 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Randomization Number:

Case ID: PPD

Serious Events: Type 1 diabetes mellitus

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 13-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 26th June 2013, for prophylaxis.

On PPD 44 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 type i diabetes mellitus. Serious criteria included hospitalization and GSK medically significant. The subject was treated with sodium chloride (Intravenous Saline Solution) and insulin aspart (Novorapid). The outcome of type i diabetes mellitus was not recovered/not resolved.

The investigator considered that there was no reasonable possibility that the type i diabetes mellitus may have been caused by Priorix vs MMR II+Havrix+Varivax.

Relevant Tests: On 23rd August 2013, ABLOOD BE result was - 6.7 mmol/L (normal low: -3, normal high: 2), ABLOOD PO2 result was 11.4 KPA (normal low: 4, normal high: 6.7) ,ARTERIAL BLOOD PCO2 result was 3.9 KPA (normal low: 5.3, normal high: 7.3), BLOOD GHB-A1C result was 8.6 % (normal low: 4, normal high: 6), BLOOD HBA1C result was 70 MMOL/MOL (normal low: 20, normal high: 42), BLOOD LEUCOCYTES result was 6.6 x10e9/L (normal low: 6, normal high: 17.5), PLASMA CRP result was 7 mg/L (normal high: BELOW 3), PLASMA OHBUTYR result was 4.04 mmol/L (normal high: BELOW 0.2), SERUM GADAB result was 10 iu/ml (normal high: BELOW 10), SERUM IA2AB result was 440 unknown (normal high: BELOW 15), SERUM LANGAB result was 80 unknown (normal high: BELOW 5), THROAT MUCUS STRAAG result was NEGATIVE unknown, URINE KETONES result was 2+ unknown. Diagnostic results (unless otherwise stated, normal values were not provided): On 23rd August 2013, Blood bicarbonate result was 19 mmol/L (normal low: 22, normal high: 26), PLASMA GLUCOSE result was 32.3 mmol/L, PLASMA POTASSIUM result was 4.7 mmol/L (normal low: 3.3, normal high: 5.2), PLASMA SODIUM result was 129 mmol/L (normal low: 137, normal high: 145) and URINE GLUCOSE result was 3+ unknown.

Relevant Risk Factors : subject s mother s father (diagnosed at age 2) and mother s father s father type 1 DM

Investigator Comments :
Hospitalisation between 23Aug2013 and 01Sep2013 due to newly diagnosed type 1 diabetes mellitus. Type 1 DM is also included in the list of EAs of specific interest. Information through telephone by the subject's parent on 09Sep2013. Further information currently pending, hospital records have been

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requested.
Follow-up information on 12Sep2013: Hospital records arrived. According to them, subject had during previous two weeks drunk and urinated a lot. During the previous week, these symptoms had became stronger. Concomitantly weight loss of approximately 0.8 kg as well as feverish upper resp tract infection symptoms. Upper respiratory tract infection is not SAE. In clin exam at admittance, subject tired, tearful, in poor contact, and dehydrated (clinical estimate 10%). Red throat and right-sided lymphadenopathy other abnormalities. Otherwise normal findings. Markedly increased blood glucose with ketoacidosis. Intravenous fluid filling 150 ml/30 was started and labs were controlled.
The following day, subject's health had improved, ketose had receded and blood glucose had normalised. Intravenous program was continued for 24 hours. Thereafter, it was transferred to Medtronic Veo - insulinpump treatment.
Subject was released home on 1Sep2013 with insulinpump treatment and follow-up was planned to be carried out at diabetes outpatient clinic.
On 13Jan2014 subject was on the follow-up visit at diabetes outpatient clinic. Subject now is a good condition. On 14Jan2014 was given second dose of Varicella and Havrix vaccine. It was last visit in the Vccine Research clinic.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Family history of type I diabetes mellitus. Reported event has no causal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Asthma

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 28 October 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

The subject's past medical history included obstructive bronchitis. Concomitant medications included Salbutamol and Flixotide.

On PPD 37 days after the dose of Blinded vaccine, 37 days after the dose of Havrix 720 Junior, 37 days after the dose of Varivax, this 13-month-old subject diagnosed of infectious asthma. The subject was hospitalised. The subject was treated with salbutamol sulphate, fluticasone propionate,

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Clinical Narrative report with Both Serious & Non-Serious Events

amoxicillin trihydrate, dexamethasone and ipratropium bromide. The event resolved on 18 December 2013. The investigator considered that there was no reasonable possibility that the infectious asthma may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an incidental illness and due to his medical condition of obstructive bronchitis

Relevant Risk Factors : Father have asthma

Investigator Comments :
The child previously had obstructive bronchitis two times. On 04Dec2013 child had fever ad 38.6 and breething was difficult. It was third obstructive bronchitis. IThe parents took the child to hospital and in hospital was diagnosed Infectious asthma. His father have asthma too. The child was hospitalized 04Dec-07Dec2013. On 07Dec2013 child was discharged from hospital in good condition with medication Flixotide 250 mcg x 2 during 2 weeks and after 125 mcg x 2. Follow up control visit to allergic hospital.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 04 April 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

Medical conditions at the time of the event included otitis media.

On PPD 44 days after the 1st dose of Blinded vaccine, 44 days after the 1st dose of Havrix 720 Junior, 44 days after the 1st dose of Varivax, this 13-month-old subject developed obstructive bronchitis. The subject was hospitalised. The subject was treated with salbutamol sulphate, amoxicillin trihydrate, fluticasone propionate and prednisolone. The event resolved on 30 June 2013. The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to viral infection.

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Clinical Narrative report with Both Serious & Non-Serious Events

Investigator Comments :
Initial SAE report submitted by study nurse because Investigator is abroad.
Investigator will submit follow up report on 25jun2013.
Causality and diagnosis received from Investigator by phone.
Update 25Jun2013 from the medical record: The subject started to have respiratory symptoms 18May2013, was taken to emergency room 20May2013 because of dyspnea. The subject was hospitalized because of obstructive bronchitis. He had had a respiratory infection a few weeks ago and medicated with Ventoline and recovered well in home care. In hospital, the oxygen saturation was found to be 93 %, his respiration was laboured. He was kept in hospital overnight for observation and treatment with Ventoline. Laboratory results were all within normal range except for slightly elevated CRP (no upper or lower limits or units provided in hospital record). Otitis media was also diagnosed in hospital on discharge day, (not considered to be serious). He started to feel better in hospital and was discharged in stabile condition. Treatment with Ventoline still continued at home. 13JUN2013 he had a check-up, Flixotide medication was started and also short treatment with Prednisolon. Flixotide medication continues at home, the subject is scheduled to have a control visit to doctor in July.
Update 02OCT2013: According to parents, the subject was fully recovered 30JUN2013. Flixotide and Ventoline medication are not in use anymore. No more information is expected.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 10 October 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 78 days after the dose of Blinded vaccine, 78 days after the dose of Havrix 720 Junior, 78 days after the dose of Varivax, this 15-month-old subject developed gastroenteritis. The subject was hospitalised. The subject was treated with paracetamol and intravenous fluid(s). The event resolved on 03 January 2014. The investigator considered that there was no reasonable possibility that the gastroenteritis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to viral infection.

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Clinical Narrative report with Both Serious & Non-Serious Events

Investigator Comments :
On 27 Dec 2013 the subject started to suffer from diarrhea and vomiting. She wasn t able to drink and eat enough so she developed hypovolemia. The subject was taken to the emergency room on 31 Dec 2013 and was hospitalized due to hypovolemia caused by gastroenteritis (viral infection). When hospitalized, the subject weighed 8,4 kilograms, 2 weeks before the onset of the illness the weight has been 9,2 kilograms so estimated hypovolemia was 8,5 percent. During the hospitalization hypovolemia was treated with intravenous fluids (name or volume not available). Fever and pain were treated with Panadol 24 milligram/milliliter oral suspension 5,5 milliliters 3 times a day from 27 Dec 2013 to 1 Jan 2014. The subject was discharged on 1 Jan 2014 when she was able to drink and eat enough again and the weight has increased. The symptoms relieved and the subject recoverd entirely on 3 Jan 2014. Follow up report on 05Jun2014: SAE term 2 hypovolemia removed, because hypovolemia is a symptom of gastroenteritis, not an independent SAE.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 78 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral infection, Otitis media, Seizure

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 17 October 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 24 days after the dose of Blinded vaccine, 24 days after the dose of Varivax, 24 days after the dose of Havrix 720 Junior, this 12-month-old subject developed viral infection. On 17 November 2013, she developed otitis media. On 20 November 2013, she developed cerebral convulsion. The subject was hospitalised. The subject was treated with ceftriaxone, intravenous fluid(s), acyclovir and paracetamol. Cerebral convulsion resolved on 20 November 2013. Viral infection and otitis media resolved on 28 November 2013. The investigator considered that there was no reasonable possibility that the viral infection, otitis media and cerebral convulsion may have been caused by investigational product, Varivax and Havrix 720 Junior and that the events were possibly due to a viral infection.

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Clinical Narrative report with Both Serious & Non-Serious Events

Investigator Comments :
The subject had had minor rhinitis starting about 10NOV2013. 17NOV2013 she started to have fever. 18NOV2013 the fever got higher and the child also vomited. She was taken to doctor and otitis media was diagnosed. Because her condition got worse, she was taken to emegency room 18NOV2013 and hospitalized the same day. She is in hospital right now, according to the mother a viral infection is suspected to be the cause of her high fever and other symptoms. She has been treated with antibiotics, antiviral medication and iv-fluids. More information will follow after the child has been discharged and her hospital records received.SAE follow up report on 23Jan2014:According to medical records on 17Nov13 fever 38 C had started.She had also rhinits.Since 18Nov13 she had high fever and she was very tired and she had vomited.Pyhysical examination on 18Nov13:small petechias on legs and arms,also otitis media was diagnosed.On 18Nov13 child was admitted to hospital and iv. keftriazone was started.In the hospital it was also noticed that her eyes were twitching.For that reason lumbar puncture was performed on 19Nov13After that iv acyclovir was started and the dose of keftriazone was increased..Cerebrospinal fluid was analyzed:no bacteria were found,also HSV,HZV and HHV antibodies were negative.When these results were received,acyclovir was stopped.On 20Nov13 child had a seizure:her hole body was shaking,she had convulsions symmetrically in her both arms,her eyes were twitching,vertical nystagmus was noticed and it was not possible to get into contact with her.According to neurologist this seizure was not a normal febrile seizure but it was cerebral convulsion due to viral infection and fever.EEG and head MRI were normal.Strabismus was also diagnosed in the hospital.According to parents starbismus had started 2-3 weeks earlier.Strabismus is not a SAE.Eye speacialist was consulted:further examinations were scheduled later due to this strabismus. On 22Nov13 neutropeny was noticed.
Neutropeny is not a SAE.Otherwise child was already in good conditionChild was discharged from the hospital on 22Nov13 in good condition.Follow up visit in hospital was schedule on 28Nov13: Then she was in good condition.Strabismus was noticed,otherwise her status was normal.All laboratory values were also normal.According to medical records final diagnosis was viral infection,otits media and cerebral convulsions.No more information is expected. On 19Mar14 SAE follow-up report: It has been noticed from source documents (diary card) that the child was treated with paracetamol during the fever on 17Nov13 and on 18Nov14. Correction on 15Apr2014: The subject was treated with paracetamol on 17Nov13 and on 18Nov13 (instead of 18Nov14).

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 24 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral infection

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency: [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 17th October 2013, for prophylaxis.

Concomitant products included amoxicillin trihydrate (Amorion).

On PPD 152 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 viral infection. Serious criteria included hospitalization. The subject was treated with antibiotics nos (Antibiotic (Name Unknown)), analgesic, nos (Painkiller Unknown), medication unknown (Fluids), vitamins nos (Vitamin), hydrocortisone and tobramycin (Tobrex). The outcome of viral infection was recovered/resolved on 6th April 2014.

The investigator considered that there was no reasonable possibility that the viral infection may have been caused by Priorix vs MMR II+Havrix+Varivax.

Diagnostic results (unless otherwise stated, normal values were not provided): On 20th March 2014, BLOOD HEMOGLOBIN result was 12.2 g/dL (normal low: 12.0, normal high: 18.0), BLOOD LYMPHOCYTES result was 3.35 x1000/uL (normal low: 0.6, normal high: 3.4), BLOOD PLATELETS result was 380 x1000/uL (normal low: 140, normal high: 425), Monocyte count result was 1.07 x1000/uL (normal low: 0.0, normal high: 0.9), Neutrophil count result was 5.38 x1000/uL (normal low: 2.0, normal high: 6.9), PLASMA CRP result was 9.49 mg/dL (normal low: 0.0, normal high: 0.5), Red blood cell count result was 4.75 M/uL (normal low: 4.04, normal high: 6.13), THROAT MUCUS STREPTCOCCUS A result was NEGATIVE unknown and White blood cell count result was 10.0 x1000/uL (normal low: 4.6, normal high: 10.2). On 31st March 2014, NASOPHARYNGEAL SWAB RESPIRATORY VIRUSES POLYMERASE CHAIN REACTION result was NEGATIVE unknown and PLASMA CRP result was 74 mg/L (normal low: 0, normal high: 10). On 2nd April 2014, BLOOD ERYTHROCYTE SEDIMENTATION RATE result was 72 mm/hr (normal low: 0, normal high: 16), BLOOD PLATELETS result was 615 x10e9/L (normal low: 200, normal high: 450) and PLASMA CRP result was 49 mg/L (normal low: 0, normal high: 10).

Investigator Comments :
On 18Mar2014, when the subject was on vacation with her family in Turkey, she started to have fever over 38 celsius degrees, rash on the face and extremities, dryness in the corners of the mouth, and conjunctival redness was also noticed in both eyes. Fever was treated with painkiller (name unknown) on 18Mar-21Mar2014. On 19Mar2014 they went to local pharmacy and started to treat eyes with Tobrex eye drops 1 drop 1 time per day in both eyes, this treatment continued until 26Mar2014. On 20Mar2014 the subject was taken to doctor and then hospitalized due to fever, tonsillitis and urticaria-like rash. C reactive proteine (CRP) was elevated 9.49 milligram/desilitre (mg/dL), blood picture was normal except of marginally elevated monocyte count 1.07 x1000/microlitre (uL), no streptococcus A was found in throat mucus. In the hospital on 20Mar-21Mar2014 the subject was treated with intravenous fluids, antibiotics, vitamins and pain killers (all names and amounts unknown). On 21Mar2014 fever decreased and the

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Clinical Narrative report with Both Serious & Non-Serious Events

subject was discharged from the hospital. They flew back home, to Finland on 22Mar2014. On 23Mar2014 the subject was taken to pediatrician, Adeno virus infection was suspected to have caused the symptoms. In physical examination no specific findings except of some eye discharge and light redness in tonsils. On 25Mar2014 skin started to flake off the fingertips. After that some rash was noticed again, mainly on belly and thighs. Also a little stuffy nose. On 29Mar-31Mar2014 the subject's mother noticed that the subject could not walk normally. On 31Mar2014 the subject was taken to primary care physician and a referral to children's emergency room was made, a suspicion of Kawasaki disease was arousen. In pediatrician's examination the Kawasaki disease's criteria was not met. In physical examination the subject walked in small steps, tympanic temperature was 37.5 degrees celsius and dry, papulous-like rash was noticed on thighs and belly, otherwise no abnormal findings.
CRP was elevated 74 milligram/litre (mg/L). No findings in blood picture except of elevated platelets count, exact results are not available. Nasopharyngeal swab was taken to find respiratory viruses by polymerase chain reaction technique, the results were negative. Anyway viral infection (unspecific) was diagnosed to cause the symptoms. On 02Apr2014 the patient was controlled in the children's outpatient department, walking was then normalized and the subject generally in good health. Dry, papulous-like rash was still noticed on thighs, belly and also on left arm. Mild topical hydrocortisone 1 percent (%) was advised to be used to the rash. CRP was decreasing, 49 mg/L. Erythrocytes sedimentation rate was elevated 72 millimetre/hour (mm/hr). Platelets count was also elevated, 615 10e9/litre. On 02Apr2014 the skin started to flake off the toes too. After 02Apr2014 the patient recovered rapidly, according to the mother the subject was totally recovered on 06Apr2014. No control visit to doctor was scheduled. No more information is to follow.
Follow up SAE report on 23May2014: Mild topical hydrocortisone was used only once on 02Apr2014 (instead of 02-06Apr2014). New information received by phone from the mother of the subject.
Follow up report on 12Jan2015: Vitamins (exact ingredients unknown) were prescribed to treat infection.

Country of occurenece has been corrected from Turkey to Finland.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia respiratory syncytial viral, Respiratory tract infection viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 30 October 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or

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Clinical Narrative report with Both Serious & Non-Serious Events

Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after a dose of Blinded vaccine, five months after a dose of Havrix 720 Junior, five months after a dose of Varivax, this 16-month-old subject developed Respiratory Syncytial Virus (RSV) pneumonia and respiratory tract infection (Rhino virus). The subject was hospitalised. The subject was treated with salbutamol sulphate, paracetamol and oxygen. The events resolved on 23 March 2014. The investigator considered that there was no reasonable possibility that the Respiratory Syncytial Virus (RSV) pneumonia and respiratory tract infection (Rhino virus) may have been caused by investigational product, Havrix 720 Junior and Varivax and that the events were possibly due to viral infection (Respiratory Syncytial Virus).

Investigator Comments :
Initial report of SAE: On 18Mar2014 in the early morning the subject got fever. During the morning respiratory rate increased and breathing seemed to be difficult, the child was using her abdominal muscles. Family attended emergency room on 18Mar2014 at 1.30 pm and the subject was hospitalized due to pneumonia caused by respiratory syncytial virus (RSV). At hospital the fever was 38,5 celsius (tympanic). The fever was treated with oral Paracetamol 125mg 3 times a day. Dyspnea was treated with Salbutamol 0,1mg 6 inhalation every two hours while awake. Supplemental oxygen was needed too during the hospitalization. The subject was discharged from hospital on 19Mar2014. The subject is recovering now, no fever on 20Mar2014. At home the medications are continuing: oral Paracetamol 125mg 3 times a day and Salbutamol 0,1mg 6 inhalations every two hours while awake. Salbutamol inhalations are planned to continue with the same frequency until 21Mar2014 and after that the dose will be decreased to 2 inhalations if needed. More information will follow when the medical records of the hospitalization will be available.
Follow up report on 17Apr2014: According to the hospital discharge report in addition to respiratory syncytial virus, also rhino virus was found from nasopharyngeal swab on 19Mar2014 by polymerase chain reaction technique. Rhino virus may also cause respiratory tract infections. When the subject was hospitalized, the blood oxygen saturation was too low 87-89 percent (%), with supplemental oxygen 1,5 litre/minute (L/min) blood oxygen saturation elevated to 92-95%. In the beginning the subject was treated with Salbutamol 0,1 milligram/inhalation 6 inhalations every 20 minutes during 1 hour (4 times), after that 6 inhalation every 2 hours while awaken. On 18Mar2014 blood serum C reactive protein (CRP) was normal 5 milligram/litre (mg/L) and blood picture was normal. The subject was discharged from hospital on 19Mar2014.
At home oral paracetamol 125mg was given 3 times a day until 21Mar2014 and Salbutamol 0,1mg 6 inhalations every 2 hours until 20Mar2014 and on 21Mar2014 Salbutamol 0,1mg was given 1 inhalation 2 times a day. According to subject s mother the subject recovered on 23Mar2014. No more information will follow.
On 29 Apr 2014 follow up report: Oral paracetamol was given 3 times a day until 22 Mar 2014 (instead of until 21 Mar 2014 as was reported previously). Corrected information received from the subject s mother on scheduled visit and it was also marked so in the diary card.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 139 days post vaccination. Reported event is due to respiratory syncytial virus infection, which has no causal relationship to administered vaccines.

Study Number: 115648

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 23 April 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD six months after the 1st dose of Blinded vaccine, six months after the 1st dose of Havrix 720 Junior, six months after the 1st dose of Varivax, this 18-month-old subject developed obstructive bronchitis. The subject was hospitalised. The subject was treated with salbutamol sulphate and dexamethasone. The event resolved on 16 October 2013. The investigator considered that there was no reasonable possibility that the obstructive bronchitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to a viral infection.

Relevant Risk Factors :
Father: diagnosed asthma

Investigator Comments :
According to parent child has been hospitalozed due to obstructive bronchitis on 14Oct-15Oct2013.Upper respiratory tract infection symptoms had started on 12Oct13.Since 14Oct13 child had also dyspnea and for that reason she was admitted to hospital the same day 14Oct13.In the hospital she was treated with inhaled Ventolin and oral cortisone.She was discharged from the hospital next day 15Oct2013 in good condition.Chlid received last dose of cortisone on 16Oct13.Since then she has been symptomless.More information will follow when medical records are available.SAE follow up report on 08Nov2013:According to medical records on 12Oct13 rhinitis had started.Since 14Oct13 she had also cough,dyspnea and fecver 38C.On 14Oct13 during lung auscultation inspiratory and expiratory stridor were heard.Obstructive bronchitis was diagnosed and she was admitted to hospital.In the hospital she was treated with inhaled Ventolin and oral dexamethasone.On 15Oct2013 child was discharged from the hospital in good condition with inhaled Ventolin.No more information is expected.According to medical records child was treated with oral dexamethasone only on 14Oct13.So the correct stop date of dexamethasone is 14Oct13.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 6 months. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Febrile convulsion

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 30 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 51 days after the dose of Blinded vaccine, 51 days after the dose of Varivax, 51 days after the dose of Havrix 720 Junior, this 13-month-old subject developed febrile convulsion. The subject was hospitalised. The subject was treated with diazepam, ibuprofen, Augmentin and paracetamol. The event resolved on 21 July 2013. The investigator considered that there was no reasonable possibility that the febrile convulsion may have been caused by investigational product, Varivax and Havrix 720 Junior and that the event was possibly due to an incidental illness.

Relevant Risk Factors : Family history: child s father and uncle has had febrile convulsions.

Investigator Comments :
According to mother and father child had experienced febrile convulsions on 20Jul2013 when the family was on holidays abroad .Suddenly the child experienced convulsions while sleeping.According to father child had had convulsions symmetrically in his both upper limbs and the child had been unconscious.This seizure had lasted for few minutes.The child had been taken to hospital by ambulance.According to medical records child had had convulsions while asleep, tonic and clonic movements that had lasted for few minutes.In the hospital he had no more convulsions.In the hospital he had fever 38,6 C rec, otherwise status normal.Laboratory tests normal.Acute viral infection was diagnosed(acute viral infection is not a SAE).In the hospital he was treated with Diazepam,Nurofen,Benuron and Augmentine.On 20Jul13 child was admitted to hospital for observation.On 21Jul13 he was discharged from the hospital in good condition,he had no more fever.Child was dsicharged with oral antibiotics and antipyretics.On 23Jul13 child visited the pediatrician after returning to home country.Then tonsillitis was diagnosed and Kefexin was started,otherwise his status was normal.Tonsillitis is not a SAE.No more information is expected.SAE follow up on 06Aug13: According to mother child received last dose of Nurofen and Benuron on 20Jul13 and last dose of Augmentine on 21Jul13 during hospitalization.So the child was discharged from the hospital on 21Jul13 in good condition.According to medical records he was discharged with antibiotics and antipyretics.But according to mother he received no medication after hospitalization until 23Jul13 when Kefexin was started.

Case unblinded due to the end of study.

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Clinical Narrative report with Both Serious & Non-Serious Events

Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pyelonephritis acute

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On14 November 2012, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 96 days after the 1st dose of Blinded vaccine, 96 days after the 1st dose of Havrix 720 Junior, 96 days after the 1st dose of Varivax, this 15-month-old subject developed pyelonephritis acute. The subject was hospitalised. The subject was treated with oseltamivir phosphate, cefuroxime sodium, sulphamethoxazole, trimethoprim, paracetamol and ibuprofen. The event resolved on 26 February 2013. The investigator considered that there was no reasonable possibility that the pyelonephritis acute may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
At the night of 18.02.2013 suddenly arised body temperature up to 40 degrees of Celsius presenting with seizures and there was vomitting too. Called ambulance hospitalised the patient 18.02.2013. Treatment was effective and body temperature normalized 19Feb2013. The patient general condition betterned and the patient was discharged from hospital 21.02.2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 3 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

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Clinical Narrative report with Both Serious & Non-Serious Events

Case ID: PPD

Serious Events: Head injury

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 21 November 2012, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD six months after the 1st dose of Blinded vaccine, six months after the 1st dose of Havrix 720 Junior, six months after the 1st dose of Varivax, this 18-month-old subject developed superficial injury of head. The subject was hospitalized. The event resolved on 18 May 2013. The investigator considered that there was no reasonable possibility that the superficial injury of head may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments:
The patient fell out from pram 16.05.2013 and the patient s head was superficialy injured. The patient was taken to ER and hospitalized 16.05.2013. No lose of consciousness, no vomiting. The patient was torpid, passive. Physical status: bump on the forehead size 3 x 3 cm. No nystagmus. Eye pupils reacted to lthe light equally. Bilateral negative Babinski s reflex. 17.05.2013 CT: no intracranial injury. No cranial bone fracture. 18.05.2013 - patient active in good mood, no torpid and the patient was discharged from the hospital.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 6 months post vaccinations. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

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Clinical Narrative report with Both Serious & Non-Serious Events

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 22 November 2012, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 47 days after the 1st dose of Blinded vaccine, 47 days after the 1st dose of Havrix 720 Junior, 47 days after the 1st dose of Varivax, this 16-month-old subject developed viral intestinal infection, unspecified. The subject was hospitalized. The subject was treated with sodium chloride and dextrose. The event resolved on 14 January 2013. The investigator considered that there was no reasonable possibility that the viral intestinal infection, unspecified may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments:
08.01.2013 the patient came down with diarrhea and vomiting (2-3 times a day). Aquatic faeces. Drunk a lot, positive diuresis. The patient did not want to eat. No stomach ache. Normal skin without rush. 12.01.2013 the called ambulance took the patient to the hospital. The patient was hospitalized 12.01.2013. Physical status: body temperature 36.6 degrees of Celsius. Satisfactory general condition. The patient was very active. Frequency 115 times per minute. Analysis of BE (base excess) - 12.2 (metabolic acidose). Clinically diagnosed viral intestinal infection, unspecified. With hospital treatment the patient general condition bettered. The patient was discharged from hospital 14.01.2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 47 days post vaccinations. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia respiratory syncytial viral, Otitis media

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 13 February 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 19 days after the dose of Blinded vaccine, 19 days after the dose of Varivax, 19 days after the dose of Havrix 720 Junior, this 15-month-old subject developed respiratory syncytial virus

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pneumonia. On 15 March 2013, she developed otitis media bilateral ears. The subject was hospitalised. The subject was treated with oxeladin, ampicillin trihydrate, salbutamol sulphate and sultamicillin. The events resolved on 23 March 2013. The investigator considered that there was no reasonable possibility that the respiratory syncytial virus pneumonia and otitis media bilateral ears may have been caused by investigational product, Varivax and Havrix 720 Junior.

Investigator Comments :
04.03.2013 the patient become sick with gough, rinitis, fever up to 38 degrees of Celsius. Complaines were cough, anxious, crying, fitful sleep. Mother went with child to GP 14.03.2013. X-ray was done and diagnosed right side pneumonia. The patient was sent to the hospital by GP. Specialist consulted the patient and diagnosed bilateral otitis of the middle ear 15.03.2013. The treatment was effective and the patient s health condition improved and was discharged from the hospital 18.03.2013. Treatment continued at home up to 23.03.2013. The child has recovered.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Upper respiratory tract infection

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 10 April 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the 1st dose of Blinded vaccine, five months after the 1st dose of Havrix 720 Junior, five months after the 1st dose of Varivax, this 20-month-old subject developed acute upper respiratory infection of multiple and unspecified sites. The subject was hospitalised. The subject was treated with paracetamol, nasal medication (unspecified) and unspecified inhalation. The event resolved on 28 September 2013. The investigator considered that there was no reasonable possibility that acute upper respiratory infection of multiple and unspecified sites may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
The patient had vomiting, cough, arise body temperature 39 - 40 degrees of Celsius since 14.09.2013.

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Called ambulance 15.09.2013 and 19.09.2013, GP visit took place 20.09.2013. Body temperature rose again 21.09.2013 and called ambulance hospitalised the patient 21.09.2013.
Physical status: cough, lot of greenish mucous secretion from nose. Bilateral vesicular breathing murmur. Throat rose. Lymphatic nodes not palpable. No rush. The patient s health condition get well and the patient was discharged from hospital 22.09.2013. The patient recovered from head cold 28.09.2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months. Reported event is due to Upper respiratory tract infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pyelonephritis acute

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 11 April 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

The subject's past medical history included acute pyelonephritis.

On PPD five months after the 1st dose of Blinded vaccine, five months after the 1st dose of Havrix 720 Junior, five months after the 1st dose of Varivax, this 19-month-old subject developed acute pyelonephritis. The subject was hospitalized. The subject was treated with paracetamol, cefuroxime and ibuprofen. The event resolved on 19 September 2013. The investigator considered that there was no reasonable possibility that the acute pyelonephritis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to her medical condition of acute pyelonephritis..

Investigator Comments :
The patient had body temperature arise up to 40 degrees of Celsius 08.09.2013. The patient was hospitalized 09.09.2013 - 13.09.2013 - diagnosed pyelonephritis acute. Ultrasound investigation of abdominal and pelvic organs - no pathological findings. The treatment was effective and the patient s health condition bettered. The patient was discharged from the hospital 13Sep2013 and treatment continuous at home. The patient recovered 19Sep2013.

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Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months. Reported event is due to bacterial infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pharyngitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 19 April 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD seven days after the 1st dose of Blinded vaccine, seven days after the 1st dose of Havrix 720 Junior, seven days after the 1st dose of Varivax, this 13-month-old subject developed pharyngitis acute . The subject was hospitalised. The event resolved on 30 April 2013. The investigator considered that there was no reasonable possibility that the pharyngitis acute may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
26.04.2013 the patient became sick with a sudden high fever 40 C, refused to drink. 28.04.2013 was hospitalized due to the sudden rise of body temperature and vomiting. Physical status: body temperature 38.8 degrees of Celsius. Patient was not active, torpid. Intensive hyperemic throat, hyperemic enlarged tonsils. 29.04.2013 the fever subsided. 30.04.2013 non-itching papulous red rash appeared on the limbs and on the trunk which disapeared to evening of the same day. The patient was discharged from the hospital in good general condition 30.04.2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

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Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Urticaria

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 20 April 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD four days after the dose of Blinded vaccine, four days after the dose of Havrix 720 Junior, four days after the dose of Varivax, this 14-month-old subject developed urticaria. The subject was hospitalised. The subject was treated with cetirizine hydrochloride. The event resolved on 09 May 2013. The investigator considered that there was no reasonable possibility that the urticaria may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
24.04.2013, a red rash appeared on the face and on the trunk of the patient. 26.04.2013 the rash subsided. 03.05.2013 the rash appeared again, the patient was anxious. The patient went to hospital and was hospitalized 03.05.2013. 05.05.2013 the rash subsided. The patient was discharged from hospital 05.05.2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Burns second degree

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

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Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 25 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD four months after the dose of Blinded vaccine, four months after the dose of Havrix 720 Junior, four months after the dose of Varivax, this 17-month-old subject sustained second degree burns. The subject was hospitalised. The subject was treated with sodium chloride, paracetamol, bismuth subnitrate, kaolin, potassium permanganate, purified water, herbal ingredient(s) not referenced, lanolin and topical skin preparation. The event resolved on 25 October 2013. The investigator considered that there was no reasonable possibility that the second degree burns may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
The patient got hot water burn 02Oct2013 to face, neck and chest region. The patient was hospitalised 02Oct2013 - 08Oct2013. Treatment: with ointment Seppo was effective. The patient recovered by patient s mother s words 25Oct2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 4 months post vaccination. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Nasopharyngitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 25 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 73 days after the 1st dose of Blinded vaccine, 73 days after the 1st dose of Havrix 720 Junior, 73 days after the 1st dose of Varivax, this 14-month-old subject developed acute nasopharyngitis. The subject was hospitalised. The subject was treated with ibuprofen, paracetamol and cetirizine hydrochloride. The event resolved on 08 August 2013. The investigator considered that there was no reasonable possibility that the acute nasopharyngitis may have been caused by investigational

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product, Havrix 720 Junior and Varivax.

Investigator Comments:
The patient vomited on 06Aug2013, called ambulance hospitalised the patient. Body temperature was 38.3 degrees of Celsius. Prescribed treatment. Symptoms and signs disappeared and the patient was discharged from the hospital 07Aug2013. By the patient s mother s words the patient was recovered 08Aug2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17
TTO 73 days. Reported event is has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis adenovirus

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 29 September 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 25 days after the of Blinded vaccine, 25 days after the dose of Varivax, 25 days after the dose of Havrix 720 Junior, this 13-month-old subject developed adenoviral enteritis. The subject was hospitalised. The subject was treated with sodium chloride. The event resolved on 29 October 2013.
The investigator considered that there was no reasonable possibility that the adenoviral enteritis may have been caused by investigational product, Varivax and Havrix 720 Junior.

Investigator Comments :
24.10.2103 the patient vomited frequently. 25.10.2013 accured diarrhea and body temperature arised to 37.5 degrees of Celsius. 26.10.2013 the patient was languid, vomited twice and has liquid stool. The patient was hospitalised by ambulance 26.10.2013 and adenoviral enteritis diagnosed. Physical status: skin turgor lower as normal, lips dry. BP 104/62 mmHg. Mild redness of palatoglossal arch. Abdomen soft, painless. Treatment was effective and the patient s health condition betterned and the patient was discharged from hospital 27.10.2013. By the patient s mother s words recovered 29Oct2013.

Case unblinded due to the end of study.

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Unblinding date is 25Oct17.
TTO 25 days post vaccination. Reported event is due to adenovirus infection, which has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Laryngitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 12 December 2012, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or a dose of Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 18 days after the 1st dose of Blinded vaccine, 18 days after the 1st dose of Havrix 720 Junior, 18 days after the 1st dose of Varivax, this 14-month-old subject developed laryngitis. The subject was hospitalised and the event was life-threatening. The subject was treated with adrenaline, sodium chloride, prednisolone, budesonide and cetirizine hydrochloride. The event resolved on 08 January 2013. The investigator considered that there was no reasonable possibility that the laryngitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to viral infection.

Investigator Comments :
Patient catch cold 30Dec2012. 31Dec2012 have already hacking couch and respiratory problems. Parents with child go to family docyor 31Dec2012 at 01.00pm. . Family doctor forwardedchild with parents to hospital. Child stayed under treatment in hospital 3 days. Patient gets home with better condition. Epicrisis from hospital doctor to investigator sended by 03Jan2013. At present symptomatic tretment continues at home. Patient will go to family doctor 7Jan2013. Patient came to family doctor visit 8Jan2013. Patient condition stabilized, treatment ended.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 18 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis rotavirus

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 29 January 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 72 days after the 1st dose of Blinded vaccine, 72 days after the 1st dose of Havrix 720 Junior, 72 days after the 1st dose of Varivax, this 14-month-old subject developed acute rotavirus gastroenteritis. The subject was hospitalised. The subject was treated with Ringers lactate and Ringer's solution. The event resolved on 16 April 2013. The investigator considered that there was no reasonable possibility that the acute rotavirus gastroenteritis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to viral infection.

Investigator Comments :
Child got ill with diarrhea 11Apr2013. 13Apr2013 added repeated vomiting.14Apr2013 parents with child went to hospital emergency room and hospitalized to infection hospital. Child stayed in hospital14-16Apr2013. 17Apr2013 no vomiting and diarrhea. Child mother informed investigator SAE case 30Apr2013. Investigator got more information for treatment and analyses from doctor who treated SAE 6May2013. Epicrisis was available to investigator 20Jun2013, because of that some details about treatment clarified.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis adenovirus, Dehydration

Non Serious Events:

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Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 31 January 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 57 days after the dose of Blinded vaccine, 57 days after the dose of Havrix 720 Junior, 57 days after the dose of Varivax, this 14-month-old subject developed adenovirus gastroenteritis and dehydration. The subject was hospitalised. The subject was treated with dextrose and Rehydron. The events resolved on 01 April 2013. The investigator considered that there was no reasonable possibility that the adenovirus gastroenteritis and dehydration may have been caused by investigational product, Havrix 720 Junior and Varivax and that the events were possibly due to a viral infection.

Investigator Comments :
Patient gets ill acutely 29MAR2013 with symptoms vomiting, diarrea and fever. Parents go with child themselves in Hospital children clinic. Patient condition solved. 01APR2013 child went in good condition at home. No more vomiting, diarrea normalized.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Tonsillitis, Otitis media

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 31 January 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the 1st dose of Blinded vaccine, five months after the 1st dose of Varivax, five months after the 1st dose of Havrix 720 Junior, this 17-month-old subject developed tonsillitis acuta. On 25 June 2013, she developed otitis media bilateralis. The subject was hospitalised. The

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subject was treated with phenoxymethylpenicillin potassium, cefuroxime sodium, paracetamol, sodium chloride, silver protein, Glucose 5% + NaCl + KCl and ibuprofen. Otitis media bilateralis resolved on 03 July 2013. Tonsillitis acuta resolved on 05 July 2013. The investigator considered that there was no reasonable possibility that the tonsillitis acuta and otitis media bilateralis may have been caused by investigational product, Varivax and Havrix 720 Junior and that the events were possibly due to a bacterial infection.

Investigator Comments :
Patient got ill with temperature 23Jun2013. Child mother informed investigator 30Jun2013 after child got ill and went to hospitalization 25Jun2013. After 2 days parents went with child to children hospital emergency room, (because CRP was under 100). Patient diagnosed tonsillitis, after that otitis. 2Jul2013 performed two-sided paracentesis with plenty of thick mucus apiration.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral infection, Neutropenic infection

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 31 January 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD six months after the 1st dose of Blinded vaccine, six months after the 1st dose of Varivax, six months after the 1st dose of Havrix 720 Junior, this 18-month-old subject developed infection viral. On 31 July 2013, she developed neutropenia parainfection. The subject was hospitalised. The subject was treated with paracetamol, ibuprofen, sodium chloride and dextrose. Infection viral resolved on 04 August 2013. Neutropenia parainfection resolved on 07 August 2013. The investigator considered that there was no reasonable possibility that the viral infection and neutropenic infection may have been caused by investigational product, Varivax and Havrix 720 Junior and that the events were possibly due to an viral infection.

Relevant Risk Factors: This was new viral infection, but child is often sick. Immunodefficient condition precluded, because IgA, IgG results were with the normal range.

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Investigator Comments:
Patient came 3. Trial visit 31Jul2013 and described to investigator that child has had fever since 29Jul2013. Because of child is often ill and cause of the fever unclear patient oriented to children hospital emergency room (investigator suggestion). Patient left the hospital for monitoring and clarifing the diagnose. Patient oriented home health care 1Aug2013. Since 02Aug2013 child has a normal temperature. 03-04.Aug2013 child has a rash (small patches) all over the body, which is resolved without sequelae 5Aug2013 (characteristic of viral exanthema). 7Aug2013 performed new blood analyses, leucocytes count turned to normal. Hepatitis A and chicken pox II vaccination due to health condition deferred.

Case unblinded due to the end of study.
Unblinding date is 25Oct17

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Burns second degree

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 28 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the dose of Blinded vaccine, five months after the dose of Havrix 720 Junior, five months after the dose of Varivax, this 17-month-old subject sustained second degree burns. The subject was hospitalised. The subject was treated with ibuprofen, topical skin preparation and ointment. The event resolved on 26 November 2013. The investigator considered that there was no reasonable possibility that the second degree burns may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to incidental illness (skin burning with hot liquid).

Investigator Comments :
The child burned yourself with hot coffee. Was the second degree burns on the body.Mom called ambulance, child was taken to hospital emergency room.The child was allowed home the next day after the monitoring in a satisfactory general condition.

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Clinical Narrative report with Both Serious & Non-Serious Events

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral infection, Febrile convulsion

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 28 May 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 87 days after the dose of Blinded vaccine, 87 days after the dose of Havrix 720 Junior, 87 days after the dose of Varivax, this 15-month-old subject developed viral infection and febrile convulsion. The subject was hospitalised. The subject was treated with paracetamol. Febrile convulsion resolved on 23 August 2013. viral infection resolved on 24 August 2013. The investigator considered that there was no reasonable possibility that the viral infection and febrile convulsion may have been caused by investigational product, Havrix 720 Junior and Varivax and that the events were possibly due to a viral infection.

Investigator Comments :
Patient hospitalized 23Aug2013 with fever convulsions. Axillary measured fever 40 C.Next day morning patient s general condition better, temperature under 38,0 C seizures did not recur. Child is allowed home from hospital 24Aug2013 evening in a satisfactory general condition (temperature 36,4). Investigator received notification of illness of child 10Sep2013. Febrile seizures intensity on a scale of Brighton was No1 (Level 1).

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Randomization Number:

Case ID: PPD

Serious Events: Enterocolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 30 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD four days after the 1st dose of Blinded vaccine, four days after the 1st dose of Varivax, four days after the 1st dose of Havrix 720 Junior, this 12-month-old subject developed enterocolitis acute. The subject was hospitalized.The subject was treated with diosmectite, paracetamol and Ringer acetate solution. The event resolved on 11 June 2013. The investigator considered that there was no reasonable possibility that the enterocolitis acute may have been caused by investigational product, Varivax and Havrix 720 Junior.

Investigator Comments:
Patient fell ill with diarrhea -excrement was watery, slimy and freaquency of excrement was 4-5 times a day. Patient temperature was 37,0C. Patient was also pink and small-pied rash in chest and scruff, also hardly seen sweat rash. 06JUN2013 was phone contact with investigator-positive dynamics, rash was lost and excrementation 1 time per day. 08JUN2013 second phonecontact with investigator-patient health condition got in negative dynamics: diarrhea deepened again, excrementation 10 times a day, fever 38,5C and patient was weak. Investigator suggested to go to children hospital emergency room. Patient was in treatment 9-11Jun2013. Patient get infusion for rehydration. After treatment condition normalized, allowed home.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Rotavirus infection

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Clinical Narrative report with Both Serious & Non-Serious Events

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 15 January 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD three days after the dose of Blinded vaccine, three days after the dose of Havrix 720 Junior, three days after the dose of Varivax, this 14-month-old subject developed rotavirus infection. The subject was hospitalised. The subject was treated with Ringer solution and saccharomyces boulardii. The event resolved on 25 January 2013. The investigator considered that there was no reasonable possibility that the rotavirus infection may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
On 18th of January patient started vomiting 3-4 times per day, stool 4-5 times per day, stool undigested food particles, water like consistance. Temperature up to 38,5 C. Emergency service took patient to Hospital. The Rotavirus was confirmed by lab tests. The patient condition stabilized and diarrhoea and vomiting stopped by 23JAN and patient was discharged from hospital on 25th of Jan 2013 in good condition.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to Rota virus infection which has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 18 December 2012, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A

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Clinical Narrative report with Both Serious & Non-Serious Events

vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the 1st dose of Blinded vaccine, five months after the 1st dose of Varivax, five months after the 1st dose of Havrix 720 Junior, this 16-month-old subject developed bronchitis. The subject was hospitalized. The subject was treated with salbutamol sulphate, budesonide and ipratropium bromide. The event resolved on 23 May 2013. The investigator considered that there was no reasonable possibility that the bronchitis may have been caused by investigational product, Varivax and Havrix 720 Junior and that the event was possibly due to viral infection.

Investigator Comments:
The patient had viral respiratory tract infection. On 13.05.2013 occured obstruction and pt needed hospitalization for activ inhalation therapy until 17.05.2013

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months post vaccinations. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral pharyngitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 08 January 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD five months after the 1st dose of Blinded vaccine, five months after the 1st dose of Havrix 720 Junior, five months after the 1st dose of Varivax, this 17-month-old subject developed viral pharyngitis. The subject was hospitalised. The subject was treated with phenoxymethylpenicillin potassium and amoxicillin trihydrate. The event resolved on 15 June 2013. The investigator considered that there was no reasonable possibility that the viral pharyngitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to enterovirus infection.

Investigator Comments :
The patient had enterovirus infection since 01.JUN2013. Had temperature, diarrhea. Since 05JUN ordinated Amoxicillin. But on 08 JUN had still temperature and patient turned to hospital. In hospital

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Clinical Narrative report with Both Serious & Non-Serious Events

diagnosed viral pharyngitis and the patient continued treatment with Penicillin until 15JUN 2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months post vaccinatio. Reported event has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 14 August 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

Medical conditions at the time of the event included bronchial hyperreactivity. Concomitant medications included Salbutamol and Ambroxol.

On PPD 112 days after the dose of Blinded vaccine, 112 days after the dose of Varivax, 112 days after the dose of Havrix 720 Junior, this 15-month-old subject developed viral pneumonia. The subject was hospitalised. The subject was treated with loratadine, adrenaline, dexamethasone, Amoxicillin/clavulanic acid, salbutamol sulphate, fluticasone propionate and methylprednisolone. The event resolved on 15 December 2013. The investigator considered that there was no reasonable possibility that the viral pneumonia may have been caused by investigational product, Varivax and Havrix 720 Junior and that the event was possibly due to her medical condition of bronchial hyperreactivity.

Investigator Comments :
Bronchial hyperreactivity on December 04, 2013, the patient started with cough without expectoration, irritability, tachypnea, with no fever so she was taken to the center on December 05. At physical exam tachypneic, temperature 36.4 C,.respiratory rate 34, cyanosis of the lips with the crying, slight intercostals retactions with disseminated rales and wheezing at the auscultation of the chest. The patient was taken to the emergency room of the hospital. At Physical exam heart rate 112 x minute, respiratory rate 46 x minute TA 111/68 pulse oximetry 84%at room air, pharingeal hyperemia , chest auscultation revealed disseminated rales in both lungs. Chest rx with difusse bilateral infiltrate. The diagnosis of viral pneumonia was done. The patient condition is improving but she still is at the emergency room.
Following the initial event reported, with diagnosis of viral pneumonia, the patient was given Loratadine

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Clinical Narrative report with Both Serious & Non-Serious Events

3.5 mg orally within 24 hours of December 5 to December 9, 2013 , Adrenaline 12 mg in 12 hours inhaled the December 5, 2013 , only that day , Oxygen, 5 liters x min, only 5 December 2013, Dexamethasone 8 mg IM single dose, Amoxicillin / Clavulanic acid, 235 mg/32.2 mg single dose orally, 600 mcg salbutamol, inhaled from December 9 to 12, 2013 , methylprednisolone 12 mgs orally from December 12 to 14 2013, Flixotide 200 mcg, inhaled on December 12 and continues, salbutamol 1.2 mg, inhaled, beginning on December 12 and continuing. The clinical evolution was satisfactory, so the subject was discharged on December 9, 2013. At follow-up, December 17, 2013, refers to the coughing, rhinorrhea and hiporexia (started on December 4th 2013) stopped on December 15, 2013, the methylprednisolone was suspended on December 14, 2013.
Physical examination: no evidence of respiratory distress, lung fields with prolonged expiration, rest of exploration unaltered. The event ends on December 15, 2013. Patient recovered.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO > 3 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchial hyperreactivity

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 14-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 18th September 2013, for prophylaxis.

Concurrent medical conditions included milk allergy and psychomotor retardation.

On PPD 58 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 bronchial hyperreactivity. Serious criteria included hospitalization. The subject was treated with ibuprofen, ambroxol, beclometasone (Beclomethasone), loratadine, phenylephrine, ipratropium, prednisone and salbutamol. The outcome of bronchial hyperreactivity was recovered/resolved on 21st November 2013.

The investigator considered that there was no reasonable possibility that the bronchial hyperreactivity may

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Clinical Narrative report with Both Serious & Non-Serious Events

have been caused by Priorix vs MMR II+Havrix+Varivax.

Diagnostic results (unless otherwise stated, normal values were not provided): On 19th November 2013, BLOOD NEUTROPHILS result was 48 %, Haematocrit result was 38.7 %, Haemoglobin result was 12.6 mg/dL, Lymphocyte count result was 51 %, Platelet count result was 223000 /mm3 and White blood cell count result was 7700 /mm3.

Investigator Comments :
Milk allergy and psychomotor retardation. On November 16, 2013, the patient started with hyaline rhinorrhea, cough and irritability, with temperature of 37.5°C. The patient was taken to the doctor who prescribed Loratadine and Phenylephrine, the patient continued with the same symptoms and was taken to the hospital on November 18. At Physical exam Heart rate 160 x minute, Respiratory rate 38 x minute, temperatures 38.0°C. pulse oximetry 83% in a room air , chest auscultation revealed basal rales and wheezing, the diagnosis of bronchial hyperactivity was made and the patient was given prednisone 20 mgs po one dose prednisone 10 mgs po one dose, salbutamol 1.5 µcms inhalated and was transferred to another hospital where she was hospitalized from 18 to 22 of November 2013. The patient was discharged asymptomatic.At this moment the administered treatment is ignored.
In the follow up, based on mother information and discharge document we have the following data. On November 15, 2013,the patient started with hyaline rinorrhea, non productive cough and was given Loratadine and Phenylephrine, the patient continued with the same symptoms and was taken on November 16, 2013 to the hospital where diagnosis of rhinopharingitis and bronchial hyperreactor was done, and the patient was given inhalated salbutamol in 2 occasions,no dosis is mentioned, and was discharged with salbutamol 800 mcms/24hrs inhalated, Beclometasona 200mcgms/24hrs inhalated, ambroxol 16.8mgs/24hrs from November 16 to 18, 2013 Dimegan D 20mgs/mgs from November 16 to 18, 2013 without improvement so the patient is taken to the hospital on November 18, 2013. At Physical exam: Heart rate 160 x minute, Respiratory rate 38 x minute, temperature 37.8°C. pulse oximetry 83% on room air, chest auscultation revealed (pharyngeal hyperemia , Wheezing on exhalation, basal rales, wheezing and rhonchi, the diagnosis of bronchial hyperactivity was made and the patient was given prednisone 20mgs one dosis po, salbutamol 4.5 mgs inhalated, ibuprofen 100mgs po one dose and was transferred to another hospital where the subject was hospitalized on November 19, 2013. At the hospital the hyaline rinorrhea turned purulent, and the cough was productive with occasional vomiting, with no respiratory distress. Treatment begins with salbutamol inhalated and Ipratopio, dose is ignored and prednisone po. Dose is ignored.
The chest xr on November 19, 2013 showed hyperinflation of the lungs with diaphragm in the 9th intercostals space and increase of parahiliar area. The clinical outcome was satisfactory and the patient was discharged asymptomatic on November 21, 2013 with diagnosis of Bronchial hyperreactivity of moderate intensity.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Serious Events: Milk allergy

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 18 September 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

Medical conditions at the time of the event included milk allergy and psychomotor retardation.

On PPD 71 days after the dose of Blinded vaccine, 71 days after the dose of Havrix 720 Junior, 71 days after the dose of Varivax, this 14-month-old subject developed milk allergy. The subject was hospitalised. The subject was treated with ranitidine hydrochloride. The event resolved on 05 December 2013. The investigator considered that there was no reasonable possibility that the milk allergy may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to her medical condition of milk allergy.

Investigator Comments:
Milk allergy and psychomotor retardation. On December 01, 2013, the patient started with melena and was taken to the hospital where she was hospitalized from 01 to 05 of december 2013, the patient was discharged asymptomatic . Is all information available. In the follow up, based on information provided by the mother and discharge document we have the following data. On November 28, 2013 the patient started with stools with liquid without mucus or blood in 3 occasions and the patient was taken to the clinic where at Physical exploration it was found abdominal distention and was given ranitidine 42mgs/24hrs PO, from November 28, 2013 and continue, the patient continued with 2 mild loosed stools at day without mucus or blood. On December 2, 2013, the patient had 3 black stools and was taken to the clinic where the patient was hospitalized, no abdominal pain is referred. During the staying the patient had normal stools with negative labstics in stools so it was ruled out the diagnosis of gastrointestinal bleeding and the patient was discharged asymptomatic on December 05, 2013 with diagnosis of milk allergy of mild intensity. On December 02, 2013 were performed the following test: blood gas analysis with pH 7.41, PCO2 38 mm Hg, PO2 65 mm Hg, HCO3 24.1, BE -0.5, Lactate 1.3.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Serious Events: Bronchial hyperreactivity

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 26th September 2013, for prophylaxis.

On PPD 104 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 bronchial hyperreactivity. Serious criteria included hospitalization. The subject was treated with amoxicillin, ibuprofen, beclometasone (Beclomethasone), salbutamol, IPRATROPIUM BROMIDE + SALBUTAMOL, budesonide, ambroxol, montelukast, AMOXICILLIN + CLAVULANIC ACID and loratadine. The outcome of bronchial hyperreactivity was recovered/resolved on 2nd February 2014.

The investigator considered that there was no reasonable possibility that the bronchial hyperreactivity may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments:
According to the mother of the subject, on January 08th, 2014, the patient started with hialine rhinorrhea, cough without expectoration, with axilar temperature of 38 C and without loss of appetite referred. On this day the subject attended to a physician and was prescribed with Amoxicillin (525mg/day PO) and Ibuprofen (159 mg/day PO), from 08th to 11th of January and Ambroxol (21.5 mg/day PO) from January 08th to 15th. Due the persistence of the symptoms the subject attended again to a physician and was prescribed with Loratadine (2.5 mg/day PO) from January 14th to 21th, without improvement. On January 24th the cough became wheezy and the subject was taken to the hospital where she was hospitalized with the diagnosis of Bronchitis. We have no information of the treatment given. The patient was discharged on January 25th with inhaled Salbutamol (600mcg/day) from January 25th to date and inhaled Betametasone (400mcg/day) from January 25th to date. This serious adverse event ended on February 02th, 2014. The Subject was recovered and the event resolved. According to the Principal investigator this SAE is NOT related to the study vaccine and the event was of moderate intensity. Following the initial event reported, with diagnosis of bronchitis, the following information was obtained with the discharge note. Due of persistent of mucous green, rhinorrea and increases cough, the subject was taken onJanuary 17-2014 (previous date reported 24 January 2014) to the clinic at the emergency room. Where the patient presents any respiratory distress, on January 17, 2014 was given salbutamol inhaled every 30 minutes an every 4 hours thereafter, and if presence of fever, paracethamol 100mgs PO (no information about doses and if paracethamol was given or not) and the patient was hospitalized. The clinical evolution was satisfactory, without respiratory distress, with pulse oximetry of 93% in room air. At Physical exam: awake, good color skin, hydrated, pharynx hiperemic and congestive, with rhonchus and prolonged expiration in both lungs fields, the patient was given salbutamol/ipratropio inhaled every 8 hrs. and budesonide inhaled every 12hrs.,from the 17 to the 18 of January 2014, with good clinical outcome. At Physical exam Heart rate 120 per minute, respiratory rate 46 per minute Temperature 36.5 C. Oximetry in room air 93%, reactive hydrated, without respiratory distress no auscultation abnormalities in both lungs fields, no

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whizzing, heart sound rhythms and with good intensity, hemodynamic stable, extremities with normal coloration and immediately filled capillary. The subject was discharged on January 18-2014 (previous date referred as January 25 2014) with diagnosis of persistent wheezing of early start of moderate intensity and Gastroesopghageal reflux. By medical criteria and according to the Principal Investigator the diagnosis corresponds to Bronchial Hyperreactivity. The event ends on February 02, 2014. The Subject recovered. According to the Principal investigator this SAE is NOT related to the study vaccine and the event was of moderate intensity.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event has no causal or relationship to vaccination

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 13-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 11th October 2013, for prophylaxis.

Concurrent medical conditions included underweight.

On PPD 29 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 bronchiolitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with ampicillin, paracetamol, salbutamol, procaine benzylpenicillin (Procaine Penicillin), beclometasone (Beclomethasone), amantadine + chlorphenamine + paracetamol (Amantadine/Chlorpheniramine/Paracetamol) and ambroxol + salbutamol. The outcome of bronchiolitis was recovered/resolved on 20th November 2013.

The investigator considered that there was no reasonable possibility that the bronchiolitis may have been caused by Priorix vs MMR II+Havrix+Varivax.

Relevant Tests: On 19th November 2013, URINE DENSITY result was 1005. Diagnostic results (unless

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Clinical Narrative report with Both Serious & Non-Serious Events

otherwise stated, normal values were not provided): On 19th November 2013, Haematocrit result was 37 %, Haemoglobin result was 12 g/dL, Lymphocyte count result was 10 %, Neutrophil count result was 58 %, Nitrite urine result was NEGATIVE unknown, Platelet count result was 616000 /mm3, URINE PH result was 6.5 unknown, White blood cell count result was 10000 /mm3 and White blood cells urine result was NEGATIVE unknown.

Investigator Comments :
Low weight. On November 9, 2013, the patient started with hyaline rhinorrhoea and cough without fever. The patient was taken to the hospital on November 12 where the diagnosis was common cold, the patient continued with the same symptoms until November 16. On November 17 the patient presented fever up to 39 °C, the patient was taken to the emergency room of the hospital where the fever was controlled so the patient was discharged the same day. However fever persists at home and subject was taken to other clinic.
When the patient arrive to the clinic, the mother notices a slight intercostal retraction, the patient was hospitalized and diagnosed bronchiolitis. The patient was hospitalized from November 17 to November 20 2013, the patient leaves the hospital at 5:00 O'clock in the afternoon. Asymptomatic. At this moment the administered treatment is ignored.
The information reveals that the patient was admitted from November 18 to November 20 2013. The medication is added at the corresponding section. Chest x ray was performed on November 19 2013 which showed increased of parahiliar area with congestion and hyperinflation of the lungs. The subject is asymptomatic. According to Principal Investigator this SAE of bronchiolitis is not associated to the investigational product.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 29 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 21 October 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

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On PPD 58 days after the 1st dose of Blinded vaccine, 58 days after the 1st dose of Havrix 720 Junior, 58 days after the 1st dose of Varivax, this 14-month-old subject developed viral pneumonia. The subject was hospitalised. The subject was treated with paracetamol, ceftriaxone and salbutamol sulphate. The event resolved on 23 December 2013. The investigator considered that there was no reasonable possibility that the viral pneumonia may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
On December 18, 2013 the subject started with hialine rhinorrhea , wet cough without exectoration, no wheezy or emetic and irritability. The December 19, 2013 the mother states that the subject had fever unquantified, not elevated that stops without medication. The December 20, 2013 , went to the center to a scheduled appointment, where a physical examination founds polypnea with respiratory rate of 32 x minute, irritable, hyperemic pharynx is discards retropharyngeal whitish, without other data of respiratory distress, rhonchus, prolonged expiration and limited wheezing, so the subject moved to the emergency room , where is the physical examination : oxygen saturation 77 % on room air, heart rate 125 per minute , respiratory rate 40 per minute , Blood presure:110 / 70 Temperature 36.7 C., nasal flaring, lung fields with fine rhonchus bibasilar, few wheezing, other examination: normal. Chest radiograph showing right basal infiltrate, blood count with 12.4gms Hb, Htc 37.5 % leukocytes 11.700/mm3 , 30 % neutrophils , 65% lymphocytes , platelets 137 000/mm3 . Diagnosis of viral pneumonia , treatment: inhaled salbutamol dose ignored. Oxygen is administered indicated dose: 5lt/min. December 21, 2013 The parents do not agree with the management and request the subjects Discharge voluntary. The subject is hospitalized in another hospital and is evolving satisfactorily. To date the report is all the information we have. Following the initial event reported, with diagnosis of viral pneumonia, hospitalized in another hospital on December 22, 2013, at admission physical exam: temperature 37.0 C, Heart rate 120 per minute, respiratory rate 28 per minute, without respiratory distress, with rales in both lungs. Chest x ray showed 8 intercostals spaces, reticular infiltrate with no evidence of consolidation PCR negative. The subject was given salbutamol 1.87 mgs/day inhalated from 22 to 23 of December 2013. The clinical evolution was satisfactory, At Physical exam without respiratory distress only with prolonged expiration in both lungs fields with no other auscultatory abnormalities. The subject was discharged on December 23, 2013 with salbutamol. The event ends on December 23, 2013. Subject recovered. This is a serious adverse event not related with the study vaccine.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 52 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia viral

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 04 November 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 33 days after the 1st dose of Blinded vaccine, 33 days after the 1st dose of Havrix 720 Junior, 33 days after the 1st dose of Varivax, this 13-month-old subject developed viral pneumonia. The subject was hospitalised. The subject was treated with paracetamol, ibuprofen, loratadine, salbutamol sulphate and prednisone. The event resolved on 17 December 2013. The investigator considered that there was no reasonable possibility that the viral pneumonia may have been caused by investigational product, Havrix 720 Junior and Varivax .

Investigator Comments :
On December 07, 2013 the patient started with fever up to 38.8 C. and the patient was given paracetamol 300 mg PO from the 07 to 07 de dic 2013, because the persistence of the fever on December 08, 2013 the patient was taken to emergency room where is given ibuprofen 150 mg PO from the 09 to 11 of dec 2013, loratadine 7.5 mg PO from the 08 to 10 of dec 2013 , on december 10 de dec2013 the patient presented diminished apetite, asthenia, and one vomit of gastric content, and non productive cough which turns with expectoration. On December 10, 2013 the patient was taken to the center where at Physical exam was tachypneic with respiratory rate of 60 x minute, pulse oximetry 93% at room air, pharynx with slight hyperemia, intermittent intercostals retractions, rales and scared wheezing at the auscultation of the chest, pulse the diagnosis of viral pneumonia of mild intensity was done, and the patient was given: salbutamol 600mcg in 24 hrs inhalated, from December 10 to 11, 2013, paracetamol 300 mg PO from December 10 to 11, 2013. On December 11, 2013, the patient is brought to the center for follow up. At physical exam: temperature 36.9 C. Heart rate: 130 x minute, Respiratory rate 36 per minute, pulse oximetry 84% at room air, intercostals retractions, and the patient is sent to emergency room where at physical exam: heart rate 142 x minute, respiratory rate 36 x minute, pulse oximetry 74% at room air, pharyngeal hyperemia, hypoventilation with disseminated wheezing in both lungs. Chest xr with parahiliar infiltrate. The diagnosis of viral pneumonia of moderated intensity was done, and the patient was given prednisone 40 mgs PO on December 11, 2013, paracetamol 100 mgs PO one dosis on December 11, 2013. It is all information available at this moment. Following the initial event reported, with diagnosis of viral pneumonia, the subject was hospitalized on December 11, 2013, the treatment was paracetamol, 300 mgs orally, only on December 12th, 2013, paracetamol 100 mgs orally only on December 13th, 2013 salbutamol 6 mg. inhaled from the 11 to the 17 of December 2013, and oxygen from 11 to the 15 of December 2013. The clinical evolution was satisfactory, without respiratory distress with pulse oximetry of 95% in room air. At Physical exam with no asucultatory abnormalities in both lungs fields, with transmitted secretions, so the subject was discharged on 17 December 2013 without medication and this date is considered the end date of the SAE.. Subject recovered.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 1 month post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 06 December 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 113 days after the dose of Blinded vaccine, 113 days after the dose of Varivax, 113 days after the dose of Havrix 720 Junior, this 16-month-old subject developed acute gastroenteritis. The subject was hospitalised. The subject was treated with racecadotril, ampicillin trihydrate, diphenidol hydrochloride, paracetamol and Meclozine + Pyridoxine. The event resolved on 09 April 2014. The investigator considered that there was no reasonable possibility that the acute gastroenteritis may have been caused by investigational product, Varivax and Havrix 720 Junior.

Investigator Comments :
Subject presented the first symptom on March 29th 2014 which was watery stools, 4 per day. The subject was taken to the center on March 31st where clinically was found with good hydration, diaper rash and gingivitis related to the tooth eruption; her clinical evolution was initially satisfactory because the stools were evolved to doughy but on April 04th 2014 started with nausea and vomiting; she was taken to the emergency service where she was found good hydrated and sent home, for persistence of the symptoms and for watery stools, the subject was taken on April 07th 2014 to the center where she was found hydrated and was diagnosed as diarrhea, started with ambulatory treatment, because persistence of the symptoms on april 07th 2014 the subject was taken to the hospital where she was found with mild dehydratation which caused her hospitalization. This is a serious adverse event which according to the PI is not related to the study vaccination.
Following the initial event reported, with diagnosis of diarrhea and dehydratation, the following information was obtained with the discharge note. Patient started on March 29-2014 with yellow green watery diarrhea with mucous, no blood in number of 4 to 6 per day, 3 days later the patient presented vomiting of gastric content up to 7 per day. On 07-april-2014 she was taken to the emergency service where she was found , irritable, with good color skin, hydrated, normal pharynx, no respiratory distress. It was performed, Blood chemistry, electrolytes, and urine test which were reported as normal (not results were given) negative ameba in stool and stool smear for leukocytes were also negative. The clinical outcome of the patient was satisfactory with good oral intake and decrease of the fecal output. At physical exam temperature: 36.5 C, heart rate 110 per minute, respiratory rate 33 per minute, normal abdomen and immediate capillary refill. The patient was discharged on April-09-2014 with diagnosis of acute gastroenteritis in remission and dehydration resolved. The serious adverse event ends on April 09, 2014. Subject attended to site on 10-

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Clinical Narrative report with Both Serious & Non-Serious Events

april-2014 where she was found hydrated, with no fever, normal pharynx and with no respiratory distress. The Subject is recovered with no sequels.
According to the Principal investigator this SAE was of moderate intensity and is NOT related to the study vaccine.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Head injury, Gastritis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 mcg <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Azithromycin]:[Unknown] <Blank> <Blank> 1D;[Ibuprofen]:[Unknown] <Blank> <Blank> 1D

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 16 December 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

Medical conditions at the time of the event included pharyngitis, febrile seizure and sleep myoclonus. Concomitant medications included Paracetamol, Rivotril and Atemperator.

On PPD six months after a dose of Blinded vaccine, six months after a dose of Havrix 720 Junior, six months after a dose of Varivax, this 19-month-old subject experienced a head injury. On 07 June 2014, one day after commencing the concomitant medication Azithromycin, and one day after commencing the concomitant medication Ibuprofen, he developed gastritis caused by drugs. The subject was hospitalised. The subject was treated with metoclopramide. The events both resolved on 08 June 2014. The investigator considered that there was no reasonable possibility that the head injury and gastritis caused by drugs may have been caused by the investigational product, Havrix 720 Junior and Varivax and that the gastritis caused by drugs was due to the concomitant drugs : Azithromycin (taken for pharyngitis, unknown manufacturer) and Ibuprofen (taken for pharyngitis, unknown manufacturer).

Investigator Comments :
As background information, the subject had been diagnosed with febrile seizures and Sleep myoclonus. On 06-june-2014 in the morning the subject had rinorrhea, poor feeding, cough and asthenia then was

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Clinical Narrative report with Both Serious & Non-Serious Events

taken to a private doctor who makes the diagnosis of Pharyngitis. The same day at 18:00 hrs. the subject fell out from the stroller, hitting face with injury in the inferior lip with crying and no loss of consciousness or abnormal movements. On 07-june-2014 at 03:00 am the subject wake up with 2 vomits of gastric content and then was taken to the emergency room where presented 3 vomits of gastroalimentary content and temperature of 38.4 C. Fever was controlled by physical methods. During his staying, the subject was evaluated by the Neopediatric service with diagnosis of febrile seizures, sleep myoclonus and simple head trauma. The subject evolution was favorable: asymptomatic, vital signs within normal parameters, without fever with good oral intake. At physical exam, the subject was alert, active, reactive, with good color skin, well hydrated, normal eyes, oral cavity well hydrated, pharynx without alterations, normal neck without adenopathies, torax: normal heart sounds, well ventilated both lung fields, abdomen prominent, soft, painless withouth visceromegaly, slight increase in bowel sounds, normal extremities and peripheral pulses, capilar feelling of one second, normal neurologycal exam. The outcome was satisfactory with improvement of the gastroenteral symptoms, and the subject was discharged on 08-june-2014 with diagnosis of head injury of mild intensity and intolerance to oral intake, that according to the Principal Investigator, correspond to the diagnosis medicamentous gastritis of mild intensity. Both events ended on 08-jun-2014. The subject is recovered with no sequels. According to the medical judgment of the Principal Investigator, the treatment for pharyngitis contributed to cause the vomiting episodes that lead to subject's hospitalization. According to the principal investigator, this serious adverse event of head trauma and gastritis per medication are not related to the study vaccine or a study procedure.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 6 months post vaccination. reported events has no causal association to the administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Epilepsy

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 16 December 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 10 days after the 1st dose of Blinded vaccine, 10 days after the 1st dose of Havrix 720 Junior, 10 days after the 1st dose of Varivax, this 14-month-old subject developed epilepsy. The

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event was clinically significant (or requiring intervention). The subject was treated with Atemperator and clonazepam. The event was unresolved at time of reporting. The investigator considered that there was no reasonable possibility that the epilepsy may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
On 26-Dec-2013 the subject presented generalized tonic-clonic movements, with upward rotation of the eyes and loss of consciousness, with duration of 90 seconds and a temperature of 38.4 C. The subject was taken to the center where at physical exam, the subject was with normal neurolgycal exam, pharynx with hyperemia and retronasal discharge, then the diagnosis of Tonsillitis(started on 25DEC2013) as well as febrile seizures was done. Subject was asymptomatic until 01-Feb-2014 when at 23.45hrs presented fixed glance, unresponsiveness to external stimuli, generalized tonic-clonic movements, oral an facial cyanosis of 2 to 3 minutes of duration, with axilar temperature of 38.1 C. The mother attended to the center on 03-Feb-2014 where the diagnosis of Rhinopharyngitis and Febrile convulsions was done and the mother was asked to perform an EEG. On 30-April-2014 the mother attended the center for a follow up visit and refers that since 25-April-2014, the subject presented several myoclonic jerks while sleeping. The subject was seen by his family doctor and diagnosis of Sleep myoclonus was done. On 01-jul-2014 the subject was taken to the centre for a study visit and the mother presented a EEG performed on 12-April-2014. The EEG showed epileptiform activity on bilateral frontal region with tendency to be generalized. The physical exam was normal, and the subject was in good clinical conditions: Temperature 36.2 C, Heart rate: 116 per minute, Respiratory rate: 28 per minute, Weight 13.030, High 85 cms. The PI consulted the results of the EEG with the Neurologist who made the diagnosis of Epilepsy. The subject is being treated for seizures and Sleep myoclonus. The epilepsy is controlled and the subject is in good conditions and has a good prognosis for life and function. Due to the EEG findings the subject must continue with medication and the outcome is considered: Not recovered/not resolved.
According to the medical judgment of the Principal Investigator the first febrile seizures (presented on December 26th 2013) were triggered by underlying epilepsy.
This event was detected during the subject participation in the study, and according to the principal investigator is a significant medical event to be considered a Serious Adverse Event. According to the principal investigator the event is not related to the study vaccine or a study procedure.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Apart from temporal relationship, available information is limited for an comprehensive assessment.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Finger amputation

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 15th January 2014, for prophylaxis.

On PPD 151 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 finger amputation. Serious criteria included hospitalization and GSK medically significant. The subject was treated with amoxicillin, clavulanic acid (Amoxicillin + Clavulanic Acid), ibuprofen, cefalotin sodium (Cephalothin), buprenorphine and midazolam. The outcome of finger amputation was resolved with sequelae on 31st July 2014.

The investigator considered that there was no reasonable possibility that the finger amputation may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments :
At 22 hrs of 15 jun12014, the subject presented an injury (crush) of the distal phalanx of the third finger of the right hand with a fixed bike on movement, the subject presents amputation of the digital distal part, with moderated bleeding and intense crying. The mother placed the amputed part in ice and the subject was taken to the emergency room. At physical exam weight: 9.600 Kg, heart rate 130 x minute, respiratory of 32 x minute, B/P 82/67, active, reactive, irritable, no cooperative, normal head, normal ocular movements, pupils isochoric with good response to light, nose with scant hialine rinorrhea, normal oral cavity, pharynx with no hyperemia, without exudates or retropharyngeal discharge, neck with normal movements, without adenopathy, chest with no respiratory distress, lung fields well ventilated, cardiac sounds with good intensity, abdomen semi prominent (no distended), soft, compressible, non tender, present bowel sounds, without visceromegaly, female genitalia Tanner 1, eutrophic extremities, complete amputation of the digital tip of distal phalanx of the third finger of the right hand with scanty bleeding, clean, with limitation to movement and function, capillary feeling of 2 seconds. It was performed a surgical amputation of the distal phalange and plastic reconstruction of the stump, with good clinical outcome and the patient was discharged on 16-june-2014.

The outcome of the amputation was referred as good for quality of life, regular for function and bad for aesthetics. The event is recovering/resolving.

According to the principal investigator this serious adverse event of severe intensity is not related with the study vaccine, a study procedure or concomitant medication.

History of surgical amputation of the distal phalanx of the third finger of the right hand. On July 31st the subject came to her follow up visit at our center and she is in good conditions, with good skin color and good capillary filling, scar in good conditions. The outcome is considered: Recovered/resolved with sequelae

According to the principal investigator this serious adverse event of severe intensity is not related with the

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Clinical Narrative report with Both Serious & Non-Serious Events

study vaccine, a study procedure or concomitant medication.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 151 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia viral, Bronchial hyperreactivity

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 21 January 2014, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 114 days after the dose of Blinded vaccine, 114 days after the dose of Havrix 720 Junior, 114 days after the dose of Varivax, this 15-month-old subject developed viral pneumonia and bronchial hyperreactivity. The subject was hospitalised. The subject was treated with paracetamol, Aluminium hydroxide + magnesium hydroxide, prednisone, loratadine, ibuprofen, salbutamol sulphate, Ipratropium bromide + salbutamol, budesonide, Ambroxol hydrochloride+salbutamol sulphate, Aluminium hydroxide+ magnesium hydroxide, fluticasone propionate and clarithromycin. The events resolved on 28 May 2014. The investigator considered that there was no reasonable possibility that the viral pneumonia and bronchial hyperreactivity may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments:
On May 15th 2014, the patient started with hyaline rhinorrhea cough without expectoration, no fever, that day the subject attended to the hospital and diagnosis of viral pharyngitis was done. On May 16th 2014 the hyaline rhinorrhea and cough episodes increased with conjunctival hyperemia, one vomit with gastric content, irritability and hiporexia, and the patient was taken at night to emergency room. At Physical exam May 17th 2014: heart rate 140 x minute, respiratory rate 32 x minute, BP 79/56, with signs of respiratory distress, pulse oximetry 88% at room air and 94% with oxygen. The patient was alert, well hydrated and good skin color with conjunctival hyperemia, normal pharynx, slight rhinorrea and normal respiratory movements, chest auscultation revealed basal rales prolonged expiration, no wheezing, normal abdomen, capillary refill two seconds, chest XR with right parahiliar infiltrate. The diagnosis of viral pneumonia was done.

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The patient was given oxygen and inhaled salbutamol and fasting. In the afternoon the patient had fever of 38.3 C. without systemic inflammatory response and at chest auscultation there were disseminated wheezing. There were not available beds and the patient was transferred to another hospital on May 18th 2014, with good clinical outcome the patient was discharged on the same date (May 18th 2014).
According to the Principal investigator the diagnosis of viral pneumonia corresponds to bronchiolitis of moderate intensity and it is not related to the study vaccine. Following the initial event reported, with diagnosis of bronchiolitis, hospitalized from May 16 to May 18 2014. The subject attended to the center for follow up on May 23-2014 and the mother refers improvement of the cough, the subject presented 3 vomits related to the cough, the subject is eating well and the mother denies respiratory distress or fever. At Physical exam Respiratory rate of 40 per minute, heart rate 140 per minute, axilar temperature 36.0 C the subjects was with good color skin, with intercostals retractions, at auscultation disseminated ronci and wheezing in the right base normal cardiac sound abdomen with no hepatomegaly normal neurological exam and the subject was taken to the emergency room where at Physical exam Respiratory rate of 44 per minute, heart rate 136 per minute, Blood pressure 68/56 pulse oximetry at room air 89% and 93% with oxygen. The patient was started on prednisone PO and inhalated salbutamol and fluticasone. It is all information up to this moment.
Following the initial event reported with diagnosis of bronchiolitis (hospitalized from May 17th to May 18th, 2014). We have the following information: The subject attended to the center for a follow up visit on 23-May-2014 At Physical exam: Temperature 36.0 C. heart rate 140 x minute, respiratory rate 40 x minute were the mother refers 2 vomits (it was referred 3 vomits) related to the cough with an eventual improvement of the cough. According to the information presented, the subject is eating well and the mother denies respiratory distress or fever. At physical examination during the visit: Respiratory rate of 40 per minute, heart rate 140 per minute, axilar temperature 36.0 C the subject was with good color skin, with intercostals retractions, at auscultation disseminated wheezing normal cardiac sound, abdomen with no hepatomegaly and normal neurological exam. The subject was taken by the subinvestigator to the emergency room where at physical exam: Respiratory rate of 44 per minute, heart rate 136 per minute, blood pressure 68/56 pulse oximetry at room air 89% and 93% with oxygen nasal flaring and wheezing in upper the right lung field, and hypoventilation in both basal lung fields. Chest Xray (23-May-2014) with right parahiliar infiltrate. The diagnosis of viral neumonia and bronchial hyperactivity was done and the subject was hospitalized. From May 24 to may 25, 2014, the clinical outcome was satisfactory with no fever, improvement of respiratory rate, and lung auscultation with no respiratory distress. On 26-May-2014 physical exam: Respiratory rate of 28 per minute, heart rate 126 per minute, blood pressure 90/60 Temperature 36.5 C. witouth respiratory distress normal auscultation of chest lung with no rales or wheezing. Thehe patient was discharged on May 26 -2014.
In retrospective the episode of Bronchiolitis corresponds to Viral Pneumonia and Bronchial Hyperreactivity of moderate intensity. According to the Principal investigator this SAE is not related to the study vaccine, nor any study procedure, concomitant medication. Following the SAE report, the subject was discharged on 26-May-2014 with diagnosis of Viral Pneumonia a Bronchial Hyperreactivity of moderate intensity. The mother brought the subject to the centre on 09-June-2014 for a follow up visit and referred that the patient had good clinical outcome with remission of all symptoms on 28-May-2014. At Physical exam: heart rate 128 per minute, respiratory rate 38 per minute temperature 36.3 C. Rest of physical exam negative. The SAE ends on 28-May-2014. The Subject is recovered with no sequels. According to the Principal Investigator this SAE is NOT related to the study vaccine or a study procedure.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 114 days, Reported event is due to viral infection, which has no causal or temporal relationship with the vaccination.

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Clinical Narrative report with Both Serious & Non-Serious Events

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia bacterial

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 30th May 2014, for prophylaxis.

On PPD 151 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 pneumonia bacterial. Serious criteria included hospitalization and GSK medically significant. The subject was treated with ambroxol + salbutamol, amoxicillin + clavulanic acid, ambroxol, clarithromycin, salbutamol, paracetamol and betamethasone + dexchlorpheniramine. The outcome of pneumonia bacterial was recovered/resolved on 17th December 2014.

The investigator considered that there was no reasonable possibility that the pneumonia bacterial may have been caused by Priorix vs MMR II+Havrix+Varivax.
Diagnostic results (unless otherwise stated, normal values were not provided): In December 2014, C-reactive protein result was 04.914 unknown, C-reactive protein result was 03.082 unknown, Haematocrit result was 34.8 %, Haematocrit result was 36.5 %, Haemoglobin result was 11.4 g/dL, Haemoglobin result was 11.9 g/dL, Lymphocyte count result was 32 %, Monocyte count result was 8 %, Neutrophil count result was 34 %, Neutrophil count result was 60 %, Platelet count result was 264000 /mm3, Platelet count result was 269000 /mm3, White blood cell count result was 10100 /mm3 and White blood cell count result was 12700 /mm3.

Investigator Comments :
On 05-dec-2014, on a telephone call for appointment reminder, the mother has informed to the center, that the subject was hospitalized on 03-Dec-2014 with diagnosis of pneumonia. On a follow up phone call with the mother on the 08- Dec-2014, she has informed us that the subject was discharged on 07-Dec-2014, with good condition. Nevertheless, the subject presented a dry cough without vomiting episodes or cyanosis and fever. The subject was eating well with no respiratory distress and the subject was not taken any medication. At this moment the administered treatment at the hospital is ignored. According to the principal investigator, this serious adverse event is of moderate intensity and is not related to the study vaccine or study procedures.

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Clinical Narrative report with Both Serious & Non-Serious Events

Following the SAE report, this new information was obtained from the copy of the hospital discharge obtained at domiciliary visit on Jan 29-2015, telephone call with the mother on Jan 30-2015 and medical follow up from source document on 29-Oct-2014.
On Oct 28, 2014, the subject started with productive cough without cyanosis, vomiting or fever and on Oct 29-2014 the subject was taken to the center where diagnosis of rhino pharyngitis was performed, the subject continued with productive cough with continuous episodes of gough in 5 to 6 occasions mainly at night in 4 occasions the cough was associated to vomiting. On Nov-26, 2014, there was an exacerbation of the cough accompanied by intermittent abundant hialine rhinorrhea with obstruction to normal breathing.
Three days before admission the patient presented temperature of 38.0 C. and on Dec-03, 2014 the subject was taken to the hospital where he was admitted. At physical exam the subject had respiratory distress with flapping nasal, subcostal retractions, chest auscultation revealed hypoventilation, disseminated rales, expiration wheezing, a chest x ray was performed (unknown date) showing reticulonodular infiltrate so the diagnosis of Community Acquired Pneumonia of undetermined etiology was done.
The clinical outcome was satisfactory with good oral intake, and the patient was discharged on Dec 07, 2014, with diagnosis of COMMUNITY ACQUIRED BACTERIAL PNEUMONIA.
At this time, the physical exam, the subject was without respiratory distress, chest auscultation revealed normal ventilation without rales or wheezing. The patient continued with cough and rhinorrea for 7 days.
The event ends on Dec 17, 2014, the subject is recovered and the SAE is considered resolved. According to the principal investigator, this serious adverse event is of moderate intensity and is not related to the study vaccine, concomitant vaccination or study procedures.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to bacterial infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 02 June 2014, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

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Clinical Narrative report with Both Serious & Non-Serious Events

On PPD 69 days after the 1st dose of Blinded vaccine, 69 days after the 1st dose of Havrix 720 Junior, 69 days after the 1st dose of Varivax, this 14-month-old subject developed community acquired pneumonia. The subject was hospitalised. The subject was treated with ampicillin trihydrate, loratadine, paracetamol, ambroxol, dipyrone, Amoxicillin + clavulanic acid, Dimacol, benzylpenicillin sodium, mefenamic acid, ceftriaxone and ibuprofen. The event resolved on 25 August 2014. The investigator considered that there was no reasonable possibility that the community acquired pneumonia may have been caused by investigational product, Havrix 720 Junior and Varivax.

Investigator Comments :
On 10-aug-2014, the subject started with cough without expectoration, hialine rhinorrhea and temperature up to 39.8 C. On 11-aug-2014 started with temperature of 38.0 C so the subect was taken to the doctor where she was prescribed with Amoxicillin, Ambroxol, Loratadine and Paracetamol without improvement; for persistence of the fever the subject was taken to the center on 13-aug-2014 where at Physical exam: Heart Rate 144 x minute, Respiratory Rate 48 x minute Temperature (axillar) 39.2 C, with green conjunctival secretion, hyperemia of the pharynx with green retro nasal discharge, no respiratory distress and normal physical exam, and diagnosis of tonsillitis was done. On 15-aug-2014, the subject attended to the center due the persistence of fever up to 39.0 C, the mother states that the cough episodes turned productive, with purulent rinorrhea and refusal to oral intake, at Physical exam: heart rate 132x minute, respiratory rate 36 x minute, Temperature (axillar) 39.2 C, tachypnea, diminished conjuntival secretion, green nasal discharge and signs of respiratory distress, so it was decided to take her to the emergency room where at Physical exam: Temperature (axillar) 36.0 C. heart rate 139 x minute, TA 88/51 pulse oximetry 83 % at room air and 100% with oxygen. The subject was alert, chest auscultation revealed bilateral basal rales prolonged expiration and no wheezing, chest x ray with slight increasse of opacity in apical right lobe (15aug2014), so the diagnosis of Community Acquired Pneumonia was done. In emergency room the subject presented fever with axillar temperature up to 40 C. On 16-aug-2014, the subject was transferred to a social security hospital. At this moment the administered treatment is ignored. According to the principal investigator, this serious adverse event is of moderate intensity and is not related to the study vaccine or study procedures.

Following the initial event reported with diagnosis of Community acquired pneumonia on a follow up phone call performed on Sep 1st the mother refers that the subject was discharged from the hospital on August 21, 2014 with diagnosis of Community acquired pneumonia. The subject was asymptomatic on Aug 25th 2014. Up to this moment, is all available information.

The subject is recovered and the event is considered resolved on 25Aug2014.

According to the principal investigator the event is considered of moderate intensity and is not related to the study vaccine or study procedures.

Subject was brought to the centre on 08-sep-2014, where subject s mother confirms medication administered. With the discharge summary, information regarding the therapy administered was obtained.

Administration of bronchodilators and antibiotics was corroborated; however doses, dates and frequency are not described. Another chest X ray was taken where soft tissue without alterations and resolution of previous right apical consolidation was observed; after that, it was determined that a subject was medically ready for discharge.

The subject is asymptomatic and the Serious Adverse Event is considered recovered/resolved on

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Clinical Narrative report with Both Serious & Non-Serious Events

25Aug2014. According to the principal investigator the event is considered of moderate intensity and is not related to the study vaccine or study procedures.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event Community acquired pneumonia has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 15-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 27th June 2014, for prophylaxis.

On PPD 90 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 gastroenteritis. Serious criteria included hospitalization. The subject was treated with amoxicillin + clavulanic acid, unknown antibiotic and paracetamol. The outcome of gastroenteritis was recovered/resolved on 27th September 2014.

The investigator considered that there was no reasonable possibility that the gastroenteritis may have been caused by Priorix vs MMR II+Havrix+Varivax.
Diagnostic results (unless otherwise stated, normal values were not provided): On an unknown date, Blood chloride result was 110 mmol/L. On an unknown date, Blood creatinine result was 0.4 mg/dL. On an unknown date, Blood glucose result was 91.9 mg/dL. On an unknown date, Blood potassium result was 3.81 mmol/L. On an unknown date, Blood sodium result was 134 mmol/L. On an unknown date, Haemoglobin result was 14.9 mg/dL. On an unknown date, Lymphocyte count result was 55 %. On an unknown date, Neutrophil count result was 29 %. On an unknown date, Platelet count result was 226000 /mm3. On an unknown date, Protein urine result was 30 /mcL. On an unknown date, Urine ketone body result was 15 /mcL. On an unknown date, Urobilinogen urine result was 0.2 /mcL. On an unknown date, White blood cell count result was 7000 /mm3. On an unknown date, White blood cells stool result was Negative unknown. On an unknown date, White blood cells urine result was 0-1 unknown.

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Clinical Narrative report with Both Serious & Non-Serious Events

Investigator Comment:
The patient started on September 25 2014, with 3 liquid stools in 24 hrs without mucous or blood, 3 vomiting of gastro alimentary content and fever of 38.3 C., the same day the subject went to a private physician who made the diagnosis of gastroenteritis, because of persistence of the symptom, the patient attended to the center on Sep 26 2014. The mother referred that during the day, the patient had had 4 liquid stools without mucous or blood without neither fever nor vomiting. At physical exam, the subject was hydrated a heart rate: 130 x minute, respiratory rate: 32 x minute, axillar temperature: 37.9 C., pharyngeal hyperemia, abdomen not distended with mild tenderness at palpation, increased bowel sound. The diagnosis of gastroenteritis without dehydration was done and the patient was sent home. The subject came to the center on Oct 01-2014 for a consult and the father referred that because of persistence of liquid stools the patient was taken to the clinic on Sep 26- 2014 where the subject was admitted with diagnosis of gastroenteritis without dehydration. The discharge note referred that the patient have had in the last 24hr. previous to the admission, 8 scare liquid stools without mucous or blood, 3 vomiting, diffuse abdominal pain with temperature of 38.0 C with intolerance to oral intake and irritability. It was performed (no dates are provided) an urine test, Ph 6.0, turbid, protein 30 mcL ketones 15 mcL, WBC 0-1/field stool cytology for leukocytes, negative and stool examination for ameba was also negative, serum glucose 91.9mgs/dL, creatinine 0.4mgs/dL. Sodium 134 mmol/L., Potasium 3.81 mmol/L., CL 110 mmol/L, Hemoglobin 14.9mgs/dL. HcT 36%, WBC 7000/mm3, Lymphocytes 55%, Neutrophils 29%, Platelets 226000/mm3. The patient was given intravenous solutions from the 26 to the 27 Sep 2014.

The clinical outcome was satisfactory at physical exam, heart rate: 115 x minute, respiratory rate: 20 x minute, axillary temperature: 36.0 C alert, reactive well hydrated abdomen not distended without tenderness at palpation, normal bowel sound, and the subject was discharged on Sep 28 2014 although the subject was asymptomatic without any medication since 27Sep2014.
The subject is asymptomatic and the Serious Adverse Event is considered recovered/resolved on 27Sep2014.
According to the principal investigator the event is considered of moderate intensity and is not related to the study vaccine or study procedures.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchiolitis, Gastroenteritis rotavirus

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 12-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.. On 22nd April 2014, the subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) for prophylaxis.

On PPD 8 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed moderate - grade 2 bronchiolitis. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included moderate - grade 2 rotavirus gastroenteritis on 30th April 2014 with serious criteria of hospitalization and GSK medically significant. The subject was treated with ceftriaxone, sucralfate (Carafate), lactobacillus acidophilus, Guaifenesin + Dextromethorphan, salbutamol (Albuterol), paracetamol (Acetaminophen), budesonide (Pulmicort), ranitidine, methylprednisolone sodium succinate (Solumedrol) and potassium chloride with normal saline. The outcome of bronchiolitis was recovered/resolved on 5th May 2014. The outcome(s) of the additional event(s) included rotavirus gastroenteritis (recovered/resolved on 5th May 2014).

The investigator considered that there was no reasonable possibility that the bronchiolitis and rotavirus gastroenteritis may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments :
12 mo old infant boy admitted 30 Apr 2014 till 05 May 2014 due to dehydration and respiratory symptoms. Rotazyme positive . RSV not reported. This hospitalization was a few days following receipt of study vaccine but is not related to the study vaccine. It is clearly more related to the occurrence of frequent cases of RSV-Bronchiolitis and Rotavirus outbreak we are seeing locally. Today PPD we conducted Visit 2 when mother informed us of these events and of the hospitalization. The visit was conducted without deviation. Infant recovered fully and his PE toady is within normal limits.

Relevant assessments: Chest X Ray- negative, Blood Culture Negative, Urine culture negative, Rotazyme Positive, CMP negative or normal.

Update 21Oct2014: RSV negative.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to rota virus infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Randomization Number:

Case ID: PPD

Serious Events: Abscess

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 22nd April 2014, for prophylaxis.

On PPD 97 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 abscess. Serious criteria included hospitalization. The subject was treated with antibiotics nos (Unknown Antibiotic) and clindamycin. The outcome of abscess was recovered/resolved on 5th August 2014.

The investigator considered that there was no reasonable possibility that the abscess may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments :
Participant s parents were called yesterday (11Aug2014) for safety follow-up and we were notified during the call that he had been admitted to the hospital for management of a lower back abscess. Symptoms of condition initially noted by mother on 28 Jul 2014 and he was taken for evaluation at Hospital on 30 Jul 2014. He was hospitalized and treated with IV antibiotic from 30 Jul 2014 to 05 Aug 2014 when he was discharged without clinical symptoms as reported by mother. He was given prescription to complete an additional 4 days of treatment with oral Clindamycin at home. Condition resolved without sequel and not related to study vaccine.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

The report was previously unblinded with wrong study group.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Serious Events: Subcutaneous abscess

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 12-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.. On 7th August 2014, the subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) for prophylaxis.

On PPD 18 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed moderate - grade 2 scalp abscess. Serious criteria included hospitalization. The subject was treated with famotidine and ceftriaxone. The outcome of scalp abscess was recovered/resolved on 29th August 2014.

The investigator considered that there was no reasonable possibility that the scalp abscess may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the scalp abscess included other.

Investigator Comments : Subject received Study vaccine on 7-Aug-2014. Developed high fever, lethargy and poor appetite on 11 Aug 2014. On physical exam on 12 Aug 2014 he was diagnosed with Tonsillitis. Prescribed Amoxicillin (10 Days). Today, 28-Aug-2014, mother reported that the rash resolved by 25 Aug 2014 but the infant developed a retroauricular node or swelling (left). Was seen in the ER and started on IV antibiotic (27 Aug 2014). Diagnosis: Left Retroauricular Scalp Infection. These are in our opinion , not related to Study vaccine. The infant is alert, active and afebrile.

Additional details:
Other possible cause(s) of the scalp abscess included bacterial superficial infection with abscess formation (left behind ear).

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
scalp abscess 18 days after vaccination; unlikely to be related to vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Serious Events: Pyrexia, Diarrhoea, Tonsillitis, Otitis media

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 15-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 24th March 2014, for prophylaxis.

On PPD 93 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 fever. Serious criteria included hospitalization. Additional event(s) included moderate - grade 2 acute tonsillitis on 25th June 2014 with serious criteria of hospitalization, moderate - grade 2 otitis media on 30th June 2014 with serious criteria of hospitalization and moderate - grade 2 diarrhea on 4th July 2014 with serious criteria of hospitalization. The subject was treated with paracetamol, ciprofloxacin, antibiotics nos, paracetamol (Febrectal), ibuprofen and amoxicillin (Amoxicilline). The outcome of fever was recovered/resolved on 11th July 2014. The outcome(s) of the additional event(s) included acute tonsillitis (recovered/resolved on 30th June 2014), otitis media (recovered/resolved on 4th July 2014) and diarrhea (recovered/resolved on 14th July 2014).

The investigator considered that there was no reasonable possibility that the fever, acute tonsillitis, otitis media and diarrhea may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments :
14jul2014: the subject Begins with fever on day 25jun2014, the subject was diagnosed of tonsillitis and was prescribed symtomatic treatment (amoxicilline and paracetamol), persist fever, the parents went back medical consultation, was diagnosed of otitis media and was precribed symtomatic treatment (cetraxal, paracetamol and amoxicilline), persist fever and the doctor decided admission to hospital for further investigation. In the hospital was only diagnosed of diarrhea. all results test normality and was discharged, the day 14jul2014 went back medical consultation and the subject is totally recovered.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis

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Clinical Narrative report with Both Serious & Non-Serious Events

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 18 February 2014, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD four months after the dose of Blinded vaccine, four months after the dose of Varivax, four months after the dose of Havrix 720 Junior, this 17-month-old subject developed acute gastroenteritis. The subject was hospitalised. The event resolved on 07 July 2014. The investigator considered that there was no reasonable possibility that the acute gastroenteritis may have been caused by investigational product, Varivax and Havrix 720 Junior.

Investigator Comments :
10/sep/2014: the subject admission to the hospital the day 04jul2014 by recurrent diarrhea and vomiting, without fever. By diarrhea persisting decided child,s admission to continuing rehidratation. Stool culture has been performed with negative result. After clinical observation patient has been discharge on 7jul2014. SAE is resolved.

Additional details:
Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Upper respiratory tract infection

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 14-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to

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Clinical Narrative report with Both Serious & Non-Serious Events

healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 5th September 2013, for prophylaxis.

Concomitant products included INFLUENZA VIRUS VACCINE INACTIVATED (FLUZONE VACCINE).

On PPD 62 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed moderate - grade 2 upper respiratory tract infection. Serious criteria included hospitalization. The subject was treated with salbutamol (Albuterol), ipratropium bromide (Atrovent) and prednisolone. The outcome of upper respiratory tract infection was recovered/resolved on 3rd December 2013.

The investigator considered that there was no reasonable possibility that the upper respiratory tract infection may have been caused by Priorix vs MMR II+Havrix+Varivax.

Relevant Risk Factors : EX 30 week premature infant
Investigator Comments :
Chest X-Ray-Patchy left perihilar and right upper lung opacity. No pneumothorax or significan effusion. Influenza swab negative for Influenza A and B. Respiratory syncytial virus swab-negative. Patient presented to the Emergency Department on November 19, 2013 with wheezing and history of rhinorrhea and cough for two weeks without fevers. Parents noted increase work of breathing and audible wheezing prior to going to the Emergency Department. Patient was started on nebulized Albuterol, Prednisolone and Amoxicillin for otits media found on exam. Chest x-ray was obtained with possible early infiltrative process noted. Swabs for respiratory syncytial virus and influenza were obtained. Patient had oxygen desaturations while on continuous nebulized Albuterol and was admitted to the hospital. After admission, patient was continued on continuous Albuterol nebulized treatments and oxygen to maintain saturation. He was slowly weaned to Albuterol treatments every 4 hours but still had desaturations while sleeping to the mid 80 s. On the day of discharge saturations improved on room air, prednisone was continued and Albuterol MDI with spacer teaching done with parent. Parent felt comfortable going home on Albuterol 2 puffs every 4 hours and completing 5 day course of prednisolone. Patient scheduled for follow up with primary physician November 22, 2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 2 months post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Febrile convulsion

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency: [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 25th March 2014, for prophylaxis.

On PPD 128 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 febrile seizure. Serious criteria included hospitalization and GSK medically significant. The outcome of febrile seizure was recovered/resolved on 1st August 2014.

The investigator considered that there was no reasonable possibility that the febrile seizure may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments:
Subject with 3 seizures at home with fever and after fall. Transported to hospital via ALS. One seizure in ED and then admitted to hospital. Subject with no further seizures during hospitalization, no fevers reported, and blood sugars reported within normal limits. Discharged next day. Unable to provide medications/lab results. Subject followed up with physician on 07AUG2014, EEG ordered for 04SEP2014. Seen outside health plan. EEG results negative. EEG Results- This EEG tracing, recorded in wake was normal. This tracing is suggestive of no increased seizure predilection. Recommendations: Clinical correlation.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Developed seizures and fever after fall. onset-4 months.bld sugar norm.No other diagnostic info.resolved. Inv-unrelated to vaccines.

The report includes a reasonable explanation for the events occurring after a fall, however other investigative information is missing. The time to onset makes a causal association with vaccination unlikely.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Asthma, Bronchiolitis

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Clinical Narrative report with Both Serious & Non-Serious Events

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (intramuscular) on 13th September 2013, for prophylaxis.

Previously administered products included FLU VACCINE.

On PPD 122 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 asthma. Serious criteria included hospitalization. Additional event(s) included severe - grade 3 bronchiolitis on 20th January 2014 with serious criteria of hospitalization and GSK medically significant. The subject was treated with salbutamol (Albuterol), sodium chloride (0.9 % Sodium Chloride), ipratropium bromide (Atrovent), prednisolone sodium phosphate (Orapred), ibuprofen, emla cream (nos) (Emla Cream), magnesium sulfate, dexamethasone (Decadron), salbutamol sulfate (Proair Hfa), paracetamol (Acetaminophen), sodium chloride, glucose + potassium chloride + sodium chloride (Dextrose + Potassium Chloride + Sodium Chloride), prednisolone sodium phosphate (Orapred) and oxygen. The outcome of asthma was recovered/resolved on 20th January 2014. The outcome(s) of the additional event(s) included bronchiolitis (recovered/resolved on 24th January 2014).

The investigator considered that there was no reasonable possibility that the asthma and bronchiolitis may have been caused by Priorix vs MMR II+Havrix+Varivax. Diagnostic results (unless otherwise stated, normal values were not provided): On 20th January 2014, BLOOD HCO3, VENOUS result was 22.9 mmol/L, BLOOD LYMPHOCYTES result was 16 %, BLOOD NEUTROPHILS AUTO COUNT result was 10.9 K/uL, BLOOD OXYGEN, PARTIAL PRESSURE, VENOUS result was 87 mmHg and Neutrophil count result was 76 %.

Investigator Comments : Chest Xray completed: Impression-Hazy airspace opacity left upper lobe consistent with focal pneumonia in the appropriate clinical setting. 16 month old with no prior history of wheezing episodes presented to the clinic on 20Jan2014 after 1 week of mild cough and 2 days of rhinorrhea. On the night prior to admission he had a restless night, and awoke the next morning in notable respiratory distress. He was seen in the clinic and received albuterol and oral prednisolone, but persisted with notable wheezing and oxygen saturations of 87% on room air. The child was transferred to the ED for continuous albuterol and longer observation in the ED the child was on oxygen by blow by and received albuterol treatments every 2 hours. His breathing became harder and faster with noted grunting. Child admitted to floor. The child's breath sounds deminished through out another albuterol treatment was given but within 30 minutes his respirations became labored and grunting was noted again. Continuous albertol was started and he was switched to HFNC at 4LPM, HFNC was increased to 8LPM over the next 2 hours. Child has made NPO, periphral IV was placed and fluids were started. After continuous albuteral and HFNC respiratory status improved slightly, but the childs sats dropped to 88-90% on HFNC and diffuse crackles and expiratory wheezing were noted. Child transferred to PICU on 21Jan2014 in the early

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morning. He was treated aggresively with albuterol in a hypertonic sodium chloride solution, slong with decadron and oxygen via HFNC at 151 pm and was gradually weaned to room air by the time of discharge on 24Jan2014. Seen in the clinic on 27Jan2014 for hospital follow-up. He will continue on albuterol inhaler every 6 hours until cough resolves. Please note, though diffuse crackles and wheezing was noted, Pneumonia was not confirmed.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 122 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Croup infectious

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 21 November 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

Medical condition at the time of the event included cough.

On PPD 120 days after the 1st dose of Blinded vaccine, 120 days after the 1st dose of Havrix 720 Junior, 120 days after the 1st dose of Varivax, 120 days after the 1st dose of Prevnar 13, this 16-month-old subject developed croup. The subject was hospitalised. The subject was treated with sodium chloride, racepinephrine, dexamethasone sodium phosphate, ibuprofen, ondansetron hydrochloride, ceftriaxone and Dextrose + normal saline + potassium chloride. The event resolved on 28 March 2014. The investigator considered that there was no reasonable possibility that the croup may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the event was possibly due to her medical condition of cough.

Investigator Comments :
Influenza Virus A + B-negative. RSV-negative. CXR narrowing of the subglottic airway. Possible peribronchial infiltrate in left lower lobe. Subject with a 4 day history of fever and cough.
Developed barky cough for 1 day and was seen in clinic and prescribed decadron which was not picked

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up at the pharmacy. Diagnosed with croup, stomatitis, and fever in clinic.
Subsequently, subject developed an episode of difficult breathing, brought in to ER in significant respiratory distress (retracting, flaring, grunting) with temperature of 101.2F. Given dexamethasone, CXR showed peribronchial infiltrate and narrowed subglottic airway. Was given NaCL 0.9% 20 ml bolus X2, cefitriaxone, dexamethasone X2 and recemic epinephrine X2 to which she responded well. In ER lungs clear, but with inspiratory stridor when agitated only. Was neutropenic during recent viral illness 3 months ago with WBC 3.7. CBC repeat ordered, results show WBC 3.9. During course of ER subject with increased worked ofbreathing. Refuse po intake. Still with stidulus sounding breath. Transferred to hospital, on arrival had soft stridor at rest with post-tussive vomiting and 1 episode of loose stool. Stool sample with C Diff negative. Given IVF overnight due to poor PO intake over past 24 hours. Vitals stable and afebrile overnight, but poor PO intake overnight.
Required no further respiratory interventions or supplement oxygen. Observed over the course of the day, had imporved po intake. No further post-tussive vomiting, still afrebrile and no increased work of breathing.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 120 days. Reported event is due to viral infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pharyngitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 31 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 74 days after the 1st dose of Blinded vaccine, 74 days after the 1st dose of Havrix 720 Junior, 74 days after the 1st dose of Varivax, this 14-month-old subject developed pharyngitis. The subject was hospitalised. The subject was treated with cefuroxime axetil and paracetamol. The event resolved on 22 October 2013. The investigator considered that there was no reasonable possibility that the pharyngitis may have been caused by investigational product, Havrix 720 Junior and Varivax .

Investigator Comments :

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17OCT2013:patient visits paediatrician on 13oct2013 due to febrile syndrome and is first diagnosed of acute tonsillitis. The doctor will schedule antibiotics (amoxicillin-clavulanate) orally. The day 15oct2013 becomes the pediatrician high fever. The pediatrician on physical examination has no serious impression. Is cited in 24 hours, not go to telephonically contact with the father and informs us that this admitted to the Hospital from the 15oct2013. The girl shows improvement by antibiotics. We are waiting for more information. Final diagnose of SAE is pharyngitis. Start date of the pharyngitis symptoms was 13.oct.13
18OCT2013: The patient was discharged on 17oct13 diagnosed with pharyngitis. The medical regimen antibiotics at home, Apiretal and zinnat oral route.
21OCT2013: Enter blood analytical data.
31OCT2013: The end date SAE is reported. Complete clinical standardization.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 74 days. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Cellulitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 02 September 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior) and Merck's Varicella vaccine (Varivax).

On PPD 90 days after the 1st dose of Blinded vaccine, 90 days after the 1st dose of Havrix 720 Junior, 90 days after the 1st dose of Varivax, this 15-month-old subject developed cellulitis. The subject was hospitalised. The subject was treated with Clavulanic acid/amoxicillin, Augmentin and povidone-iodine. The event resolved on 04 January 2014. The investigator considered that there was no reasonable possibility that the cellulitis may have been caused by investigational product, Havrix 720 Junior and Varivax and that the event was possibly due to an infection in area genital by oral aphthosis.

Investigator Comments:
The subject goes to the hospital emergency room for injuries in the mouth on 01dec13 . In emergency is diagnosed with herpetic gingivostomatitis and genital region cellulite. The doctor prescribed amoxicillin-clavulinic acid. Subject return in 24 hours to health center because worsening . The pediatrician saw signs of inflammation in genital area and refered again to the emergency room. The subject was

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hospitalized. (waiting for new data). During subject admission, bacteremia or deep tissues affectation is discarded. Antibiotics intravenously is contunuated during 6 days. After discharge, oral antibiotics and local treatment were prescribed,if subject would be sick.(prophylaxis) .Data end os SAE is 04january2014(data end of medication).

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 90 days. Reported event is due to has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral infection

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 18-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 27th January 2014, for prophylaxis.

On PPD 167 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 viral infection. Serious criteria included hospitalization. The subject was treated with paracetamol (Tylenol), ibuprofen and potassium nos, sodium chloride (Normal Saline And Potassium). The outcome of viral infection was recovered/resolved on 15th July 2014.

The investigator considered that there was no reasonable possibility that the viral infection may have been caused by Priorix vs MMR II+Havrix+Varivax. Diagnostic results (unless otherwise stated, normal values were not provided): On 13th July 2014, Blood creatinine result was 0.33 mg/dL (normal low: 0.60, normal high: 1.30), Blood potassium result was 4.5 mcg/dl (normal low: 3.5, normal high: 5.1), Blood urea result was 20 mg/dL (normal low: 7, normal high: 18) and Blood urea result was 20 mg/dL (normal low: 7, normal high: 18).

Investigator Comments : Subject brought to emerrgency room with parent having fever and decreased oral intake. Subject admitted to hospital on 13Jul2014 and discharged on 15JUL2014.

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Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 167 days post vaccination, Reported event has no causal relationship to the administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Gastroenteritis, Dehydration

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 13-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 25th March 2014, for prophylaxis.

On PPD 31 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 acute gastroenteritis. Serious criteria included hospitalization. Additional event(s) included moderate - grade 2 dehydration on 25th April 2014 with serious criteria of hospitalization. The subject was treated with potassium chloride, sodium chloride (Normal Saline), glucose + sodium chloride (5% Dextrose + 1/2 Normal Saline) and paracetamol (Acetaminophen). The outcome of acute gastroenteritis was recovered/resolved on 28th April 2014. The outcome(s) of the additional event(s) included dehydration (recovered/resolved on 28th April 2014).

The investigator considered that there was no reasonable possibility that the acute gastroenteritis and dehydration may have been caused by Priorix vs MMR II+Havrix+Varivax.
Diagnostic results (unless otherwise stated, normal values were not provided): On 27th April 2014, Blood calcium result was 10.0 unknown (normal low: 9.0, normal high: 11.0), Blood chloride result was 111 unknown (normal low: 97, normal high: 109), Blood creatinine result was 0,4 unknown (normal low: 0.7, normal high: 1.2), Blood glucose result was 72 unknown (normal low: 65, normal high: 125), Blood potassium result was 4.2 unknown (normal low: 3.5, normal high: 5.2), Blood sodium result was 139 unknown (normal low: 135, normal high: 145), Blood urea result was 40.0 unknown (normal low: 7.0, normal high: 25.0), Blood urea result was 14 unknown (normal low: 4, normal high: 15), Carbon dioxide result was 11 unknown (normal low: 20, normal high: 29), Haematocrit result was 35 unknown (normal low: 36.0, normal high: 51.0), Haemoglobin result was 11.5 unknown (normal low: 10.0, normal high: 16.4), Lymphocyte count result was 73 % (normal low: 20, normal high: 70), Mean cell haemoglobin result

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was 27.1 unknown (normal low: 23.0, normal high: 31.0), Mean cell volume result was 82.3 unknown (normal low: 90.0, normal high: 112.0), Mean platelet volume result was 8.0 unknown (normal low: 7.4, normal high: 10.4), Monocyte count result was 9 % (normal low: 0, normal high: 7), Neutrophil percentage result was 18 % (normal low: 16, normal high: 60), Platelet count result was 366 unknown (normal low: 140, normal high: 400), Red blood cell count result was 4.25 unknown (normal low: 3.40, normal high: 5.20), Red cell distribution width result was 14.8 % (normal low: 11.5, normal high: 15.0) and White blood cell count result was 13.4 iu/ml (normal low: 5.0, normal high: 17.5).

Investigator Comment:
Subject had symptoms of vomiting and diarrhea for 2 days., Was not wetting diapers, Taken to emergency room and admitted on 27APR2014. and discharged on 28APR2014.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 31 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 12-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 31st July 2014, for prophylaxis.

Concurrent medical conditions included bronchiolitis.

On PPD 1 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed moderate - grade 2 bronchiolitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with salbutamol sulfate (Albuterol Sulfate). The outcome of bronchiolitis was recovered/resolved on 18th August 2014.

The investigator considered that there was no reasonable possibility that the bronchiolitis may have been

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caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the bronchiolitis included medical condition. Diagnostic results (unless otherwise stated, normal values were not provided): On 2nd August 2014, Blood culture result was NEG unknown.

Investigator Comments :
Subject was brought into ER on 01 AUG 2014 with wheezing, cough and fever that was ongoing for 5 days and worsened on 01AUG2014. Subject Admitted to pediatric unit for observation with a diagnosis of Bronchiolitis, Nebulizer treatments as ordered .Chest xray was performed and was normal. Subject discharged on 03 AUG 2014.

Additional details:
Other possible cause(s) of the bronchiolitis exacerbation included medical condition bronchiolitis.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Dehydration

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 05 August 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

Concomitant medications included Ibuprofen.

On PPD 115 days after the 1st dose of Blinded vaccine, 115 days after the 1st dose of Havrix 720 Junior, 115 days after the 1st dose of Varivax and 115 days after the 1st doseo f Prevnar 13, this 18-month-old subject developed dehydration. The subject was hospitalised. The subject was treated with sodium chloride, simethicone, ranitidine hydrochloride, paracetamol, Ondansetron HCl and intravenous fluid(s). The event resolved on 08 December 2013. The investigator considered that there was no reasonable possibility that the dehydration may have been caused by investigational product and

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Clinical Narrative report with Both Serious & Non-Serious Events

that the event was possibly due to viral infection.

Investigator Comments : Description: Patient is an 18 month old female who was admitted to the Hospital for Influenza with both respiratory and GI symptoms on 5 Dec2013. Five days prior to hospitalization subject experienced moderate watery to mucusys runny nose, frequent cough and an elevated temperatures. Subject was seen at local urgent care where rapid Flu test was reported as negative, after continued symptoms subject was seen by PCP were a rapid Flu test was repeated and reported as positive. Subject was not given Tamiflu due to several days of illness at that point. Day prior to hospitalization patient began to have black tarry stools. This was after several doses of Ibuprofen. Soon after patient began to have multiple frequent episodes of emesis and became lethargic, at that point stools became watery and frequent. After several episodes of emesis, mom brought subject to hospital and she was admitted for Influenza, with both respiratory and GI symptoms, Dehydration secondary to Flu and Melena, possibly due to previous Ibuprofen vs. Flu. This information was relayed to the site on 10 Feb 2014 during the final visit. Mom did not call the office because she thought once her child was no longer a patient of PPD her child was no longer enrolled in the study. Treatment: On 12/5/2013 the following procedures were completed ,CBC Diff reflux, Comp Metabolic panel, Abdomen x-rays and ultrasound of the abdomen. Subject was given the following medications Sodium Chloride from Dec. 6-8 2013,Simethicone Dec 7-8 2013, Ranitidine Dec. 6-8 2013, IV Bolis Dec. 6-7 2013,Acetaminophen PRN Dec. 6-8 2013, Ondansetron HCl Dec. 6-8 2013, 13 June 2014 SAE Diagnosis was updated to dehydration

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 115 days Reported event is due has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchial hyperreactivity

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 18-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 24th March 2014, for prophylaxis.

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Clinical Narrative report with Both Serious & Non-Serious Events

Concurrent medical conditions included eczema.

On PPD 173 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 reactive airways disease. Serious criteria included hospitalization and life threatening. The subject was treated with paracetamol (Tylenol), salbutamol (Albuterol), dermatologicals nos (Ointment), budesonide, hydrocortisone (Hydrocortisone Cream), ibuprofen, ipratropium, benzathine benzylpenicillin (Penicillin G Benzathine) and prednisolone. The outcome of reactive airways disease was recovered/resolved on 19th September 2014.

The investigator considered that there was no reasonable possibility that the reactive airways disease may have been caused by Priorix vs MMR II+Havrix+Varivax.

Relevant Tests: Saliva rapid strep group A result was POSITIVE Unit : Negative (normal low: NA, normal high: NA).

Relevant Risk Factors : Patient s father smoke in presence of patient.

Investigator Comments :
Per patient's mother, patient brought in to emergency department on 14 September 2014 for progression of difficulty in breathing. Stated he had had a fever one day prior. Did not specify temperature. Patient's mother did not report a family history of asthma. Mom requested strep test due to concern for strep pharyngitis contacts. She did not specify with whom. Patient's father smokes in front of child. Child does not have any known allergies. On admission to emergency department, child had coughing, wheezing, increased work of breathing without stridor. Patient's temperature was 97.6 degrees Fareinheit. Heart rate = 160, respiratory rate=52, Oxygen saturation= 97% room air. a rapid strep Group A test resulted in a positive result, The normal result for this test would be negative. Chest x-ray demonstrated hyperinflation. Child was admitted to hospital from emergency department for respiratory distress. Medications not already listed under treatments include: Proventil 2.5mg nebulizer every 2 hours, Atrovent 0.02% nebulizer at a dose of 0.25mg every 4 hours, Orapred 1mg/kg given orally twice daily, and penicillin G benzathine (Bicillin) 0.6 million units intramuscular injection at a one-time dose on 15 September 2014. Update: Patient was discharged home from hospital on 16 September 2014. The final discharge diagnosis is listed as reactive airway disease. Secondary diagnoses include viral upper respiratory infection, strep pharyngitis, and severe eczema. These are not extra SAES, but concominent AEs which will be reported separately.

Additional details:

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

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Clinical Narrative report with Both Serious & Non-Serious Events

Serious Events: Bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 5th August 2014, for prophylaxis.

Concomitant products included diphtheria toxoid + pertussis toxoid acellular + tetanus toxoid (Dtap), haemophilus influenza B vaccine (Hib) and poliomyelitis vaccine (Ipv).

On PPD 169 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed mild - grade 1 acute bronchiolitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with paracetamol (Acetaminophen), salbutamol sulfate (Proventil Solution), amoxicillin (Amoxicillin Suspension), ceftriaxone (Rocephin), ipratropium bromide (Atrovent 0.02%) and prednisolone sodium phosphate (Orapred). The outcome of acute bronchiolitis was recovered/resolved on 1st February 2015.

The investigator considered that there was no reasonable possibility that the acute bronchiolitis may have been caused by Priorix vs MMR II+Havrix+Varivax.

Relevant Tests: On 23Jan2015, NASAL SWAB RAPID FLU A and NASAL SWAB RAPID FLU B were negative. Diagnostic results (unless otherwise stated, normal values were not provided): On 22nd January 2015, Streptococcus test result was Negative unknown. On 23rd January 2015, Influenza virus test result was Negative unknown, Respiratory syncytial virus test result was Negative unknown and Streptococcus test result was Negative unknown.

Investigator Comments:
Patient presented in ER on 23JAN2015 with increased work of breathing and cough which began on 21JAN2015. Patient found to be in respiratory distress with wheezing, tightness, and retractions. Fever=103.4 degrees Fahrenheit. Rapid Group A strep found to be negative, no Rapid Synctial virus antigen detected, and rapid flu A and B were both negative. Patient given Albuterol MN inhalation, continued wheezing. Patient given Albuterol HL and Orapred with nasaltrachea suctioning. Saw improvement in oxygen saturation 90-91% on room air. A two-view chest AP supine and lateral xray performed on 22JAN2015 demonstrated prominence of the perihilar and peribronchial markings suggestive of viral and/or reactive airway disease. No parenchymal infiltrate seen. Patient was admitted for further treatment of bronchiolitis and respiratory distress. Also found to have a left acute suppurative otitis media which is a non-serious adverse event, but a secondary diagnosis. Patient showed good response to albuterol inhalation every four hours with improvement in wheezing. She required no supplemental oxygen, had normal appetite and no concerns for dehydration. Steroid regimen not

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continued because it was believed to be bronchiolitis and not an exacerbation of asthma. Was started on amoxicillin for otits media, one dose of IM cephalexin due to difficulty with amoxicillin. Patient discharged home and instructed to follow up with primary care pediatrician. Patient followed up with pedicatrician on 04FEB2015 and was found to be well. Patient's mother stated that symptoms of bronchiolitis had completely disapated 01FEB2015.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 169 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Dehydration

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 24 January 2014, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

Medical condition at the time of the event included gastroenteritis.

On PPD 57 days after the 1st dose of Blinded vaccine, 57 days after the 1st dose of Varivax, 57 days after the 1st dose of Havrix 720 Junior, 57 days after the 1st dose of Prevnar 13, this 16-month-old subject developed dehydration. The subject was hospitalised. The subject was treated with dextrose, sodium chloride and Dextrose 5% in normal saline. The event resolved on 07 April 2014. The investigator considered that there was no reasonable possibility that the dehydration may have been caused by investigational product, Varivax, Havrix 720 Junior and Prevnar 13 and that the event was possibly due to her medical condition of gastroenteritis.

Investigator Comments :
Laboratory done on the day of admission revealed significant dehydration with a CO2 of 13. The patient was admitted for IV fluid rehydration. On 3-27-14 day of discharge CO2 was 21. This patient had no significant past medical history who presents with a three day history of vomiting, progressively decreased appetite and activity and urine output was decreased, also refusal of P.O intake.

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Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 57 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Asthma

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 20-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.. On 17th March 2014, the subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) for prophylaxis.

Concurrent medical conditions included upper respiratory infection.

On PPD 192 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 asthma. Serious criteria included hospitalization. The subject was treated with prednisolone sodium phosphate (Orapred), ipratropium bromide (Atrovent), fluticasone propionate (Flovent), ceftriaxone (Rocephin), prednisolone (Prelone) and salbutamol (Albuterol). The outcome of asthma was recovered/resolved on 4th October 2014.

The investigator considered that there was no reasonable possibility that the asthma may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the asthma included medical condition.

Relevant Risk Factors : Grandmother and twin brother had upper respiratory infection (and sick contacts), history of RSV at 1 month of age. History of bronchiolitis.

Investigator Comments : Subject taken to ER 26SEP2014 night for wheezing associated with upper respiratory infection. O2 sats 88-90%. X-ray showed hyperinflation. He received continuous albuterol 10mg/hr x2 hours, atrovent and prednisone with only minimal improvement so hospitalized 27SEP2014. Upon admit he received continuous albuterol 5mg/hr and prednisone twice a day. He was tappered to

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intermittent albuterol nebulizer treatment and discharged home on 28SEP2014. Discharge meds: Prelone 1.5ml oral BID x5 days, Flovent 44mcg 2 puffs BID and Albuterol 6 puffs q 2-4 hours. At follow up appointment with MD on 01OCT2014 asthma improved (resolved per mother). The upper respiratory infection resolved 04OCT2014. Flovent 2 puffs BID continues. Albuterol decreased to 2 puffs q 4 hours and now only PRN. Well child per mom (phone call 06OCT2014). Chest X-ray: Hyperinflated Lungs.

Additional Information:Other possible cause of the asthma included due to his medical condition of upper respiratory infection.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
time to onset 192 days; unlikely to be related to vaccination

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Escherichia urinary tract infection

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 13-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (intramuscular) on 23rd June 2014, for prophylaxis.

On PPD 48 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 escherichia urinary tract infection. Serious criteria included hospitalization and GSK medically significant. The subject was treated with potassium chloride + sodium chloride, sodium chloride, ibuprofen, paracetamol (Acetaminophen), ceftriaxone and CEFZIL (NOS). The outcome of escherichia urinary tract infection was recovered/resolved on 10th September 2014.

The investigator considered that there was no reasonable possibility that the escherichia urinary tract infection may have been caused by Priorix vs MMR II+Havrix+Varivax.

Relevant Tests: 27aug2014 : NASOPHARYNGEAL SWAB INFLUENZA A AND B: negative
27aug2014: THROAT MUCUS RAPID STREP : negative

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Clinical Narrative report with Both Serious & Non-Serious Events

Diagnostic results (unless otherwise stated, normal values were not provided): On 25th August 2014, White blood cell count result was 9.7 x10e3/mcL. On 27th August 2014, BLOOD Alkaline phosphatase result was 563 IU/L, BLOOD CHLORIDE result was 97 mEq/L, BLOOD CREATININE result was 0.25 mg/dL, BLOOD SODIUM result was 131 mEq/L, Blood urea result was 40.0 mg/dL, Culture stool result was NEGATIVE, Respiratory syncytial virus test result was negative, URINE CULTURE result was POSITIVE, White blood cell count result was 5.6 x10e3/mcL and White blood cells urine positive result was 43.

Investigator Comments :
Patient presented to office with parents on 8/27/14, with a history of previous office and ER visit. Onset of fever was 5 days ago. Fever to maximum of 103. Fever attributed to final diagnosis of Urinary Tract Infection. Temperature was taken axillary. Temperature comes and goes. Not drinking as well. Not eating well. Decreased activity level. UOP decreased. Other Symptoms Present: runny nose, cough and irritability. She denies vomiting and diarrhea. No history of ill contact. Review of systems positive for Weight decreased 1/2 lb past 2 days voiding decreased not active. Patient had previously went to ER and office 2 days ago, and workup was completely negative. Had E. Coli UTI 2 weeks ago. Vital signs stable. Well developed, ill appearing, Appears 5% dehydrated. Skin normal without rash. Her HEENT exam is normal except as below. TM s normal. Posterior Pharynx with erythema. Her neck is supple. No lympnadenopathy noted. Cardiovascular exam: regular rate and rhythm without murmur. Abdomen soft, non-tender, non-distended, with positive bowel sounds. Her neurologic exam is intact. PETs: PETs are in place bilaterally. Right PET is not draining fluid. Left PET is not draining fluid. Her ear canals are normal bilaterally. Nose Her nasal mucosa is mildly inflamed and swollen. There is a mild nasal discharge seen which is serous. Chest There are no rales noted. Mild ronchi are noted in the RUL and in the LUL. Chest There is no increased work of breathing. Aeration is good. There is no stridor. There is no wheezing noted. Review of office visit on 8/25/14 noted child had onset of fever was 2 days ago. Fever to maximum of 102.. Fever attributed to final diagnosis of Urinary Tract Infection. Temperature was taken axillary. Temperature comes and goes. Still drinking OK. Not eating well. Decreased activity level. Other Symptoms Present: irritability. She denies cough, vomiting and diarrhea. No history of ill contact. Patient was active, playful, Appears well hydrated. Skin normal without rash. Her HEENT exam is normal except as below. TM s normal. No oral ulcers seen. Posterior Pharynx normal. Her neck is supple. No lympnadenopathy noted. Her chest is clear to auscultation. Cardiovascular exam: regular rate and rhythm without murmur. Abdomen soft, non-tender, non-distended, with positive bowel sounds. ER visit on 8/24/14 noted patient to have 102.8 temperature and advised Tylenol and ibuprofen as needed. Workup was negative. A CBC was obtained both 8/25/14 and 8/27/14 and both were unremarkable. Strep came back negative. A chest xray on 8/25/14 was negative. Urinalysis was negative on 8/25/14. Urine (clean catch) was negative on 8/27/14. RSV, Influenza, and Strep were all negative. Overnight strep, rotavirus, urine culture, and stool culture are pending at time of narrative. Chest xray on 8/27/14 shows a mild infiltrate. Patient was admitted to hospital on 8/27/14 with admitting diagnosis of dehydration and viral syndrome. Advised to start IV fluids, obtain CMP, Tylenol and ibuprofen as needed, and obtain cultures Updated information shows that patient was discharged home from the hospital on 30Aug2014. Overnight strep was negative, rotavirus was negative, and stool culture was negative. The urine culture was positive for an isolate. The isolate was noted to be a 50,000 colony forming units/ML of Escherichia coli. This culture was resistant to Bactrim, ampicillin, and sensitive to cephalosporin. The patient was noted to have a urinary tract infection and started on Rocephin injectable through IV infusion. Patient received two doses of Rocephin while in hospital, where mother noted patient to be a different baby. Patient was discharged on 30Aug2014 and sent with a prescription of Cefzil to continue to treat urinary tract infection. Patient was told to follow up in office once antibiotic was completed. The initial SAE diagnosis of dehydration was changed to Urinary Tract Infection based on lab results. Dehydration was changed to an adverse event.

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Patient returned to office on 09Sep2014 for a hospital recheck and for follow up of recent UTI that she was admitted to the hospital for. Mother noted that her urine had been foul smelling over the past day or two. The patient did complete her full course of prescribed antibiotics. She has had no fever. She has been eating and drinking well. The remainder of review of systems is negative. The patient has not had renal ultrasound or VCUG. On examination, patient was well appearing. Vital signs were stable. Mucous membranes moist. OP clear. TM s are normal. Heart is regular rate and rhythm with no murmur. Lungs are clear to auscultation bilaterally. Abdominal exam is benign. Urine done in the office today was negative. Urine culture was performed to rule out continue urinary tract infection. Results were negative. Renal ultrasound was ordered and performed and noted to be normal. Patient s urinary tract infection resolved on 10Sep2014. additional information on 04apr2016: SAE start date has been updated to 10aug2014

Additional Details:
additional information on 04apr2016: SAE start date has been updated to 10aug2014
On 07Apr2016 This case was deleted in error in RDE and re-encoded on 11APR2016

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to E coli infection, which has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Febrile convulsion

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.. On 28th February 2014, the subject received Priorix vs MMR II+Havrix+Varivax (subcutaneous) for prophylaxis.

On PPD 98 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 complex febrile seizure. Serious criteria included hospitalization and GSK medically significant. The subject was treated with lorazepam (Ativan), paracetamol (Tylenol) and sodium chloride (Normal Saline). The outcome of complex febrile seizure was recovered/resolved on 7th June 2014.

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The investigator considered that there was no reasonable possibility that the complex febrile seizure may have been caused by Priorix vs MMR II+Havrix+Varivax. Other possible cause(s) of the complex febrile seizure included other.

Relevant Tests: On 06 June 2014 Urine Nitrate was reported as negative.
On 06 June 2014 Urine lecukocytes was reported as negative.
On 06 June 2014 Blood culture was done result unknown.

Diagnostic results (unless otherwise stated, normal values were not provided): On 6th June 2014, BLOOD BLOOD CULTURE result was unknown , BLOOD BUN result was 18 , BLOOD CRP result was 0.4 , BLOOD HEMATOCRIT result was 33 , BLOOD NEUTROPHILS result was 65% , BLOOD PLATELETS result was 329 , BLOOD TOTAL C02 result was 19 , BLOOD WHITE COUNT result was 12.5 , Blood chloride result was 108 , Blood chloride result was 108 unknown, Blood co2 result was 19 unknown, Blood creatinine result was 0.2 , Blood glucose result was 132 , Blood glucose result was 132 unknown, Blood sodium result was 135 , Blood sodium result was 135 unknown, Blood urea result was 18 unknown, Neutrophil count result was 65 %, Platelet count result was 329 unknown, URINE LEUKOCYTES result was NEG , URINE NITRITE result was NEG , White blood cell count result was 12.5 unknown, blood creatnine result was 0.2 unknown, blood crp result was 0.4 unknown and heamtocrit result was 33 unknown.

Investigator Comments : female who presented to the Emergency department for seizure activity that was witnessed by EMS personnel and family. subject was at babysitters when the patient became sick, father picked up child and took home. While at home the patient appeared to be shaking and was not responding normally. child was transported to local hospital treated with Ativan for seizure, CT, Labs, Vitals taken,Temps was 101.2. Per medical notes from the emergency room- generalized, shaking all over. symptoms stable for transportation to local children s hospital. Subject was held over for observation, neurology consult. No further seizure activity was reported and Neurology consult completed. final Diagnose was complex febrile seizure. Child was discharged to parents and in stable condition per parents.

Other possible cause(s) of the complex febrile seizure included incidental illness.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia

Non Serious Events:

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Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 17-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 11th February 2014, for prophylaxis.

On PPD 121 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 pneumonia. Serious criteria included hospitalization and GSK medically significant. The subject was treated with ceftriaxone sodium (Rocefin) and salbutamol (Albuterol). The outcome of pneumonia was recovered/resolved on 16th June 2014.

The investigator considered that there was no reasonable possibility that the pneumonia may have been caused by Priorix vs MMR II+Havrix+Varivax.

Investigator Comments :
Mom reported hospitalization for hypoxia on 26Aug2014. Further information pending. 04DEC2014 Discharge summary received, discharged with diagnosis of pneumonia. Subject was hypoxic due to shortness of breath, admitted for observation, confirmed pneumonia, given antibiotics and albuterol. Subject discharged on 14 Jun 2014.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 121 days post vaccination. Reported event has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Respiratory syncytial virus bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).

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On 29 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD four months after the 1st dose of Blinded vaccine, four months after the 1st dose of Havrix 720 Junior, four months after the 1st dose of Varivax, four months after the 1st dose of Prevnar 13, this 16-month-old subject developed respiratory syncytial virus bronchiolitis. The subject was hospitalised. The subject was treated with paracetamol, salbutamol sulphate, dexamethasone and ibuprofen. The event resolved on 11 December 2013. The investigator considered that there was no reasonable possibility that the respiratory syncytial virus bronchiolitis may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the event was possibly due to acute respiratory viral illness.

Investigator Comments:
16 Month old girl, previously healthy, admitted from December 5,2013 TO December 10,2013 with fever, respiratory distress, cough and vomiting for 4 days and decreased oral intake. Testing of nasal secretions was positive for (RESPIRATORY SYNCYTIAL VIRUS), and chest Xray was consistant with bronchiolitis. Patient was treated with medications Tylenol, Motrin, Albuteral Sulfate and Dexamethasone, and required Oxygen by nasal cannula for first 2 days of hospitalization. On the day of discharge, she had improved was stable and tolerating oral intake. Patient saw primary physician the day after discharge from hospital and was found to be clinically stable and recovered.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 4 months post vaccination. Reported event is due to Respiratory syncytial virus infection. which has no causal relationship to administered vaccines.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Viral upper respiratory tract infection, Hypoxia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 18 October 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A

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Clinical Narrative report with Both Serious & Non-Serious Events

vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD 34 days after the dose of Blinded vaccine, 34 days after the dose of Havrix 720 Junior, 34 days after the dose of Varivax, 34 days after the dose of Prevnar 13, this 13-month-old subject developed upper respiratory viral infection. On 25 November 2013, she developed hypoxia. The subject was hospitalised. The subject was treated with salbutamol sulphate, paracetamol and ibuprofen. Hypoxia resolved on 26 November 2013. Upper respiratory viral infection resolved on 30 November 2013. The investigator considered that there was no reasonable possibility that the upper respiratory viral infection and hypoxia may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the events were possibly due to a viral infection.

Relevant Risk Factors : exposure to RSV at day care

Investigator Comments :
Subject was exposed to pneumonia and RSV at daycare but she was not tested for or diagnosed with either. Subject had a cough for 2 days with wheezing and a fever which subject s dad reported was up to 102.3 degrees F. The subject had a decreased appetitie. Subject was brought into the clinic on 25NOV2013, and was found to have an axillary temperature of 99.1 degrees F, pulse rate of 150bpm and SpO2 of 90%. Subject was given an albuterol breathing treatment and SpO2 increased to 91-92%. Doctor noted nasal discharge and wheezes and coarse breath sounds throughout upon physical examination. Doctor admitted patient to neighboring hospital for observation due to hypoxia. Subject stayed there in the hospital overnight and was not given any supplemental oxygen or further treatments. Subject was discharged 26NOV2013. While in the hospital, admitting physician marked hypoxia as resolved but also diagnosed subject with viral upper respiratory infection. Discharged with instructions to take Ibuprofen and Tylenol as needed for the viral upper respiratory infection but parents never administered it.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
Reported event is due to respiratory syncytial virus infection, which has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Bronchiolitis, Leukocytosis, Conjunctivitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] 720 elisa unit <Blank>

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Clinical Narrative report with Both Serious & Non-Serious Events

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 11 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 11 July 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD six months after the dose of Blinded vaccine, six months after the dose of Prevnar 13, six months after the dose of Varivax, six months after the dose of Havrix 720 Junior, this 18-month-old subject developed conjunctivitis. On 10 January 2014, she developed bronchiolitis. On 15 January 2014, she developed leukocytosis. The subject was hospitalised. The subject was treated with oxygen and moxifloxacin hydrochloride. Conjunctivitis resolved on 15 January 2014. Bronchiolitis and leukocytosis resolved on 22 January 2014. The investigator considered that there was no reasonable possibility that the bronchiolitis, leukocytosis and conjunctivitis may have been caused by investigational product, Prevnar 13, Varivax and Havrix 720 Junior and that the events were possibly due to a viral illness.

Relevant Risk Factors :
Attends Day Care

Investigator Comments :
Subject has been ill with repiratory symptoms and fever for 5 days prior to 15 Jan2014. She was also being treated at home for 6 days for eye drainage with Moxifloxacin. Her condition did not improve at home and was brought to the emergency room. She was in some mild respiratory distress and had fevers 103-104. RSV antigen and Influenza A/B were both negative.. CXR showed bilateral perihilar infiltrates. She was admitted for IV fluid hydartion. No antibiotics were started. A Respiratory viral panel was done. It was positive for Coronavirus HKU1P PCR and RSV PCR. She was started on O2 at 1/2-1 liter/min as sats would decrease. Respiratory suctioning is required. WBC is 23.5 with 52 Segs, 11 Band, and 22 Lymph. On 1/16/14, respiratory status had improved, was off oxygen, eating and drinking better. WBC had decreased to 15.8 and CRP was down to 6.2. Was discharged home on the evening of 1/16/14. Hospital follow up on 22Jan2014 with primary provider. Bronchiolitis, leukocytosis, and conjunctivitis had resolved.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia

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Clinical Narrative report with Both Serious & Non-Serious Events

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 01 August 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD 53 days after the dose of Blinded vaccine, 53 days after the dose of Varivax, 53 days after the dose of Havrix 720 Junior, 53 days after the dose of Prevnar 13, this 13-month-old subject developed pneumonia. The subject was hospitalised. The subject was treated with azithromycin, ceftriaxone, Augmentin and cefdinir. The event resolved on 15 October 2013. The investigator considered that there was no reasonable possibility that the pneumonia may have been caused by investigational product, Varivax, Havrix 720 Junior and Prevnar 13 and that the event was possibly due to bacterial infection.

Investigator Comments :
Reported cough for several weeks in otherwise healthy child. Seen at PCP office on 23Sep13 for fever cough and treated with Amoxicillin for otitis media. The family had been camping the previous weekend and had an unknown insect bite on her right arm. Fever persisted 100.4-103. Was seen again at PCP on 26Sep2013 and antibiotic changed to Cefdinir. Evening of 26Sep13 mother reported child was very listless, not drinking, and felt cold. Referred to ED where she was admitted for pneumonia, otits media, and dehydration. Chest xray showed Right Middle Lobe infiltrate. She received IV Azithromycin and Ceftriaxone on 27 Sep13-28Sep13. She was dismissed on 28 Sep13 to take Augmentin. Follow up in 2 weeks with PCP.
04Nov2013Subject was seen by PCP on 15Oct2013. Pneumonia had resolved. Subject was not taking any medications.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 53 days. Reported event has no causal or temporal relationship with the vaccination.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Respiratory syncytial virus bronchiolitis, Dehydration

Non Serious Events:

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 23 January 2014, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD 16 days after the 1st dose of Blinded vaccine, 16 days after the 1st dose of Havrix 720 Junior, 16 days after the 1st dose of Varivax, 16 days after the 1st dose of Prevnar 13, this 13-month-old subject developed respiratory syncytial virus bronchiolitis. On 09 February 2014, she developed dehydration. The subject was hospitalised. The subject was treated with intravenous fluid(s). The events resolved on 20 February 2014. The investigator considered that there was no reasonable possibility that the respiratory syncytial virus bronchiolitis and dehydration may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the events were possibly due to a viral illness.

Investigator Comments :
saw primary care physician on 11feb2014 for 3 day history of cough and congestion. Developed low grade fever on 10feb2014. Vomiting started on 9feb2014 and has had some loose stools over the last 2 weeks. She was eating and drinking less with associated decrease in urine output. There are sick contacts at home. Did not improve overnight so went to the emergency room and was admitted for bronchioltis and dehydration. RSV was positive. Other labs were normal. Chest xray was consistent with viral illness or reactive airway disease. No medications administered. IV fluids given for treatment. Dehydration resolved. Test for Rotovirus was negative. Blood cultures and urine culture were both negative. Oral intake improved. Subject continued to have lots of respiratory secrtions but was able to handle them on her own. She was dismissed home on 14 Feb2014 at 1200. Dehydration and bronchiolitis resolved at follow up visit with primary on 20Feb2014.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Dehydration, Leukocytosis, Otitis media acute

Non Serious Events:

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [M-M-R II]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 13-month-old female subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age.. On 24th September 2013, the subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) for prophylaxis.

Concomitant products included INFLUENZA VIRUS VACCINE INACTIVATED (FLUZONE VACCINE).

On PPD 50 days after receiving Priorix vs MMR II+Havrix+Varivax the subject developed severe - grade 3 acute otits media. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included severe - grade 3 dehydration on 14th November 2013 with serious criteria of hospitalization and moderate - grade 2 leukocytosis on 14th November 2013 with serious criteria of hospitalization. The subject was treated with ceftriaxone (Rocephin), medication unknown (Tylenol), ibuprofen (Motrin) and cefdinir. The outcome of acute otits media was recovered/resolved on 18th November 2013. The outcome(s) of the additional event(s) included dehydration (recovered/resolved on 18th November 2013) and leukocytosis (recovered/resolved on 18th November 2013).

The investigator considered that there was no reasonable possibility that the acute otits media, dehydration and leukocytosis may have been caused by Priorix vs MMR II+Havrix+Varivax.

Diagnostic results (unless otherwise stated, normal values were not provided): On 15th November 2013, Blood albumin result was 3.1 g/dL (normal low: 3.2, normal high: 4.7), Blood bilirubin result was 0.2 mg/dL (normal low: 0.3, normal high: 1.2), Blood chloride result was 100 mcmol/L (normal low: 102, normal high: 112), Blood glucose result was 143 mg/dL (normal low: 70, normal high: 99), SERUM A1-GLOBULIN result was 0.89 % (normal low: 0.95, normal high: 1.59), SERUM ALAT result was 18 u/L (normal low: 21, normal high: 61), SERUM ALBUMIN result was 3.1 g/dL (normal low: 3.2, normal high: 4.7), SERUM BILIRUBIN result was 0.2 mg/dL (normal low: 0.3, normal high: 1.2), SERUM CHLORIDE result was 100 mcmol/L (normal low: 102, normal high: 112) and SERUM GLUCOSE result was 143 mg/dL (normal low: 70, normal high: 99).

Investigator Comments :
Subject came to pediatric office to be seen for temperature 103.0, with loss of appetite, drinking less and less active. Upon exam was found to have Acute otitis media, and leukosytosis. Recieved 1 dose Rocephin IM in the office. Later in the evening physician called to check on subject was was still less active and poor intake. Subject was then taken to the hospital for admission. Upon further lab tesing was found to also be dehydrated. 11/14/2013 Treatment IV fluids were started as well as Tylenol, Motrin and Rocephin IV. Discharged home on oral Cefdinir X 10 days.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.

Study Number: 115648

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old male subject was enrolled in a blinded study titled A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR vaccine (M M R®II), as a first dose, both co-administered with Varivax, Havrix and Prevnar 13 (subset of children) to healthy children 12 to 15 months of age. The subject received the 1st dose of Priorix vs MMR II+Havrix+Varivax (subcutaneous) on 14th January 2013, for prophylaxis.

Concurrent medical conditions included asthma and bronchiolitis.

On PPD 98 days after receiving Priorix vs MMR II+Havrix+Varivax, the subject developed severe - grade 3 pneumonia. Serious criteria included hospitalization and GSK medically significant. The subject was treated with amoxicillin. The outcome of pneumonia was recovered/resolved on 29th April 2013.

The investigator considered that there was no reasonable possibility that the pneumonia may have been caused by Priorix vs MMR II+Havrix+Varivax.
Other possible cause(s) of the pneumonia included medical condition.

Investigator Comments :
Patient seen at ER for wheezing, cough, runny nose and fever. Patient was admitted and diagnosed with Pneumonia. Site will update as more information becomes available.
PAtient was released from hospital and went home. Patient had recovered within the week.

Additional details:
Other possible cause of the pneumonia included medical conditions asthma and bronchiolitis.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 98 days post vaccinations. Reported event pneumonia has no causal relationship to the administered vaccines

Study Number: 115648

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Pneumonia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the observer blind study 115648 (MMR-160).
On 23 May 2013, she received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

Medical conditions at the time of the event included acute bronchitis and asthma.

On PPD 26 days after the dose of Blinded vaccine, 26 days after the dose of Varivax, 26 days after the dose of Havrix 720 Junior, 26 days after the dose of Prevnar 13, this 12-month-old subject developed pneumonia. The subject was hospitalised. The event resolved on 12 July 2013. The investigator considered that there was no reasonable possibility that the pneumonia may have been caused by investigational product, Varivax, Havrix 720 Junior and Prevnar 13 and that the event was possibly due to her medical conditions of acute bronchitis and asthma.

Investigator Comments :
Patient seen at hospital for wheezing. Patient had cough, runny nose and fever. Transferred to hospital on 18jun2013 with pneumonia. Treated and released on 19jun2013.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 26 days. Reported event pneumonia has no causal relationship to the administered vaccines

Study Number: 115648

Study Center ID: PPD

Subject ID: PPD

Randomization Number:

Case ID: PPD

Serious Events: Foot fracture, Concussion

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [MMR vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis A vaccine]:[Solution for injection] 720 elisa unit <Blank>;[Varivax]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This male subject was enrolled in the observer blind study 115648 (MMR-160).
On 30 May 2013, he received a dose of GSK combined measles, mumps, rubella vaccine (Priorix) or Merck's combined measles, mumps, rubella vaccine (M-M-R II) co-administered with GSK hepatitis A vaccine (Havrix 720 Junior), Merck's Varicella vaccine (Varivax) and Pfizer's 13 valent pneumococcal vaccine (Prevnar 13).

On PPD six months after the dose of Blinded vaccine, six months after the dose of Havrix 720 Junior, six months after the dose of Varivax, six months after the dose of Prevnar 13, this 18-month-old subject developed foot fracture and concussion. The subject was hospitalised. The subject was treated with sodium chloride. The events resolved on 05 December 2013. The investigator considered that there was no reasonable possibility that the foot fracture and concussion may have been caused by investigational product, Havrix 720 Junior, Varivax and Prevnar 13 and that the event was possibly due to an PPD

Investigator Comments :
patient s parent reported at Visit 3 on PPD that they were involved in an PPD on 22NOV2013 that caused patient to have a fracture to his right foot. He was hospitalized from 22NOV2013 to 23NOV2013 subject was unresponsive when EMTs arrived at scene. By the time subject reached the ER he was responsive and crying. Subject received xrays and a ct scan. subject was diagnosed with concussion and fractured right foot, acute traumatic pain, and abrasion. Subject remained stable therought visit. subject was discharged on 23nov2013 home with his parents. no con meds were given.

Case unblinded due to the end of study.
Unblinding date is 25Oct17.
TTO 5 months post vaccination. Reported event has no causal relationship to administered vaccines.

Overall Case Count : 108

13. POST-TEXT TABLES AND FIGURES

Table 6.1 Number of subjects by center (Total vaccinated cohort)

	INV_MMR_1	INV_MMR_2	INV_MMR_3	INV_MMR	COM_MMR	Total	
Center	n	n	n	n	n	n	%
PPD	10	10	10	30	10	40	0.8
	8	7	6	21	8	29	0.6
	4	5	4	13	5	18	0.4
	38	37	37	112	38	150	3.0
	8	7	7	22	8	30	0.6
	12	12	12	36	12	48	1.0
	7	8	8	23	9	32	0.6
	4	3	3	10	3	13	0.3
	11	11	11	33	12	45	0.9
	1	0	1	2	2	4	0.1
	14	13	13	40	14	54	1.1
	20	20	20	60	20	80	1.6
	11	10	11	32	12	44	0.9
	21	21	20	62	21	83	1.7
	2	0	1	3	2	5	0.1
	12	12	12	36	14	50	1.0
	5	4	5	14	6	20	0.4
	8	9	9	26	8	34	0.7
	4	5	4	13	5	18	0.4
	7	7	6	20	7	27	0.5
	1	2	3	6	2	8	0.2
	22	21	22	65	22	87	1.7
	8	8	7	23	8	31	0.6
	7	6	7	20	7	27	0.5
	6	6	6	18	6	24	0.5
	9	9	9	27	10	37	0.7
	16	15	16	47	16	63	1.3
	10	10	11	31	11	42	0.8
	8	9	9	26	9	35	0.7
	2	2	2	6	4	10	0.2
	6	8	7	21	8	29	0.6
	0	0	1	1	1	2	0.0
	1	0	1	2	2	4	0.1
	8	8	9	25	8	33	0.7
	1	1	1	3	2	5	0.1
	4	4	5	13	4	17	0.3
	9	10	10	29	10	39	0.8
	26	26	25	77	26	103	2.1
	8	8	9	25	8	33	0.7
	6	6	6	18	8	26	0.5
	13	14	13	40	14	54	1.1
	0	0	0	0	1	1	0.0
	45	42	42	129	43	172	3.4
	49	50	50	149	50	199	4.0
	25	26	25	76	26	102	2.0
	24	24	24	72	24	96	1.9
	32	31	32	95	32	127	2.5
	35	35	36	106	36	142	2.8
	28	28	28	84	29	113	2.3
	36	36	36	108	36	144	2.9
	12	12	12	36	12	48	1.0
	26	25	26	77	26	103	2.1

	INV_MMR_1	INV_MMR_2	INV_MMR_3	INV_MMR	COM_MMR	Total	
Center	**n**	**n**	**n**	**n**	**n**	**n**	**%**
PPD	26	26	26	78	26	104	2.1
	1	2	2	5	2	7	0.1
	80	79	80	239	80	319	6.4
	12	12	12	36	12	48	1.0
	14	15	15	44	16	60	1.2
	11	11	10	32	11	43	0.9
	6	6	6	18	6	24	0.5
	0	0	1	1	0	1	0.0
	82	82	83	247	83	330	6.6
	4	4	4	12	4	16	0.3
	7	7	8	22	8	30	0.6
	13	14	15	42	14	56	1.1
	10	9	9	28	10	38	0.8
	12	12	13	37	13	50	1.0
	16	16	16	48	16	64	1.3
	34	33	33	100	34	134	2.7
	42	42	42	126	43	169	3.4
	30	29	29	88	30	118	2.4
	21	21	20	62	21	83	1.7
	14	15	14	43	14	57	1.1
	6	6	6	18	7	25	0.5
	6	6	5	17	7	24	0.5
	10	10	10	30	10	40	0.8
	5	4	5	14	6	20	0.4
	2	2	3	7	2	9	0.2
	16	15	16	47	16	63	1.3
	0	1	0	1	0	1	0.0
	4	5	5	14	6	20	0.4
	10	10	10	30	10	40	0.8
	5	5	5	15	6	21	0.4
	9	9	9	27	10	37	0.7
	1	2	2	5	3	8	0.2
	15	14	15	44	15	59	1.2
	5	5	5	15	6	21	0.4
	5	5	4	14	6	20	0.4
	4	5	5	14	6	20	0.4
	1	2	2	5	2	7	0.1
	3	2	2	7	3	10	0.2
	4	3	3	10	4	14	0.3
	3	3	3	9	4	13	0.3
All	1239	1232	1243	3714	1289	5003	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
n = number of subjects included in each group or in total for a given center or for all centers
All = sum of all subjects in each group or in total (sum of all groups)
% = n/All x 100
Center = GSK Biologicals assigned center number

Table 6.2 Number of subjects at each visit and list of withdrawn subjects (Total vaccinated cohort)

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
INV_MMR_1	VISIT 1 (D0)	1239		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Protocol violation
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Protocol violation
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				Non-serious adverse event
				Non-serious adverse event

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Migrated / moved from the study area
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up*Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
	VISIT 2 (D42)	1199		
			PPD	PARENTS TO BUSY. SPOKE TO MOTHER. INFO FROM HEALTH CONNECT
				LOST HEALTH PLAN
				Lost to follow-up
				Protocol violation
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				LOST HEALTH PLAN
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				BY JOB AND PERSONAL REASONS THE PARENTS CAN NOT ASSIST TO THE SITE
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				LOST HEALTH PLAN

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
	VISIT 3 (D180)	1175		
INV_MMR_2	VISIT 1 (D0)	1232		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
	VISIT 2 (D42)	1192		
			PPD	LOST HEALTH PLAN
				LOST HEALTH PLAN
				LOST HEALTH PLAN
				LOST HEALTH PLAN
				LOST HEALTH PLAN
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				MOTHER TRANSFERRED CARE AND DID NOT WANT TO COME IN BUT REVIEWED AE'S
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
	VISIT 3 (D180)	1162		
INV_MMR_3	VISIT 1 (D0)	1243		
			PPD	Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Migrated / moved from the study area

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
	VISIT 2 (D42)	1211		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Protocol violation
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				BY LACK OF TIME, THE MOTHER CAN NOT ASSIST WITH THE SUBJECT TO THE SITE
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
	VISIT 3 (D180)	1190		
COM_MMR	VISIT 1 (D0)	1289		
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
	VISIT 2 (D42)	1258		
			PPD	LOST HEALTH PLAN
				LOST COVERAGE
				LOST HEALTH PLAN
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			PPD	Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Migrated / moved from the study area
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Lost to follow-up
				Consent withdrawal, not due to an adverse event
				Consent withdrawal, not due to an adverse event
				Lost to follow-up
				Lost to follow-up
	VISIT 3 (D180)	1232		

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
N = Number of subjects who are still in the study up to the visit
Withdrawn = Subject who did not return after the visit

Table 6.3 Deviations from specifications for age and intervals between study visits (Total vaccinated cohort)

		Age	Dose:1-PI(D42)	VISIT 1 (D0)-VISIT 3 (D180)
Group		**Protocol**	**Protocol**	**Protocol**
		from 12 to 15 months	from 35 to 77 days	from 180 to 210 days
INV_MMR_1	N	1239	1166	1175
	n	1	8	51
	%	0.1	0.7	4.3
	range	12 to 16	35 to 160	137 to 337
INV_MMR_2	N	1232	1160	1162
	n	0	10	46
	%	0.0	0.9	4.0
	range	12 to 15	35 to 119	99 to 313
INV_MMR_3	N	1243	1183	1190
	n	1	11	51
	%	0.1	0.9	4.3
	range	12 to 16	35 to 243	152 to 264
COM_MMR	N	1289	1220	1232
	n	1	13	59
	%	0.1	1.1	4.8
	range	11 to 15	29 to 126	88 to 355

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Dose: 1 = study dose 1 received at Day 0
PI(D42) = Day 42 post-vaccination
N = total number of subjects with available results
n/% = number / percentage of subjects with results outside of the interval
range = minimum-maximum for age and intervals

Table 6.4 Study population (Total vaccinated cohort)

Number of subjects	INV_MMR_1	INV_MMR_2	INV_MMR_3	COM_MMR	Total
Planned, N	1250	1250	1250	1250	5000
Randomised, N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Completed, n (%)	1175 (94.8)	1162 (94.3)	1190 (95.7)	1232 (95.6)	4759 (95.1)
Demographics	INV_MMR_1	INV_MMR_2	INV_MMR_3	COM_MMR	Total
N (Total Vaccinated Cohort)	1239	1232	1243	1289	5003
Females:Males	607:632	594:638	615:628	618:671	2434:2569
Mean Age, months (SD)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)	12.3 (0.7)
Median Age, months (minimum, maximum)	12 (12, 16)	12 (12, 15)	12 (12, 16)	12 (11, 15)	12 (11, 16)
White - Caucasian / European Heritage, n (%)	932 (75.2)	938 (76.1)	944 (75.9)	970 (75.3)	3784 (75.6)
Other, n (%)	170 (13.7)	155 (12.6)	162 (13.0)	163 (12.6)	650 (13.0)
African Heritage / African American, n (%)	60 (4.8)	52 (4.2)	57 (4.6)	70 (5.4)	239 (4.8)

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR

Table 6.5 Summary of demographic characteristics (Total vaccinated cohort)

		INV_MMR_1 N = 1239		INV_MMR_2 N = 1232		INV_MMR_3 N = 1243		INV_MMR N = 3714		COM_MMR N = 1289		Total N = 5003	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-	12.3	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	11	-	11	-
	Maximum	16	-	15	-	16	-	16	-	15	-	16	-
Gender	Female	607	49.0	594	48.2	615	49.5	1816	48.9	618	47.9	2434	48.7
	Male	632	51.0	638	51.8	628	50.5	1898	51.1	671	52.1	2569	51.3
Ethnicity	American hispanic or latino	219	17.7	239	19.4	234	18.8	692	18.6	240	18.6	932	18.6
	Not american hispanic or latino	1020	82.3	993	80.6	1009	81.2	3022	81.4	1049	81.4	4071	81.4
Geographic Ancestry	African Heritage / African American	60	4.8	52	4.2	57	4.6	169	4.6	70	5.4	239	4.8
	American Indian or Alaskan Native	25	2.0	37	3.0	33	2.7	95	2.6	31	2.4	126	2.5
	Asian - Central/South Asian Heritage	14	1.1	6	0.5	7	0.6	27	0.7	9	0.7	36	0.7
	Asian - East Asian Heritage	8	0.6	10	0.8	10	0.8	28	0.8	10	0.8	38	0.8
	Asian - Japanese Heritage	1	0.1	2	0.2	2	0.2	5	0.1	1	0.1	6	0.1
	Asian - South East Asian Heritage	21	1.7	25	2.0	21	1.7	67	1.8	26	2.0	93	1.9
	Native Hawaiian or Other Pacific Islander	3	0.2	1	0.1	5	0.4	9	0.2	2	0.2	11	0.2
	White - Arabic / North African Heritage	5	0.4	6	0.5	2	0.2	13	0.4	7	0.5	20	0.4
	White - Caucasian / European Heritage	932	75.2	938	76.1	944	75.9	2814	75.8	970	75.3	3784	75.6
	Other	170	13.7	155	12.6	162	13.0	487	13.1	163	12.6	650	13.0
Country	Estonia	124	10.0	125	10.1	125	10.1	374	10.1	127	9.9	501	10.0
	Spain	61	4.9	62	5.0	64	5.1	187	5.0	69	5.4	256	5.1
	Finland	338	27.3	335	27.2	337	27.1	1010	27.2	340	26.4	1350	27.0
	Mexico	98	7.9	98	8.0	99	8.0	295	7.9	99	7.7	394	7.9
	United States	618	49.9	612	49.7	618	49.7	1848	49.8	654	50.7	2502	50.0
Subset	VZV and HAV subset	309	24.9	306	24.8	308	24.8	923	24.9	334	25.9	1257	25.1
	VZV and PCV subset	306	24.7	302	24.5	306	24.6	914	24.6	317	24.6	1231	24.6
	Not in subset	624	50.4	624	50.6	629	50.6	1877	50.5	638	49.5	2515	50.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.6 Summary of demographic characteristics (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124		INV_MMR_2 N = 125		INV_MMR_3 N = 125		INV_MMR N = 374		COM_MMR N = 127		Total N = 501	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.8	-	12.8	-	12.8	-	12.8	-	12.8	-	12.8	-
	SD	1.0	-	1.0	-	1.0	-	1.0	-	0.9	-	1.0	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	16	-	15	-	16	-	16	-	15	-	16	-
Gender	Female	71	57.3	54	43.2	68	54.4	193	51.6	57	44.9	250	49.9
	Male	53	42.7	71	56.8	57	45.6	181	48.4	70	55.1	251	50.1
Ethnicity	American hispanic or latino	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not american hispanic or latino	124	100	125	100	125	100	374	100	127	100	501	100
Geographic Ancestry	African Heritage / African American	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	1	0.8	0	0.0	1	0.3	0	0.0	1	0.2
	White - Caucasian / European Heritage	124	100	124	99.2	125	100	373	99.7	127	100	500	99.8
	Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Country	Estonia	124	100	125	100	125	100	374	100	127	100	501	100
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	124	100	125	100	125	100	374	100	127	100	501	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.7 Summary of demographic characteristics (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61		INV_MMR_2 N = 62		INV_MMR_3 N = 64		INV_MMR N = 187		COM_MMR N = 69		Total N = 256	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.2	-	12.1	-	12.2	-	12.1	-	12.1	-	12.1	-
	SD	0.5	-	0.3	-	0.4	-	0.4	-	0.4	-	0.4	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	11	-	11	-
	Maximum	14	-	13	-	14	-	14	-	13	-	14	-
Gender	Female	34	55.7	36	58.1	27	42.2	97	51.9	38	55.1	135	52.7
	Male	27	44.3	26	41.9	37	57.8	90	48.1	31	44.9	121	47.3
Ethnicity	American hispanic or latino	3	4.9	3	4.8	1	1.6	7	3.7	2	2.9	9	3.5
	Not american hispanic or latino	58	95.1	59	95.2	63	98.4	180	96.3	67	97.1	247	96.5
Geographic Ancestry	African Heritage / African American	1	1.6	1	1.6	0	0.0	2	1.1	0	0.0	2	0.8
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	3	4.9	0	0.0	1	1.6	4	2.1	0	0.0	4	1.6
	Asian - East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	1	1.6	0	0.0	0	0.0	1	0.5	0	0.0	1	0.4
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	1	1.6	1	1.6	0	0.0	2	1.1	2	2.9	4	1.6
	White - Caucasian / European Heritage	52	85.2	57	91.9	62	96.9	171	91.4	66	95.7	237	92.6
	Other	3	4.9	3	4.8	1	1.6	7	3.7	1	1.4	8	3.1
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	61	100	62	100	64	100	187	100	69	100	256	100
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	61	100	62	100	64	100	187	100	69	100	256	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.8 Summary of demographic characteristics (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338		INV_MMR_2 N = 335		INV_MMR_3 N = 337		INV_MMR N = 1010		COM_MMR N = 340		Total N = 1350	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.4	-	12.5	-	12.4	-	12.4	-	12.4	-	12.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	167	49.4	142	42.4	157	46.6	466	46.1	164	48.2	630	46.7
	Male	171	50.6	193	57.6	180	53.4	544	53.9	176	51.8	720	53.3
Ethnicity	American hispanic or latino	0	0.0	1	0.3	0	0.0	1	0.1	1	0.3	2	0.1
	Not american hispanic or latino	338	100	334	99.7	337	100	1009	99.9	339	99.7	1348	99.9
Geographic Ancestry	African Heritage / African American	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	0	0.0	0	0.0	1	0.3	1	0.1	0	0.0	1	0.1
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3	1	0.1
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	0	0.0	2	0.6	2	0.2	1	0.3	3	0.2
	White - Caucasian / European Heritage	329	97.3	329	98.2	329	97.6	987	97.7	333	97.9	1320	97.8
	Other	9	2.7	6	1.8	5	1.5	20	2.0	5	1.5	25	1.9
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	338	100	335	100	337	100	1010	100	340	100	1350	100
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	338	100	335	100	337	100	1010	100	340	100	1350	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.9 Summary of demographic characteristics (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98		INV_MMR_2 N = 98		INV_MMR_3 N = 99		INV_MMR N = 295		COM_MMR N = 99		Total N = 394	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.3	-	12.3	-	12.3	-	12.3	-	12.4	-	12.3	-
	SD	0.6	-	0.7	-	0.6	-	0.6	-	0.7	-	0.7	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	45	45.9	40	40.8	48	48.5	133	45.1	50	50.5	183	46.4
	Male	53	54.1	58	59.2	51	51.5	162	54.9	49	49.5	211	53.6
Ethnicity	American hispanic or latino	98	100	95	96.9	99	100	292	99.0	97	98.0	389	98.7
	Not american hispanic or latino	0	0.0	3	3.1	0	0.0	3	1.0	2	2.0	5	1.3
Geographic Ancestry	African Heritage / African American	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	American Indian or Alaskan Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - Japanese Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	White - Caucasian / European Heritage	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Other	98	100	98	100	99	100	295	100	99	100	394	100
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	98	100	98	100	99	100	295	100	99	100	394	100
	United States	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subset	VZV and HAV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	VZV and PCV subset	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not in subset	98	100	98	100	99	100	295	100	99	100	394	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.10 Summary of demographic characteristics (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618		INV_MMR_2 N = 612		INV_MMR_3 N = 618		INV_MMR N = 1848		COM_MMR N = 654		Total N = 2502	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age (months) at vaccination dose: 1	Mean	12.2	-	12.2	-	12.2	-	12.2	-	12.2	-	12.2	-
	SD	0.6	-	0.5	-	0.6	-	0.5	-	0.5	-	0.5	-
	Median	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-	12.0	-
	Minimum	12	-	12	-	12	-	12	-	12	-	12	-
	Maximum	15	-	15	-	15	-	15	-	15	-	15	-
Gender	Female	290	46.9	322	52.6	315	51.0	927	50.2	309	47.2	1236	49.4
	Male	328	53.1	290	47.4	303	49.0	921	49.8	345	52.8	1266	50.6
Ethnicity	American hispanic or latino	118	19.1	140	22.9	134	21.7	392	21.2	140	21.4	532	21.3
	Not american hispanic or latino	500	80.9	472	77.1	484	78.3	1456	78.8	514	78.6	1970	78.7
Geographic Ancestry	African Heritage / African American	59	9.5	51	8.3	57	9.2	167	9.0	70	10.7	237	9.5
	American Indian or Alaskan Native	25	4.0	37	6.0	33	5.3	95	5.1	31	4.7	126	5.0
	Asian - Central/South Asian Heritage	11	1.8	6	1.0	6	1.0	23	1.2	9	1.4	32	1.3
	Asian - East Asian Heritage	8	1.3	10	1.6	9	1.5	27	1.5	10	1.5	37	1.5
	Asian - Japanese Heritage	1	0.2	2	0.3	2	0.3	5	0.3	1	0.2	6	0.2
	Asian - South East Asian Heritage	20	3.2	25	4.1	21	3.4	66	3.6	25	3.8	91	3.6
	Native Hawaiian or Other Pacific Islander	3	0.5	1	0.2	5	0.8	9	0.5	2	0.3	11	0.4
	White - Arabic / North African Heritage	4	0.6	4	0.7	0	0.0	8	0.4	4	0.6	12	0.5
	White - Caucasian / European Heritage	427	69.1	428	69.9	428	69.3	1283	69.4	444	67.9	1727	69.0
	Other	60	9.7	48	7.8	57	9.2	165	8.9	58	8.9	223	8.9
Country	Estonia	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Spain	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Finland	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mexico	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	United States	618	100	612	100	618	100	1848	100	654	100	2502	100
Subset	VZV and HAV subset	309	50.0	306	50.0	308	49.8	923	49.9	334	51.1	1257	50.2
	VZV and PCV subset	306	49.5	302	49.3	306	49.5	914	49.5	317	48.5	1231	49.2
	Not in subset	3	0.5	4	0.7	4	0.6	11	0.6	3	0.5	14	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2

INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = total number of subjects
n/% = number / percentage of subjects in a given category
Value = value of the considered parameter
SD = standard deviation

Table 6.11 Time between visits/vaccinations/blood samples (Total vaccinated cohort)

		INV_MMR_1 N = 1239	INV_MMR_2 N = 1232	INV_MMR_3 N = 1243	COM_MMR N = 1289	Total N = 5003
Characteristics	**Parameters**	**Value**	**Value**	**Value**	**Value**	**Value**
Time[Days] Dose:1-*PI[D42]	N	1166	1160	1183	1220	4729
	Mean	48.5	48.2	48.3	48.0	48.2
	SD	9.2	8.4	10.4	9.1	9.3
	Minimum	35.0	35.0	35.0	29.0	29.0
	Maximum	160.0	119.0	243.0	126.0	243.0
	Missing	73	72	60	69	274

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
PI(D42) = Post-vaccination blood sample at Day 42
Value = value of the considered parameter
SD = Standard deviation

Table 7.1 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity)

		INV_MMR_1 N=1108		INV_MMR_2 N=1098		INV_MMR_3 N=1130		INV_MMR N=3336		COM_MMR N=1162		Total N=4498	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	1090	99.9	1085	100	1112	100	3287	100	1147	100	4434	100
	S+	1	0.1	0	0.0	0	0.0	1	0.0	0	0.0	1	0.0
	Unknown	17	.	13	.	18	.	48	.	15	.	63	.
anti-Mumps (PPD) antibody (EU/mL)	S-	1062	95.8	1047	95.4	1078	95.4	3187	95.5	1107	95.3	4294	95.5
	S+	46	4.2	51	4.6	52	4.6	149	4.5	55	4.7	204	4.5
anti-Rubella antibody (IU/mL)	S-	1090	99.9	1083	99.8	1111	99.9	3284	99.9	1146	99.9	4430	99.9
	S+	1	0.1	2	0.2	1	0.1	4	0.1	1	0.1	5	0.1
	Unknown	17	.	13	.	18	.	48	.	15	.	63	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.2 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Estonia)

		INV_MMR_1 N=115		INV_MMR_2 N=115		INV_MMR_3 N=119		INV_MMR N=349		COM_MMR N=119		Total N=468	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	110	100	114	100	116	100	340	100	114	100	454	100
	Unknown	5	.	1	.	3	.	9	.	5	.	14	.
anti-Mumps (PPD) antibody (EU/mL)	S-	111	96.5	110	95.7	114	95.8	335	96.0	114	95.8	449	95.9
	S+	4	3.5	5	4.3	5	4.2	14	4.0	5	4.2	19	4.1
anti-Rubella antibody (IU/mL)	S-	110	100	114	100	116	100	340	100	114	100	454	100
	Unknown	5	.	1	.	3	.	9	.	5	.	14	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.3 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Spain)

		INV_MMR_1 N=56		INV_MMR_2 N=56		INV_MMR_3 N=55		INV_MMR N=167		COM_MMR N=61		Total N=228	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	52	98.1	54	100	55	100	161	99.4	60	100	221	99.5
	S+	1	1.9	0	0.0	0	0.0	1	0.6	0	0.0	1	0.5
	Unknown	3	.	2	.	-	.	5	.	1	.	6	.
anti-Mumps (PPD) antibody (EU/mL)	S-	53	94.6	54	96.4	52	94.5	159	95.2	57	93.4	216	94.7
	S+	3	5.4	2	3.6	3	5.5	8	4.8	4	6.6	12	5.3
anti-Rubella antibody (IU/mL)	S-	53	100	54	100	55	100	162	100	60	100	222	100
	Unknown	3	.	2	.	-	.	5	.	1	.	6	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.4 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Finland)

		INV_MMR_1 N=326		INV_MMR_2 N=318		INV_MMR_3 N=330		INV_MMR N=974		COM_MMR N=330		Total N=1304	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	324	100	317	100	330	100	971	100	330	100	1301	100
	Unknown	2	.	1	.	-	.	3	.	-	.	3	.
anti-Mumps (PPD) antibody (EU/mL)	S-	317	97.2	310	97.5	320	97.0	947	97.2	327	99.1	1274	97.7
	S+	9	2.8	8	2.5	10	3.0	27	2.8	3	0.9	30	2.3
anti-Rubella antibody (IU/mL)	S-	324	100	317	100	330	100	971	100	329	99.7	1300	99.9
	S+	0	0.0	0	0.0	0	0.0	0	0.0	1	0.3	1	0.1
	Unknown	2	.	1	.	-	.	3	.	-	.	3	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.5 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, Mexico)

		INV_MMR_1 N=86		INV_MMR_2 N=93		INV_MMR_3 N=94		INV_MMR N=273		COM_MMR N=93		Total N=366	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	86	100	93	100	93	100	272	100	93	100	365	100
	Unknown	-	.	-	.	1	.	1	.	-	.	1	.
anti-Mumps (PPD) antibody (EU/mL)	S-	84	97.7	87	93.5	87	92.6	258	94.5	85	91.4	343	93.7
	S+	2	2.3	6	6.5	7	7.4	15	5.5	8	8.6	23	6.3
anti-Rubella antibody (IU/mL)	S-	86	100	92	98.9	93	100	271	99.6	93	100	364	99.7
	S+	0	0.0	1	1.1	0	0.0	1	0.4	0	0.0	1	0.3
	Unknown	-	.	-	.	1	.	1	.	-	.	1	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.6 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, United States)

		INV_MMR_1 N=525		INV_MMR_2 N=516		INV_MMR_3 N=532		INV_MMR N=1573		COM_MMR N=559		Total N=2132	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	518	100	507	100	518	100	1543	100	550	100	2093	100
	Unknown	7	.	9	.	14	.	30	.	9	.	39	.
anti-Mumps (PPD) antibody (EU/mL)	S-	497	94.7	486	94.2	505	94.9	1488	94.6	524	93.7	2012	94.4
	S+	28	5.3	30	5.8	27	5.1	85	5.4	35	6.3	120	5.6
anti-Rubella antibody (IU/mL)	S-	517	99.8	506	99.8	517	99.8	1540	99.8	550	100	2090	99.9
	S+	1	0.2	1	0.2	1	0.2	3	0.2	0	0.0	3	0.1
	Unknown	7	.	9	.	14	.	30	.	9	.	39	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.7 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, by gender)

		INV_MMR_1				INV_MMR_2				INV_MMR_3				INV_MMR			
		F N= 542		M N= 566		F N= 529		M N= 569		F N= 550		M N= 580		F N= 1621		M N= 1715	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	532	99.8	558	100	520	100	565	100	542	100	570	100	1594	99.9	1693	100
	S+	1	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.1	0	0.0
	Unknown	9	.	8	.	9	.	4	.	8	.	10	.	26	.	22	.
anti-Mumps (PPD) antibody (EU/mL)	S-	517	95.4	545	96.3	502	94.9	545	95.8	523	95.1	555	95.7	1542	95.1	1645	95.9
	S+	25	4.6	21	3.7	27	5.1	24	4.2	27	4.9	25	4.3	79	4.9	70	4.1
anti-Rubella antibody (IU/mL)	S-	533	100	557	99.8	519	99.8	564	99.8	541	99.8	570	100	1593	99.9	1691	99.9
	S+	0	0.0	1	0.2	1	0.2	1	0.2	1	0.2	0	0.0	2	0.1	2	0.1
	Unknown	9	.	8	.	9	.	4	.	8	.	10	.	26	.	22	.

		COM_MMR				Total			
		F N= 562		M N= 600		F N= 2183		M N= 2315	
		n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	554	100	593	100	2148	100	2286	100
	S+	0	0.0	0	0.0	1	0.0	0	0.0
	Unknown	8	.	7	.	34	.	29	.
anti-Mumps (PPD) antibody (EU/mL)	S-	534	95.0	573	95.5	2076	95.1	2218	95.8
	S+	28	5.0	27	4.5	107	4.9	97	4.2
anti-Rubella antibody (IU/mL)	S-	553	99.8	593	100	2146	99.9	2284	99.9
	S+	1	0.2	0	0.0	3	0.1	2	0.1
	Unknown	8	.	7	.	34	.	29	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male

S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination

S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination

N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).

n = number of subjects with the considered pre-vaccination status.

% = n / (seronegative + seropositive).

Table 7.8 Pre-vaccination status for anti-measles, anti-mumps, and anti-rubella antibodies (ATP cohort for immunogenicity, by geographic ancestry)

		INV_MMR_1						INV_MMR_2						INV_MMR_3			
		WH N= 847		OT N= 108		AF N= 49		WH N= 841		OT N= 111		AF N= 36		WH N= 869		OT N= 111	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	832	100	107	100	49	100	830	100	111	100	35	100	855	100	110	100
	Unknown	15	.	1	.	-	.	11	.	-	.	1	.	14	.	1	.
anti-Mumps (PPD) antibody (EU/mL)	S-	814	96.1	106	98.1	45	91.8	800	95.1	105	94.6	35	97.2	836	96.2	102	91.9
	S+	33	3.9	2	1.9	4	8.2	41	4.9	6	5.4	1	2.8	33	3.8	9	8.1
anti-Rubella antibody (IU/mL)	S-	831	99.9	107	100	49	100	830	100	110	99.1	35	100	854	99.9	110	100
	S+	1	0.1	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.1	0	0.0
	Unknown	15	.	1	.	-	.	11	.	-	.	1	.	14	.	1	.

		INV_MMR_3		INV_MMR						COM_MMR						Total	
		AF N= 44		WH N= 2557		OT N= 330		AF N= 129		WH N= 889		OT N= 114		AF N= 56		WH N= 3446	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-Measles antibody (mIU/mL)	S-	41	100	2517	100	328	100	125	100	875	100	114	100	55	100	3392	100
	Unknown	3	.	40	.	2	.	4	.	14	.	-	.	1	.	54	.
anti-Mumps (PPD) antibody (EU/mL)	S-	41	93.2	2450	95.8	313	94.8	121	93.8	850	95.6	105	92.1	54	96.4	3300	95.8
	S+	3	6.8	107	4.2	17	5.2	8	6.2	39	4.4	9	7.9	2	3.6	146	4.2
anti-Rubella antibody (IU/mL)	S-	41	100	2515	99.9	327	99.7	125	100	874	99.9	114	100	55	100	3389	99.9
	S+	0	0.0	2	0.1	1	0.3	0	0.0	1	0.1	0	0.0	0	0.0	3	0.1
	Unknown	3	.	40	.	2	.	4	.	14	.	-	.	1	.	54	.

		Total			
		OT N= 444		AF N= 185	
		n	%	n	%
anti-Measles antibody (mIU/mL)	S-	442	100	180	100
	Unknown	2	.	5	.
anti-Mumps (PPD) antibody (EU/mL)	S-	418	94.1	175	94.6
	S+	26	5.9	10	5.4
anti-Rubella antibody (IU/mL)	S-	441	99.8	180	100
	S+	1	0.2	0	0.0
	Unknown	2	.	5	.

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
S- = seronegative subjects (antibody concentration < 4 IU/mL for anti-Rubella antibody, concentration < 5 EU/mL for anti-Mumps (PPD) antibody, concentration < 150 mIU/mL for anti-Measles antibody) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 4 IU/mL for anti-Rubella antibody, concentration ≥ 5 EU/mL for anti-Mumps (PPD) antibody, concentration ≥ 150 mIU/mL for anti-Measles antibody) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.9 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Measles antibody	INV_MMR_1	PI(D42)	1083	1064	98.2	97.3	98.9	1062	98.1	97.1	98.8	2970.3	2813.2	3136.2
	INV_MMR_2	PI(D42)	1069	1057	98.9	98.0	99.4	1054	98.6	97.7	99.2	3023.6	2864.5	3191.6
	INV_MMR_3	PI(D42)	1096	1075	98.1	97.1	98.8	1072	97.8	96.8	98.6	3058.3	2893.9	3232.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.10 Difference between groups (INV_MMR_1 minus INV_MMR_2) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_2)		
		INV_MMR_1			INV_MMR_2				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	1083	1062	98.1	1069	1054	98.6	-0.54	-1.69	0.58

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.11 Difference between groups (INV_MMR_1 minus INV_MMR_3) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_3)		
		INV_MMR_1			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	1083	1062	98.1	1096	1072	97.8	0.25	-0.98	1.50

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.12 Difference between groups (INV_MMR_2 minus INV_MMR_3) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_2 minus INV_MMR_3)		
		INV_MMR_2			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	1069	1054	98.6	1096	1072	97.8	0.79	-0.35	1.98

INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.13 Ratios of Anti-Measles antibody GMCs at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

						Adjusted GMC ratio			
								95% CI	
Group description	N	Adjusted GMC	Group description	N	Adjusted GMC	Ratio order	Value	LL	UL
INV_MMR_1	1083	3128.5	INV_MMR_2	1069	3174.4	INV_MMR_1 /INV_MMR_2	0.99	0.91	1.06
INV_MMR_1	1083	3128.5	INV_MMR_3	1096	3217.7	INV_MMR_1 /INV_MMR_3	0.97	0.90	1.05
INV_MMR_2	1069	3174.4	INV_MMR_1	1083	3128.5	INV_MMR_2 /INV_MMR_1	1.01	0.94	1.09
INV_MMR_2	1069	3174.4	INV_MMR_3	1096	3217.7	INV_MMR_2 /INV_MMR_3	0.99	0.91	1.06
INV_MMR_3	1096	3217.7	INV_MMR_1	1083	3128.5	INV_MMR_3 /INV_MMR_1	1.03	0.95	1.11
INV_MMR_3	1096	3217.7	INV_MMR_2	1069	3174.4	INV_MMR_3 /INV_MMR_2	1.01	0.94	1.09

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit

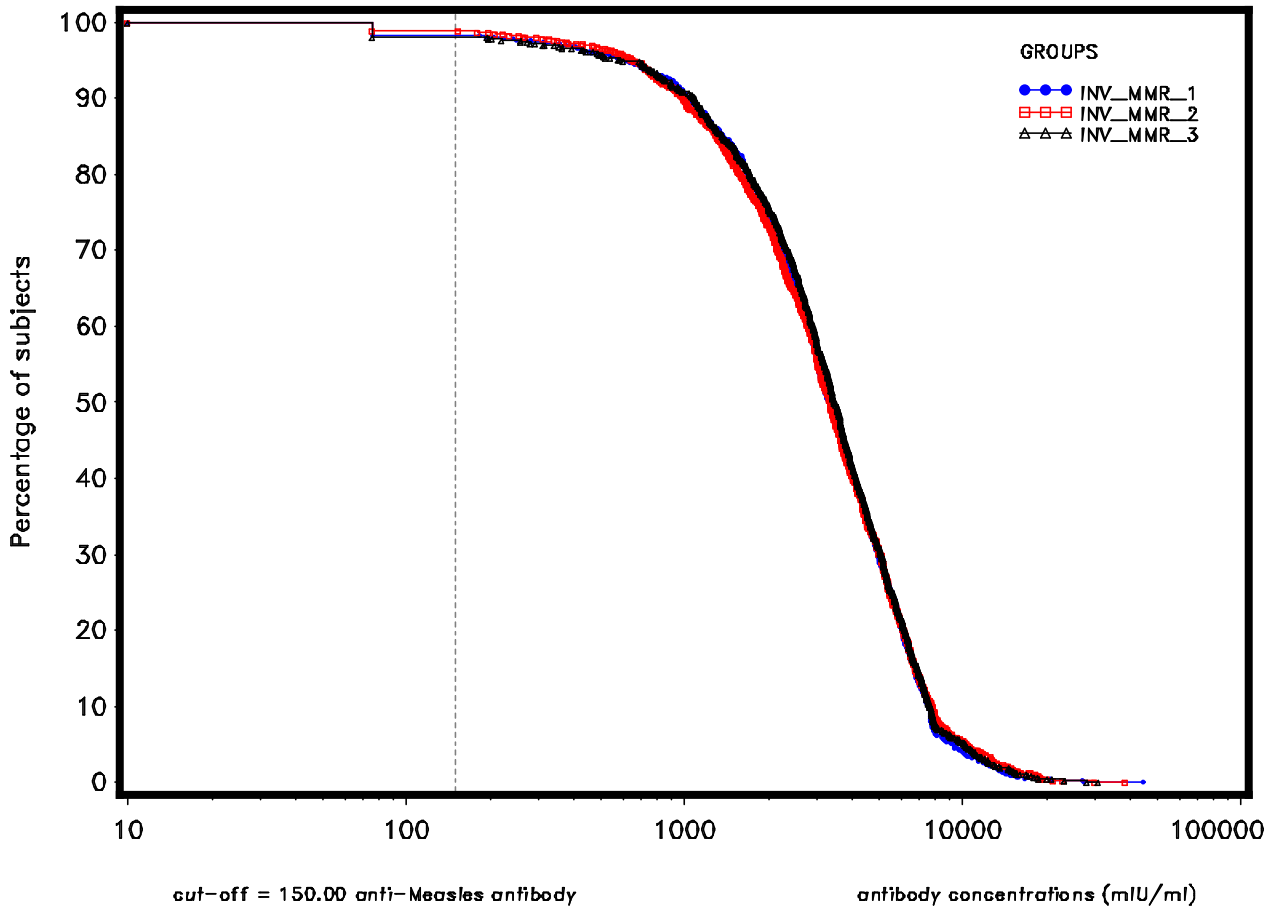
Table 7.14 Distribution of Anti-Measles antibody concentrations - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥150 mIU/mL				≥200 mIU/mL				≥300 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR_1	PI(D42)	1083	1064	98.2	97.3	98.9	1062	98.1	97.1	98.8	1055	97.4	96.3	98.3
	INV_MMR_2	PI(D42)	1069	1057	98.9	98.0	99.4	1054	98.6	97.7	99.2	1047	97.9	96.9	98.7
	INV_MMR_3	PI(D42)	1096	1075	98.1	97.1	98.8	1072	97.8	96.8	98.6	1065	97.2	96.0	98.1

				≥600 mIU/mL				≥1200 mIU/mL				≥2400 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR_1	PI(D42)	1083	1030	95.1	93.6	96.3	951	87.8	85.7	89.7	732	67.6	64.7	70.4
	INV_MMR_2	PI(D42)	1069	1024	95.8	94.4	96.9	928	86.8	84.6	88.8	702	65.7	62.7	68.5
	INV_MMR_3	PI(D42)	1096	1041	95.0	93.5	96.2	962	87.8	85.7	89.7	760	69.3	66.5	72.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.1 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3

Table 7.15 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Mumps (PPD) antibody	INV_MMR_1	PI(D42)	1062	1059	99.7	99.2	99.9	1047	98.6	97.7	99.2	71.7	68.3	75.2
	INV_MMR_2	PI(D42)	1047	1040	99.3	98.6	99.7	1032	98.6	97.6	99.2	76.9	73.2	80.8
	INV_MMR_3	PI(D42)	1078	1069	99.2	98.4	99.6	1056	98.0	96.9	98.7	69.0	65.5	72.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.16 Difference between groups (INV_MMR_1 minus INV_MMR_2) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_2)		
		INV_MMR_1			INV_MMR_2				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Mumps (PPD) antibody	10 EU/mL	1062	1047	98.6	1047	1032	98.6	0.02	-1.05	1.09

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.17 Difference between groups (INV_MMR_1 minus INV_MMR_3) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_3)		
		INV_MMR_1			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Mumps (PPD) antibody	10 EU/mL	1062	1047	98.6	1078	1056	98.0	0.63	-0.50	1.81

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.18 Difference between groups (INV_MMR_2 minus INV_MMR_3) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_2 minus INV_MMR_3)		
		INV_MMR_2			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Mumps (PPD) antibody	10 EU/mL	1047	1032	98.6	1078	1056	98.0	0.61	-0.53	1.79

INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.19 Ratios of Anti-Mumps (PPD) antibody GMCs at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

						Adjusted GMC ratio			
								95% CI	
Group description	N	Adjusted GMC	Group description	N	Adjusted GMC	Ratio order	Value	LL	UL
INV_MMR_1	1062	75.2	INV_MMR_2	1047	80.5	INV_MMR_1 /INV_MMR_2	0.93	0.87	1.00
INV_MMR_1	1062	75.2	INV_MMR_3	1078	72.3	INV_MMR_1 /INV_MMR_3	1.04	0.97	1.11
INV_MMR_2	1047	80.5	INV_MMR_1	1062	75.2	INV_MMR_2 /INV_MMR_1	1.07	1.00	1.15
INV_MMR_2	1047	80.5	INV_MMR_3	1078	72.3	INV_MMR_2 /INV_MMR_3	1.11	1.04	1.19
INV_MMR_3	1078	72.3	INV_MMR_1	1062	75.2	INV_MMR_3 /INV_MMR_1	0.96	0.90	1.03
INV_MMR_3	1078	72.3	INV_MMR_2	1047	80.5	INV_MMR_3 /INV_MMR_2	0.90	0.84	0.96

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit

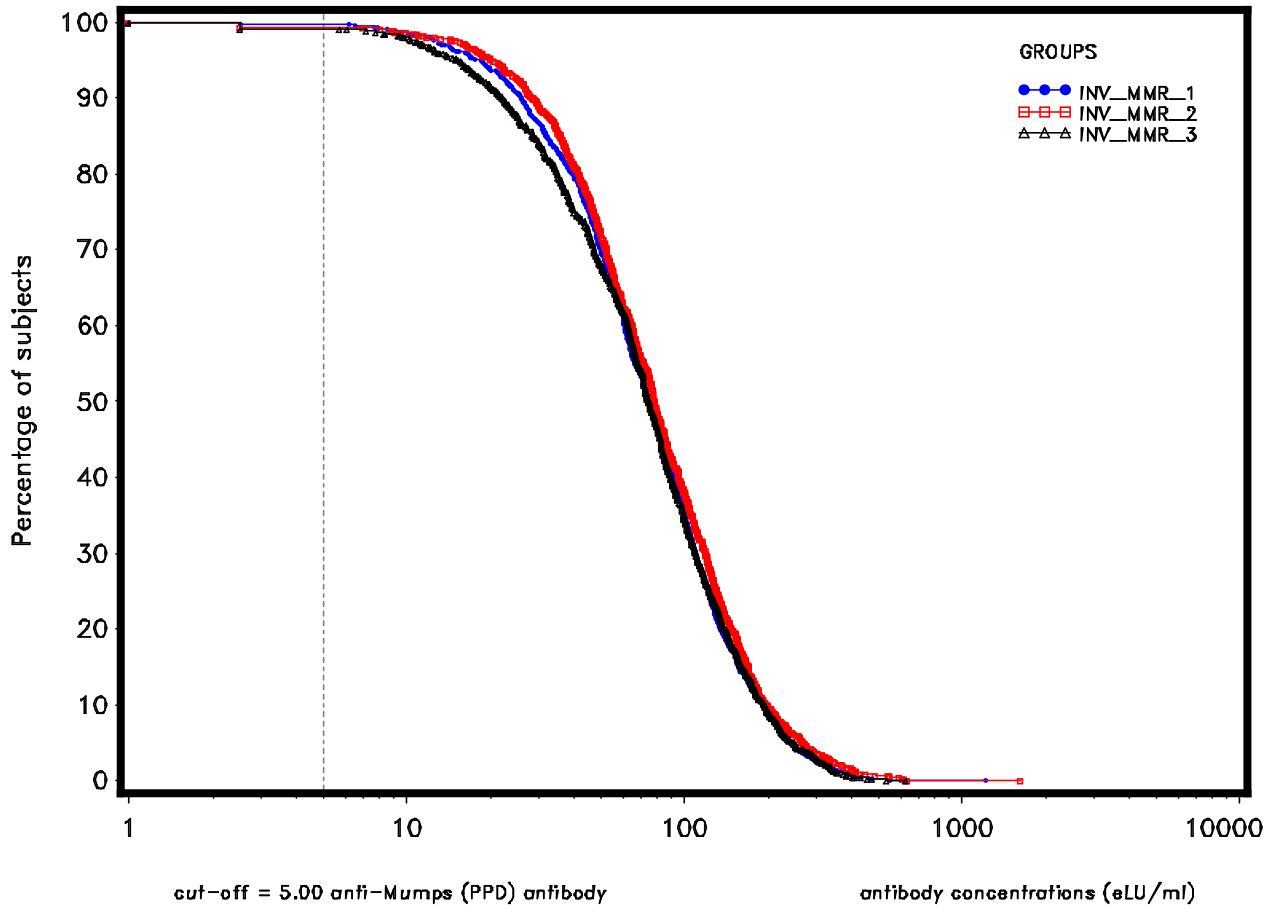
Table 7.20 Distribution of Anti-Mumps (PPD) antibody concentrations - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥5 EU/mL				≥10 EU/mL				≥15 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR_1	PI(D42)	1062	1059	99.7	99.2	99.9	1047	98.6	97.7	99.2	1023	96.3	95.0	97.4
	INV_MMR_2	PI(D42)	1047	1040	99.3	98.6	99.7	1032	98.6	97.6	99.2	1022	97.6	96.5	98.4
	INV_MMR_3	PI(D42)	1078	1069	99.2	98.4	99.6	1056	98.0	96.9	98.7	1028	95.4	93.9	96.5

				≥20 EU/mL				≥30 EU/mL				≥40 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR_1	PI(D42)	1062	996	93.8	92.2	95.2	920	86.6	84.4	88.6	846	79.7	77.1	82.0
	INV_MMR_2	PI(D42)	1047	999	95.4	94.0	96.6	933	89.1	87.1	90.9	851	81.3	78.8	83.6
	INV_MMR_3	PI(D42)	1078	988	91.7	89.8	93.2	907	84.1	81.8	86.3	812	75.3	72.6	77.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.2 Reverse cumulative distribution curve of Anti-Mumps (PPD) antibody concentrations at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3

Table 7.21 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Rubella antibody	INV_MMR_1	PI(D42)	1083	1077	99.4	98.8	99.8	1053	97.2	96.1	98.1	57.2	54.4	60.1
	INV_MMR_2	PI(D42)	1067	1064	99.7	99.2	99.9	1036	97.1	95.9	98.0	53.1	50.5	55.7
	INV_MMR_3	PI(D42)	1095	1088	99.4	98.7	99.7	1070	97.7	96.6	98.5	57.0	54.3	59.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.22 Difference between groups (INV_MMR_1 minus INV_MMR_2) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_2)		
		INV_MMR_1			INV_MMR_2				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	1083	1053	97.2	1067	1036	97.1	0.14	-1.30	1.58

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.23 Difference between groups (INV_MMR_1 minus INV_MMR_3) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_1 minus INV_MMR_3)		
		INV_MMR_1			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	1083	1053	97.2	1095	1070	97.7	-0.49	-1.86	0.86

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.24 Difference between groups (INV_MMR_2 minus INV_MMR_3) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR_2 minus INV_MMR_3)		
		INV_MMR_2			INV_MMR_3				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	1067	1036	97.1	1095	1070	97.7	-0.62	-2.02	0.74

INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.25 Ratios of Anti-Rubella antibody GMCs at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)

						Adjusted GMC ratio			
								95% CI	
Group description	N	Adjusted GMC	Group description	N	Adjusted GMC	Ratio order	Value	LL	UL
INV_MMR_1	1083	54.5	INV_MMR_2	1067	50.5	INV_MMR_1 /INV_MMR_2	1.08	1.01	1.15
INV_MMR_1	1083	54.5	INV_MMR_3	1095	54.3	INV_MMR_1 /INV_MMR_3	1.00	0.94	1.07
INV_MMR_2	1067	50.5	INV_MMR_1	1083	54.5	INV_MMR_2 /INV_MMR_1	0.93	0.87	0.99
INV_MMR_2	1067	50.5	INV_MMR_3	1095	54.3	INV_MMR_2 /INV_MMR_3	0.93	0.87	0.99
INV_MMR_3	1095	54.3	INV_MMR_1	1083	54.5	INV_MMR_3 /INV_MMR_1	1.00	0.93	1.07
INV_MMR_3	1095	54.3	INV_MMR_2	1067	50.5	INV_MMR_3 /INV_MMR_2	1.08	1.01	1.15

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit

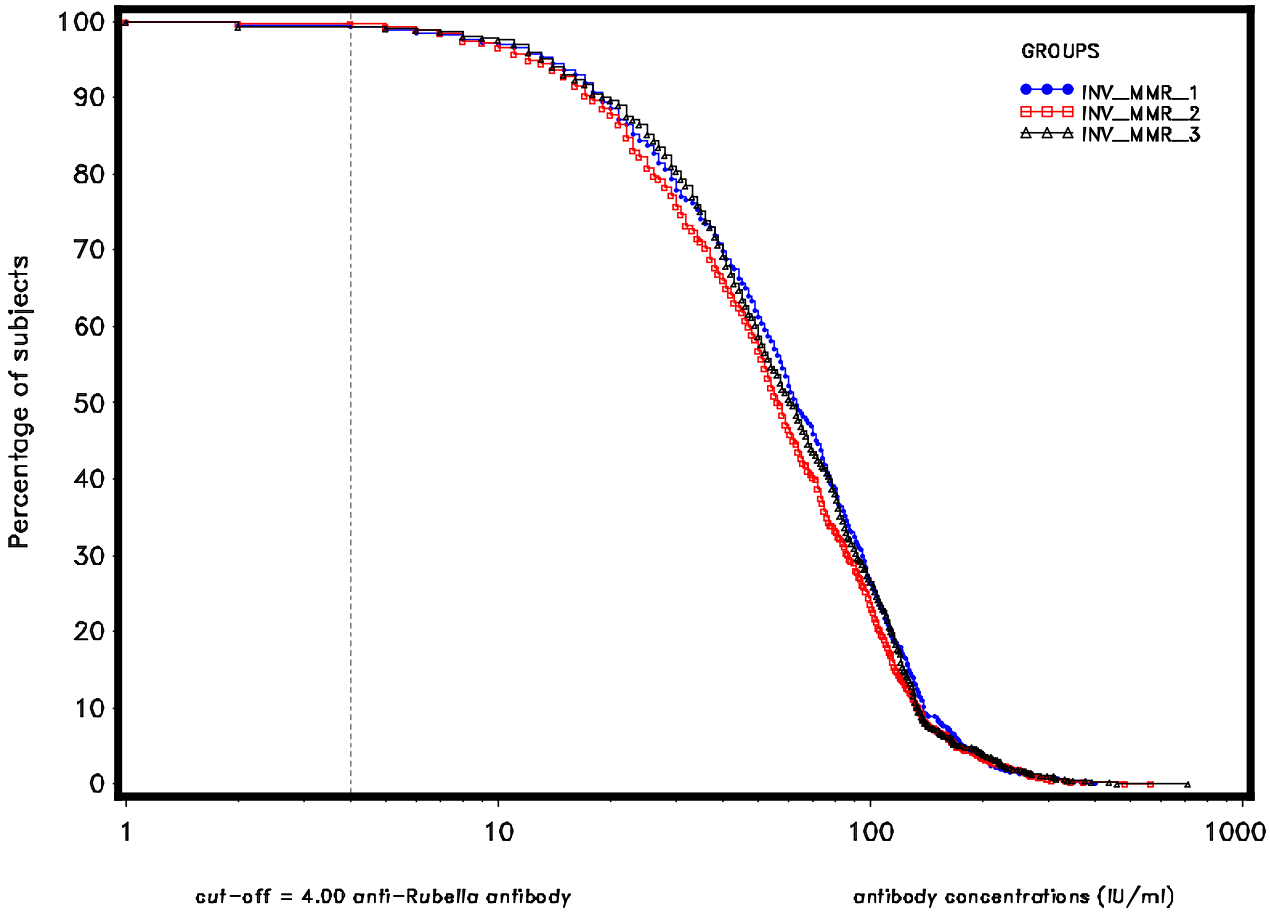
Table 7.26 Distribution of Anti-Rubella antibody concentrations - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥4 IU/mL				≥8 IU/mL				≥10 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR_1	PI(D42)	1083	1077	99.4	98.8	99.8	1063	98.2	97.2	98.9	1053	97.2	96.1	98.1
	INV_MMR_2	PI(D42)	1067	1064	99.7	99.2	99.9	1050	98.4	97.5	99.1	1036	97.1	95.9	98.0
	INV_MMR_3	PI(D42)	1095	1088	99.4	98.7	99.7	1080	98.6	97.8	99.2	1070	97.7	96.6	98.5

				≥16 IU/mL				≥32 IU/mL				≥64 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR_1	PI(D42)	1083	1014	93.6	92.0	95.0	835	77.1	74.5	79.6	539	49.8	46.7	52.8
	INV_MMR_2	PI(D42)	1067	990	92.8	91.1	94.3	796	74.6	71.9	77.2	476	44.6	41.6	47.7
	INV_MMR_3	PI(D42)	1095	1018	93.0	91.3	94.4	869	79.4	76.8	81.7	531	48.5	45.5	51.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.3 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - initially seronegative subjects only (ATP cohort for immunogenicity)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3

Table 7.27 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an Anti-Measles antibody concentration equal to or above 200 MIU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Measles antibody	200 mIU/mL	3248	3188	98.2	1137	1114	98.0	0.18	-0.68	1.25

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.28 Ratios of Anti-Measles antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				Adjusted GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
3248	3165.2	1137	3215.4	0.98	0.93	1.05

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance); LL = lower limit, UL = upper limit

Table 7.29 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Measles antibody	INV_MMR	PI(D42)	334	329	98.5	96.5	99.5	329	98.5	96.5	99.5	2858.2	2618.7	3119.6
	COM_MMR	PI(D42)	114	111	97.4	92.5	99.5	110	96.5	91.3	99.0	2694.6	2252.5	3223.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.30 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	164	161	98.2	94.7	99.6	160	97.6	93.9	99.3	3187.3	2735.0	3714.5
	COM_MMR	PI(D42)	60	60	100	94.0	100	60	100	94.0	100	3430.4	2692.1	4371.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.31 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	974	959	98.5	97.5	99.1	953	97.8	96.7	98.7	2409.7	2274.2	2553.2
	COM_MMR	PI(D42)	329	321	97.6	95.3	98.9	321	97.6	95.3	98.9	2414.2	2175.1	2679.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.32 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	273	271	99.3	97.4	99.9	271	99.3	97.4	99.9	4477.4	4058.9	4939.0
	COM_MMR	PI(D42)	93	91	97.8	92.4	99.7	91	97.8	92.4	99.7	4358.5	3656.3	5195.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.33 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)

				≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	1549	1522	98.3	97.5	98.8	1521	98.2	97.4	98.8	3273.3	3129.6	3423.6
	COM_MMR	PI(D42)	554	545	98.4	96.9	99.3	545	98.4	96.9	99.3	3404.1	3159.7	3667.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.34 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by gender)

					≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	F	PI(D42)	1572	1548	98.5	97.7	99.0	1544	98.2	97.4	98.8	3180.4	3041.1	3326.1
		M	PI(D42)	1676	1648	98.3	97.6	98.9	1644	98.1	97.3	98.7	2872.0	2748.0	3001.6
	COM_MMR	F	PI(D42)	551	545	98.9	97.6	99.6	545	98.9	97.6	99.6	3276.0	3048.1	3520.9
		M	PI(D42)	586	570	97.3	95.6	98.4	569	97.1	95.4	98.3	2896.1	2670.0	3141.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.35 Number and percentage of subjects with an Anti-Measles antibody concentration equal to or above 150 and 200 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by geographic ancestry)

					≥ 150 mIU/mL				≥ 200 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Measles antibody	INV_MMR	WH	PI(D42)	2481	2440	98.3	97.8	98.8	2433	98.1	97.4	98.6	2784.9	2686.6	2886.8
		OT	PI(D42)	327	323	98.8	96.9	99.7	323	98.8	96.9	99.7	4401.4	4008.7	4832.6
		AF	PI(D42)	123	120	97.6	93.0	99.5	120	97.6	93.0	99.5	4211.8	3563.4	4978.1
	COM_MMR	WH	PI(D42)	866	849	98.0	96.9	98.9	848	97.9	96.7	98.8	2831.4	2658.2	3016.0
		OT	PI(D42)	114	112	98.2	93.8	99.8	112	98.2	93.8	99.8	4559.5	3941.8	5274.0
		AF	PI(D42)	54	54	100	93.4	100	54	100	93.4	100	4653.4	3798.8	5700.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

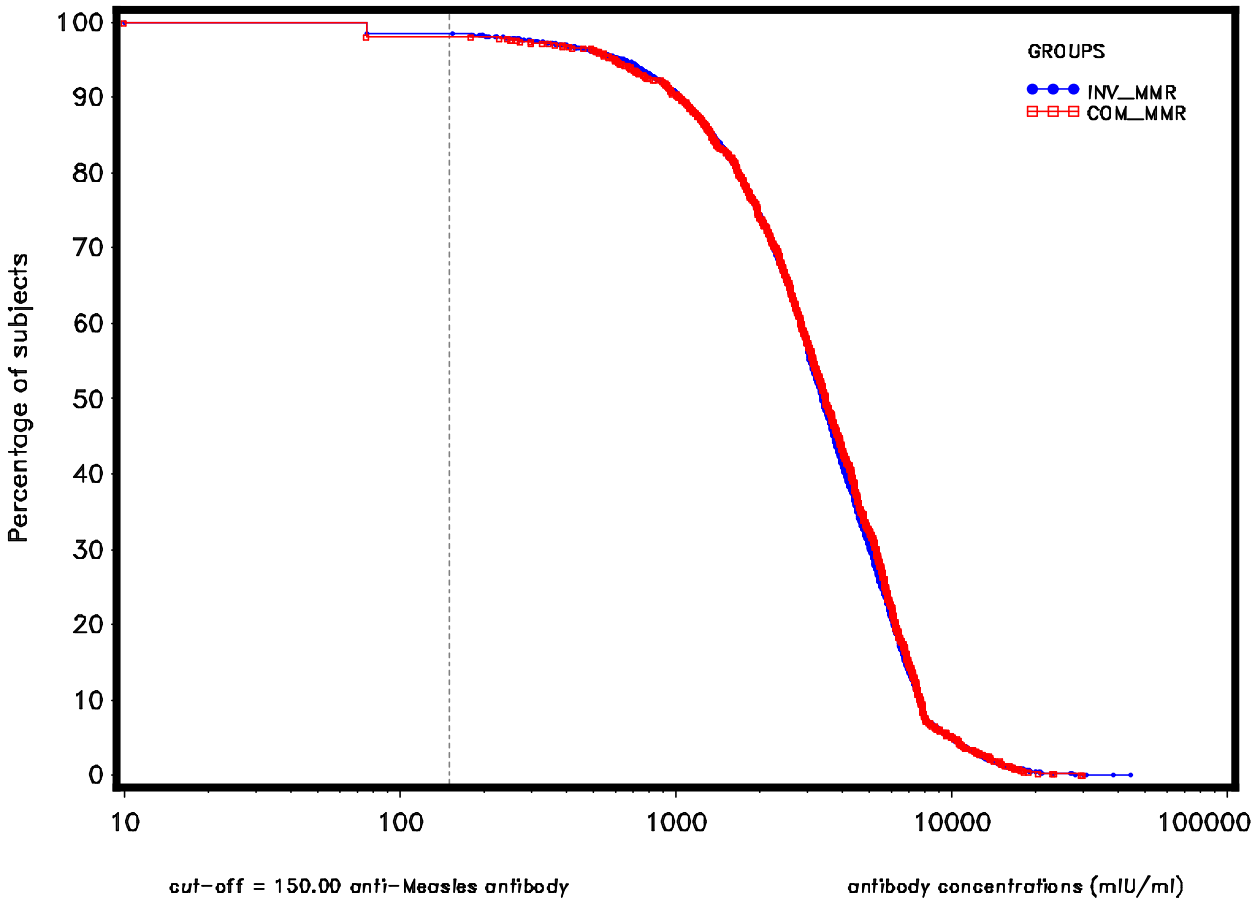
Table 7.36 Distribution of Anti-Measles antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥150 mIU/mL				≥200 mIU/mL				≥300 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3196	98.4	97.9	98.8	3188	98.2	97.6	98.6	3167	97.5	96.9	98.0
	COM_MMR	PI(D42)	1137	1115	98.1	97.1	98.8	1114	98.0	97.0	98.7	1107	97.4	96.3	98.2

				≥600 mIU/mL				≥1200 mIU/mL				≥2400 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Measles antibody	INV_MMR	PI(D42)	3248	3095	95.3	94.5	96.0	2841	87.5	86.3	88.6	2194	67.5	65.9	69.2
	COM_MMR	PI(D42)	1137	1083	95.3	93.8	96.4	998	87.8	85.7	89.6	779	68.5	65.7	71.2

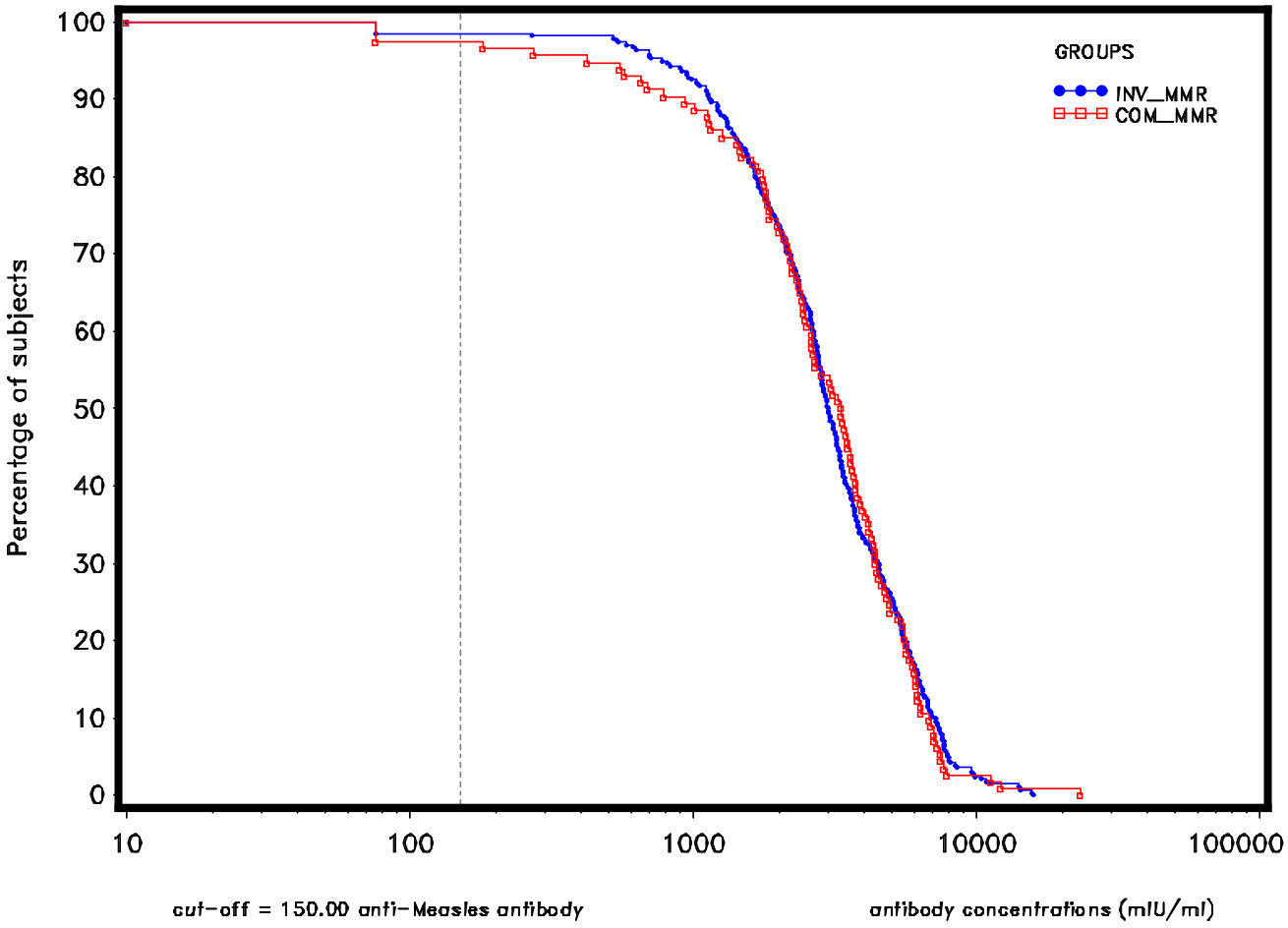
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.4 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)



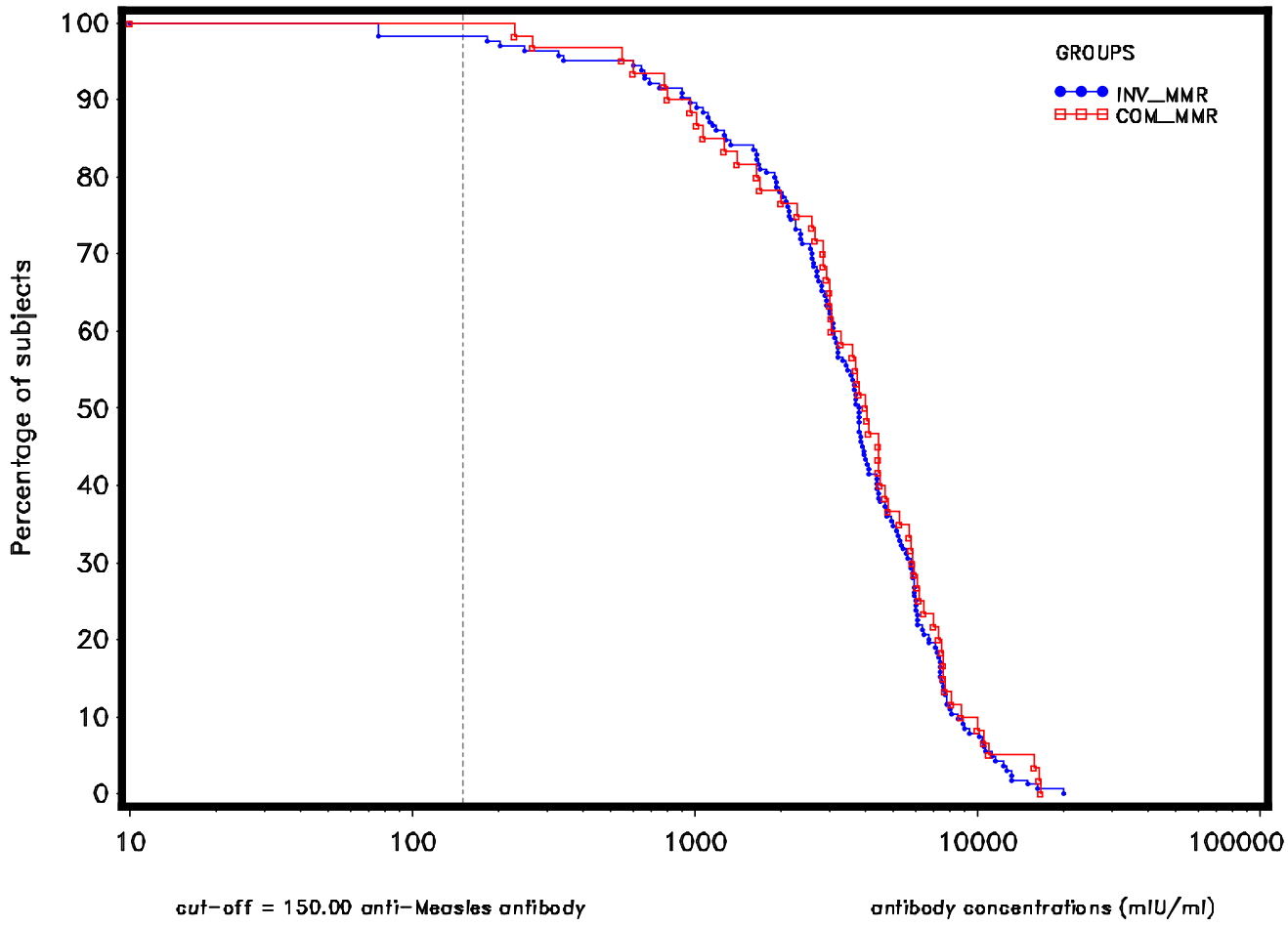
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.5 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)



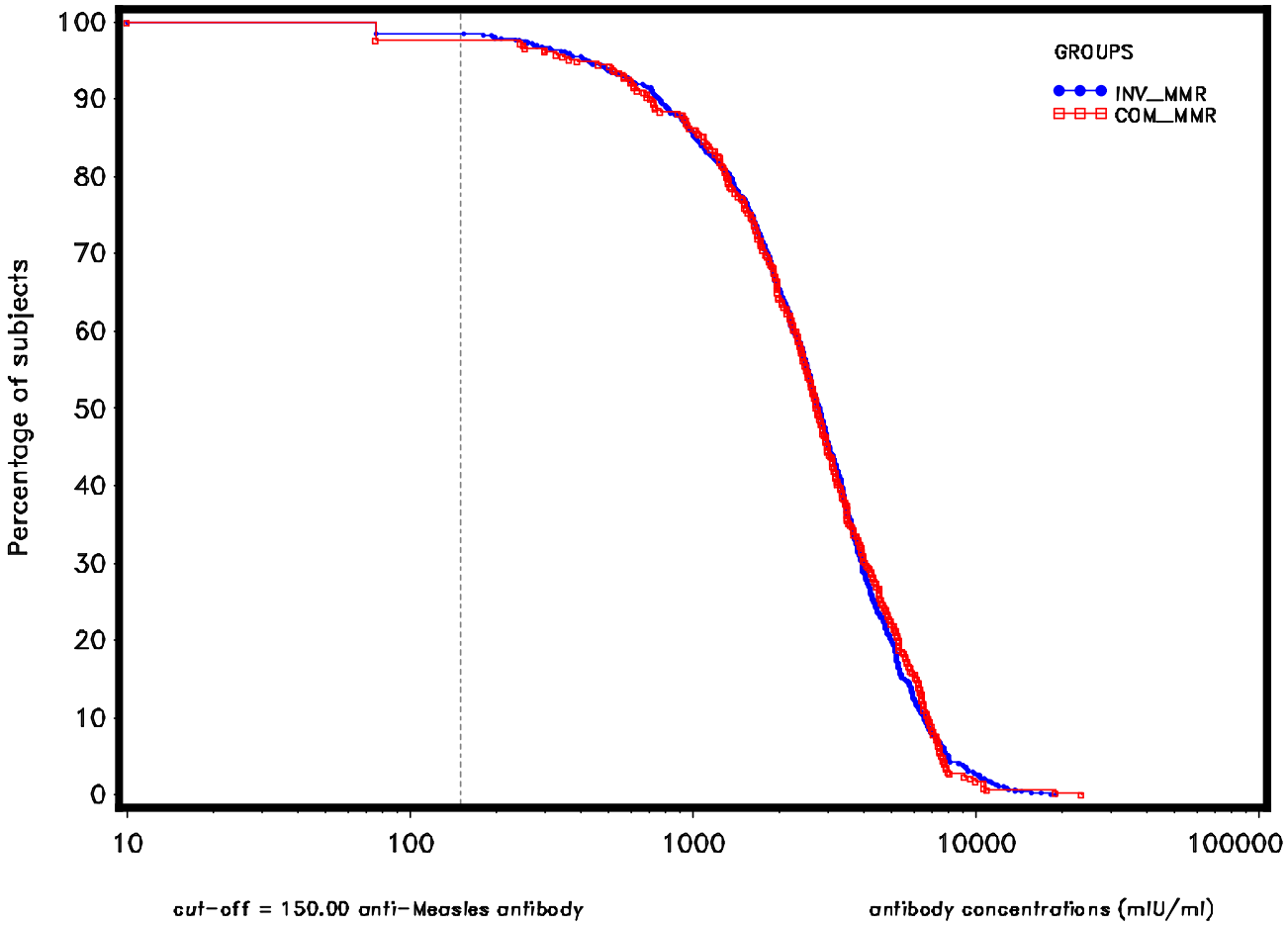
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.6 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)



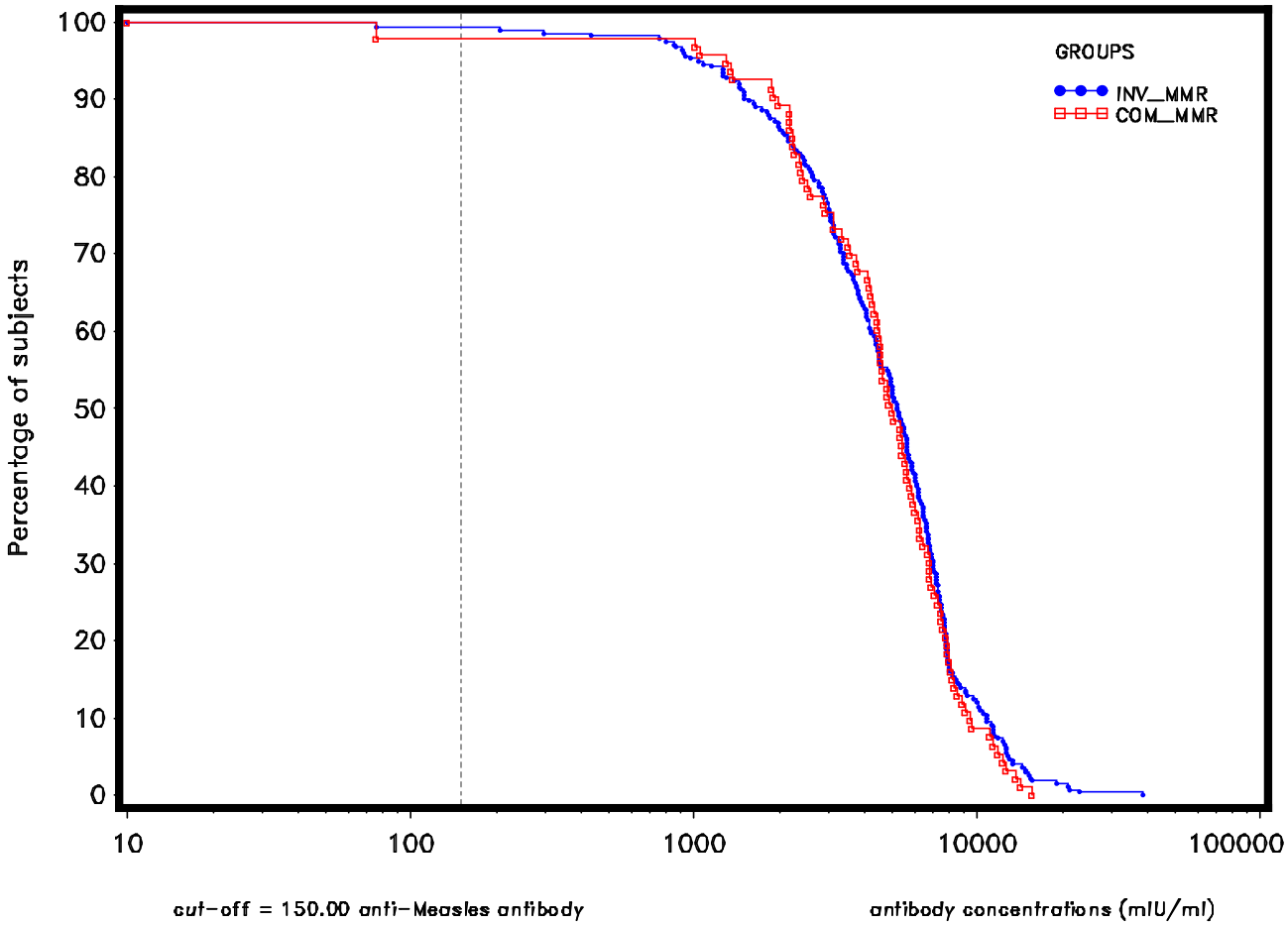
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.7 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)



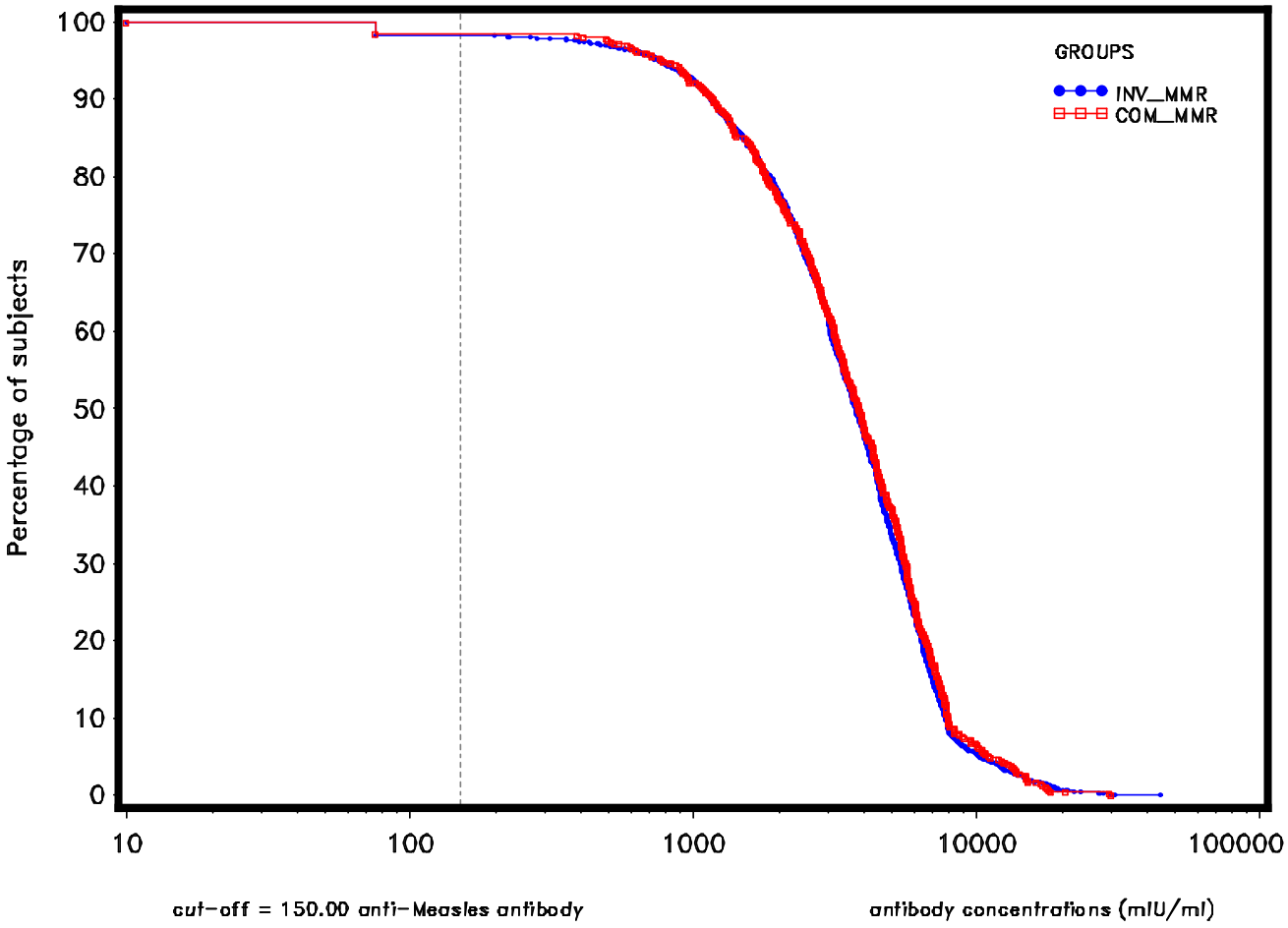
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.8 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.9 Reverse cumulative distribution curve of Anti-Measles antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.37 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 10 ELU/ML at Day 42- initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Mumps (PPD) antibody	10 EU/mL	3187	3135	98.4	1107	1080	97.6	0.81	-0.10	1.96

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.38 Ratios of Anti-Mumps (PPD) antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				Adjusted GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
3187	76.4	1107	73.0	1.05	0.99	1.11

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance); LL = lower limit, UL = upper limit

Table 7.39 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	349	347	99.4	97.9	99.9	340	97.4	95.2	98.8	68.4	62.7	74.5
	COM_MMR	PI(D42)	119	116	97.5	92.8	99.5	113	95.0	89.3	98.1	64.4	54.3	76.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.40 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	167	166	99.4	96.7	100	166	99.4	96.7	100	77.8	68.9	87.8
	COM_MMR	PI(D42)	61	61	100	94.1	100	61	100	94.1	100	76.6	64.0	91.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.41 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	974	964	99.0	98.1	99.5	952	97.7	96.6	98.6	62.7	59.6	66.1
	COM_MMR	PI(D42)	330	330	100	98.9	100	323	97.9	95.7	99.1	62.0	56.9	67.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.42 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	273	273	100	98.7	100	271	99.3	97.4	99.9	101.3	91.8	111.8
	COM_MMR	PI(D42)	93	92	98.9	94.2	100	89	95.7	89.4	98.8	101.4	84.0	122.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.43 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)

				≥ 5 EU/mL				≥ 10 EU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	1573	1567	99.6	99.2	99.9	1555	98.9	98.2	99.3	76.7	73.7	79.9
	COM_MMR	PI(D42)	559	555	99.3	98.2	99.8	548	98.0	96.5	99.0	70.3	65.5	75.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.44 Number and percentage of subjects with an Anti-Mumps (PPD) antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by gender)

					≥ 5 EU/mL				≥ 10 EU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	F	PI(D42)	1542	1530	99.2	98.6	99.6	1517	98.4	97.6	98.9	74.0	70.9	77.2
		M	PI(D42)	1645	1638	99.6	99.1	99.8	1618	98.4	97.6	98.9	71.0	68.3	73.9
	COM_MMR	F	PI(D42)	534	532	99.6	98.7	100	519	97.2	95.4	98.4	72.7	67.6	78.2
		M	PI(D42)	573	567	99.0	97.7	99.6	561	97.9	96.4	98.9	65.9	61.5	70.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.45 Number and percentage of subjects with an Anti-Mumps PPD antibody concentration equal to or above 5 and 10 ELU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by geographic ancestry)

					≥ 5 EU/mL				≥ 10 EU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	WH	PI(D42)	2450	2433	99.3	98.9	99.6	2406	98.2	97.6	98.7	68.9	66.7	71.2
		OT	PI(D42)	313	313	100	98.8	100	311	99.4	97.7	99.9	99.1	90.5	108.5
		AF	PI(D42)	121	120	99.2	95.5	100	118	97.5	92.9	99.5	72.3	61.4	85.1
	COM_MMR	WH	PI(D42)	850	846	99.5	98.8	99.9	830	97.6	96.4	98.6	65.7	62.1	69.5
		OT	PI(D42)	105	104	99.0	94.8	100	102	97.1	91.9	99.4	101.9	86.1	120.5
		AF	PI(D42)	54	53	98.1	90.1	100	52	96.3	87.3	99.5	83.1	65.2	106.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

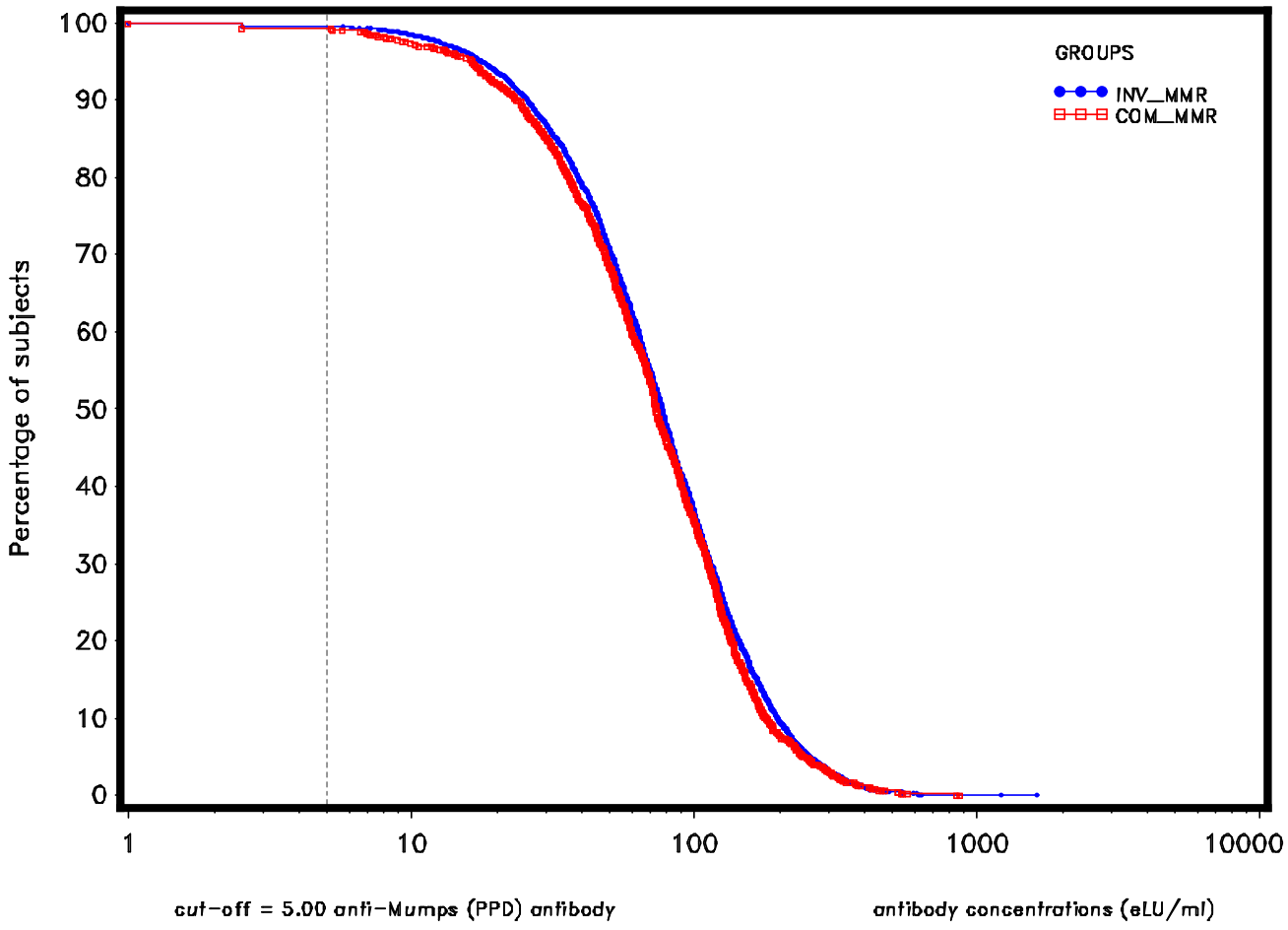
Table 7.46 Distribution of Anti-Mumps (PPD) antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥5 EU/mL				≥10 EU/mL				≥15 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3336	3317	99.4	99.1	99.7	3284	98.4	98.0	98.8	3219	96.5	95.8	97.1
	COM_MMR	PI(D42)	1162	1154	99.3	98.6	99.7	1134	97.6	96.5	98.4	1113	95.8	94.5	96.9

				≥20 EU/mL				≥30 EU/mL				≥40 EU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Mumps (PPD) antibody	INV_MMR	PI(D42)	3336	3125	93.7	92.8	94.5	2896	86.8	85.6	87.9	2637	79.0	77.6	80.4
	COM_MMR	PI(D42)	1162	1072	92.3	90.6	93.7	991	85.3	83.1	87.3	894	76.9	74.4	79.3

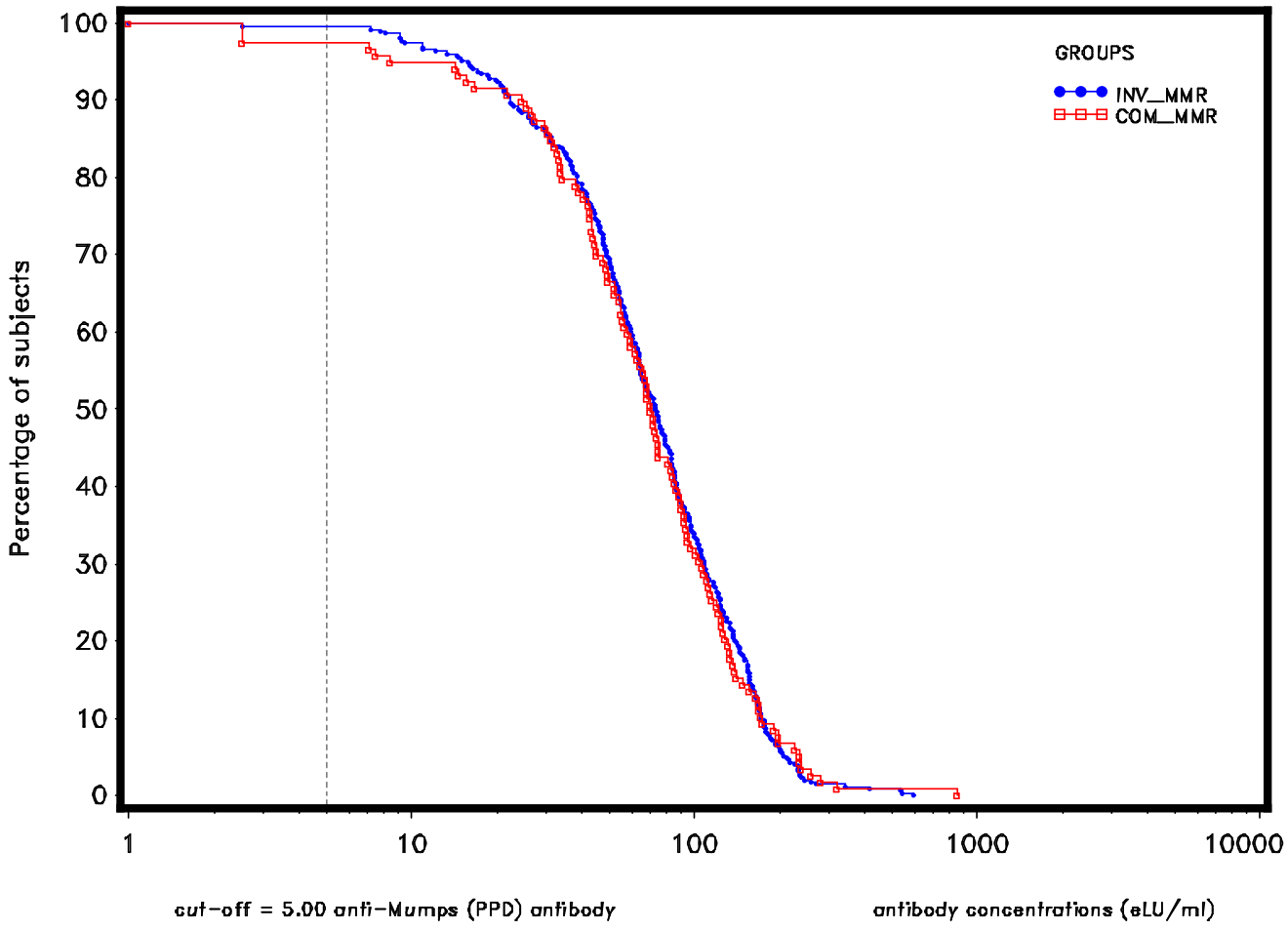
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.10 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)



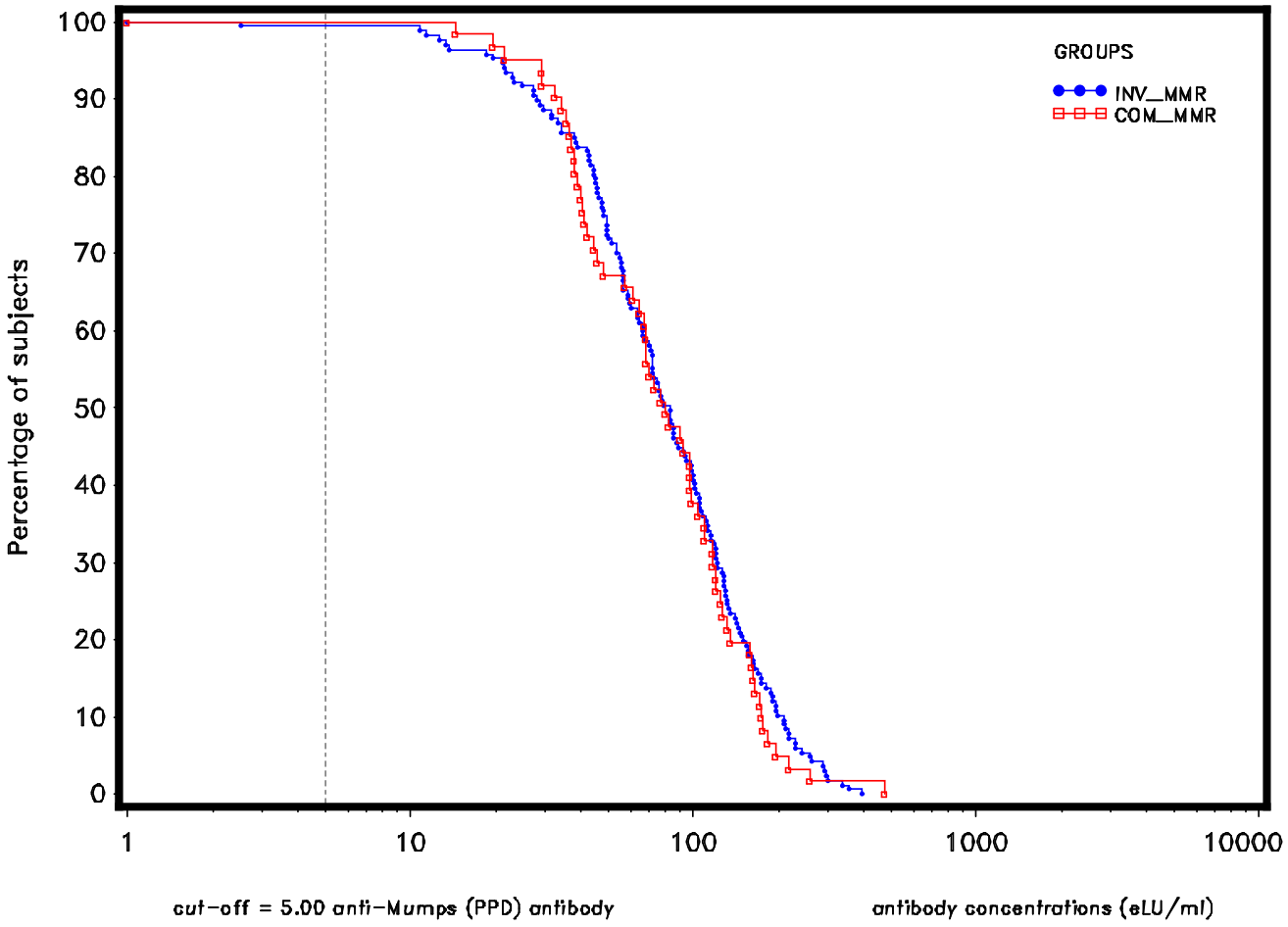
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.11 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Estonia)



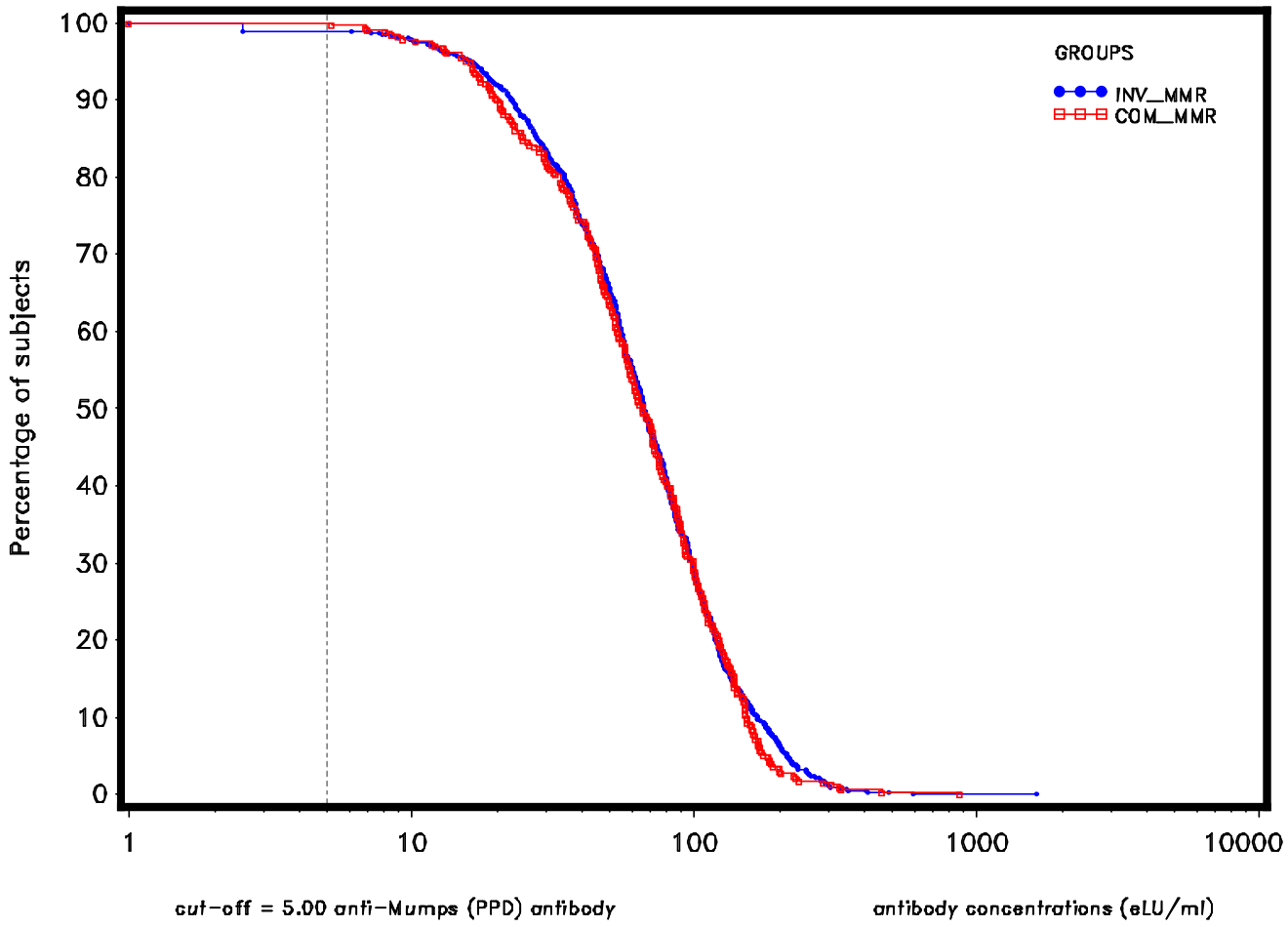
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.12 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Spain)



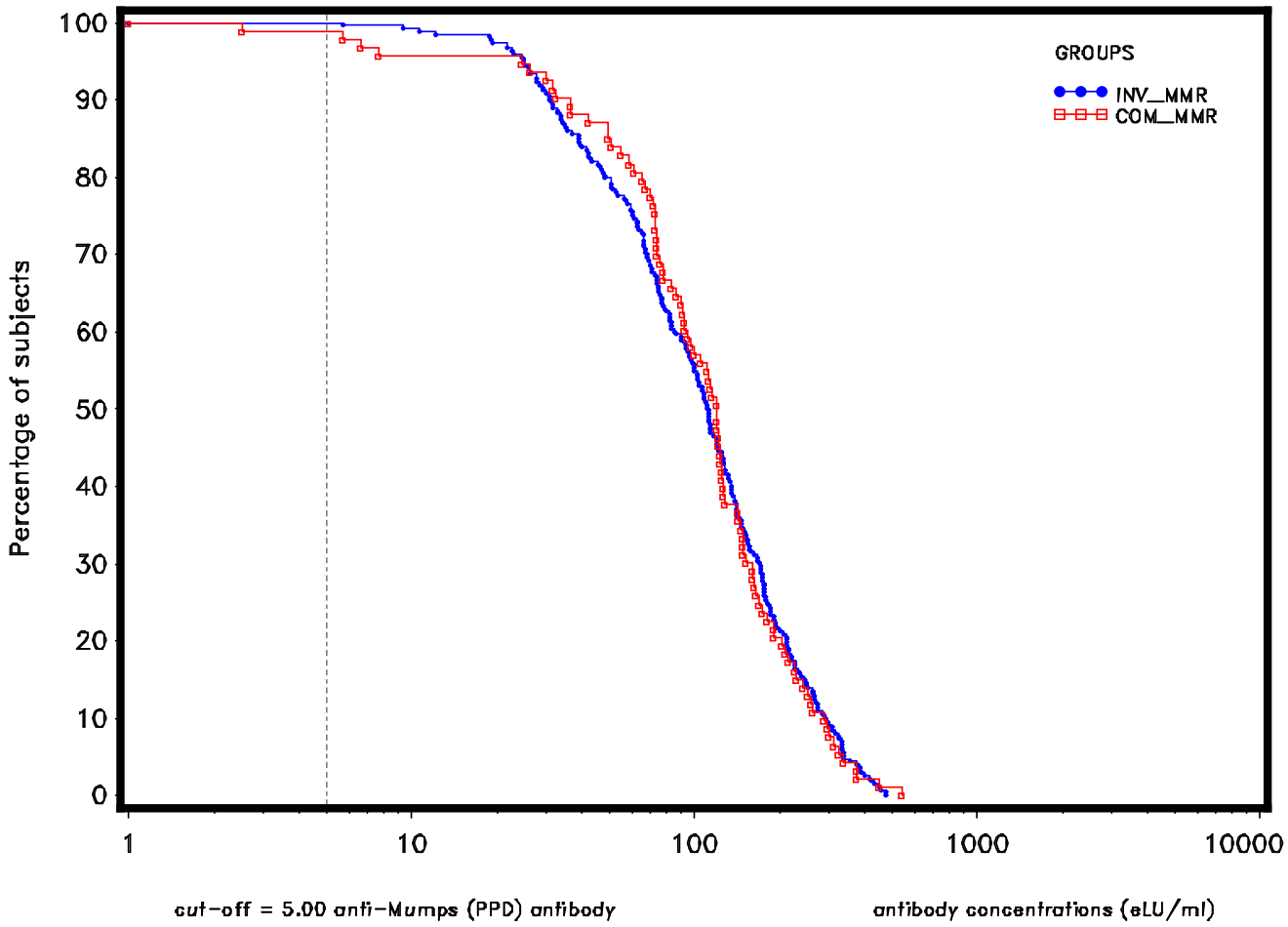
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.13 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Finland)



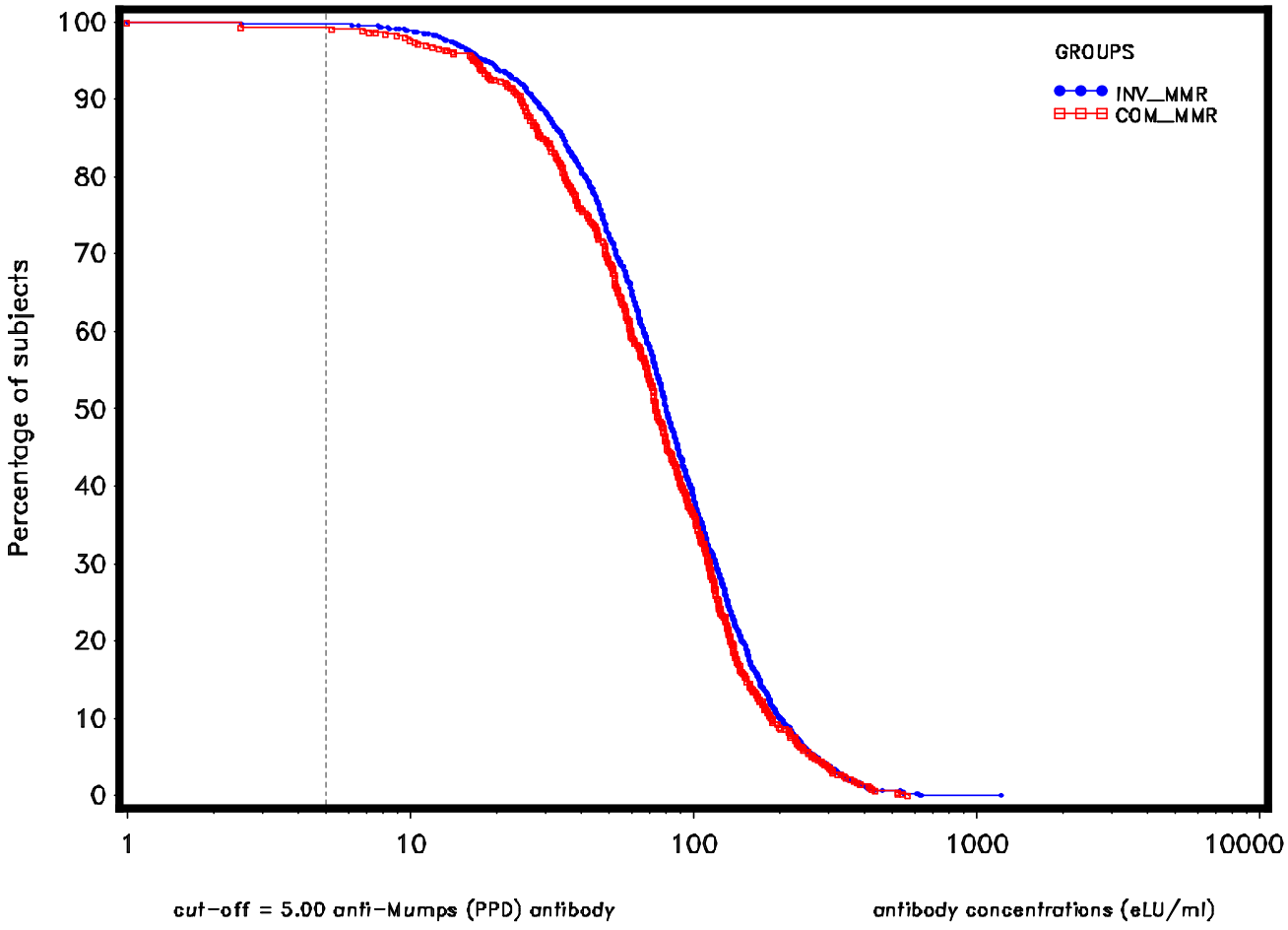
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.14 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, Mexico)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.15 Reverse cumulative distribution curve of Anti-Mumps antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, UnitedStates)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.47 Difference between groups (INV_MMR minus COM_MMR) in percentage of subjects with an Anti-Rubella antibody concentration equal to or above 10 IU/ML - initially seronegative subjects only (ATP cohort for immunogenicity)

								Difference in percentage (INV_MMR minus COM_MMR)		
		INV_MMR			COM_MMR				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-Rubella antibody	10 IU/mL	3245	3159	97.3	1135	1118	98.5	-1.15	-2.00	-0.15

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.48 Ratios of Anti-Rubella antibody GMCs at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				Adjusted GMC ratio (INV_MMR / COM_MMR)		
INV_MMR		COM_MMR			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
3245	52.5	1135	60.0	0.87	0.83	0.92

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
Adjusted GMC = geometric mean antibody concentration adjusted for country
N = Number of subjects with post-vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (Anova model : adjustment for country - pooled variance); LL = lower limit, UL = upper limit

Table 7.49 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Estonia)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-Rubella antibody	INV_MMR	PI(D42)	334	330	98.8	97.0	99.7	316	94.6	91.6	96.8	41.6	37.8	45.7
	COM_MMR	PI(D42)	114	113	99.1	95.2	100	112	98.2	93.8	99.8	42.5	36.9	49.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.50 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Spain)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	164	162	98.8	95.7	99.9	157	95.7	91.4	98.3	54.5	47.1	63.0
	COM_MMR	PI(D42)	60	59	98.3	91.1	100	57	95.0	86.1	99.0	54.6	41.7	71.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.51 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Finland)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	974	967	99.3	98.5	99.7	943	96.8	95.5	97.8	45.6	43.4	47.9
	COM_MMR	PI(D42)	329	328	99.7	98.3	100	324	98.5	96.5	99.5	56.0	51.8	60.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.52 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, Mexico)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	273	273	100	98.7	100	266	97.4	94.8	99.0	61.2	55.5	67.5
	COM_MMR	PI(D42)	93	92	98.9	94.2	100	91	97.8	92.4	99.7	67.7	57.0	80.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.53 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - seronegative subjects only (ATP cohort for immunogenicity, United States)

				≥ 4 IU/mL				≥ 10 IU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	1549	1546	99.8	99.4	100	1526	98.5	97.8	99.1	66.5	64.0	69.1
	COM_MMR	PI(D42)	553	552	99.8	99.0	100	548	99.1	97.9	99.7	75.8	71.3	80.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.54 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by gender)

					≥ 4 IU/mL				≥ 10 IU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	F	PI(D42)	1571	1565	99.6	99.2	99.9	1537	97.8	97.0	98.5	60.0	57.6	62.5
		M	PI(D42)	1674	1664	99.4	98.9	99.7	1622	96.9	95.9	97.7	52.0	50.0	54.1
	COM_MMR	F	PI(D42)	550	548	99.6	98.7	100	544	98.9	97.6	99.6	67.2	63.0	71.8
		M	PI(D42)	585	582	99.5	98.5	99.9	574	98.1	96.7	99.1	61.1	57.3	65.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.55 Number and percentage of subjects with an Anti-Rubella antibody concentration equal to or above 4 and 10 IU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, by geographic ancestry)

					≥ 4 IU/mL				≥ 10 IU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	WH	PI(D42)	2479	2463	99.4	99.0	99.6	2404	97.0	96.2	97.6	51.9	50.3	53.7
		OT	PI(D42)	326	326	100	98.9	100	318	97.5	95.2	98.9	64.1	58.6	70.2
		AF	PI(D42)	123	123	100	97.0	100	123	100	97.0	100	84.1	75.5	93.8
	COM_MMR	WH	PI(D42)	865	861	99.5	98.8	99.9	851	98.4	97.3	99.1	59.6	56.6	62.7
		OT	PI(D42)	114	113	99.1	95.2	100	112	98.2	93.8	99.8	71.4	61.1	83.4
		AF	PI(D42)	54	54	100	93.4	100	54	100	93.4	100	101.0	87.4	116.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

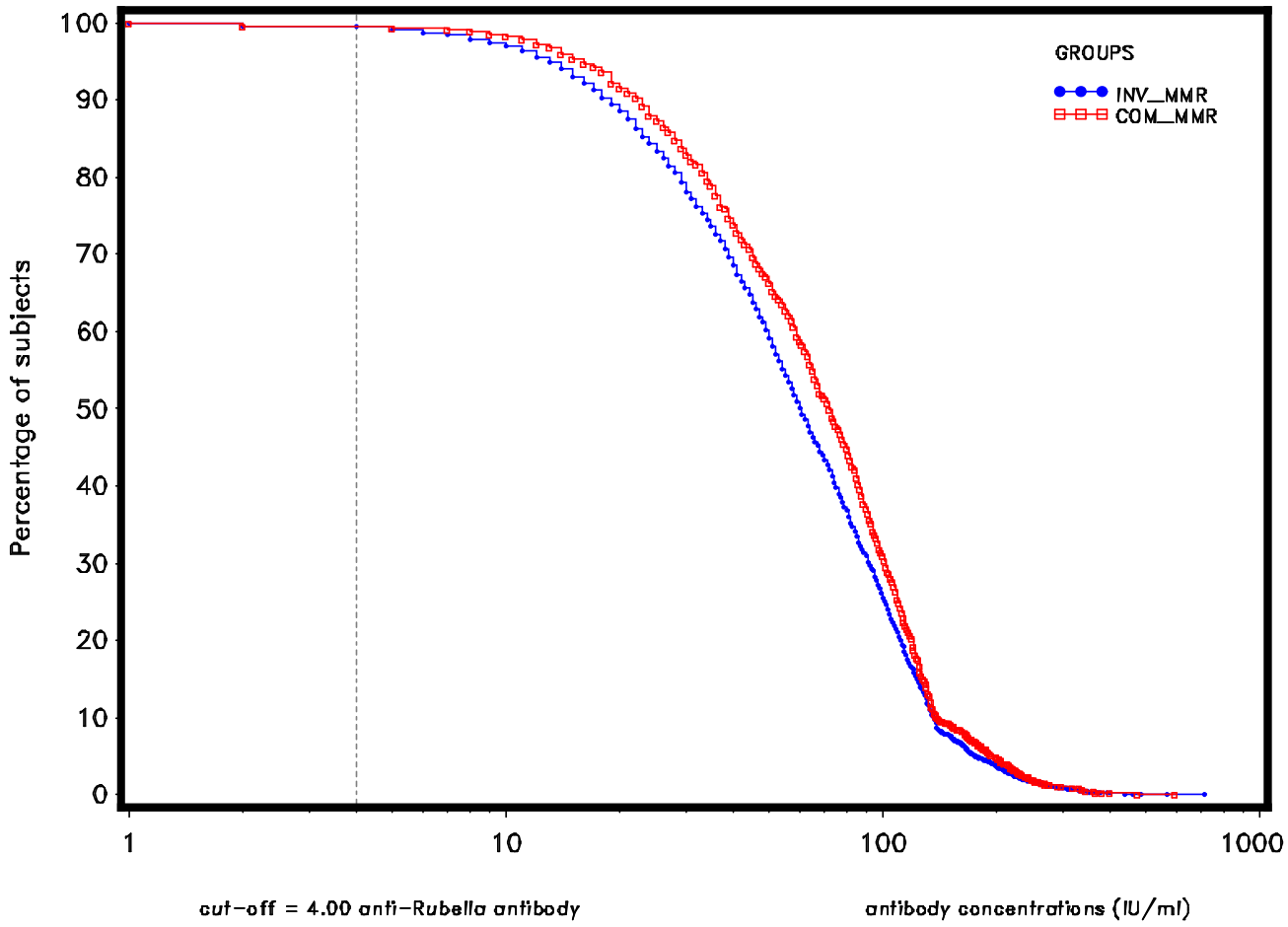
Table 7.56 Distribution of Anti-Rubella antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)

				≥4 IU/mL				≥8 IU/mL				≥10 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3294	3278	99.5	99.2	99.7	3242	98.4	97.9	98.8	3208	97.4	96.8	97.9
	COM_MMR	PI(D42)	1149	1144	99.6	99.0	99.9	1139	99.1	98.4	99.6	1132	98.5	97.6	99.1

				≥16 IU/mL				≥32 IU/mL				≥64 IU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-Rubella antibody	INV_MMR	PI(D42)	3294	3066	93.1	92.2	93.9	2542	77.2	75.7	78.6	1575	47.8	46.1	49.5
	COM_MMR	PI(D42)	1149	1095	95.3	93.9	96.5	943	82.1	79.7	84.2	653	56.8	53.9	59.7

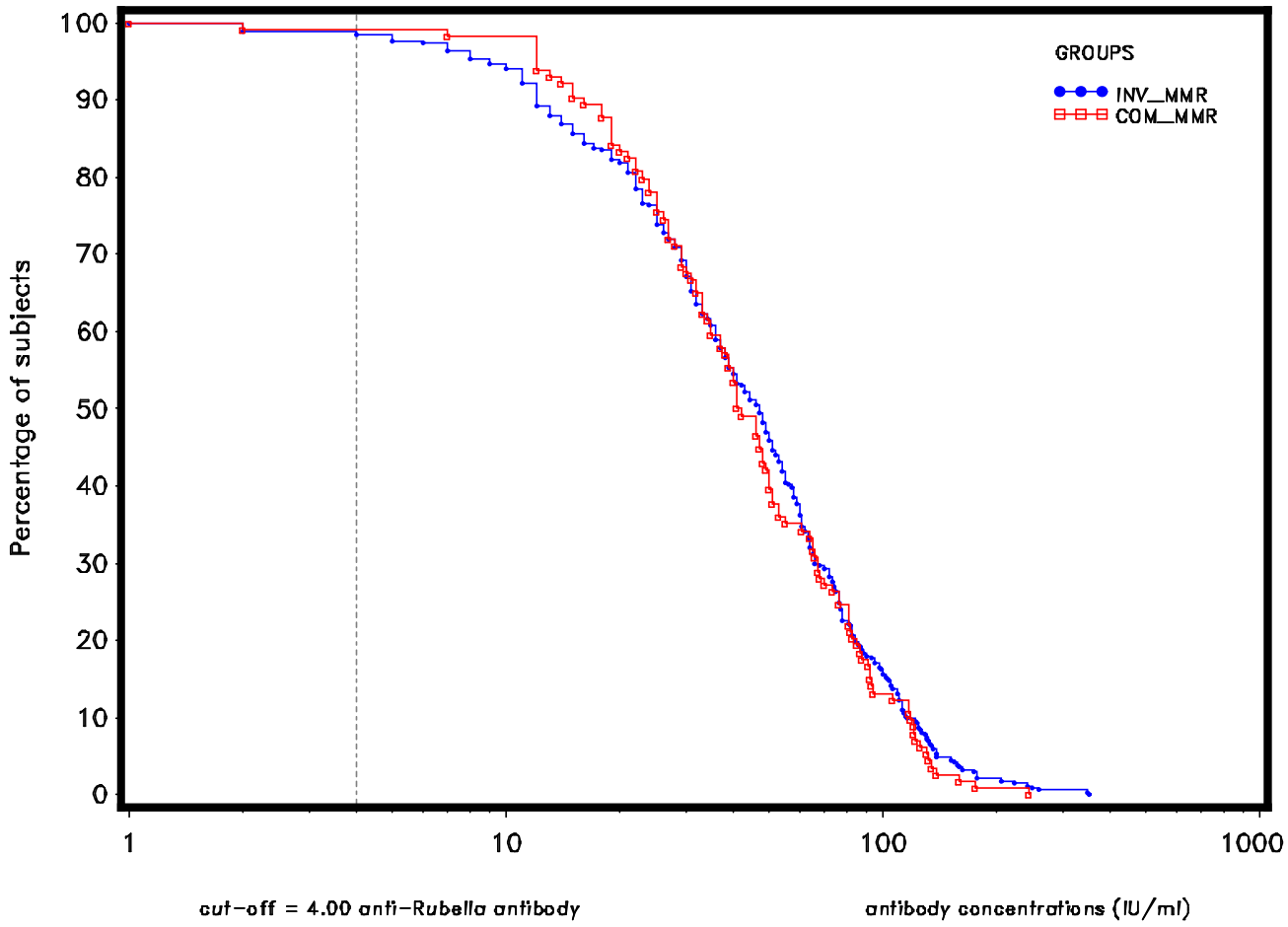
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.16 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity)



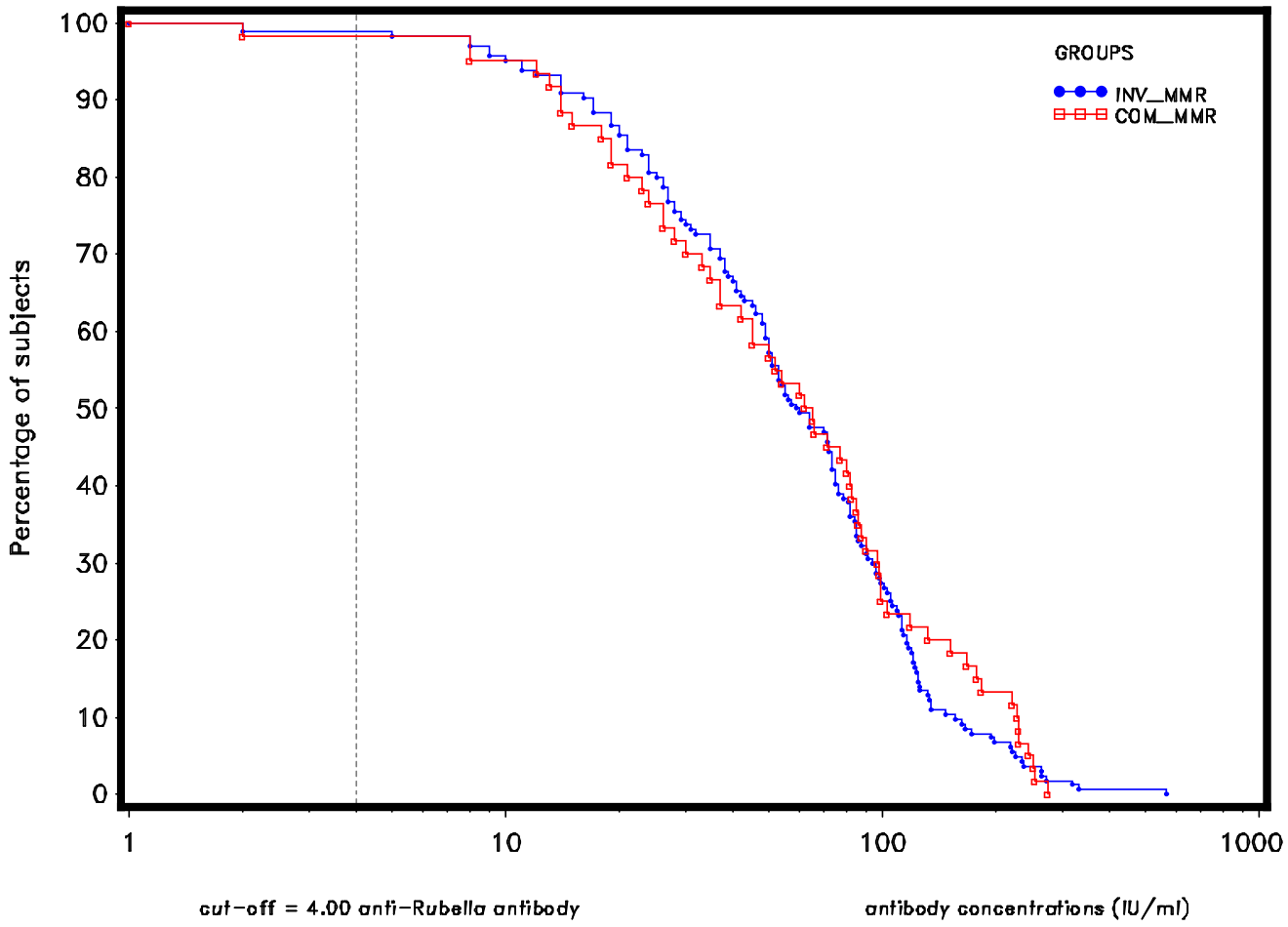
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.17 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Estonia)



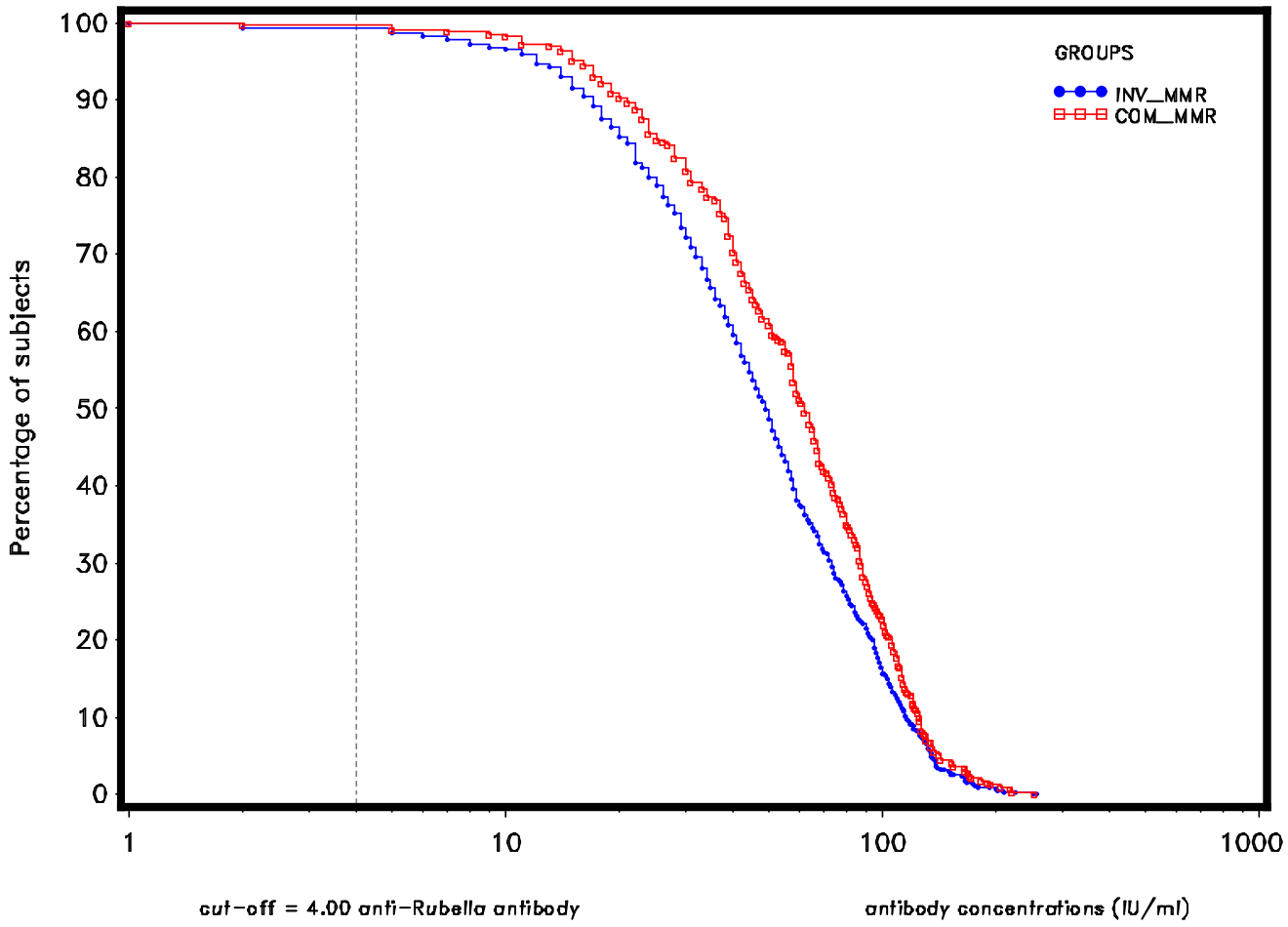
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.18 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Spain)



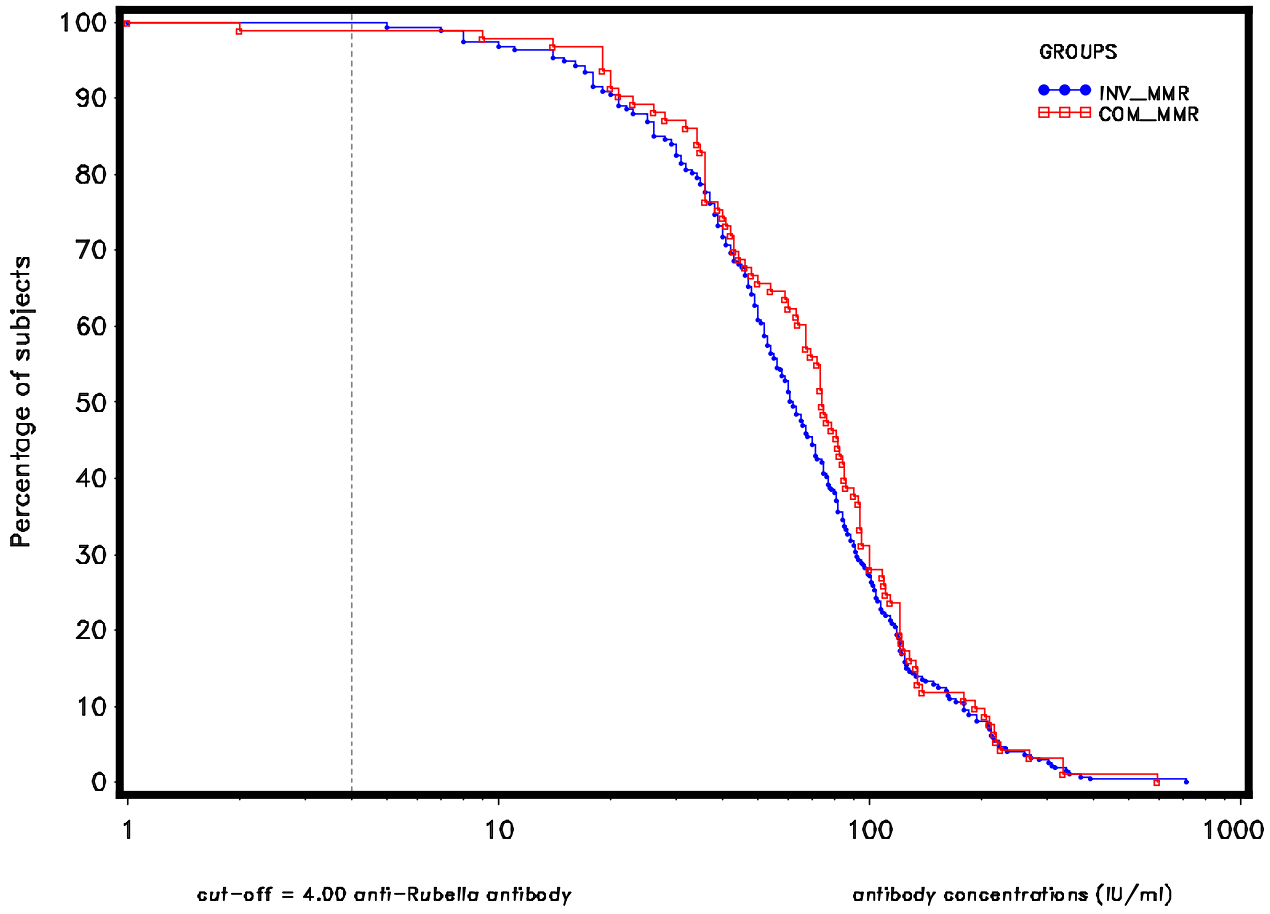
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.19 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Finland)



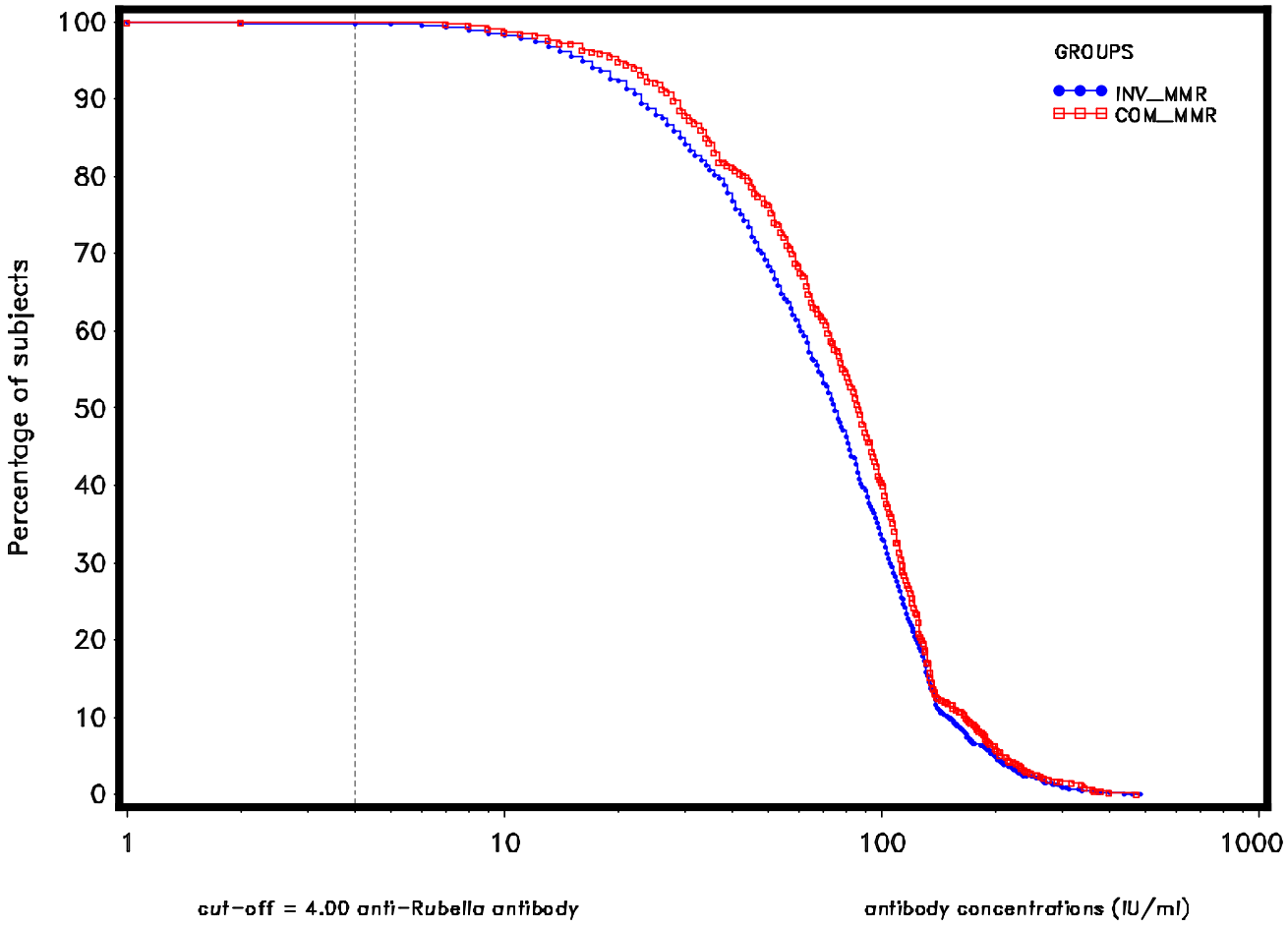
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.20 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, Mexico)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.21 Reverse cumulative distribution curve of Anti-Rubella antibody concentrations at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, United States)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.57 Pre-vaccination status for anti-VZV antibodies - pooled INV_MMR groups (ATP cohort for immunogenicity, VZV subset)

		INV_MMR N=1564		COM_MMR N=556		Total N=2120	
		n	%	n	%	n	%
anti-VZV antibody (mIU/mL)	S-	1514	98.7	544	99.5	2058	98.9
	S+	20	1.3	3	0.5	23	1.1
	Unknown	30	.	9	.	39	.

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
S- = seronegative subjects (antibody concentration < 25 mIU/mL for anti-VZV antibody, titre < . for) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 25 mIU/mL for anti-VZV antibody, titre ≥ . for) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.58 Pre-vaccination status for anti-VZV antibodies - pooled INV_MMR groups (ATP cohort for immunogenicity, VZV subset, by gender)

		INV_MMR				COM_MMR				Total			
		F N= 779		M N= 785		F N= 264		M N= 292		F N= 1043		M N= 1077	
		n	%	n	%	n	%	n	%	n	%	n	%
anti-VZV antibody (mIU/mL)	S-	758	99.2	756	98.2	258	99.6	286	99.3	1016	99.3	1042	98.5
	S+	6	0.8	14	1.8	1	0.4	2	0.7	7	0.7	16	1.5
	Unknown	15	.	15	.	5	.	4	.	20	.	19	.

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
S- = seronegative subjects (antibody concentration < 25 mIU/mL for anti-VZV antibody, titre < . for) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 25 mIU/mL for anti-VZV antibody, titre ≥ . for) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.59 Pre-vaccination status for anti-VZV antibodies - pooled INV_MMR groups (ATP cohort for immunogenicity, VZV subset, by geographic ancestry)

		INV_MMR						COM_MMR						Total			
		WH N= 1096		OT N= 52		AF N= 127		WH N= 386		OT N= 21		AF N= 56		WH N= 1482		OT N= 73	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
anti-VZV antibody (mIU/mL)	S-	1059	98.8	50	98.0	121	98.4	376	99.5	21	100	54	98.2	1435	99.0	71	98.6
	S+	13	1.2	1	2.0	2	1.6	2	0.5	0	0.0	1	1.8	15	1.0	1	1.4
	Unknown	24	.	1	.	4	.	8	.	-	.	1	.	32	.	1	.

		Total AF N= 183	
		n	%
anti-VZV antibody (mIU/mL)	S-	175	98.3
	S+	3	1.7
	Unknown	5	.

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
S- = seronegative subjects (antibody concentration < 25 mIU/mL for anti-VZV antibody, titre < . for) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 25 mIU/mL for anti-VZV antibody, titre ≥ . for) prior to vaccination
N = number of subjects regardless of whether there is a result (sum of S-, S+ and Unknown).
n = number of subjects with the considered pre-vaccination status.
% = n / (seronegative + seropositive).

Table 7.60 Number and percentage of subjects with an Anti-VZV antibody concentration equal to or above 25 and 75 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset, by gender)

					≥ 25 mIU/mL				≥ 75 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-VZV antibody	INV_MMR	F	PI(D42)	744	741	99.6	98.8	99.9	689	92.6	90.5	94.4	175.5	167.7	183.7
		M	PI(D42)	748	747	99.9	99.3	100	687	91.8	89.6	93.7	163.9	156.9	171.2
	COM_MMR	F	PI(D42)	257	257	100	98.6	100	239	93.0	89.2	95.8	177.5	163.9	192.2
		M	PI(D42)	283	281	99.3	97.5	99.9	252	89.0	84.8	92.4	158.4	146.8	170.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.61 Number and percentage of subjects with an Anti-VZV antibody concentration equal to or above 25 and 75 MIU/ML and GMCs - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset, by geographic ancestry)

					≥ 25 mIU/mL				≥ 75 mIU/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-VZV antibody	INV_MMR	WH	PI(D42)	1040	1036	99.6	99.0	99.9	954	91.7	89.9	93.3	162.4	156.4	168.6
		OT	PI(D42)	49	49	100	92.7	100	46	93.9	83.1	98.7	187.8	157.5	224.0
		AF	PI(D42)	119	119	100	96.9	100	111	93.3	87.2	97.1	184.5	164.4	207.1
	COM_MMR	WH	PI(D42)	373	371	99.5	98.1	99.9	335	89.8	86.3	92.7	158.5	148.2	169.5
		OT	PI(D42)	21	21	100	83.9	100	21	100	83.9	100	213.9	157.3	290.9
		AF	PI(D42)	53	53	100	93.3	100	50	94.3	84.3	98.8	177.2	151.2	207.8

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

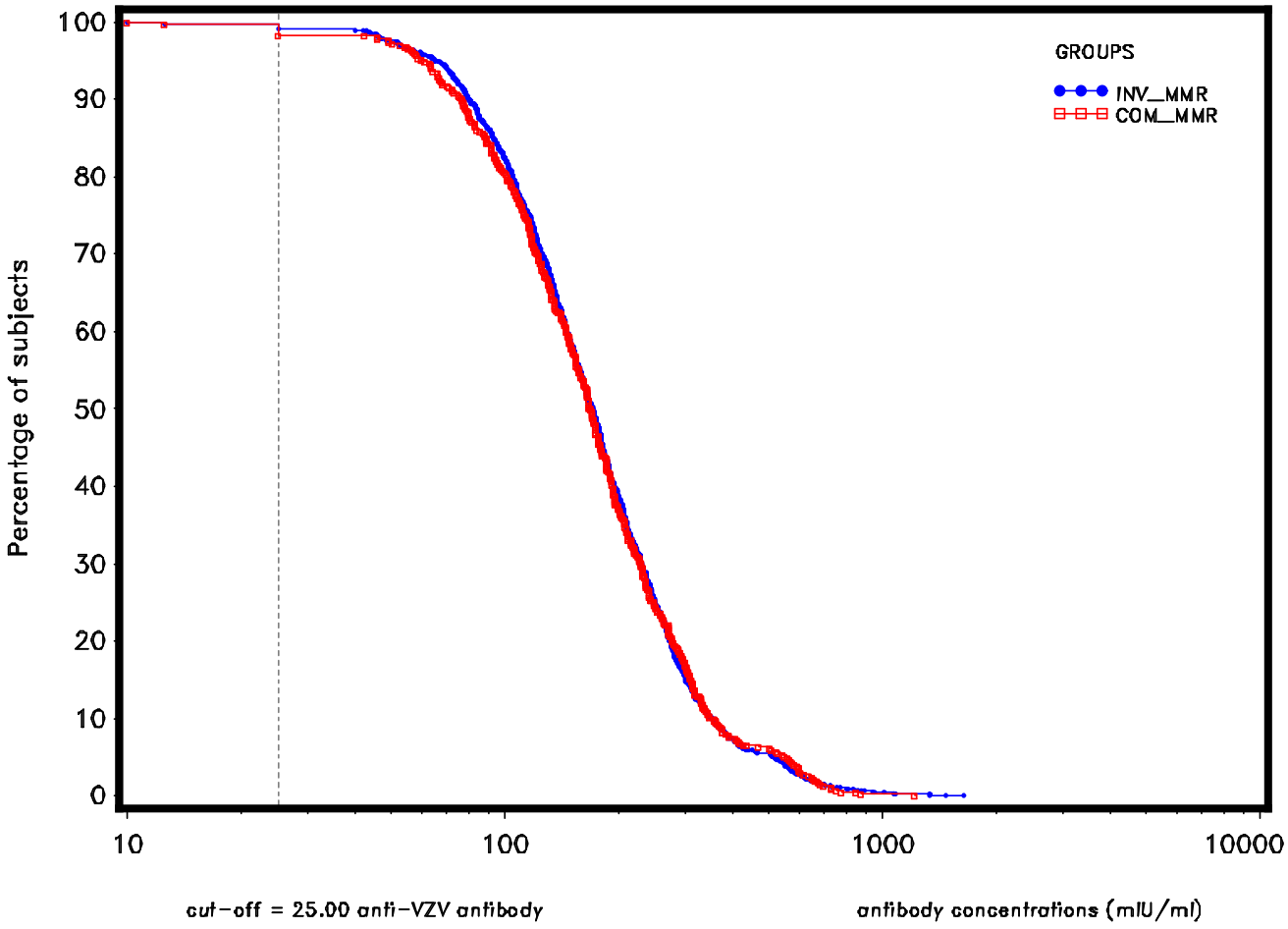
Table 7.62 Distribution of Anti-VZV antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)

				≥25 mIU/mL				≥50 mIU/mL				≥75 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-VZV antibody	INV_MMR	PI(D42)	1492	1488	99.7	99.3	99.9	1455	97.5	96.6	98.2	1376	92.2	90.7	93.5
	COM_MMR	PI(D42)	540	538	99.6	98.7	100	526	97.4	95.7	98.6	491	90.9	88.2	93.2

				≥100 mIU/mL				≥200 mIU/mL				≥400 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-VZV antibody	INV_MMR	PI(D42)	1492	1228	82.3	80.3	84.2	577	38.7	36.2	41.2	110	7.4	6.1	8.8
	COM_MMR	PI(D42)	540	436	80.7	77.2	84.0	202	37.4	33.3	41.6	41	7.6	5.5	10.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.22 Reverse cumulative distribution curve of Anti-VZV antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, VZV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.63 Number and percentage of subjects with an Anti-HAV antibody concentration equal to or above 15 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset, by gender)

						≥ 15 mIU/mL				GMC		
								95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Pre-vacc status**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-HAV antibody	INV_MMR	F	S-	PI(D42)	353	315	89.2	85.5	92.3	43.7	39.7	48.2
			S+	PI(D42)	20	18	90.0	68.3	98.8	38.8	25.5	59.0
			Total	PI(D42)	373	333	89.3	85.7	92.2	43.5	39.6	47.7
		M	S-	PI(D42)	395	349	88.4	84.8	91.3	40.2	36.7	44.1
			S+	PI(D42)	15	14	93.3	68.1	99.8	54.4	32.1	92.3
			Total	PI(D42)	410	363	88.5	85.0	91.5	40.7	37.2	44.5
	COM_MMR	F	S-	PI(D42)	132	116	87.9	81.1	92.9	47.2	40.0	55.7
			S+	PI(D42)	6	6	100	54.1	100	51.8	31.7	84.6
			Total	PI(D42)	138	122	88.4	81.9	93.2	47.4	40.4	55.6
		M	S-	PI(D42)	139	120	86.3	79.5	91.6	39.0	33.5	45.4
			S+	PI(D42)	8	7	87.5	47.3	99.7	26.3	14.9	46.5
			Total	PI(D42)	147	127	86.4	79.8	91.5	38.2	33.0	44.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
S- = seronegative subjects (antibody concentration < 15 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL) prior to vaccination
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.64 Number and percentage of subjects with an Anti-HAV antibody concentration equal to or above 15 MIU/ML and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, HAV subset, by geographic ancestry)

						≥ 15 mIU/mL				GMC		
								95% CI			95% CI	
Antibody	Group	Sub-group	Pre-vacc status	Timing	N	n	%	LL	UL	value	LL	UL
anti-HAV antibody	INV_MMR	WH	S-	PI(D42)	547	478	87.4	84.3	90.1	37.7	35.0	40.6
			S+	PI(D42)	18	17	94.4	72.7	99.9	41.8	27.3	63.9
			Total	PI(D42)	565	495	87.6	84.6	90.2	37.8	35.1	40.7
		OT	S-	PI(D42)	24	23	95.8	78.9	99.9	46.4	32.0	67.4
			S+	PI(D42)	1	1	100	2.5	100	19.0	-	-
			Total	PI(D42)	25	24	96.0	79.6	99.9	44.8	31.1	64.5
		AF	S-	PI(D42)	56	53	94.6	85.1	98.9	58.7	45.9	75.1
			S+	PI(D42)	1	1	100	2.5	100	83.0	-	-
			Total	PI(D42)	57	54	94.7	85.4	98.9	59.1	46.4	75.3
	COM_MMR	WH	S-	PI(D42)	203	170	83.7	77.9	88.5	37.3	32.8	42.4
			S+	PI(D42)	5	5	100	47.8	100	30.6	21.1	44.3
			Total	PI(D42)	208	175	84.1	78.4	88.8	37.1	32.7	42.0
		OT	S-	PI(D42)	6	6	100	54.1	100	63.2	31.2	127.9
			S+	PI(D42)	3	2	66.7	9.4	99.2	29.2	1.4	613.2
			Total	PI(D42)	9	8	88.9	51.8	99.7	48.9	24.5	97.5
		AF	S-	PI(D42)	22	20	90.9	70.8	98.9	69.3	46.3	103.6
			S+	PI(D42)	1	1	100	2.5	100	18.0	-	-
			Total	PI(D42)	23	21	91.3	72.0	98.9	65.3	43.6	97.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
S- = seronegative subjects (antibody concentration < 15 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 15 mIU/mL) prior to vaccination
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

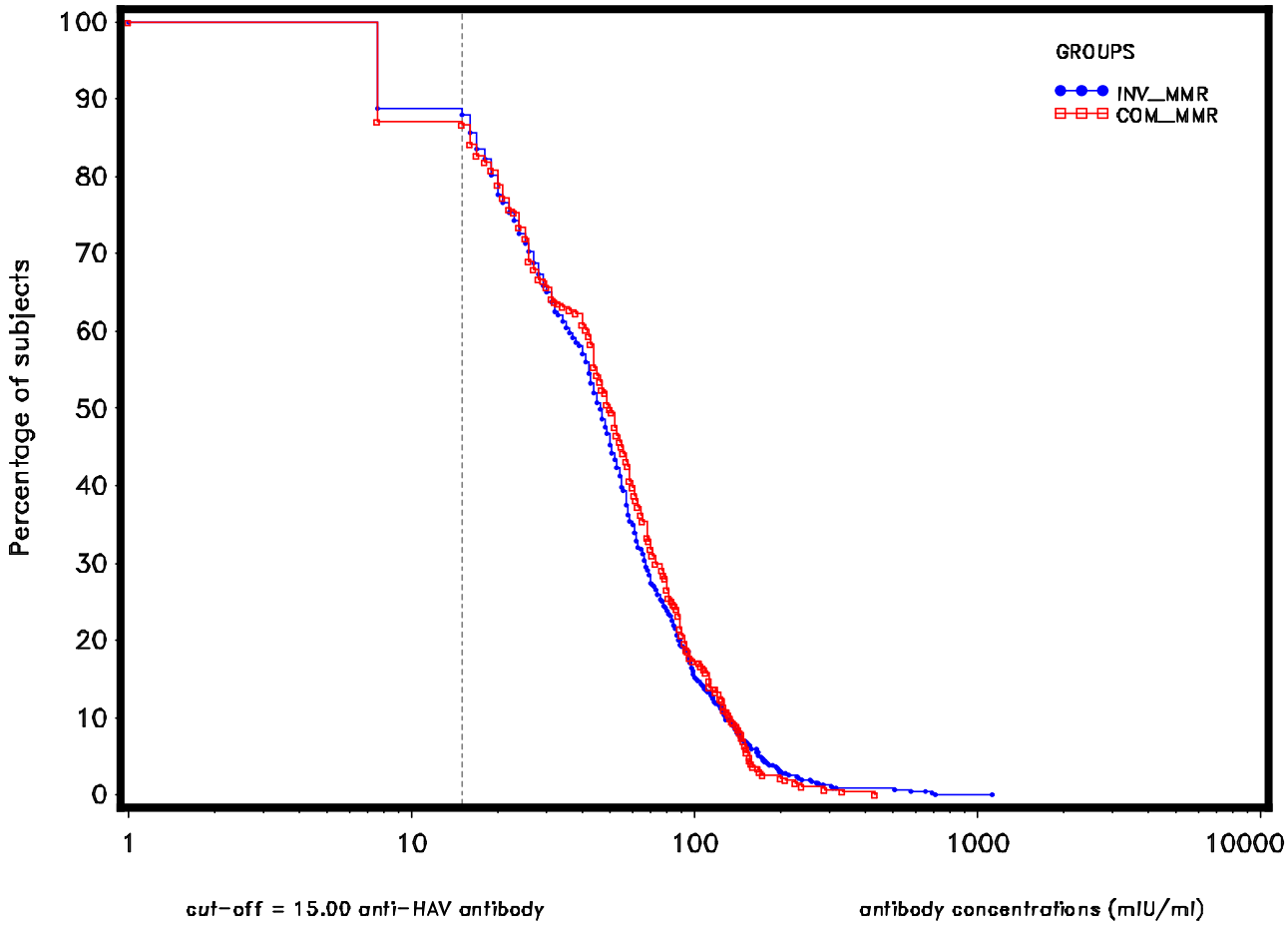
Table 7.65 Distribution of Anti-HAV antibody concentrations - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)

				≥15 mIU/mL				≥20 mIU/mL				≥25 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-HAV antibody	INV_MMR	PI(D42)	748	664	88.8	86.3	90.9	600	80.2	77.2	83.0	543	72.6	69.2	75.8
	COM_MMR	PI(D42)	271	236	87.1	82.5	90.8	219	80.8	75.6	85.3	199	73.4	67.8	78.6

				≥30 mIU/mL				≥35 mIU/mL				≥40 mIU/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
anti-HAV antibody	INV_MMR	PI(D42)	748	492	65.8	62.3	69.2	458	61.2	57.6	64.7	434	58.0	54.4	61.6
	COM_MMR	PI(D42)	271	180	66.4	60.5	72.0	171	63.1	57.1	68.9	169	62.4	56.3	68.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.23 Reverse cumulative distribution curve of Anti-HAV antibody concentrations at Day 42 - pooled INV_MMR groups - initially seronegative subjects only (ATP cohort for immunogenicity, HAV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 7.66 Number and percentage of subjects with an Anti-S.Pneu antibody concentration equal to or above the specified assay cut-off and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset, by gender)

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-PnPS 1 antibody(ECL)(assay cut-off=0.08 µg/ml)	INV_MMR	F	PRE	393	391	99.5	98.2	99.9	275	70.0	65.2	74.5	0.526	0.487	0.568
			PI(D42)	393	390	99.2	97.8	99.8	388	98.7	97.1	99.6	2.520	2.306	2.754
		M	PRE	357	352	98.6	96.8	99.5	194	54.3	49.0	59.6	0.427	0.390	0.467
			PI(D42)	366	365	99.7	98.5	100	363	99.2	97.6	99.8	2.005	1.841	2.184
	COM_MMR	F	PRE	121	121	100	97.0	100	87	71.9	63.0	79.7	0.512	0.455	0.576
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.683	2.320	3.102
		M	PRE	139	139	100	97.4	100	86	61.9	53.3	70.0	0.473	0.417	0.537
			PI(D42)	142	142	100	97.4	100	140	98.6	95.0	99.8	2.220	1.936	2.546
anti-PnPS 3 antibody(ECL)(assay cut-off=0.075 µg/ml)	INV_MMR	F	PRE	393	341	86.8	83.0	90.0	66	16.8	13.2	20.9	0.165	0.150	0.180
			PI(D42)	392	389	99.2	97.8	99.8	285	72.7	68.0	77.1	0.547	0.508	0.589
		M	PRE	357	278	77.9	73.2	82.1	50	14.0	10.6	18.0	0.137	0.124	0.152
			PI(D42)	366	365	99.7	98.5	100	246	67.2	62.1	72.0	0.465	0.433	0.500
	COM_MMR	F	PRE	121	100	82.6	74.7	88.9	13	10.7	5.8	17.7	0.136	0.118	0.156
			PI(D42)	124	123	99.2	95.6	100	86	69.4	60.4	77.3	0.480	0.425	0.541
		M	PRE	139	110	79.1	71.4	85.6	22	15.8	10.2	23.0	0.150	0.125	0.179
			PI(D42)	141	141	100	97.4	100	98	69.5	61.2	77.0	0.511	0.449	0.582
anti-PnPS 4 antibody(ECL)(assay cut-off=0.061 µg/ml)	INV_MMR	F	PRE	392	384	98.0	96.0	99.1	169	43.1	38.2	48.2	0.298	0.275	0.323
			PI(D42)	390	387	99.2	97.8	99.8	382	97.9	96.0	99.1	1.876	1.711	2.057
		M	PRE	356	342	96.1	93.5	97.8	123	34.6	29.6	39.7	0.245	0.224	0.268
			PI(D42)	363	362	99.7	98.5	100	356	98.1	96.1	99.2	1.381	1.268	1.505
	COM_MMR	F	PRE	120	118	98.3	94.1	99.8	52	43.3	34.3	52.7	0.303	0.265	0.346
			PI(D42)	124	124	100	97.1	100	121	97.6	93.1	99.5	2.143	1.832	2.506
		M	PRE	139	137	98.6	94.9	99.8	46	33.1	25.4	41.6	0.260	0.225	0.300
			PI(D42)	142	142	100	97.4	100	137	96.5	92.0	98.8	1.663	1.425	1.942
anti-PnPS 5 antibody(ECL)(assay cut-off=0.198 µg/ml)	INV_MMR	F	PRE	393	366	93.1	90.2	95.4	288	73.3	68.6	77.6	0.543	0.502	0.587
			PI(D42)	392	389	99.2	97.8	99.8	388	99.0	97.4	99.7	2.356	2.182	2.544
		M	PRE	357	311	87.1	83.2	90.4	222	62.2	56.9	67.2	0.438	0.402	0.478
			PI(D42)	365	364	99.7	98.5	100	360	98.6	96.8	99.6	1.867	1.721	2.025
	COM_MMR	F	PRE	121	117	96.7	91.8	99.1	90	74.4	65.6	81.9	0.524	0.467	0.587
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.606	2.306	2.945

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
		M	PRE	139	122	87.8	81.1	92.7	92	66.2	57.7	74.0	0.454	0.394	0.524
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	2.029	1.788	2.303
anti-PnPS 6A antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	F	PRE	393	392	99.7	98.6	100	346	88.0	84.4	91.1	0.803	0.743	0.867
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	6.335	5.825	6.889
		M	PRE	357	345	96.6	94.2	98.3	273	76.5	71.7	80.8	0.637	0.581	0.700
			PI(D42)	366	365	99.7	98.5	100	365	99.7	98.5	100	5.352	4.937	5.801
	COM_MMR	F	PRE	121	119	98.3	94.2	99.8	104	86.0	78.5	91.6	0.804	0.695	0.930
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	6.372	5.551	7.313
		M	PRE	139	138	99.3	96.1	100	110	79.1	71.4	85.6	0.637	0.558	0.727
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	5.245	4.625	5.949
anti-PnPS 6B antibody(ECL)(assay cut-off=0.102 µg/ml)	INV_MMR	F	PRE	393	373	94.9	92.2	96.9	288	73.3	68.6	77.6	0.635	0.572	0.704
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	6.665	6.081	7.306
		M	PRE	357	322	90.2	86.6	93.1	207	58.0	52.7	63.2	0.441	0.393	0.495
			PI(D42)	365	364	99.7	98.5	100	364	99.7	98.5	100	5.123	4.686	5.602
	COM_MMR	F	PRE	121	113	93.4	87.4	97.1	90	74.4	65.6	81.9	0.630	0.516	0.770
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	6.930	5.987	8.023
		M	PRE	139	127	91.4	85.4	95.5	81	58.3	49.6	66.6	0.419	0.350	0.502
			PI(D42)	142	142	100	97.4	100	141	99.3	96.1	100	5.026	4.305	5.867
anti-PnPS 7F antibody(ECL)(assay cut-off=0.063 µg/ml)	INV_MMR	F	PRE	393	393	100	99.1	100	357	90.8	87.5	93.5	0.924	0.862	0.991
			PI(D42)	392	389	99.2	97.8	99.8	389	99.2	97.8	99.8	3.907	3.594	4.248
		M	PRE	357	357	100	99.0	100	314	88.0	84.1	91.1	0.798	0.740	0.860
			PI(D42)	366	365	99.7	98.5	100	365	99.7	98.5	100	3.473	3.222	3.743
	COM_MMR	F	PRE	121	121	100	97.0	100	111	91.7	85.3	96.0	0.859	0.770	0.958
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	4.041	3.615	4.518
		M	PRE	139	139	100	97.4	100	125	89.9	83.7	94.4	0.774	0.687	0.873
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	3.627	3.154	4.170
anti-PnPS 9V antibody(ECL)(assay cut-off=0.066 µg/ml)	INV_MMR	F	PRE	393	390	99.2	97.8	99.8	223	56.7	51.7	61.7	0.399	0.367	0.433
			PI(D42)	393	390	99.2	97.8	99.8	386	98.2	96.4	99.3	2.534	2.326	2.762
		M	PRE	357	344	96.4	93.9	98.0	155	43.4	38.2	48.7	0.320	0.289	0.354
			PI(D42)	366	365	99.7	98.5	100	362	98.9	97.2	99.7	2.106	1.940	2.287
	COM_MMR	F	PRE	121	120	99.2	95.5	100	60	49.6	40.4	58.8	0.361	0.315	0.414
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.445	2.145	2.787
		M	PRE	139	136	97.8	93.8	99.6	66	47.5	39.0	56.1	0.327	0.283	0.378

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
			PI(D42)	142	142	100	97.4	100	140	98.6	95.0	99.8	2.148	1.851	2.493
anti-PnPS 14 antibody(ECL)(assay cut-off=0.16 µg/ml)	INV_MMR	F	PRE	393	388	98.7	97.1	99.6	379	96.4	94.1	98.0	1.933	1.764	2.118
			PI(D42)	392	389	99.2	97.8	99.8	388	99.0	97.4	99.7	7.187	6.527	7.913
		M	PRE	357	352	98.6	96.8	99.5	325	91.0	87.6	93.8	1.479	1.336	1.638
			PI(D42)	365	364	99.7	98.5	100	364	99.7	98.5	100	5.981	5.463	6.548
	COM_MMR	F	PRE	121	120	99.2	95.5	100	119	98.3	94.2	99.8	1.848	1.593	2.144
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	7.950	6.822	9.264
		M	PRE	139	135	97.1	92.8	99.2	130	93.5	88.1	97.0	1.525	1.291	1.802
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	6.353	5.544	7.279
anti-PnPS 18C antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	F	PRE	393	366	93.1	90.2	95.4	182	46.3	41.3	51.4	0.316	0.290	0.343
			PI(D42)	393	390	99.2	97.8	99.8	389	99.0	97.4	99.7	2.234	2.042	2.444
		M	PRE	357	309	86.6	82.6	89.9	125	35.0	30.1	40.2	0.256	0.233	0.281
			PI(D42)	366	365	99.7	98.5	100	360	98.4	96.5	99.4	1.970	1.800	2.156
	COM_MMR	F	PRE	121	113	93.4	87.4	97.1	55	45.5	36.4	54.8	0.297	0.259	0.340
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	2.387	2.068	2.756
		M	PRE	139	117	84.2	77.0	89.8	53	38.1	30.0	46.7	0.256	0.220	0.299
			PI(D42)	141	141	100	97.4	100	138	97.9	93.9	99.6	2.077	1.771	2.437
anti-PnPS 19A antibody(ECL)(assay cut-off=0.199 µg/ml)	INV_MMR	F	PRE	392	358	91.3	88.1	93.9	273	69.6	64.8	74.2	0.567	0.516	0.624
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	5.467	5.045	5.925
		M	PRE	357	294	82.4	78.0	86.2	202	56.6	51.3	61.8	0.456	0.408	0.510
			PI(D42)	366	365	99.7	98.5	100	363	99.2	97.6	99.8	4.050	3.726	4.403
	COM_MMR	F	PRE	121	108	89.3	82.3	94.2	86	71.1	62.1	79.0	0.519	0.446	0.604
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	5.685	4.990	6.476
		M	PRE	139	116	83.5	76.2	89.2	82	59.0	50.3	67.3	0.440	0.370	0.524
			PI(D42)	141	141	100	97.4	100	141	100	97.4	100	4.171	3.623	4.802
anti-PnPS 19F antibody(ECL)(assay cut-off=0.163 µg/ml)	INV_MMR	F	PRE	393	385	98.0	96.0	99.1	317	80.7	76.4	84.4	0.725	0.663	0.794
			PI(D42)	393	390	99.2	97.8	99.8	390	99.2	97.8	99.8	4.841	4.464	5.249
		M	PRE	357	339	95.0	92.1	97.0	260	72.8	67.9	77.4	0.584	0.531	0.642
			PI(D42)	366	365	99.7	98.5	100	364	99.5	98.0	99.9	3.698	3.413	4.008
	COM_MMR	F	PRE	121	118	97.5	92.9	99.5	98	81.0	72.9	87.6	0.682	0.585	0.797
			PI(D42)	124	124	100	97.1	100	124	100	97.1	100	5.244	4.617	5.955
		M	PRE	139	133	95.7	90.8	98.4	91	65.5	56.9	73.3	0.522	0.455	0.599
			PI(D42)	142	142	100	97.4	100	142	100	97.4	100	3.554	3.106	4.065

					≥ assay cut-off				≥ 0.35 µg/mL				GMC		
							95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PnPS 23F antibody(ECL)(assay cut-off=0.073 µg/ml)	INV_MMR	F	PRE	381	347	91.1	87.8	93.7	146	38.3	33.4	43.4	0.286	0.255	0.320
			PI(D42)	385	382	99.2	97.7	99.8	380	98.7	97.0	99.6	2.424	2.206	2.665
		M	PRE	347	297	85.6	81.4	89.1	120	34.6	29.6	39.8	0.218	0.194	0.246
			PI(D42)	357	356	99.7	98.4	100	350	98.0	96.0	99.2	1.978	1.788	2.187
	COM_MMR	F	PRE	119	110	92.4	86.1	96.5	50	42.0	33.0	51.4	0.302	0.248	0.367
			PI(D42)	119	119	100	96.9	100	118	99.2	95.4	100	2.777	2.333	3.305
		M	PRE	135	113	83.7	76.4	89.5	41	30.4	22.8	38.9	0.202	0.166	0.246
			PI(D42)	137	136	99.3	96.0	100	133	97.1	92.7	99.2	1.938	1.633	2.300

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Table 7.67 Number and percentage of subjects with an Anti-S.Pneu antibody concentration equal to or above the specified assay cut-off and GMCs - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset, by geographic ancestry)

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PnPS 1 antibody(ECL)(assay cut-off=0.08 µg/ml)	INV_MMR	PRE	598	592	99.0	97.8	99.6	361	60.4	56.3	64.3	0.448	0.420	0.478
		PI(D42)	607	604	99.5	98.6	99.9	601	99.0	97.9	99.6	2.114	1.977	2.261
	COM_MMR	PRE	214	214	100	98.3	100	139	65.0	58.2	71.3	0.467	0.425	0.514
		PI(D42)	218	218	100	98.3	100	216	99.1	96.7	99.9	2.293	2.055	2.560
anti-PnPS 3 antibody(ECL)(assay cut-off=0.075 µg/ml)	INV_MMR	PRE	598	477	79.8	76.3	82.9	82	13.7	11.1	16.7	0.139	0.129	0.151
		PI(D42)	607	604	99.5	98.6	99.9	416	68.5	64.7	72.2	0.492	0.464	0.521
	COM_MMR	PRE	214	170	79.4	73.4	84.6	30	14.0	9.7	19.4	0.139	0.122	0.159
		PI(D42)	217	216	99.5	97.5	100	148	68.2	61.6	74.3	0.495	0.446	0.548
anti-PnPS 4 antibody(ECL)(assay cut-off=0.061 µg/ml)	INV_MMR	PRE	596	574	96.3	94.5	97.7	215	36.1	32.2	40.1	0.252	0.235	0.269
		PI(D42)	602	599	99.5	98.6	99.9	588	97.7	96.1	98.7	1.533	1.430	1.644
	COM_MMR	PRE	213	209	98.1	95.3	99.5	73	34.3	27.9	41.1	0.264	0.236	0.294
		PI(D42)	218	218	100	98.3	100	211	96.8	93.5	98.7	1.774	1.571	2.003
anti-PnPS 5 antibody(ECL)(assay cut-off=0.198 µg/ml)	INV_MMR	PRE	598	533	89.1	86.4	91.5	386	64.5	60.6	68.4	0.462	0.433	0.493
		PI(D42)	605	602	99.5	98.6	99.9	597	98.7	97.4	99.4	2.009	1.887	2.138
	COM_MMR	PRE	214	194	90.7	85.9	94.2	146	68.2	61.5	74.4	0.467	0.421	0.518
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	2.213	2.006	2.441
anti-PnPS 6A antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	598	586	98.0	96.5	99.0	480	80.3	76.8	83.4	0.690	0.644	0.740
		PI(D42)	607	604	99.5	98.6	99.9	604	99.5	98.6	99.9	5.689	5.335	6.067
	COM_MMR	PRE	214	211	98.6	96.0	99.7	176	82.2	76.5	87.1	0.699	0.626	0.780
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	5.704	5.129	6.344
anti-PnPS 6B antibody(ECL)(assay cut-off=0.102 µg/ml)	INV_MMR	PRE	598	547	91.5	88.9	93.6	377	63.0	59.0	66.9	0.505	0.462	0.553
		PI(D42)	607	604	99.5	98.6	99.9	604	99.5	98.6	99.9	5.667	5.276	6.086
	COM_MMR	PRE	214	195	91.1	86.5	94.6	138	64.5	57.7	70.9	0.483	0.414	0.564
		PI(D42)	218	218	100	98.3	100	217	99.5	97.5	100	5.636	4.999	6.355
anti-PnPS 7F antibody(ECL)(assay cut-off=0.063 µg/ml)	INV_MMR	PRE	598	598	100	99.4	100	534	89.3	86.5	91.7	0.844	0.797	0.895
		PI(D42)	607	604	99.5	98.6	99.9	604	99.5	98.6	99.9	3.596	3.382	3.824
	COM_MMR	PRE	214	214	100	98.3	100	196	91.6	87.0	94.9	0.810	0.742	0.884
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	3.818	3.459	4.215
anti-PnPS 9V antibody(ECL)(assay cut-off=0.066 µg/ml)	INV_MMR	PRE	598	582	97.3	95.7	98.5	288	48.2	44.1	52.2	0.337	0.313	0.362

				≥ assay cut-off				≥ 0.35 µg/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
		PI(D42)	607	604	99.5	98.6	99.9	597	98.4	97.0	99.2	2.229	2.087	2.380
	COM_MMR	PRE	214	211	98.6	96.0	99.7	96	44.9	38.1	51.8	0.323	0.290	0.360
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	2.222	1.996	2.475
anti-PnPS 14 antibody(ECL)(assay cut-off=0.16 µg/ml)	INV_MMR	PRE	598	590	98.7	97.4	99.4	556	93.0	90.6	94.9	1.583	1.466	1.710
		PI(D42)	606	603	99.5	98.6	99.9	602	99.3	98.3	99.8	6.277	5.829	6.758
	COM_MMR	PRE	214	211	98.6	96.0	99.7	205	95.8	92.2	98.1	1.696	1.502	1.915
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	7.060	6.303	7.909
anti-PnPS 18C antibody(ECL)(assay cut-off=0.111 µg/ml)	INV_MMR	PRE	598	530	88.6	85.8	91.1	230	38.5	34.5	42.5	0.271	0.252	0.291
		PI(D42)	607	604	99.5	98.6	99.9	598	98.5	97.2	99.3	1.992	1.857	2.137
	COM_MMR	PRE	214	187	87.4	82.2	91.5	85	39.7	33.1	46.6	0.262	0.233	0.293
		PI(D42)	217	217	100	98.3	100	215	99.1	96.7	99.9	2.143	1.902	2.414
anti-PnPS 19A antibody(ECL)(assay cut-off=0.199 µg/ml)	INV_MMR	PRE	597	512	85.8	82.7	88.5	366	61.3	57.3	65.2	0.485	0.447	0.526
		PI(D42)	607	604	99.5	98.6	99.9	602	99.2	98.1	99.7	4.597	4.306	4.908
	COM_MMR	PRE	214	181	84.6	79.0	89.1	129	60.3	53.4	66.9	0.442	0.391	0.500
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	4.648	4.177	5.172
anti-PnPS 19F antibody(ECL)(assay cut-off=0.163 µg/ml)	INV_MMR	PRE	598	573	95.8	93.9	97.3	442	73.9	70.2	77.4	0.615	0.572	0.663
		PI(D42)	607	604	99.5	98.6	99.9	603	99.3	98.3	99.8	4.099	3.843	4.373
	COM_MMR	PRE	214	205	95.8	92.2	98.1	147	68.7	62.0	74.8	0.553	0.492	0.623
		PI(D42)	218	218	100	98.3	100	218	100	98.3	100	4.199	3.771	4.676
anti-PnPS 23F antibody(ECL)(assay cut-off=0.073 µg/ml)	INV_MMR	PRE	582	509	87.5	84.5	90.0	202	34.7	30.8	38.7	0.237	0.216	0.260
		PI(D42)	593	590	99.5	98.5	99.9	583	98.3	96.9	99.2	2.127	1.973	2.293
	COM_MMR	PRE	208	179	86.1	80.6	90.5	69	33.2	26.8	40.0	0.231	0.196	0.271
		PI(D42)	210	209	99.5	97.4	100	205	97.6	94.5	99.2	2.158	1.881	2.475

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

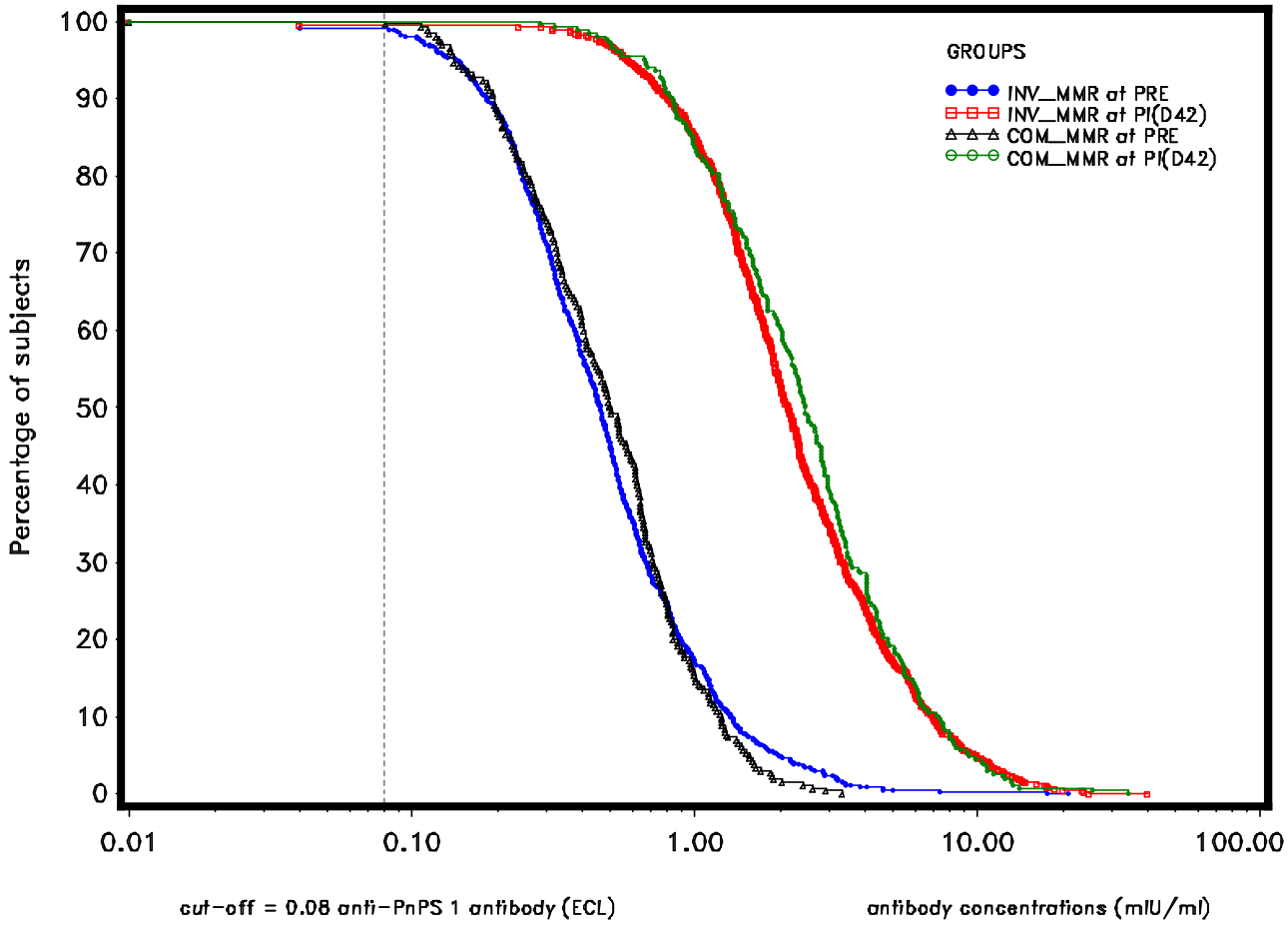
Table 7.68 Distribution of Anti-S.Pneu antibody concentrations - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)

				≥0.1 µg/mL				≥1 µg/mL				≥10 µg/mL			
						95% CI				95% CI				95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
anti-PnPS 1 antibody (ECL)	INV_MMR	PRE	750	736	98.1	96.9	99.0	128	17.1	14.4	20.0	2	0.3	0.0	1.0
		PI(D42)	759	755	99.5	98.7	99.9	648	85.4	82.7	87.8	38	5.0	3.6	6.8
	COM_MMR	PRE	260	259	99.6	97.9	100	41	15.8	11.6	20.8	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	223	83.8	78.8	88.0	12	4.5	2.4	7.7
anti-PnPS 3 antibody (ECL)	INV_MMR	PRE	750	530	70.7	67.3	73.9	25	3.3	2.2	4.9	0	0.0	0.0	0.5
		PI(D42)	758	751	99.1	98.1	99.6	108	14.2	11.8	16.9	0	0.0	0.0	0.5
	COM_MMR	PRE	260	181	69.6	63.6	75.1	8	3.1	1.3	6.0	0	0.0	0.0	1.4
		PI(D42)	265	263	99.2	97.3	99.9	38	14.3	10.4	19.1	0	0.0	0.0	1.4
anti-PnPS 4 antibody (ECL)	INV_MMR	PRE	748	668	89.3	86.9	91.4	38	5.1	3.6	6.9	1	0.1	0.0	0.7
		PI(D42)	753	749	99.5	98.6	99.9	536	71.2	67.8	74.4	22	2.9	1.8	4.4
	COM_MMR	PRE	259	230	88.8	84.3	92.4	16	6.2	3.6	9.8	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	202	75.9	70.3	80.9	11	4.1	2.1	7.3
anti-PnPS 5 antibody (ECL)	INV_MMR	PRE	750	677	90.3	87.9	92.3	140	18.7	15.9	21.6	1	0.1	0.0	0.7
		PI(D42)	757	753	99.5	98.7	99.9	641	84.7	81.9	87.2	20	2.6	1.6	4.1
	COM_MMR	PRE	260	239	91.9	87.9	94.9	43	16.5	12.2	21.6	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	230	86.5	81.8	90.3	10	3.8	1.8	6.8
anti-PnPS 6A antibody (ECL)	INV_MMR	PRE	750	737	98.3	97.1	99.1	243	32.4	29.1	35.9	3	0.4	0.1	1.2
		PI(D42)	759	755	99.5	98.7	99.9	752	99.1	98.1	99.6	176	23.2	20.2	26.4
	COM_MMR	PRE	260	257	98.8	96.7	99.8	89	34.2	28.5	40.3	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	263	98.9	96.7	99.8	61	22.9	18.0	28.5
anti-PnPS 6B antibody (ECL)	INV_MMR	PRE	750	695	92.7	90.6	94.4	204	27.2	24.0	30.5	4	0.5	0.1	1.4
		PI(D42)	758	754	99.5	98.7	99.9	739	97.5	96.1	98.5	198	26.1	23.0	29.4
	COM_MMR	PRE	260	240	92.3	88.4	95.2	72	27.7	22.3	33.6	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	260	97.7	95.2	99.2	73	27.4	22.2	33.2
anti-PnPS 7F antibody (ECL)	INV_MMR	PRE	750	749	99.9	99.3	100	295	39.3	35.8	42.9	3	0.4	0.1	1.2
		PI(D42)	758	754	99.5	98.7	99.9	737	97.2	95.8	98.3	74	9.8	7.7	12.1
	COM_MMR	PRE	260	260	100	98.6	100	96	36.9	31.0	43.1	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	255	95.9	92.7	97.9	18	6.8	4.1	10.5
anti-PnPS 9V antibody (ECL)	INV_MMR	PRE	750	709	94.5	92.7	96.0	82	10.9	8.8	13.4	1	0.1	0.0	0.7
		PI(D42)	759	755	99.5	98.7	99.9	663	87.4	84.8	89.6	27	3.6	2.4	5.1
	COM_MMR	PRE	260	247	95.0	91.6	97.3	28	10.8	7.3	15.2	0	0.0	0.0	1.4
		PI(D42)	266	266	100	98.6	100	226	85.0	80.1	89.0	12	4.5	2.4	7.7
anti-PnPS 14 antibody (ECL)	INV_MMR	PRE	750	740	98.7	97.6	99.4	551	73.5	70.2	76.6	18	2.4	1.4	3.8
		PI(D42)	757	753	99.5	98.7	99.9	740	97.8	96.4	98.7	251	33.2	29.8	36.6
	COM_MMR	PRE	260	255	98.1	95.6	99.4	193	74.2	68.5	79.4	3	1.2	0.2	3.3
		PI(D42)	266	266	100	98.6	100	263	98.9	96.7	99.8	97	36.5	30.7	42.6
anti-PnPS 18C antibody (ECL)	INV_MMR	PRE	750	675	90.0	87.6	92.1	52	6.9	5.2	9.0	1	0.1	0.0	0.7
		PI(D42)	759	755	99.5	98.7	99.9	619	81.6	78.6	84.3	39	5.1	3.7	7.0
	COM_MMR	PRE	260	230	88.5	83.9	92.1	16	6.2	3.6	9.8	0	0.0	0.0	1.4
		PI(D42)	265	265	100	98.6	100	215	81.1	75.9	85.7	14	5.3	2.9	8.7
anti-PnPS 19A antibody (ECL)	INV_MMR	PRE	749	652	87.0	84.4	89.4	176	23.5	20.5	26.7	7	0.9	0.4	1.9
		PI(D42)	759	755	99.5	98.7	99.9	738	97.2	95.8	98.3	131	17.3	14.6	20.1
	COM_MMR	PRE	260	224	86.2	81.3	90.1	50	19.2	14.6	24.6	2	0.8	0.1	2.8
		PI(D42)	265	265	100	98.6	100	256	96.6	93.7	98.4	45	17.0	12.7	22.1
anti-PnPS 19F antibody (ECL)	INV_MMR	PRE	750	724	96.5	95.0	97.7	206	27.5	24.3	30.8	9	1.2	0.6	2.3
		PI(D42)	759	755	99.5	98.7	99.9	737	97.1	95.6	98.2	109	14.4	11.9	17.1
	COM_MMR	PRE	260	251	96.5	93.5	98.4	66	25.4	20.2	31.1	2	0.8	0.1	2.8
		PI(D42)	266	266	100	98.6	100	257	96.6	93.7	98.4	37	13.9	10.0	18.7
anti-PnPS 23F antibody (ECL)	INV_MMR	PRE	728	586	80.5	77.4	83.3	78	10.7	8.6	13.2	2	0.3	0.0	1.0
		PI(D42)	742	738	99.5	98.6	99.9	592	79.8	76.7	82.6	40	5.4	3.9	7.3

				≥0.1 µg/mL				≥1 µg/mL				≥10 µg/mL			
						95% CI				95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	COM_MMR	PRE	254	199	78.3	72.8	83.3	31	12.2	8.4	16.9	0	0.0	0.0	1.4
		PI(D42)	256	255	99.6	97.8	100	209	81.6	76.3	86.2	18	7.0	4.2	10.9

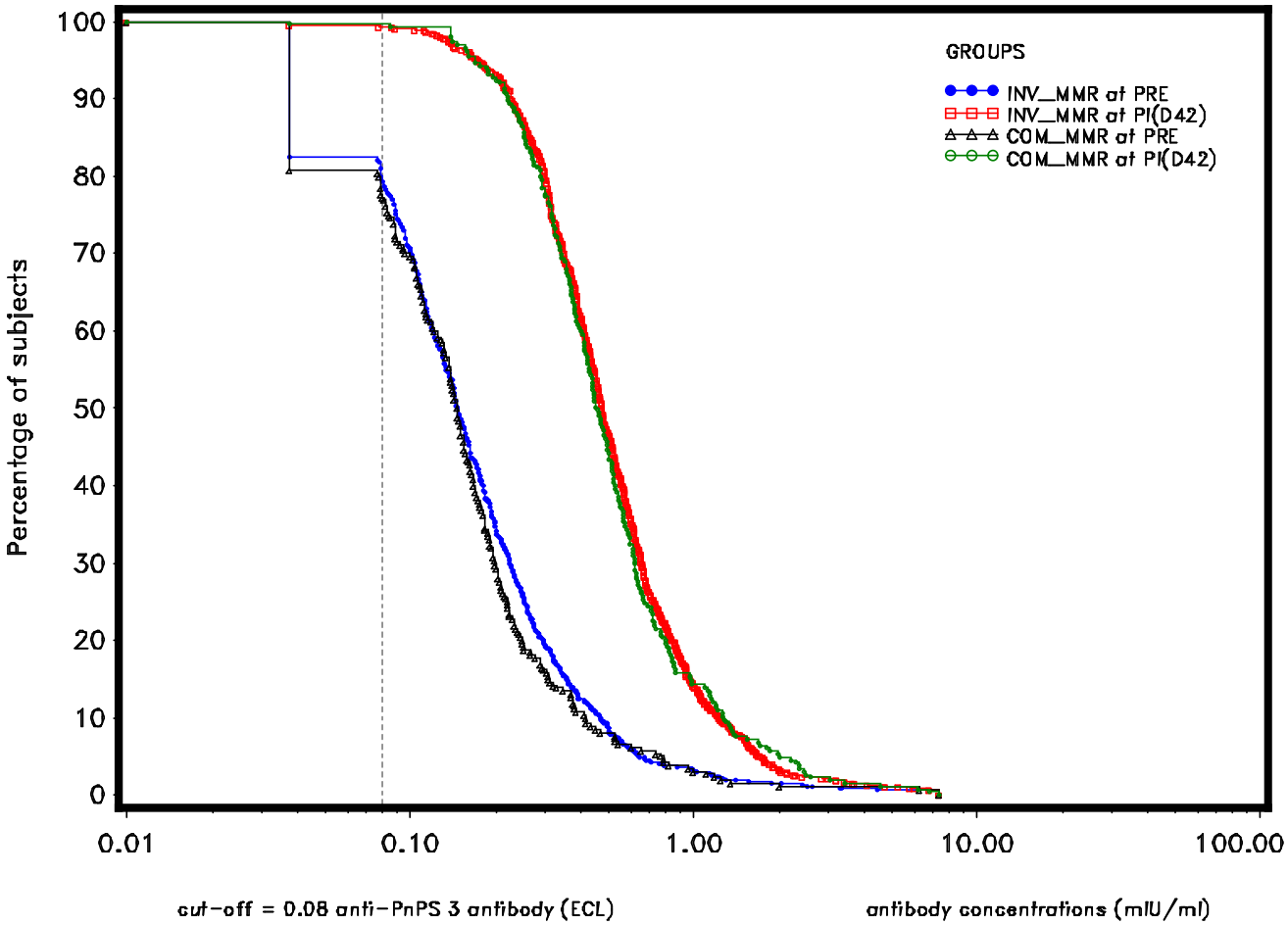
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PI(D42) = Post-vaccination blood sample at Day 42

Figure 7.24 Reverse cumulative distribution curve of Anti-1 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



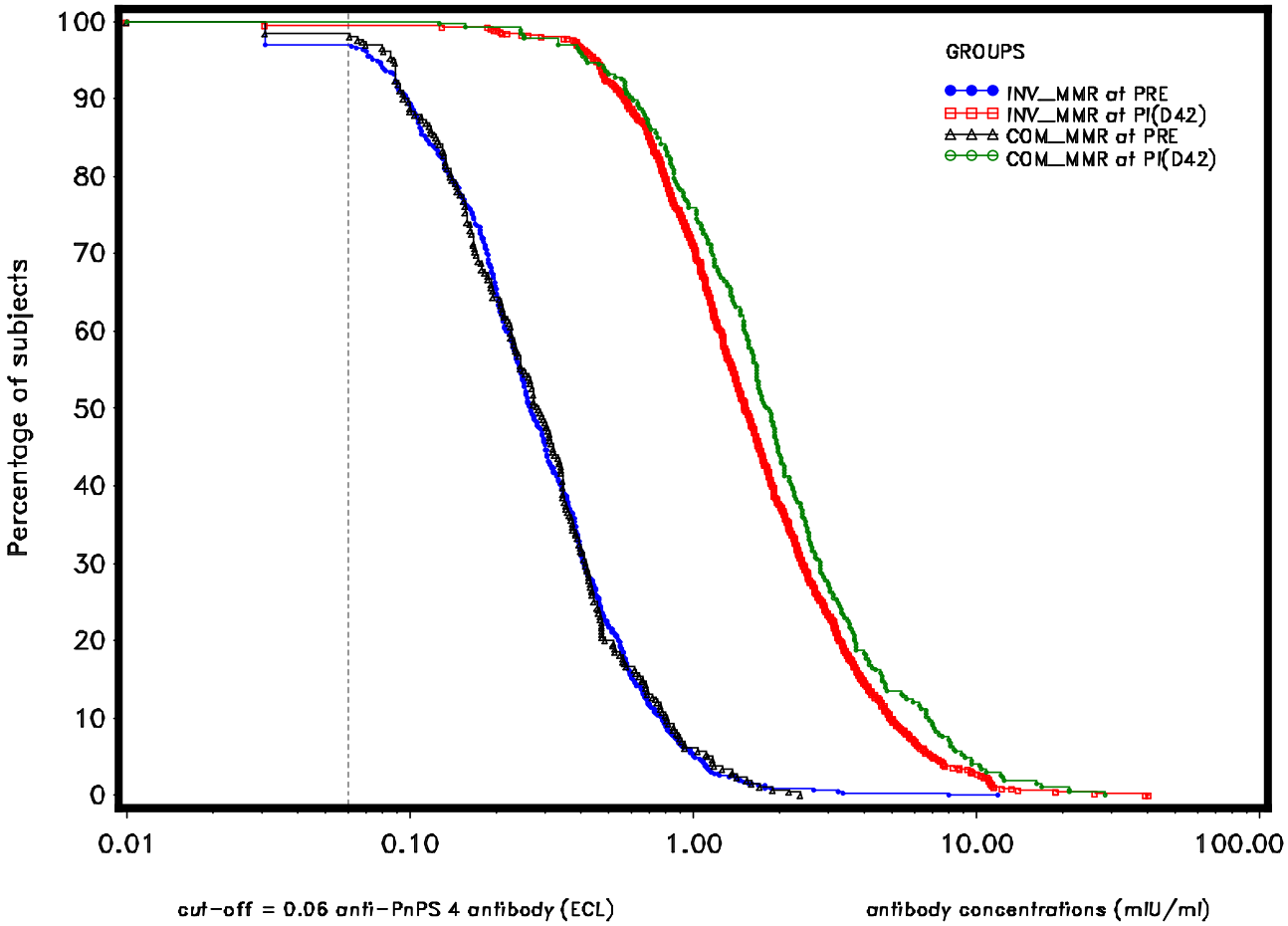
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.25 Reverse cumulative distribution curve of Anti-3 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



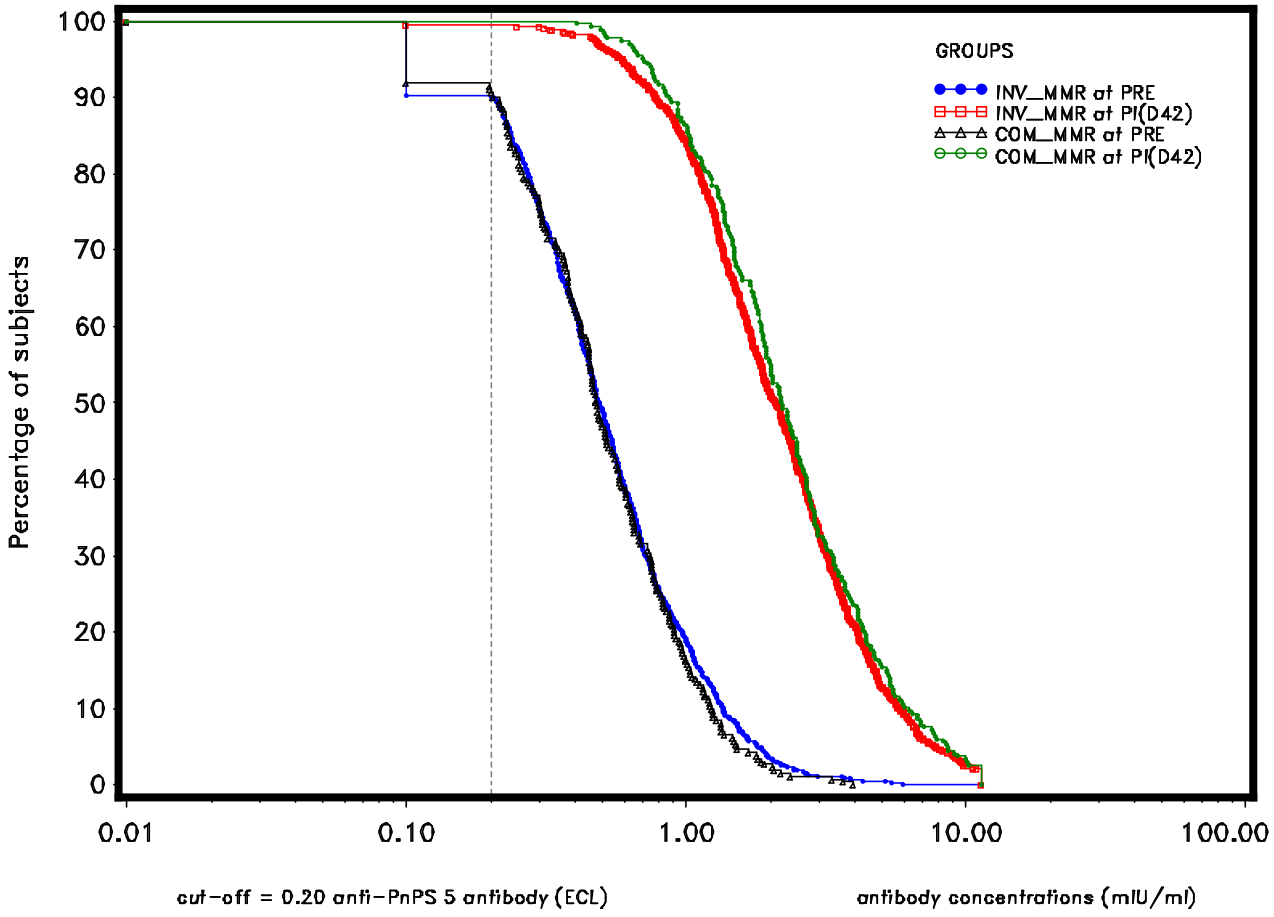
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.26 Reverse cumulative distribution curve of Anti-4 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



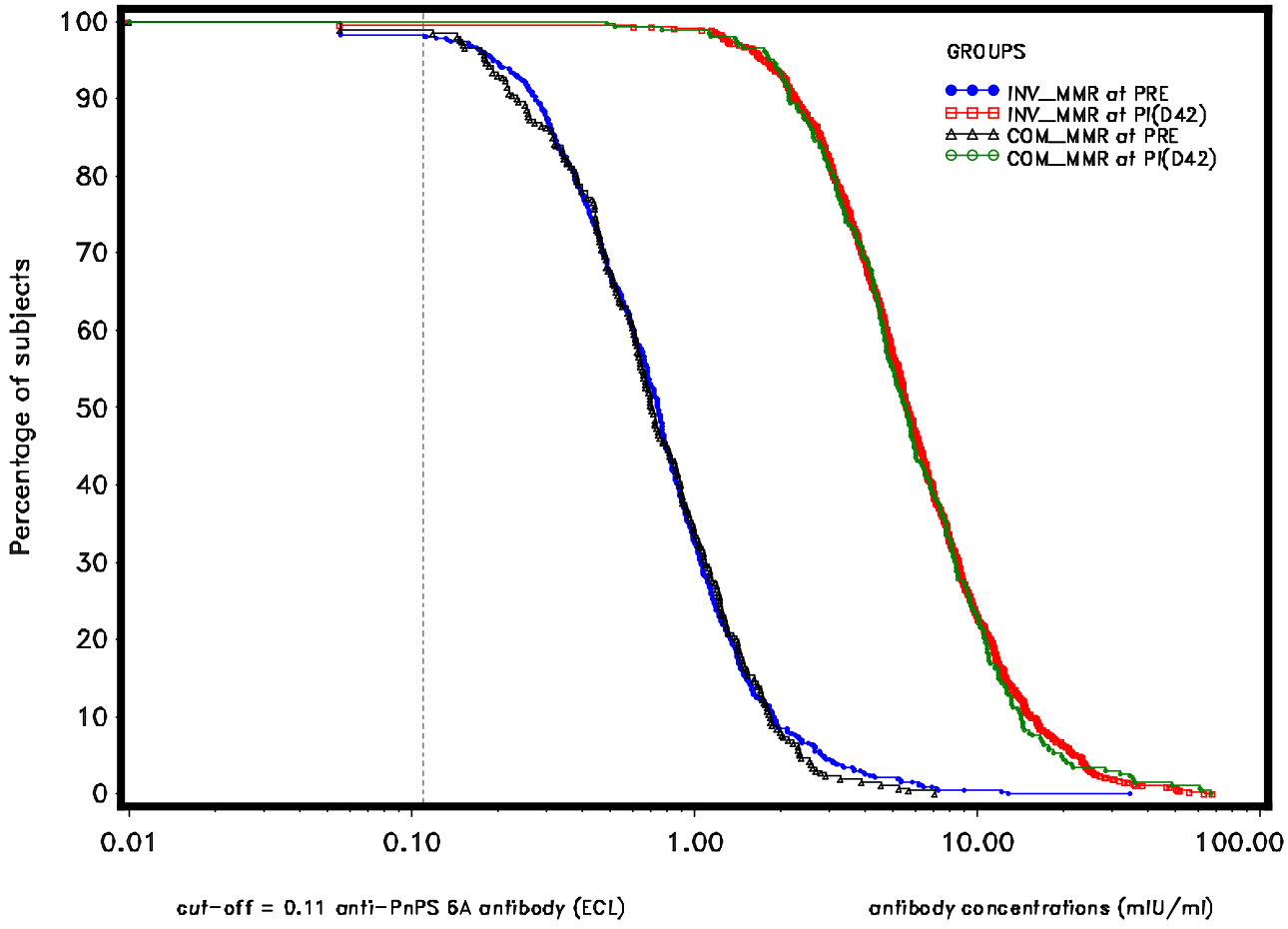
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.27 Reverse cumulative distribution curve of Anti-5 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



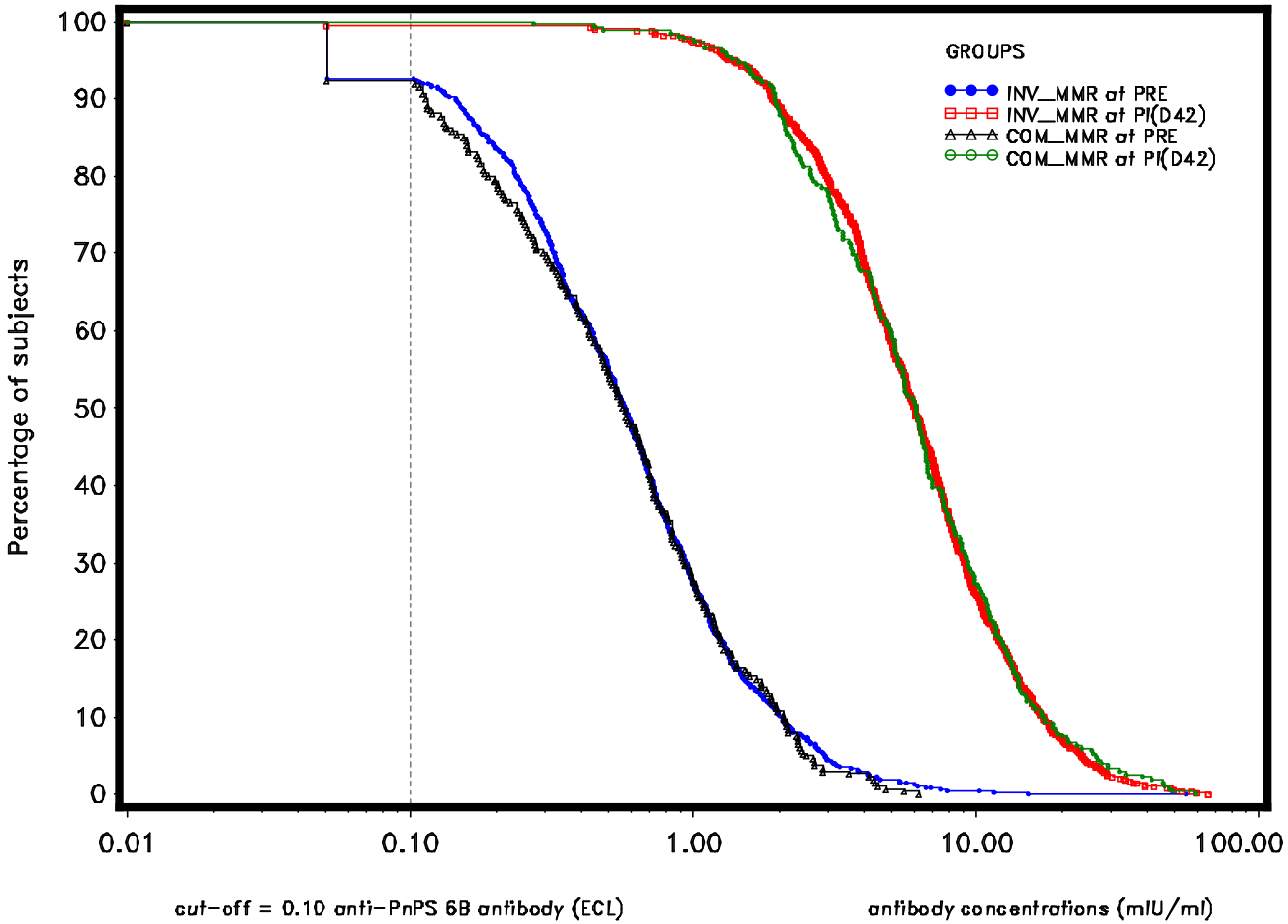
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.28 Reverse cumulative distribution curve of Anti-6A antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



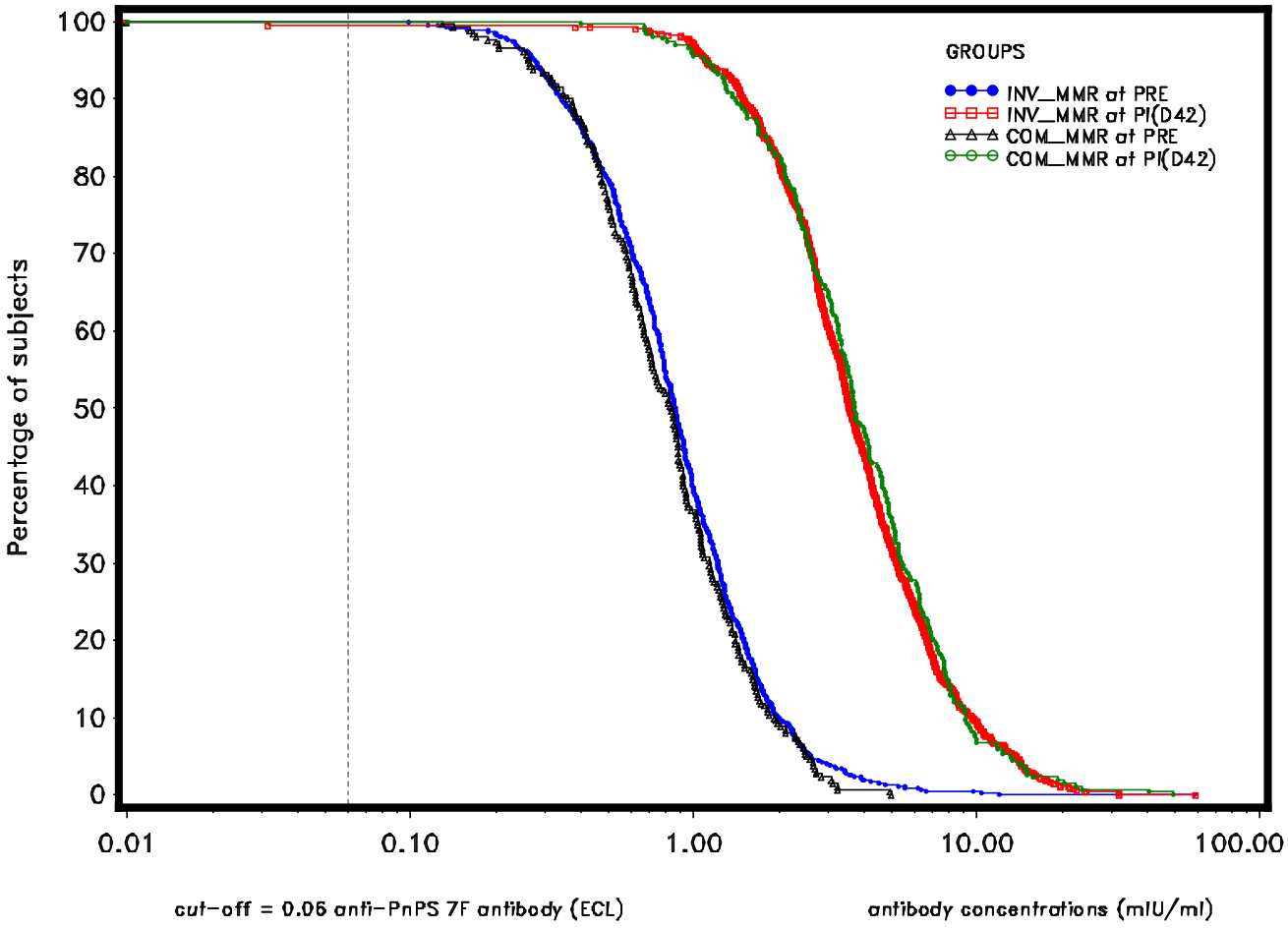
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.29 Reverse cumulative distribution curve of Anti-6B antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



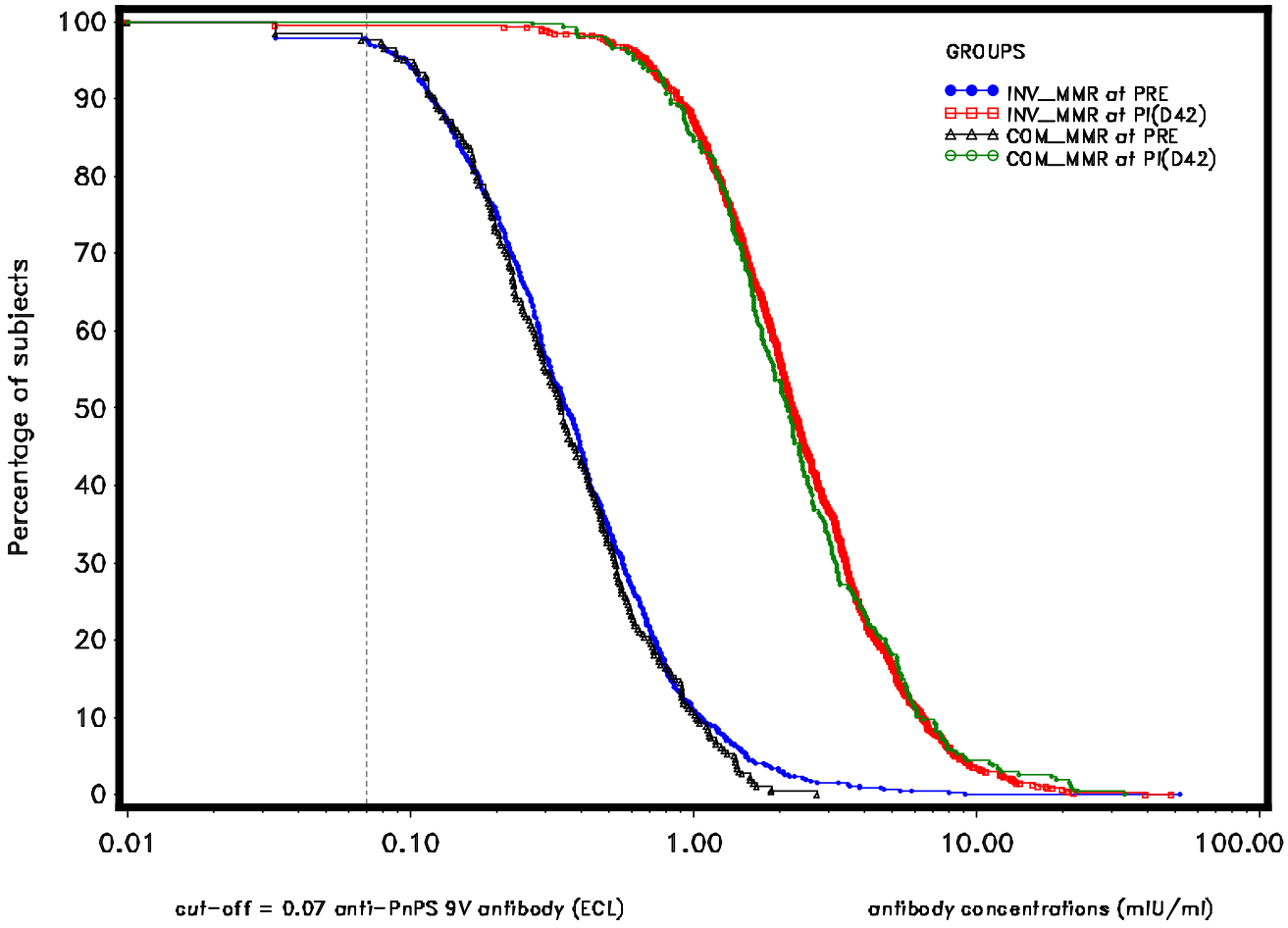
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.30 Reverse cumulative distribution curve of Anti-7F antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



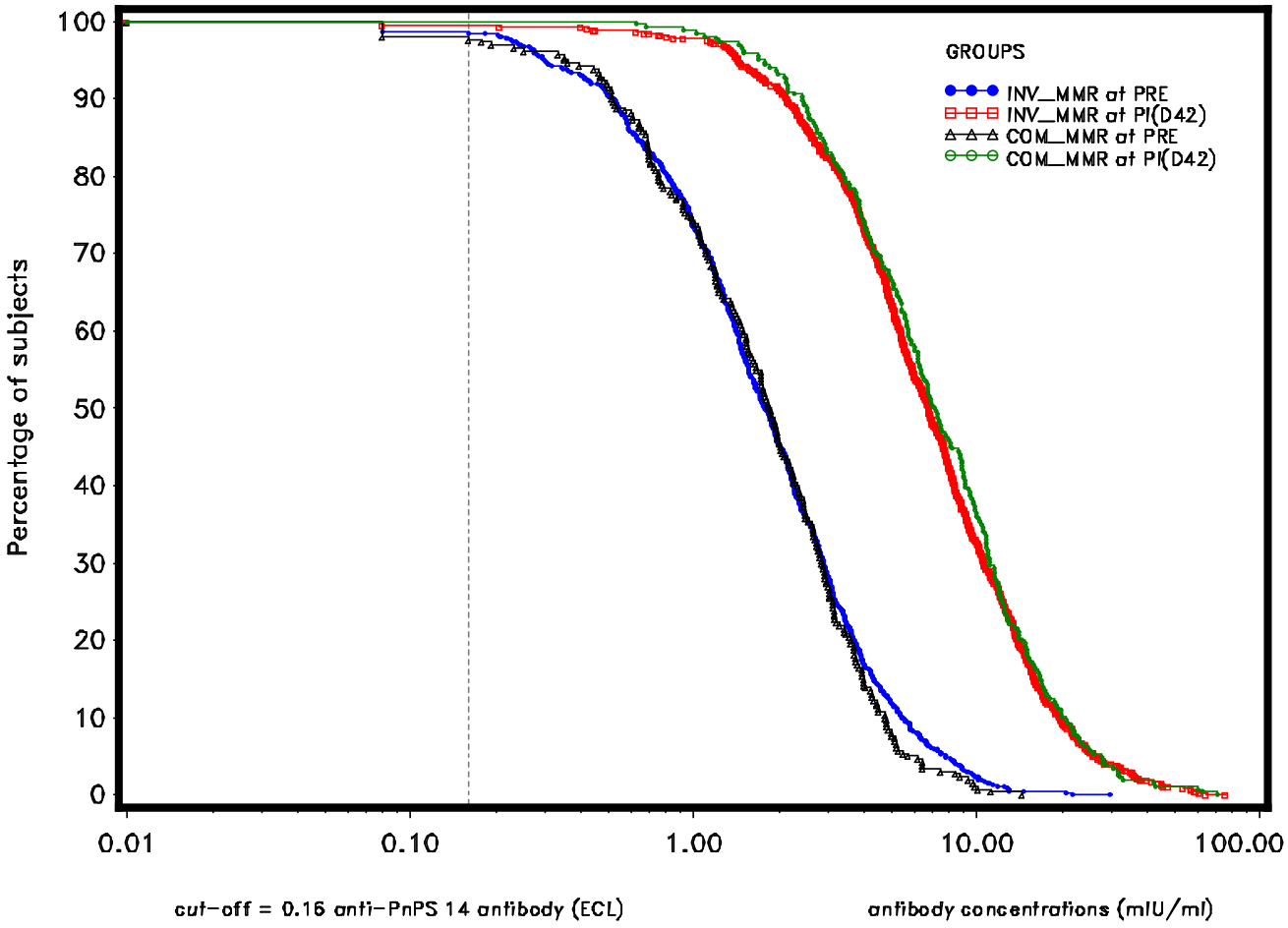
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.31 Reverse cumulative distribution curve of Anti-9V antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



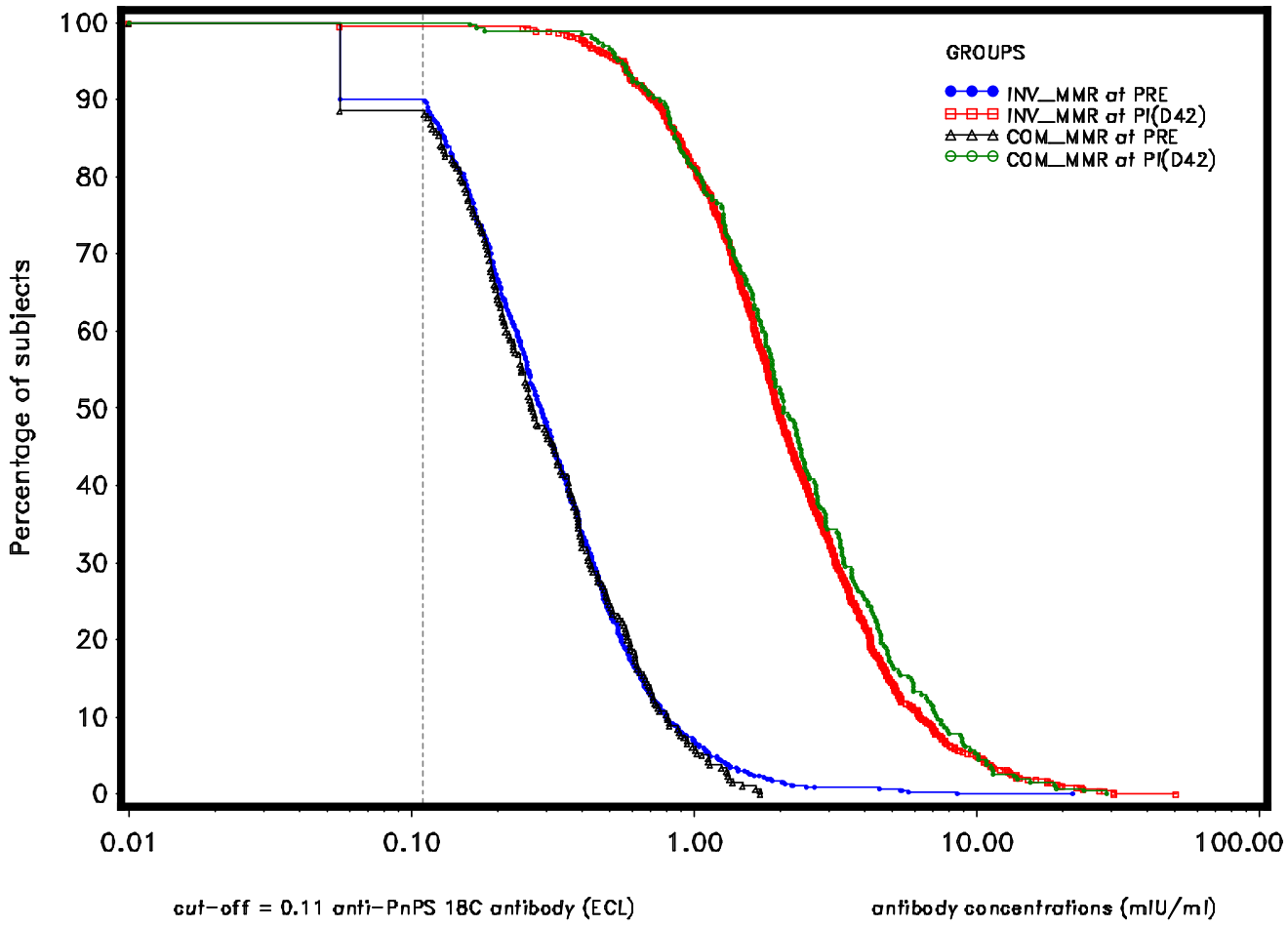
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.32 Reverse cumulative distribution curve of Anti-14 antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



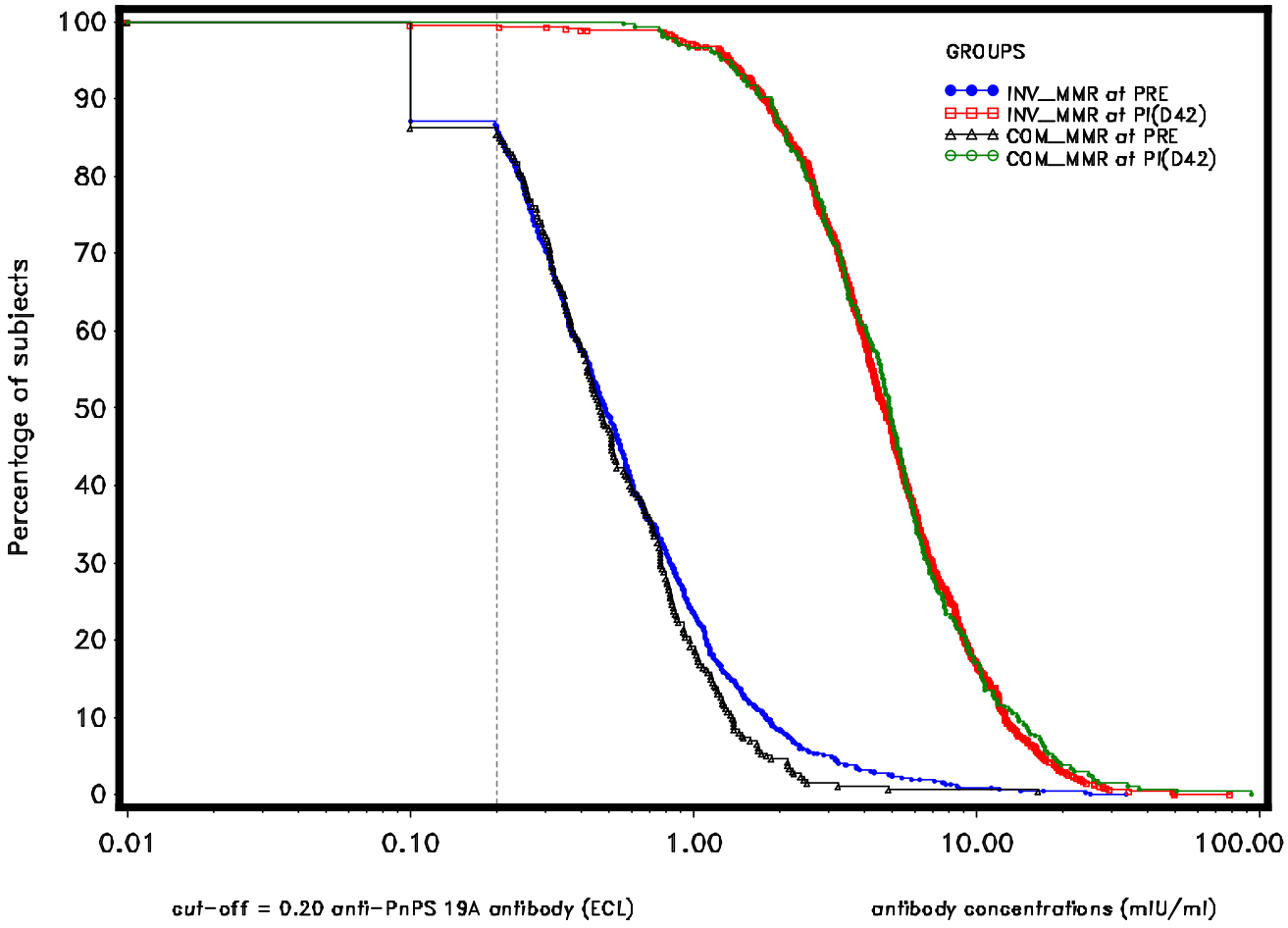
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.33 Reverse cumulative distribution curve of Anti-18C antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



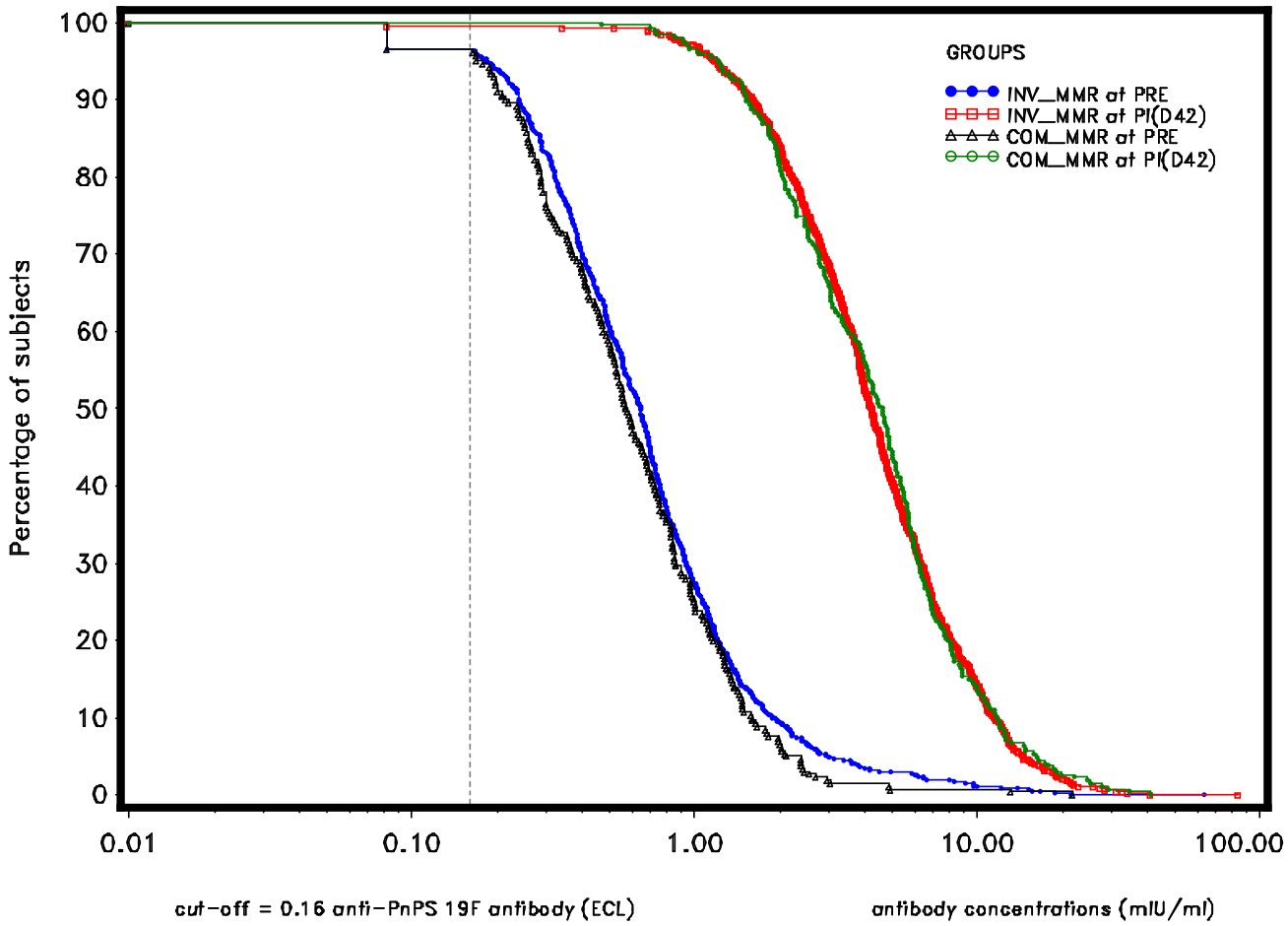
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.34 Reverse cumulative distribution curve of Anti-19A antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



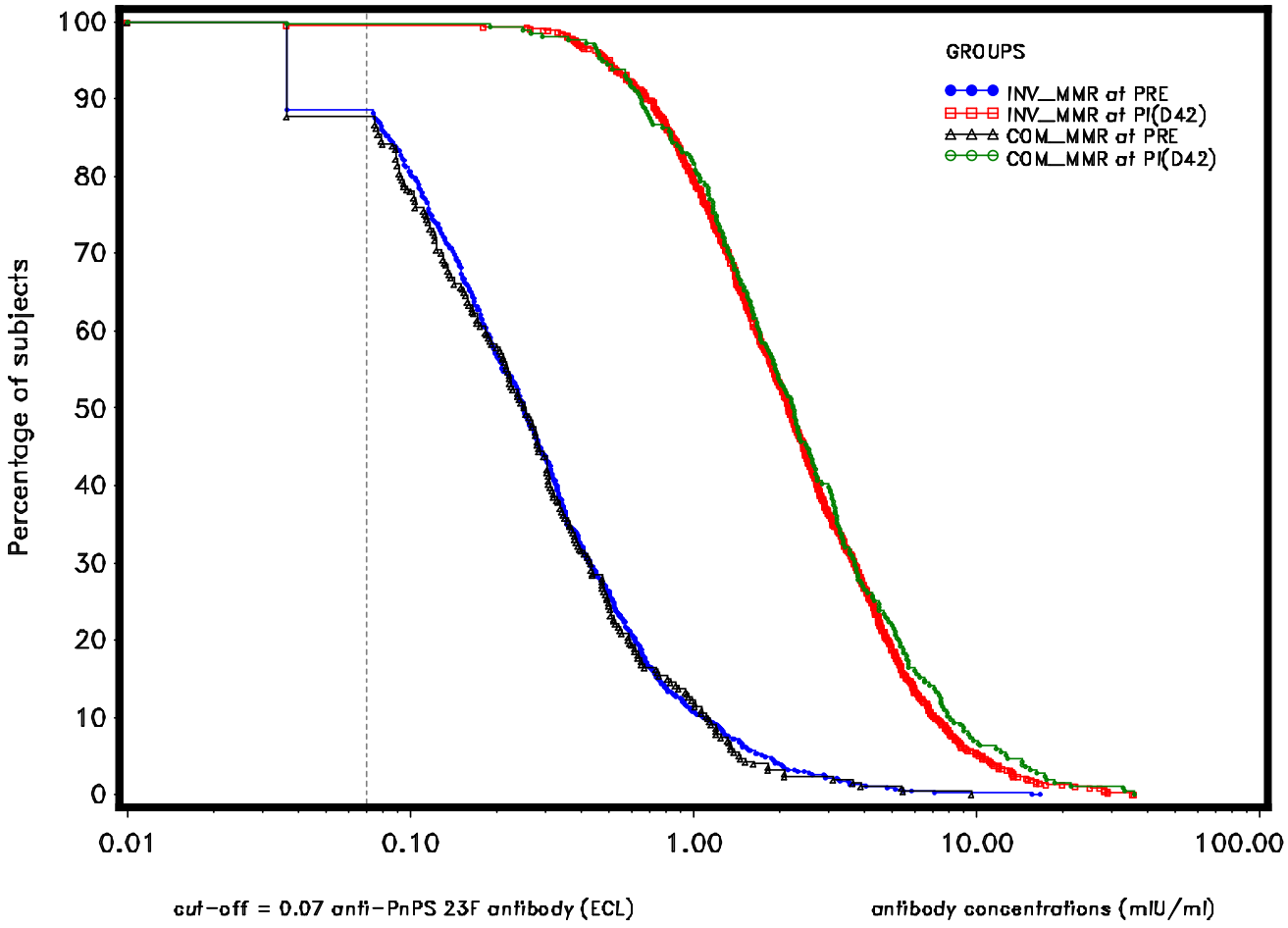
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.35 Reverse cumulative distribution curve of Anti-19F antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Figure 7.36 Reverse cumulative distribution curve of Anti-23F antibody concentrations prior to vaccination and at Day 42 - pooled INV_MMR groups (ATP cohort for immunogenicity, PCV subset)



INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

Table 8.1 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Estonia)

INV_MMR_1 HAVRIX N = 124		INV_MMR_1 MEMURU N = 124		INV_MMR_1 VARIVAX VACCINE N = 124		INV_MMR_2 HAVRIX N = 125		INV_MMR_2 MEMURU N = 125		INV_MMR_2 VARIVAX VACCINE N = 125		INV_MMR_3 HAVRIX N = 125		INV_MMR_3 MEMURU N = 125		INV_MMR_3 VARIVAX VACCINE N = 125		INV_MMR HAVRIX N = 374		INV_MMR MEMURU N = 374		INV_MMR VARIVAX VACCINE N = 374		COM_MMR HAVRIX N = 127		COM_MMR MMR II VACCINE N = 127		COM_MMR VARIVAX VACCINE N = 127	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
124	100	124	100	124	100	125	100	125	100	125	100	125	100	125	100	125	100	374	100	374	100	374	100	127	100	127	100	127	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.2 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Spain)

INV_MMR_1 HAVRIX N = 61		INV_MMR_1 MEMURU N = 61		INV_MMR_1 VARIVAX VACCINE N = 61		INV_MMR_2 HAVRIX N = 62		INV_MMR_2 MEMURU N = 62		INV_MMR_2 VARIVAX VACCINE N = 62		INV_MMR_3 HAVRIX N = 64		INV_MMR_3 MEMURU N = 64		INV_MMR_3 VARIVAX VACCINE N = 64		INV_MMR HAVRIX N = 187		INV_MMR MEMURU N = 187		INV_MMR VARIVAX VACCINE N = 187		COM_MMR HAVRIX N = 69		COM_MMR MMR II VACCINE N = 69		COM_MMR VARIVAX VACCINE N = 69	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
61	100	61	100	61	100	62	100	62	100	62	100	64	100	64	100	64	100	187	100	187	100	187	100	69	100	69	100	69	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.3 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Finland)

INV_MMR_1 HAVRIX N = 338		INV_MMR_1 MEMURU N = 338		INV_MMR_1 VARIVAX VACCINE N = 338		INV_MMR_2 HAVRIX N = 335		INV_MMR_2 MEMURU N = 335		INV_MMR_2 VARIVAX VACCINE N = 335		INV_MMR_3 HAVRIX N = 337		INV_MMR_3 MEMURU N = 337		INV_MMR_3 VARIVAX VACCINE N = 337		INV_MMR HAVRIX N = 1010		INV_MMR MEMURU N = 1010		INV_MMR VARIVAX VACCINE N = 1010		COM_MMR HAVRIX N = 340		COM_MMR MMR II VACCINE N = 340		COM_MMR VARIVAX VACCINE N = 340	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
338	100	338	100	338	100	335	100	335	100	335	100	337	100	337	100	337	100	1010	100	1010	100	1010	100	340	100	340	100	340	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.4 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, Mexico)

INV_MMR_1 HAVRIX N = 98		INV_MMR_1 MEMURU N = 98		INV_MMR_1 VARIVAX VACCINE N = 98		INV_MMR_2 HAVRIX N = 98		INV_MMR_2 MEMURU N = 98		INV_MMR_2 VARIVAX VACCINE N = 98		INV_MMR_3 HAVRIX N = 99		INV_MMR_3 MEMURU N = 99		INV_MMR_3 VARIVAX VACCINE N = 99		INV_MMR HAVRIX N = 295		INV_MMR MEMURU N = 295		INV_MMR VARIVAX VACCINE N = 295		COM_MMR HAVRIX N = 99		COM_MMR MMR II VACCINE N = 99		COM_MMR VARIVAX VACCINE N = 99	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
98	100	98	100	98	100	98	100	98	100	98	100	99	100	99	100	99	100	295	100	295	100	295	100	99	100	99	100	99	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.5 Number and percentage of subjects who received the study vaccine dose by vaccine (Total cohort, United States)

	INV_MMR_1 HAVRIX N = 618		INV_MMR_1 MEMURU N = 618		INV_MMR_1 PREVENAR 13 N = 618		INV_MMR_1 VARIVAX VACCINE N = 618		INV_MMR_2 HAVRIX N = 614		INV_MMR_2 MEMURU N = 614		INV_MMR_2 PREVENAR 13 N = 614		INV_MMR_2 VARIVAX VACCINE N = 614		INV_MMR_3 HAVRIX N = 621		INV_MMR_3 MEMURU N = 621		INV_MMR_3 PREVENAR 13 N = 621		INV_MMR_3 VARIVAX VACCINE N = 621		INV_MMR HAVRIX N = 1853		INV_MMR MEMURU N = 1853		INV_MMR PREVENAR 13 N = 1853	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	1	0.2	0	0.0	0	0.0	0	0.0	2	0.3	2	0.3	2	0.3	2	0.3	5	0.8	3	0.5	4	0.6	4	0.6	8	0.4	5	0.3	6	0.3
1	617	99.8	618	100	618	100	618	100	612	99.7	612	99.7	612	99.7	612	99.7	616	99.2	618	99.5	617	99.4	617	99.4	1845	99.6	1848	99.7	1847	99.7

	INV_MMR VARIVAX VACCINE N = 1853		COM_MMR HAVRIX N = 656		COM_MMR MMR II VACCINE N = 656		COM_MMR PREVENAR 13 N = 656		COM_MMR VARIVAX VACCINE N = 656	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
0	6	0.3	2	0.3	2	0.3	2	0.3	2	0.3
1	1847	99.7	654	99.7	654	99.7	654	99.7	654	99.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.6 Number and percentage of subjects who received the study vaccine dose (Total vaccinated cohort, by gender)

INV_MMR				COM_MMR			
F N = 1816		M N = 1898		F N = 618		M N = 671	
n	%	n	%	n	%	n	%
1816	100	1898	100	618	100	671	100

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.7 Number and percentage of subjects who received the study vaccine dose (Total vaccinated cohort, by geographic ancestry)

INV_MMR						COM_MMR					
WH N = 2814		OT N = 364		AF N = 169		WH N = 970		OT N = 124		AF N = 70	
n	%	n	%	n	%	n	%	n	%	n	%
2814	100	364	100	169	100	970	100	124	100	70	100

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

Table 8.8 Compliance in returning symptom information (Total vaccinated cohort, Estonia)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	124	0	123	99.2	123	99.2
INV_MMR_2	125	0	125	100	125	100
INV_MMR_3	125	0	125	100	125	100
INV_MMR	374	0	373	99.7	373	99.7
COM_MMR	127	0	127	100	127	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.9 Compliance in returning symptom information (Total vaccinated cohort, Spain)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	61	0	61	100	61	100
INV_MMR_2	62	0	62	100	62	100
INV_MMR_3	64	0	63	98.4	63	98.4
INV_MMR	187	0	186	99.5	186	99.5
COM_MMR	69	0	68	98.6	68	98.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.10 Compliance in returning symptom information (Total vaccinated cohort, Finland)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	338	1	336	99.4	336	99.4
INV_MMR_2	335	2	332	99.1	332	99.1
INV_MMR_3	337	1	337	100	337	100
INV_MMR	1010	4	1005	99.5	1005	99.5
COM_MMR	340	0	340	100	340	100

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.11 Compliance in returning symptom information (Total vaccinated cohort, Mexico)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	98	0	93	94.9	93	94.9
INV_MMR_2	98	0	97	99.0	97	99.0
INV_MMR_3	99	0	98	99.0	98	99.0
INV_MMR	295	0	288	97.6	288	97.6
COM_MMR	99	0	96	97.0	96	97.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.12 Compliance in returning symptom information (Total vaccinated cohort, United States)

Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR_1	618	4	577	93.4	573	92.7
INV_MMR_2	612	3	560	91.5	559	91.3
INV_MMR_3	618	5	577	93.4	571	92.4
INV_MMR	1848	12	1714	92.7	1703	92.2
COM_MMR	654	5	612	93.6	611	93.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.13 Compliance in returning symptom information (Total vaccinated cohort, by gender)

Group	Sub-group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR	F	1816	8	1734	95.5	1729	95.2
	M	1898	8	1832	96.5	1826	96.2
COM_MMR	F	618	2	598	96.8	597	96.6
	M	671	3	645	96.1	645	96.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.14 Compliance in returning symptom information (Total vaccinated cohort, by geographic ancestry)

Group	Sub-group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
INV_MMR	WH	2814	13	2720	96.7	2714	96.4
	OT	364	3	352	96.7	351	96.4
	AF	169	0	151	89.3	148	87.6
COM_MMR	WH	970	3	947	97.6	945	97.4
	OT	124	1	119	96.0	119	96.0
	AF	70	1	64	91.4	65	92.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
SS = Symptom screens/sheets used for the collection of local and general solicited AEs
Compliance % = (number of doses with symptom screen/sheet return / number of administered doses) X 100

Table 8.15 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR_1	124	112	90.3	83.7	94.9	124	106	85.5	78.0	91.2	124	64	51.6	42.5	60.7
INV_MMR_2	125	106	84.8	77.3	90.6	125	102	81.6	73.7	88.0	125	54	43.2	34.4	52.4
INV_MMR_3	125	112	89.6	82.9	94.3	125	105	84.0	76.4	89.9	125	51	40.8	32.1	49.9
INV_MMR	374	330	88.2	84.5	91.3	374	313	83.7	79.5	87.3	374	169	45.2	40.1	50.4
COM_MMR	127	111	87.4	80.3	92.6	127	106	83.5	75.8	89.5	127	55	43.3	34.5	52.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.16 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR_1	61	51	83.6	71.9	91.8	61	50	82.0	70.0	90.6	61	12	19.7	10.6	31.8
INV_MMR_2	62	56	90.3	80.1	96.4	62	55	88.7	78.1	95.3	62	14	22.6	12.9	35.0
INV_MMR_3	64	56	87.5	76.8	94.4	64	55	85.9	75.0	93.4	64	21	32.8	21.6	45.7
INV_MMR	187	163	87.2	81.5	91.6	187	160	85.6	79.7	90.3	187	47	25.1	19.1	32.0
COM_MMR	69	63	91.3	82.0	96.7	69	62	89.9	80.2	95.8	69	22	31.9	21.2	44.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.17 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR_1	338	322	95.3	92.4	97.3	338	318	94.1	91.0	96.3	338	144	42.6	37.3	48.1
INV_MMR_2	335	315	94.0	90.9	96.3	335	312	93.1	89.9	95.6	335	152	45.4	40.0	50.9
INV_MMR_3	337	323	95.8	93.1	97.7	337	318	94.4	91.3	96.6	337	149	44.2	38.8	49.7
INV_MMR	1010	960	95.0	93.5	96.3	1010	948	93.9	92.2	95.3	1010	445	44.1	41.0	47.2
COM_MMR	340	327	96.2	93.6	97.9	340	316	92.9	89.7	95.4	340	152	44.7	39.3	50.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.18 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
INV_MMR_1	98	89	90.8	83.3	95.7	98	86	87.8	79.6	93.5	98	37	37.8	28.2	48.1
INV_MMR_2	98	85	86.7	78.4	92.7	98	82	83.7	74.8	90.4	98	29	29.6	20.8	39.7
INV_MMR_3	99	88	88.9	81.0	94.3	99	83	83.8	75.1	90.5	99	38	38.4	28.8	48.7
INV_MMR	295	262	88.8	84.6	92.2	295	251	85.1	80.5	88.9	295	104	35.3	29.8	41.0
COM_MMR	99	81	81.8	72.8	88.9	99	80	80.8	71.7	88.0	99	35	35.4	26.0	45.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.19 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

	Any symptom					General symptoms					Local symptoms				
				95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR_1	618	516	83.5	80.3	86.3	618	500	80.9	77.6	83.9	618	256	41.4	37.5	45.4
INV_MMR_2	612	492	80.4	77.0	83.5	612	479	78.3	74.8	81.5	612	238	38.9	35.0	42.9
INV_MMR_3	618	511	82.7	79.5	85.6	618	497	80.4	77.1	83.5	618	234	37.9	34.0	41.8
INV_MMR	1848	1519	82.2	80.4	83.9	1848	1476	79.9	78.0	81.7	1848	728	39.4	37.2	41.7
COM_MMR	654	556	85.0	82.0	87.7	654	546	83.5	80.4	86.3	654	276	42.2	38.4	46.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.20 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		Any symptom					General symptoms					Local symptoms				
					95% CI					95% CI					95% CI	
Group	Sub-group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR	F	1816	1572	86.6	84.9	88.1	1816	1533	84.4	82.7	86.1	1816	736	40.5	38.3	42.8
	M	1898	1662	87.6	86.0	89.0	1898	1615	85.1	83.4	86.7	1898	757	39.9	37.7	42.1
COM_MMR	F	618	535	86.6	83.6	89.2	618	514	83.2	80.0	86.0	618	257	41.6	37.7	45.6
	M	671	603	89.9	87.3	92.0	671	596	88.8	86.2	91.1	671	283	42.2	38.4	46.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.21 Incidence and nature of symptoms (solicited and unsolicited) reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		Any symptom					General symptoms					Local symptoms				
					95% CI					95% CI					95% CI	
Group	Sub-group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
INV_MMR	WH	2814	2489	88.5	87.2	89.6	2814	2431	86.4	85.1	87.6	2814	1194	42.4	40.6	44.3
	OT	364	321	88.2	84.4	91.3	364	310	85.2	81.1	88.7	364	130	35.7	30.8	40.9
	AF	169	126	74.6	67.3	80.9	169	120	71.0	63.5	77.7	169	47	27.8	21.2	35.2
COM_MMR	WH	970	878	90.5	88.5	92.3	970	856	88.2	86.1	90.2	970	430	44.3	41.2	47.5
	OT	124	104	83.9	76.2	89.9	124	103	83.1	75.3	89.2	124	46	37.1	28.6	46.2
	AF	70	55	78.6	67.1	87.5	70	54	77.1	65.6	86.3	70	24	34.3	23.3	46.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.22 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	123	34	27.6	20.0	36.4	125	32	25.6	18.2	34.2	125	20	16.0	10.1	23.6	373	86	23.1	18.9	27.7	127	32	25.2	17.9	33.7
	Grade 2 or 3	123	6	4.9	1.8	10.3	125	7	5.6	2.3	11.2	125	3	2.4	0.5	6.9	373	16	4.3	2.5	6.9	127	7	5.5	2.2	11.0
	Grade 3	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
Redness (mm)	All	123	45	36.6	28.1	45.7	125	35	28.0	20.3	36.7	125	35	28.0	20.3	36.7	373	115	30.8	26.2	35.8	127	35	27.6	20.0	36.2
	>5	123	9	7.3	3.4	13.4	125	7	5.6	2.3	11.2	125	6	4.8	1.8	10.2	373	22	5.9	3.7	8.8	127	6	4.7	1.8	10.0
	>20	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	1	0.8	0.0	4.3
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
Swelling (mm)	All	123	8	6.5	2.8	12.4	125	11	8.8	4.5	15.2	125	11	8.8	4.5	15.2	373	30	8.0	5.5	11.3	127	9	7.1	3.3	13.0
	>5	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	1	0.8	0.0	4.3
	>20	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.23 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	61	7	11.5	4.7	22.2	62	5	8.1	2.7	17.8	63	10	15.9	7.9	27.3	186	22	11.8	7.6	17.4	68	17	25.0	15.3	37.0
	Grade 2 or 3	61	2	3.3	0.4	11.3	62	1	1.6	0.0	8.7	63	2	3.2	0.4	11.0	186	5	2.7	0.9	6.2	68	2	2.9	0.4	10.2
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
Redness (mm)	All	61	9	14.8	7.0	26.2	62	10	16.1	8.0	27.7	63	15	23.8	14.0	36.2	186	34	18.3	13.0	24.6	68	17	25.0	15.3	37.0
	>5	61	0	0.0	0.0	5.9	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5	186	3	1.6	0.3	4.6	68	1	1.5	0.0	7.9
	>20	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
Swelling (mm)	All	61	2	3.3	0.4	11.3	62	4	6.5	1.8	15.7	63	5	7.9	2.6	17.6	186	11	5.9	3.0	10.3	68	9	13.2	6.2	23.6
	>5	61	0	0.0	0.0	5.9	62	2	3.2	0.4	11.2	63	0	0.0	0.0	5.7	186	2	1.1	0.1	3.8	68	0	0.0	0.0	5.3
	>20	61	0	0.0	0.0	5.9	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.24 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	336	73	21.7	17.4	26.5	332	82	24.7	20.2	29.7	337	55	16.3	12.5	20.7	1005	210	20.9	18.4	23.5	340	79	23.2	18.8	28.1
	Grade 2 or 3	336	17	5.1	3.0	8.0	332	9	2.7	1.2	5.1	337	12	3.6	1.9	6.1	1005	38	3.8	2.7	5.2	340	22	6.5	4.1	9.6
	Grade 3	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	1	0.3	0.0	1.6
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
Redness (mm)	All	336	83	24.7	20.2	29.7	332	84	25.3	20.7	30.3	337	94	27.9	23.2	33.0	1005	261	26.0	23.3	28.8	340	88	25.9	21.3	30.9
	>5	336	14	4.2	2.3	6.9	332	19	5.7	3.5	8.8	337	18	5.3	3.2	8.3	1005	51	5.1	3.8	6.6	340	13	3.8	2.1	6.4
	>20	336	1	0.3	0.0	1.6	332	1	0.3	0.0	1.7	337	4	1.2	0.3	3.0	1005	6	0.6	0.2	1.3	340	3	0.9	0.2	2.6
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
Swelling (mm)	All	336	24	7.1	4.6	10.4	332	28	8.4	5.7	12.0	337	28	8.3	5.6	11.8	1005	80	8.0	6.4	9.8	340	29	8.5	5.8	12.0
	>5	336	1	0.3	0.0	1.6	332	8	2.4	1.0	4.7	337	6	1.8	0.7	3.8	1005	15	1.5	0.8	2.4	340	9	2.6	1.2	5.0
	>20	336	0	0.0	0.0	1.1	332	2	0.6	0.1	2.2	337	3	0.9	0.2	2.6	1005	5	0.5	0.2	1.2	340	4	1.2	0.3	3.0
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.25 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	93	27	29.0	20.1	39.4	97	21	21.6	13.9	31.2	98	19	19.4	12.1	28.6	288	67	23.3	18.5	28.6	96	18	18.8	11.5	28.0
	Grade 2 or 3	93	6	6.5	2.4	13.5	97	5	5.2	1.7	11.6	98	5	5.1	1.7	11.5	288	16	5.6	3.2	8.9	96	3	3.1	0.6	8.9
	Grade 3	93	2	2.2	0.3	7.6	97	1	1.0	0.0	5.6	98	3	3.1	0.6	8.7	288	6	2.1	0.8	4.5	96	1	1.0	0.0	5.7
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	1	1.0	0.0	5.7
Redness (mm)	All	93	18	19.4	11.9	28.9	97	19	19.6	12.2	28.9	98	25	25.5	17.2	35.3	288	62	21.5	16.9	26.7	96	22	22.9	15.0	32.6
	>5	93	2	2.2	0.3	7.6	97	3	3.1	0.6	8.8	98	0	0.0	0.0	3.7	288	5	1.7	0.6	4.0	96	2	2.1	0.3	7.3
	>20	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
Swelling (mm)	All	93	11	11.8	6.1	20.2	97	5	5.2	1.7	11.6	98	9	9.2	4.3	16.7	288	25	8.7	5.7	12.5	96	16	16.7	9.8	25.6
	>5	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	3	3.1	0.6	8.9
	>20	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.26 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	573	190	33.2	29.3	37.2	559	175	31.3	27.5	35.3	571	169	29.6	25.9	33.5	1703	534	31.4	29.2	33.6	611	203	33.2	29.5	37.1
	Grade 2 or 3	573	45	7.9	5.8	10.4	559	49	8.8	6.6	11.4	571	51	8.9	6.7	11.6	1703	145	8.5	7.2	9.9	611	55	9.0	6.9	11.6
	Grade 3	573	4	0.7	0.2	1.8	559	7	1.3	0.5	2.6	571	6	1.1	0.4	2.3	1703	17	1.0	0.6	1.6	611	10	1.6	0.8	3.0
	Medical advice	573	1	0.2	0.0	1.0	559	0	0.0	0.0	0.7	571	1	0.2	0.0	1.0	1703	2	0.1	0.0	0.4	611	1	0.2	0.0	0.9
Redness (mm)	All	573	141	24.6	21.1	28.3	559	125	22.4	19.0	26.0	571	132	23.1	19.7	26.8	1703	398	23.4	21.4	25.5	611	151	24.7	21.3	28.3
	>5	573	21	3.7	2.3	5.5	559	14	2.5	1.4	4.2	571	24	4.2	2.7	6.2	1703	59	3.5	2.6	4.4	611	19	3.1	1.9	4.8
	>20	573	5	0.9	0.3	2.0	559	1	0.2	0.0	1.0	571	2	0.4	0.0	1.3	1703	8	0.5	0.2	0.9	611	3	0.5	0.1	1.4
	Medical advice	573	2	0.3	0.0	1.3	559	1	0.2	0.0	1.0	571	0	0.0	0.0	0.6	1703	3	0.2	0.0	0.5	611	0	0.0	0.0	0.6
Swelling (mm)	All	573	71	12.4	9.8	15.4	559	51	9.1	6.9	11.8	571	50	8.8	6.6	11.4	1703	172	10.1	8.7	11.6	611	70	11.5	9.0	14.3
	>5	573	14	2.4	1.3	4.1	559	8	1.4	0.6	2.8	571	13	2.3	1.2	3.9	1703	35	2.1	1.4	2.8	611	12	2.0	1.0	3.4
	>20	573	1	0.2	0.0	1.0	559	1	0.2	0.0	1.0	571	3	0.5	0.1	1.5	1703	5	0.3	0.1	0.7	611	1	0.2	0.0	0.9
	Medical advice	573	1	0.2	0.0	1.0	559	0	0.0	0.0	0.7	571	0	0.0	0.0	0.6	1703	1	0.1	0.0	0.3	611	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.27 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	1729	455	26.3	24.3	28.5	1826	464	25.4	23.4	27.5	597	174	29.1	25.5	33.0	645	175	27.1	23.7	30.7
	Grade 2 or 3	1729	118	6.8	5.7	8.1	1826	102	5.6	4.6	6.7	597	49	8.2	6.1	10.7	645	40	6.2	4.5	8.3
	Grade 3	1729	9	0.5	0.2	1.0	1826	15	0.8	0.5	1.4	597	7	1.2	0.5	2.4	645	5	0.8	0.3	1.8
	Medical advice	1729	0	0.0	0.0	0.2	1826	2	0.1	0.0	0.4	597	1	0.2	0.0	0.9	645	1	0.2	0.0	0.9
Redness (mm)	All	1729	437	25.3	23.2	27.4	1826	433	23.7	21.8	25.7	597	147	24.6	21.2	28.3	645	166	25.7	22.4	29.3
	>5	1729	67	3.9	3.0	4.9	1826	73	4.0	3.1	5.0	597	20	3.4	2.1	5.1	645	21	3.3	2.0	4.9
	>20	1729	7	0.4	0.2	0.8	1826	7	0.4	0.2	0.8	597	4	0.7	0.2	1.7	645	4	0.6	0.2	1.6
	Medical advice	1729	1	0.1	0.0	0.3	1826	2	0.1	0.0	0.4	597	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
Swelling (mm)	All	1729	155	9.0	7.7	10.4	1826	163	8.9	7.7	10.3	597	62	10.4	8.1	13.1	645	71	11.0	8.7	13.7
	>5	1729	18	1.0	0.6	1.6	1826	36	2.0	1.4	2.7	597	13	2.2	1.2	3.7	645	12	1.9	1.0	3.2
	>20	1729	4	0.2	0.1	0.6	1826	8	0.4	0.2	0.9	597	5	0.8	0.3	1.9	645	0	0.0	0.0	0.6
	Medical advice	1729	0	0.0	0.0	0.2	1826	1	0.1	0.0	0.3	597	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.28 Incidence of solicited local symptoms reported during the 4-day(Days 0-3) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	2714	704	25.9	24.3	27.6	351	88	25.1	20.6	29.9	148	42	28.4	21.3	36.4	945	278	29.4	26.5	32.4	119	26	21.8	14.8	30.4
	Grade 2 or 3	2714	165	6.1	5.2	7.0	351	26	7.4	4.9	10.7	148	13	8.8	4.8	14.6	945	68	7.2	5.6	9.0	119	5	4.2	1.4	9.5
	Grade 3	2714	15	0.6	0.3	0.9	351	7	2.0	0.8	4.1	148	1	0.7	0.0	3.7	945	9	1.0	0.4	1.8	119	1	0.8	0.0	4.6
	Medical advice	2714	2	0.1	0.0	0.3	351	0	0.0	0.0	1.0	148	0	0.0	0.0	2.5	945	0	0.0	0.0	0.4	119	1	0.8	0.0	4.6
Redness (mm)	All	2714	713	26.3	24.6	28.0	351	75	21.4	17.2	26.0	148	17	11.5	6.8	17.8	945	253	26.8	24.0	29.7	119	27	22.7	15.5	31.3
	>5	2714	118	4.3	3.6	5.2	351	6	1.7	0.6	3.7	148	4	2.7	0.7	6.8	945	35	3.7	2.6	5.1	119	3	2.5	0.5	7.2
	>20	2714	12	0.4	0.2	0.8	351	0	0.0	0.0	1.0	148	1	0.7	0.0	3.7	945	8	0.8	0.4	1.7	119	0	0.0	0.0	3.1
	Medical advice	2714	3	0.1	0.0	0.3	351	0	0.0	0.0	1.0	148	0	0.0	0.0	2.5	945	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
Swelling (mm)	All	2714	249	9.2	8.1	10.3	351	32	9.1	6.3	12.6	148	13	8.8	4.8	14.6	945	94	9.9	8.1	12.0	119	20	16.8	10.6	24.8
	>5	2714	42	1.5	1.1	2.1	351	3	0.9	0.2	2.5	148	4	2.7	0.7	6.8	945	17	1.8	1.1	2.9	119	5	4.2	1.4	9.5
	>20	2714	10	0.4	0.2	0.7	351	0	0.0	0.0	1.0	148	2	1.4	0.2	4.8	945	4	0.4	0.1	1.1	119	1	0.8	0.0	4.6
	Medical advice	2714	1	0.0	0.0	0.2	351	0	0.0	0.0	1.0	148	0	0.0	0.0	2.5	945	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Pain	All	65	18	27.7	17.3	40.2
	Grade 2 or 3	65	9	13.8	6.5	24.7
	Grade 3	65	2	3.1	0.4	10.7
	Medical advice	65	1	1.5	0.0	8.3
Redness (mm)	All	65	9	13.8	6.5	24.7
	>5	65	0	0.0	0.0	5.5
	>20	65	0	0.0	0.0	5.5
	Medical advice	65	0	0.0	0.0	5.5
Swelling (mm)	All	65	5	7.7	2.5	17.0
	>5	65	0	0.0	0.0	5.5
	>20	65	0	0.0	0.0	5.5
	Medical advice	65	0	0.0	0.0	5.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.29 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	123	45	36.6	28.1	45.7	125	49	39.2	30.6	48.3	125	38	30.4	22.5	39.3	373	132	35.4	30.5	40.5	127	47	37.0	28.6	46.0
	Grade 2 or 3	123	9	7.3	3.4	13.4	125	12	9.6	5.1	16.2	125	7	5.6	2.3	11.2	373	28	7.5	5.0	10.7	127	11	8.7	4.4	15.0
	Grade 3	123	0	0.0	0.0	3.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	2	1.6	0.2	5.6
	Medical advice	123	0	0.0	0.0	3.0	125	3	2.4	0.5	6.9	125	3	2.4	0.5	6.9	373	6	1.6	0.6	3.5	127	3	2.4	0.5	6.7
Irritability / fussiness	All	123	69	56.1	46.9	65.0	125	72	57.6	48.4	66.4	125	67	53.6	44.5	62.6	373	208	55.8	50.6	60.9	127	82	64.6	55.6	72.8
	Grade 2 or 3	123	21	17.1	10.9	24.9	125	27	21.6	14.7	29.8	125	22	17.6	11.4	25.4	373	70	18.8	14.9	23.1	127	31	24.4	17.2	32.8
	Grade 3	123	1	0.8	0.0	4.4	125	4	3.2	0.9	8.0	125	4	3.2	0.9	8.0	373	9	2.4	1.1	4.5	127	5	3.9	1.3	8.9
	Medical advice	123	0	0.0	0.0	3.0	125	5	4.0	1.3	9.1	125	4	3.2	0.9	8.0	373	9	2.4	1.1	4.5	127	7	5.5	2.2	11.0
Loss of appetite	All	123	60	48.8	39.7	58.0	125	62	49.6	40.5	58.7	125	48	38.4	29.8	47.5	373	170	45.6	40.4	50.8	127	61	48.0	39.1	57.1
	Grade 2 or 3	123	13	10.6	5.7	17.4	125	19	15.2	9.4	22.7	125	8	6.4	2.8	12.2	373	40	10.7	7.8	14.3	127	10	7.9	3.8	14.0
	Grade 3	123	3	2.4	0.5	7.0	125	4	3.2	0.9	8.0	125	0	0.0	0.0	2.9	373	7	1.9	0.8	3.8	127	0	0.0	0.0	2.9
	Medical advice	123	1	0.8	0.0	4.4	125	3	2.4	0.5	6.9	125	4	3.2	0.9	8.0	373	8	2.1	0.9	4.2	127	4	3.1	0.9	7.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.30 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	61	15	24.6	14.5	37.3	62	15	24.2	14.2	36.7	63	17	27.0	16.6	39.7	186	47	25.3	19.2	32.1	68	18	26.5	16.5	38.6
	Grade 2 or 3	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	3	4.8	1.0	13.3	186	11	5.9	3.0	10.3	68	7	10.3	4.2	20.1
	Grade 3	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	2	2.9	0.4	10.2
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	2	2.9	0.4	10.2
Irritability / fussiness	All	61	33	54.1	40.8	66.9	62	18	29.0	18.2	41.9	63	23	36.5	24.7	49.6	186	74	39.8	32.7	47.2	68	35	51.5	39.0	63.8
	Grade 2 or 3	61	11	18.0	9.4	30.0	62	5	8.1	2.7	17.8	63	10	15.9	7.9	27.3	186	26	14.0	9.3	19.8	68	13	19.1	10.6	30.5
	Grade 3	61	2	3.3	0.4	11.3	62	0	0.0	0.0	5.8	63	2	3.2	0.4	11.0	186	4	2.2	0.6	5.4	68	4	5.9	1.6	14.4
	Medical advice	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	2	2.9	0.4	10.2
Loss of appetite	All	61	23	37.7	25.6	51.0	62	23	37.1	25.2	50.3	63	21	33.3	22.0	46.3	186	67	36.0	29.1	43.4	68	34	50.0	37.6	62.4
	Grade 2 or 3	61	11	18.0	9.4	30.0	62	3	4.8	1.0	13.5	63	8	12.7	5.6	23.5	186	22	11.8	7.6	17.4	68	10	14.7	7.3	25.4
	Grade 3	61	5	8.2	2.7	18.1	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5	186	8	4.3	1.9	8.3	68	3	4.4	0.9	12.4
	Medical advice	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	2	2.9	0.4	10.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.31 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	336	155	46.1	40.7	51.6	332	160	48.2	42.7	53.7	337	166	49.3	43.8	54.7	1005	481	47.9	44.7	51.0	340	163	47.9	42.5	53.4
	Grade 2 or 3	336	37	11.0	7.9	14.9	332	46	13.9	10.3	18.0	337	47	13.9	10.4	18.1	1005	130	12.9	10.9	15.2	340	35	10.3	7.3	14.0
	Grade 3	336	3	0.9	0.2	2.6	332	7	2.1	0.9	4.3	337	6	1.8	0.7	3.8	1005	16	1.6	0.9	2.6	340	3	0.9	0.2	2.6
	Medical advice	336	1	0.3	0.0	1.6	332	0	0.0	0.0	1.1	337	1	0.3	0.0	1.6	1005	2	0.2	0.0	0.7	340	1	0.3	0.0	1.6
Irritability / fussiness	All	336	249	74.1	69.1	78.7	332	248	74.7	69.7	79.3	337	250	74.2	69.2	78.8	1005	747	74.3	71.5	77.0	340	252	74.1	69.1	78.7
	Grade 2 or 3	336	115	34.2	29.2	39.6	332	116	34.9	29.8	40.3	337	123	36.5	31.3	41.9	1005	354	35.2	32.3	38.3	340	116	34.1	29.1	39.4
	Grade 3	336	13	3.9	2.1	6.5	332	20	6.0	3.7	9.2	337	11	3.3	1.6	5.8	1005	44	4.4	3.2	5.8	340	14	4.1	2.3	6.8
	Medical advice	336	9	2.7	1.2	5.0	332	5	1.5	0.5	3.5	337	4	1.2	0.3	3.0	1005	18	1.8	1.1	2.8	340	8	2.4	1.0	4.6
Loss of appetite	All	336	159	47.3	41.9	52.8	332	178	53.6	48.1	59.1	337	182	54.0	48.5	59.4	1005	519	51.6	48.5	54.8	340	158	46.5	41.1	51.9
	Grade 2 or 3	336	48	14.3	10.7	18.5	332	50	15.1	11.4	19.4	337	48	14.2	10.7	18.4	1005	146	14.5	12.4	16.9	340	41	12.1	8.8	16.0
	Grade 3	336	6	1.8	0.7	3.8	332	7	2.1	0.9	4.3	337	4	1.2	0.3	3.0	1005	17	1.7	1.0	2.7	340	2	0.6	0.1	2.1
	Medical advice	336	2	0.6	0.1	2.1	332	1	0.3	0.0	1.7	337	3	0.9	0.2	2.6	1005	6	0.6	0.2	1.3	340	2	0.6	0.1	2.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.32 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	93	37	39.8	29.8	50.5	97	39	40.2	30.4	50.7	98	37	37.8	28.2	48.1	288	113	39.2	33.6	45.1	96	37	38.5	28.8	49.0
	Grade 2 or 3	93	11	11.8	6.1	20.2	97	15	15.5	8.9	24.2	98	12	12.2	6.5	20.4	288	38	13.2	9.5	17.7	96	11	11.5	5.9	19.6
	Grade 3	93	3	3.2	0.7	9.1	97	7	7.2	3.0	14.3	98	1	1.0	0.0	5.6	288	11	3.8	1.9	6.7	96	0	0.0	0.0	3.8
	Medical advice	93	6	6.5	2.4	13.5	97	4	4.1	1.1	10.2	98	9	9.2	4.3	16.7	288	19	6.6	4.0	10.1	96	3	3.1	0.6	8.9
Irritability / fussiness	All	93	50	53.8	43.1	64.2	97	46	47.4	37.2	57.8	98	48	49.0	38.7	59.3	288	144	50.0	44.1	55.9	96	41	42.7	32.7	53.2
	Grade 2 or 3	93	18	19.4	11.9	28.9	97	20	20.6	13.1	30.0	98	16	16.3	9.6	25.2	288	54	18.8	14.4	23.7	96	14	14.6	8.2	23.3
	Grade 3	93	2	2.2	0.3	7.6	97	7	7.2	3.0	14.3	98	4	4.1	1.1	10.1	288	13	4.5	2.4	7.6	96	0	0.0	0.0	3.8
	Medical advice	93	7	7.5	3.1	14.9	97	7	7.2	3.0	14.3	98	12	12.2	6.5	20.4	288	26	9.0	6.0	12.9	96	6	6.3	2.3	13.1
Loss of appetite	All	93	53	57.0	46.3	67.2	97	48	49.5	39.2	59.8	98	47	48.0	37.8	58.3	288	148	51.4	45.5	57.3	96	39	40.6	30.7	51.1
	Grade 2 or 3	93	14	15.1	8.5	24.0	97	20	20.6	13.1	30.0	98	18	18.4	11.3	27.5	288	52	18.1	13.8	23.0	96	11	11.5	5.9	19.6
	Grade 3	93	2	2.2	0.3	7.6	97	6	6.2	2.3	13.0	98	6	6.1	2.3	12.9	288	14	4.9	2.7	8.0	96	4	4.2	1.1	10.3
	Medical advice	93	7	7.5	3.1	14.9	97	8	8.2	3.6	15.6	98	9	9.2	4.3	16.7	288	24	8.3	5.4	12.1	96	6	6.3	2.3	13.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.33 Incidence of solicited general symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	577	281	48.7	44.6	52.9	560	272	48.6	44.4	52.8	577	275	47.7	43.5	51.8	1714	828	48.3	45.9	50.7	612	321	52.5	48.4	56.5
	Grade 2 or 3	577	99	17.2	14.2	20.5	560	105	18.8	15.6	22.2	577	100	17.3	14.3	20.7	1714	304	17.7	16.0	19.6	612	111	18.1	15.2	21.4
	Grade 3	577	16	2.8	1.6	4.5	560	22	3.9	2.5	5.9	577	15	2.6	1.5	4.3	1714	53	3.1	2.3	4.0	612	15	2.5	1.4	4.0
	Medical advice	577	12	2.1	1.1	3.6	560	8	1.4	0.6	2.8	577	10	1.7	0.8	3.2	1714	30	1.8	1.2	2.5	612	8	1.3	0.6	2.6
Irritability / fussiness	All	577	363	62.9	58.8	66.9	560	345	61.6	57.4	65.7	577	377	65.3	61.3	69.2	1714	1085	63.3	61.0	65.6	612	409	66.8	62.9	70.6
	Grade 2 or 3	577	161	27.9	24.3	31.8	560	156	27.9	24.2	31.8	577	167	28.9	25.3	32.8	1714	484	28.2	26.1	30.4	612	197	32.2	28.5	36.1
	Grade 3	577	38	6.6	4.7	8.9	560	32	5.7	3.9	8.0	577	36	6.2	4.4	8.5	1714	106	6.2	5.1	7.4	612	35	5.7	4.0	7.9
	Medical advice	577	18	3.1	1.9	4.9	560	15	2.7	1.5	4.4	577	20	3.5	2.1	5.3	1714	53	3.1	2.3	4.0	612	19	3.1	1.9	4.8
Loss of appetite	All	577	251	43.5	39.4	47.7	560	225	40.2	36.1	44.4	577	228	39.5	35.5	43.6	1714	704	41.1	38.7	43.4	612	256	41.8	37.9	45.9
	Grade 2 or 3	577	78	13.5	10.8	16.6	560	76	13.6	10.8	16.7	577	64	11.1	8.6	13.9	1714	218	12.7	11.2	14.4	612	92	15.0	12.3	18.1
	Grade 3	577	8	1.4	0.6	2.7	560	10	1.8	0.9	3.3	577	8	1.4	0.6	2.7	1714	26	1.5	1.0	2.2	612	22	3.6	2.3	5.4
	Medical advice	577	16	2.8	1.6	4.5	560	10	1.8	0.9	3.3	577	16	2.8	1.6	4.5	1714	42	2.5	1.8	3.3	612	10	1.6	0.8	3.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.34 Incidence of solicited local symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	1734	756	43.6	41.2	46.0	1832	845	46.1	43.8	48.4	598	272	45.5	41.4	49.6	645	314	48.7	44.8	52.6
	Grade 2 or 3	1734	240	13.8	12.2	15.6	1832	271	14.8	13.2	16.5	598	78	13.0	10.4	16.0	645	97	15.0	12.4	18.0
	Grade 3	1734	48	2.8	2.0	3.7	1832	37	2.0	1.4	2.8	598	11	1.8	0.9	3.3	645	11	1.7	0.9	3.0
	Medical advice	1734	28	1.6	1.1	2.3	1832	29	1.6	1.1	2.3	598	5	0.8	0.3	1.9	645	12	1.9	1.0	3.2
Irritability / fussiness	All	1734	1100	63.4	61.1	65.7	1832	1158	63.2	61.0	65.4	598	381	63.7	59.7	67.6	645	438	67.9	64.2	71.5
	Grade 2 or 3	1734	448	25.8	23.8	28.0	1832	540	29.5	27.4	31.6	598	173	28.9	25.3	32.7	645	198	30.7	27.2	34.4
	Grade 3	1734	82	4.7	3.8	5.8	1832	94	5.1	4.2	6.2	598	26	4.3	2.9	6.3	645	32	5.0	3.4	6.9
	Medical advice	1734	51	2.9	2.2	3.8	1832	56	3.1	2.3	4.0	598	19	3.2	1.9	4.9	645	23	3.6	2.3	5.3
Loss of appetite	All	1734	782	45.1	42.7	47.5	1832	826	45.1	42.8	47.4	598	264	44.1	40.1	48.2	645	284	44.0	40.2	48.0
	Grade 2 or 3	1734	208	12.0	10.5	13.6	1832	270	14.7	13.1	16.4	598	75	12.5	10.0	15.5	645	89	13.8	11.2	16.7
	Grade 3	1734	30	1.7	1.2	2.5	1832	42	2.3	1.7	3.1	598	15	2.5	1.4	4.1	645	16	2.5	1.4	4.0
	Medical advice	1734	36	2.1	1.5	2.9	1832	46	2.5	1.8	3.3	598	10	1.7	0.8	3.1	645	14	2.2	1.2	3.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.35 Incidence of solicited local symptoms reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	2720	1272	46.8	44.9	48.7	352	137	38.9	33.8	44.2	151	61	40.4	32.5	48.7	947	462	48.8	45.6	52.0	119	49	41.2	32.2	50.6
	Grade 2 or 3	2720	389	14.3	13.0	15.7	352	48	13.6	10.2	17.7	151	25	16.6	11.0	23.5	947	134	14.1	12.0	16.5	119	14	11.8	6.6	19.0
	Grade 3	2720	57	2.1	1.6	2.7	352	12	3.4	1.8	5.9	151	6	4.0	1.5	8.4	947	17	1.8	1.0	2.9	119	2	1.7	0.2	5.9
	Medical advice	2720	31	1.1	0.8	1.6	352	20	5.7	3.5	8.6	151	1	0.7	0.0	3.6	947	13	1.4	0.7	2.3	119	2	1.7	0.2	5.9
Irritability / fussiness	All	2720	1807	66.4	64.6	68.2	352	183	52.0	46.6	57.3	151	69	45.7	37.6	54.0	947	663	70.0	67.0	72.9	119	56	47.1	37.8	56.4
	Grade 2 or 3	2720	806	29.6	27.9	31.4	352	65	18.5	14.6	22.9	151	36	23.8	17.3	31.4	947	306	32.3	29.3	35.4	119	21	17.6	11.3	25.7
	Grade 3	2720	132	4.9	4.1	5.7	352	15	4.3	2.4	6.9	151	6	4.0	1.5	8.4	947	48	5.1	3.8	6.7	119	2	1.7	0.2	5.9
	Medical advice	2720	69	2.5	2.0	3.2	352	28	8.0	5.4	11.3	151	2	1.3	0.2	4.7	947	32	3.4	2.3	4.7	119	6	5.0	1.9	10.7
Loss of appetite	All	2720	1250	46.0	44.1	47.9	352	169	48.0	42.7	53.4	151	48	31.8	24.5	39.9	947	432	45.6	42.4	48.9	119	48	40.3	31.4	49.7
	Grade 2 or 3	2720	360	13.2	12.0	14.6	352	57	16.2	12.5	20.5	151	21	13.9	8.8	20.5	947	123	13.0	10.9	15.3	119	14	11.8	6.6	19.0
	Grade 3	2720	51	1.9	1.4	2.5	352	14	4.0	2.2	6.6	151	4	2.6	0.7	6.6	947	20	2.1	1.3	3.2	119	6	5.0	1.9	10.7
	Medical advice	2720	48	1.8	1.3	2.3	352	25	7.1	4.6	10.3	151	2	1.3	0.2	4.7	947	15	1.6	0.9	2.6	119	6	5.0	1.9	10.7

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	64	28	43.8	31.4	56.7
	Grade 2 or 3	64	11	17.2	8.9	28.7
	Grade 3	64	1	1.6	0.0	8.4
	Medical advice	64	0	0.0	0.0	5.6
Irritability / fussiness	All	64	35	54.7	41.7	67.2
	Grade 2 or 3	64	15	23.4	13.8	35.7
	Grade 3	64	3	4.7	1.0	13.1
	Medical advice	64	1	1.6	0.0	8.4
Loss of appetite	All	64	22	34.4	22.9	47.3
	Grade 2 or 3	64	10	15.6	7.8	26.9
	Grade 3	64	0	0.0	0.0	5.6
	Medical advice	64	1	1.6	0.0	8.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.36 Primary temperature recording route (Total vaccinated cohort)

		INV_MMR_1 N = 1239		INV_MMR_2 N = 1232		INV_MMR_3 N = 1243		INV_MMR N = 3714		COM_MMR N = 1289		Total N = 5003	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	1105	93.2	1106	94.1	1114	93.1	3325	93.5	1161	93.7	4486	93.5
	Oral	4	0.3	6	0.5	10	0.8	20	0.6	10	0.8	30	0.6
	Rectal	29	2.4	30	2.6	26	2.2	85	2.4	17	1.4	102	2.1
	Tympanic	24	2.0	21	1.8	27	2.3	72	2.0	27	2.2	99	2.1
	Temporal	24	2.0	12	1.0	20	1.7	56	1.6	24	1.9	80	1.7
	Missing confirmed*	4	0.3	1	0.1	3	0.3	8	0.2	4	0.3	12	0.3
	Missing**	49	4.1	56	4.8	43	3.6	148	4.2	46	3.7	194	4.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.37 Primary temperature recording route (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124		INV_MMR_2 N = 125		INV_MMR_3 N = 125		INV_MMR N = 374		COM_MMR N = 127		Total N = 501	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	118	95.9	121	96.8	119	95.2	358	96.0	118	92.9	476	95.2
	Oral	0	0.0	1	0.8	1	0.8	2	0.5	3	2.4	5	1.0
	Rectal	3	2.4	1	0.8	2	1.6	6	1.6	0	0.0	6	1.2
	Tympanic	0	0.0	1	0.8	1	0.8	2	0.5	2	1.6	4	0.8
	Temporal	2	1.6	1	0.8	2	1.6	5	1.3	4	3.1	9	1.8
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	1	0.8	0	0.0	0	0.0	1	0.3	0	0.0	1	0.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.38 Primary temperature recording route (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61		INV_MMR_2 N = 62		INV_MMR_3 N = 64		INV_MMR N = 187		COM_MMR N = 69		Total N = 256	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	61	100	59	95.2	61	96.8	181	97.3	67	98.5	248	97.6
	Oral	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Rectal	0	0.0	3	4.8	0	0.0	3	1.6	0	0.0	3	1.2
	Tympanic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Temporal	0	0.0	0	0.0	2	3.2	2	1.1	1	1.5	3	1.2
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	0	0.0	0	0.0	1	1.6	1	0.5	1	1.5	2	0.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.39 Primary temperature recording route (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338		INV_MMR_2 N = 335		INV_MMR_3 N = 337		INV_MMR N = 1010		COM_MMR N = 340		Total N = 1350	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	300	89.3	299	90.1	293	86.9	892	88.8	310	91.2	1202	89.4
	Oral	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Rectal	20	6.0	22	6.6	17	5.0	59	5.9	14	4.1	73	5.4
	Tympanic	15	4.5	10	3.0	24	7.1	49	4.9	13	3.8	62	4.6
	Temporal	1	0.3	1	0.3	3	0.9	5	0.5	3	0.9	8	0.6
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	2	0.6	3	0.9	0	0.0	5	0.5	0	0.0	5	0.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.40 Primary temperature recording route (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98		INV_MMR_2 N = 98		INV_MMR_3 N = 99		INV_MMR N = 295		COM_MMR N = 99		Total N = 394	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	92	98.9	97	100	98	100	287	99.7	96	100	383	99.7
	Oral	1	1.1	0	0.0	0	0.0	1	0.3	0	0.0	1	0.3
	Rectal	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Tympanic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Temporal	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing confirmed*	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing**	5	5.4	1	1.0	1	1.0	7	2.4	3	3.1	10	2.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.41 Primary temperature recording route (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618		INV_MMR_2 N = 612		INV_MMR_3 N = 618		INV_MMR N = 1848		COM_MMR N = 654		Total N = 2502	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	534	93.2	530	94.8	543	94.6	1607	94.2	570	93.8	2177	94.1
	Oral	3	0.5	5	0.9	9	1.6	17	1.0	7	1.2	24	1.0
	Rectal	6	1.0	4	0.7	7	1.2	17	1.0	3	0.5	20	0.9
	Tympanic	9	1.6	10	1.8	2	0.3	21	1.2	12	2.0	33	1.4
	Temporal	21	3.7	10	1.8	13	2.3	44	2.6	16	2.6	60	2.6
	Missing confirmed*	4	0.7	1	0.2	3	0.5	8	0.5	4	0.7	12	0.5
	Missing**	41	7.2	52	9.3	41	7.1	134	7.9	42	6.9	176	7.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.42 Primary temperature recording route (Total vaccinated cohort, by gender)

		INV_MMR				COM_MMR				Total			
		F N = 1816		M N = 1898		F N = 618		M N = 671		F N = 2434		M N = 2569	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	1615	93.4	1710	93.5	553	93.1	608	94.3	2168	93.3	2318	93.7
	Oral	10	0.6	10	0.5	5	0.8	5	0.8	15	0.6	15	0.6
	Rectal	40	2.3	45	2.5	8	1.3	9	1.4	48	2.1	54	2.2
	Tympanic	40	2.3	32	1.7	19	3.2	8	1.2	59	2.5	40	1.6
	Temporal	24	1.4	32	1.7	9	1.5	15	2.3	33	1.4	47	1.9
	Missing confirmed*	5	0.3	3	0.2	4	0.7	0	0.0	9	0.4	3	0.1
	Missing**	82	4.7	66	3.6	20	3.4	26	4.0	102	4.4	92	3.7

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.43 Primary temperature recording route (Total vaccinated cohort, by geographic ancestry)

		INV_MMR						COM_MMR					
		WH N = 2814		OT N = 364		AF N = 169		WH N = 970		OT N = 124		AF N = 70	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	2522	92.9	343	97.7	145	96.0	882	93.3	115	96.6	61	96.8
	Oral	13	0.5	2	0.6	1	0.7	8	0.8	0	0.0	2	3.2
	Rectal	80	2.9	0	0.0	1	0.7	17	1.8	0	0.0	0	0.0
	Tympanic	62	2.3	3	0.9	0	0.0	20	2.1	3	2.5	0	0.0
	Temporal	38	1.4	3	0.9	4	2.6	18	1.9	1	0.8	0	0.0
	Missing confirmed*	5	0.2	1	0.3	0	0.0	2	0.2	0	0.0	1	1.6
	Missing**	94	3.5	12	3.4	18	11.9	23	2.4	5	4.2	6	9.5

		Total					
		WH N = 3784		OT N = 488		AF N = 239	
Characteristics	**Categories**	**n**	**%**	**n**	**%**	**n**	**%**
Route	Axillary	3404	93.0	458	97.4	206	96.3
	Oral	21	0.6	2	0.4	3	1.4
	Rectal	97	2.7	0	0.0	1	0.5
	Tympanic	82	2.2	6	1.3	0	0.0
	Temporal	56	1.5	4	0.9	4	1.9
	Missing confirmed*	7	0.2	1	0.2	1	0.5
	Missing**	117	3.2	17	3.6	24	11.2

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects with this primary temperature route
* Diary cards were returned for these subjects, but the primary temperature recording route was missing
** Diary cards were not returned for these subjects

Table 8.44 Incidence of fever reported during the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1190	404	33.9	31.3	36.7	1176	422	35.9	33.1	38.7	1200	418	34.8	32.1	37.6	3566	1244	34.9	33.3	36.5	1243	412	33.1	30.5	35.8
	≥38	1190	402	33.8	31.1	36.5	1176	422	35.9	33.1	38.7	1200	415	34.6	31.9	37.4	3566	1239	34.7	33.2	36.3	1243	411	33.1	30.5	35.8
	>38.5	1190	226	19.0	16.8	21.3	1176	242	20.6	18.3	23.0	1200	217	18.1	15.9	20.4	3566	685	19.2	17.9	20.5	1243	216	17.4	15.3	19.6
	>39.0	1190	108	9.1	7.5	10.9	1176	95	8.1	6.6	9.8	1200	95	7.9	6.5	9.6	3566	298	8.4	7.5	9.3	1243	95	7.6	6.2	9.3
	>39.5	1190	36	3.0	2.1	4.2	1176	37	3.1	2.2	4.3	1200	32	2.7	1.8	3.7	3566	105	2.9	2.4	3.6	1243	32	2.6	1.8	3.6
	>40.0	1190	4	0.3	0.1	0.9	1176	13	1.1	0.6	1.9	1200	11	0.9	0.5	1.6	3566	28	0.8	0.5	1.1	1243	8	0.6	0.3	1.3
	≥38 Related	1190	224	18.8	16.6	21.2	1176	225	19.1	16.9	21.5	1200	225	18.8	16.6	21.1	3566	674	18.9	17.6	20.2	1243	219	17.6	15.5	19.9
	>38.5 Related	1190	109	9.2	7.6	10.9	1176	114	9.7	8.1	11.5	1200	118	9.8	8.2	11.7	3566	341	9.6	8.6	10.6	1243	111	8.9	7.4	10.7
	>39.0 Related	1190	45	3.8	2.8	5.0	1176	37	3.1	2.2	4.3	1200	51	4.3	3.2	5.6	3566	133	3.7	3.1	4.4	1243	42	3.4	2.4	4.5
	>39.5 Related	1190	16	1.3	0.8	2.2	1176	13	1.1	0.6	1.9	1200	17	1.4	0.8	2.3	3566	46	1.3	0.9	1.7	1243	14	1.1	0.6	1.9
	>40.0 Related	1190	1	0.1	0.0	0.5	1176	5	0.4	0.1	1.0	1200	4	0.3	0.1	0.9	3566	10	0.3	0.1	0.5	1243	6	0.5	0.2	1.0
	Medical advice	1190	126	10.6	8.9	12.5	1176	120	10.2	8.5	12.1	1200	130	10.8	9.1	12.7	3566	376	10.5	9.6	11.6	1243	130	10.5	8.8	12.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.45 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	123	44	35.8	27.3	44.9	125	53	42.4	33.6	51.6	125	57	45.6	36.7	54.7	373	154	41.3	36.2	46.5	127	41	32.3	24.3	41.2
	≥38	123	44	35.8	27.3	44.9	125	53	42.4	33.6	51.6	125	57	45.6	36.7	54.7	373	154	41.3	36.2	46.5	127	41	32.3	24.3	41.2
	>38.5	123	23	18.7	12.2	26.7	125	27	21.6	14.7	29.8	125	29	23.2	16.1	31.6	373	79	21.2	17.1	25.7	127	19	15.0	9.3	22.4
	>39.0	123	7	5.7	2.3	11.4	125	16	12.8	7.5	20.0	125	10	8.0	3.9	14.2	373	33	8.8	6.2	12.2	127	4	3.1	0.9	7.9
	>39.5	123	2	1.6	0.2	5.8	125	7	5.6	2.3	11.2	125	4	3.2	0.9	8.0	373	13	3.5	1.9	5.9	127	1	0.8	0.0	4.3
	>40.0	123	0	0.0	0.0	3.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	≥38 Related	123	18	14.6	8.9	22.1	125	13	10.4	5.7	17.1	125	15	12.0	6.9	19.0	373	46	12.3	9.2	16.1	127	13	10.2	5.6	16.9
	>38.5 Related	123	11	8.9	4.5	15.4	125	8	6.4	2.8	12.2	125	8	6.4	2.8	12.2	373	27	7.2	4.8	10.4	127	5	3.9	1.3	8.9
	>39.0 Related	123	3	2.4	0.5	7.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	7	1.9	0.8	3.8	127	0	0.0	0.0	2.9
	>39.5 Related	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	>40.0 Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	11	8.9	4.5	15.4	125	12	9.6	5.1	16.2	125	13	10.4	5.7	17.1	373	36	9.7	6.9	13.1	127	13	10.2	5.6	16.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.46 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	61	26	42.6	30.0	55.9	62	27	43.5	31.0	56.7	63	34	54.0	40.9	66.6	186	87	46.8	39.4	54.2	68	30	44.1	32.1	56.7
	≥38	61	26	42.6	30.0	55.9	62	27	43.5	31.0	56.7	63	34	54.0	40.9	66.6	186	87	46.8	39.4	54.2	68	30	44.1	32.1	56.7
	>38.5	61	17	27.9	17.1	40.8	62	13	21.0	11.7	33.2	63	14	22.2	12.7	34.5	186	44	23.7	17.7	30.4	68	15	22.1	12.9	33.8
	>39.0	61	9	14.8	7.0	26.2	62	3	4.8	1.0	13.5	63	5	7.9	2.6	17.6	186	17	9.1	5.4	14.2	68	9	13.2	6.2	23.6
	>39.5	61	1	1.6	0.0	8.8	62	2	3.2	0.4	11.2	63	0	0.0	0.0	5.7	186	3	1.6	0.3	4.6	68	2	2.9	0.4	10.2
	>40.0	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	≥38 Related	61	8	13.1	5.8	24.2	62	11	17.7	9.2	29.5	63	10	15.9	7.9	27.3	186	29	15.6	10.7	21.6	68	14	20.6	11.7	32.1
	>38.5 Related	61	4	6.6	1.8	15.9	62	4	6.5	1.8	15.7	63	4	6.3	1.8	15.5	186	12	6.5	3.4	11.0	68	4	5.9	1.6	14.4
	>39.0 Related	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>39.5 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	>40.0 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	13	21.3	11.9	33.7	62	15	24.2	14.2	36.7	63	13	20.6	11.5	32.7	186	41	22.0	16.3	28.7	68	19	27.9	17.7	40.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.47 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	336	123	36.6	31.4	42.0	332	134	40.4	35.0	45.9	337	131	38.9	33.6	44.3	1005	388	38.6	35.6	41.7	340	109	32.1	27.1	37.3
	≥38	336	123	36.6	31.4	42.0	332	134	40.4	35.0	45.9	337	131	38.9	33.6	44.3	1005	388	38.6	35.6	41.7	340	109	32.1	27.1	37.3
	>38.5	336	60	17.9	13.9	22.4	332	74	22.3	17.9	27.2	337	65	19.3	15.2	23.9	1005	199	19.8	17.4	22.4	340	53	15.6	11.9	19.9
	>39.0	336	30	8.9	6.1	12.5	332	28	8.4	5.7	12.0	337	26	7.7	5.1	11.1	1005	84	8.4	6.7	10.2	340	23	6.8	4.3	10.0
	>39.5	336	12	3.6	1.9	6.2	332	7	2.1	0.9	4.3	337	5	1.5	0.5	3.4	1005	24	2.4	1.5	3.5	340	6	1.8	0.7	3.8
	>40.0	336	0	0.0	0.0	1.1	332	1	0.3	0.0	1.7	337	1	0.3	0.0	1.6	1005	2	0.2	0.0	0.7	340	2	0.6	0.1	2.1
	≥38 Related	336	83	24.7	20.2	29.7	332	93	28.0	23.2	33.2	337	92	27.3	22.6	32.4	1005	268	26.7	24.0	29.5	340	74	21.8	17.5	26.5
	>38.5 Related	336	34	10.1	7.1	13.9	332	42	12.7	9.3	16.7	337	43	12.8	9.4	16.8	1005	119	11.8	9.9	14.0	340	35	10.3	7.3	14.0
	>39.0 Related	336	16	4.8	2.7	7.6	332	16	4.8	2.8	7.7	337	18	5.3	3.2	8.3	1005	50	5.0	3.7	6.5	340	11	3.2	1.6	5.7
	>39.5 Related	336	5	1.5	0.5	3.4	332	4	1.2	0.3	3.1	337	3	0.9	0.2	2.6	1005	12	1.2	0.6	2.1	340	2	0.6	0.1	2.1
	>40.0 Related	336	0	0.0	0.0	1.1	332	1	0.3	0.0	1.7	337	0	0.0	0.0	1.1	1005	1	0.1	0.0	0.6	340	1	0.3	0.0	1.6
	Medical advice	336	24	7.1	4.6	10.4	332	24	7.2	4.7	10.6	337	20	5.9	3.7	9.0	1005	68	6.8	5.3	8.5	340	24	7.1	4.6	10.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.48 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	93	33	35.5	25.8	46.1	97	32	33.0	23.8	43.3	98	28	28.6	19.9	38.6	288	93	32.3	26.9	38.0	96	31	32.3	23.1	42.6
	≥38	93	33	35.5	25.8	46.1	97	32	33.0	23.8	43.3	98	28	28.6	19.9	38.6	288	93	32.3	26.9	38.0	96	31	32.3	23.1	42.6
	>38.5	93	15	16.1	9.3	25.2	97	19	19.6	12.2	28.9	98	14	14.3	8.0	22.8	288	48	16.7	12.6	21.5	96	9	9.4	4.4	17.1
	>39.0	93	4	4.3	1.2	10.6	97	4	4.1	1.1	10.2	98	6	6.1	2.3	12.9	288	14	4.9	2.7	8.0	96	3	3.1	0.6	8.9
	>39.5	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	3	3.1	0.6	8.7	288	4	1.4	0.4	3.5	96	2	2.1	0.3	7.3
	>40.0	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	≥38 Related	93	10	10.8	5.3	18.9	97	7	7.2	3.0	14.3	98	8	8.2	3.6	15.5	288	25	8.7	5.7	12.5	96	3	3.1	0.6	8.9
	>38.5 Related	93	4	4.3	1.2	10.6	97	2	2.1	0.3	7.3	98	5	5.1	1.7	11.5	288	11	3.8	1.9	6.7	96	1	1.0	0.0	5.7
	>39.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	2	2.0	0.2	7.2	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>39.5 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	>40.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	23	24.7	16.4	34.8	97	23	23.7	15.7	33.4	98	19	19.4	12.1	28.6	288	65	22.6	17.9	27.8	96	21	21.9	14.1	31.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.49 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	577	178	30.8	27.1	34.8	560	176	31.4	27.6	35.5	577	168	29.1	25.4	33.0	1714	522	30.5	28.3	32.7	612	201	32.8	29.1	36.7
	≥38	577	176	30.5	26.8	34.4	560	176	31.4	27.6	35.5	577	165	28.6	24.9	32.5	1714	517	30.2	28.0	32.4	612	200	32.7	29.0	36.6
	>38.5	577	111	19.2	16.1	22.7	560	109	19.5	16.3	23.0	577	95	16.5	13.5	19.7	1714	315	18.4	16.6	20.3	612	120	19.6	16.5	23.0
	>39.0	577	58	10.1	7.7	12.8	560	44	7.9	5.8	10.4	577	48	8.3	6.2	10.9	1714	150	8.8	7.5	10.2	612	56	9.2	7.0	11.7
	>39.5	577	21	3.6	2.3	5.5	560	20	3.6	2.2	5.5	577	20	3.5	2.1	5.3	1714	61	3.6	2.7	4.5	612	21	3.4	2.1	5.2
	>40.0	577	3	0.5	0.1	1.5	560	8	1.4	0.6	2.8	577	9	1.6	0.7	2.9	1714	20	1.2	0.7	1.8	612	6	1.0	0.4	2.1
	≥38 Related	577	105	18.2	15.1	21.6	560	101	18.0	14.9	21.5	577	100	17.3	14.3	20.7	1714	306	17.9	16.1	19.7	612	115	18.8	15.8	22.1
	>38.5 Related	577	56	9.7	7.4	12.4	560	58	10.4	8.0	13.2	577	58	10.1	7.7	12.8	1714	172	10.0	8.7	11.6	612	66	10.8	8.4	13.5
	>39.0 Related	577	25	4.3	2.8	6.3	560	18	3.2	1.9	5.0	577	29	5.0	3.4	7.1	1714	72	4.2	3.3	5.3	612	30	4.9	3.3	6.9
	>39.5 Related	577	9	1.6	0.7	2.9	560	8	1.4	0.6	2.8	577	12	2.1	1.1	3.6	1714	29	1.7	1.1	2.4	612	11	1.8	0.9	3.2
	>40.0 Related	577	1	0.2	0.0	1.0	560	4	0.7	0.2	1.8	577	4	0.7	0.2	1.8	1714	9	0.5	0.2	1.0	612	5	0.8	0.3	1.9
	Medical advice	577	55	9.5	7.3	12.2	560	46	8.2	6.1	10.8	577	65	11.3	8.8	14.1	1714	166	9.7	8.3	11.2	612	53	8.7	6.6	11.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.50 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1734	599	34.5	32.3	36.8	1832	645	35.2	33.0	37.4	598	201	33.6	29.8	37.6	645	211	32.7	29.1	36.5
	≥38	1734	597	34.4	32.2	36.7	1832	642	35.0	32.9	37.3	598	200	33.4	29.7	37.4	645	211	32.7	29.1	36.5
	>38.5	1734	340	19.6	17.8	21.6	1832	345	18.8	17.1	20.7	598	110	18.4	15.4	21.7	645	106	16.4	13.7	19.5
	>39.0	1734	133	7.7	6.5	9.0	1832	165	9.0	7.7	10.4	598	42	7.0	5.1	9.4	645	53	8.2	6.2	10.6
	>39.5	1734	46	2.7	1.9	3.5	1832	59	3.2	2.5	4.1	598	16	2.7	1.5	4.3	645	16	2.5	1.4	4.0
	>40.0	1734	15	0.9	0.5	1.4	1832	13	0.7	0.4	1.2	598	4	0.7	0.2	1.7	645	4	0.6	0.2	1.6
	≥38 Related	1734	337	19.4	17.6	21.4	1832	337	18.4	16.6	20.2	598	109	18.2	15.2	21.6	645	110	17.1	14.2	20.2
	>38.5 Related	1734	179	10.3	8.9	11.9	1832	162	8.8	7.6	10.2	598	59	9.9	7.6	12.5	645	52	8.1	6.1	10.4
	>39.0 Related	1734	58	3.3	2.5	4.3	1832	75	4.1	3.2	5.1	598	19	3.2	1.9	4.9	645	23	3.6	2.3	5.3
	>39.5 Related	1734	20	1.2	0.7	1.8	1832	26	1.4	0.9	2.1	598	7	1.2	0.5	2.4	645	7	1.1	0.4	2.2
	>40.0 Related	1734	6	0.3	0.1	0.8	1832	4	0.2	0.1	0.6	598	3	0.5	0.1	1.5	645	3	0.5	0.1	1.4
	Medical advice	1734	179	10.3	8.9	11.9	1832	197	10.8	9.4	12.3	598	58	9.7	7.4	12.4	645	72	11.2	8.8	13.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.51 Incidence of fever reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	2720	979	36.0	34.2	37.8	352	117	33.2	28.3	38.4	151	46	30.5	23.2	38.5	947	314	33.2	30.2	36.3	119	41	34.5	26.0	43.7
	≥38	2720	976	35.9	34.1	37.7	352	116	33.0	28.1	38.1	151	46	30.5	23.2	38.5	947	313	33.1	30.1	36.1	119	41	34.5	26.0	43.7
	>38.5	2720	530	19.5	18.0	21.0	352	61	17.3	13.5	21.7	151	27	17.9	12.1	24.9	947	170	18.0	15.6	20.5	119	16	13.4	7.9	20.9
	>39.0	2720	239	8.8	7.7	9.9	352	22	6.3	4.0	9.3	151	14	9.3	5.2	15.1	947	71	7.5	5.9	9.4	119	6	5.0	1.9	10.7
	>39.5	2720	83	3.1	2.4	3.8	352	7	2.0	0.8	4.1	151	4	2.6	0.7	6.6	947	24	2.5	1.6	3.7	119	2	1.7	0.2	5.9
	>40.0	2720	20	0.7	0.4	1.1	352	1	0.3	0.0	1.6	151	3	2.0	0.4	5.7	947	6	0.6	0.2	1.4	119	0	0.0	0.0	3.1
	≥38 Related	2720	537	19.7	18.3	21.3	352	38	10.8	7.8	14.5	151	24	15.9	10.5	22.7	947	173	18.3	15.9	20.9	119	11	9.2	4.7	15.9
	>38.5 Related	2720	259	9.5	8.4	10.7	352	19	5.4	3.3	8.3	151	15	9.9	5.7	15.9	947	87	9.2	7.4	11.2	119	5	4.2	1.4	9.5
	>39.0 Related	2720	103	3.8	3.1	4.6	352	7	2.0	0.8	4.1	151	8	5.3	2.3	10.2	947	31	3.3	2.2	4.6	119	1	0.8	0.0	4.6
	>39.5 Related	2720	34	1.3	0.9	1.7	352	3	0.9	0.2	2.5	151	3	2.0	0.4	5.7	947	11	1.2	0.6	2.1	119	0	0.0	0.0	3.1
	>40.0 Related	2720	5	0.2	0.1	0.4	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7	947	4	0.4	0.1	1.1	119	0	0.0	0.0	3.1
	Medical advice	2720	272	10.0	8.9	11.2	352	71	20.2	16.1	24.7	151	16	10.6	6.2	16.6	947	98	10.3	8.5	12.5	119	23	19.3	12.7	27.6

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	64	20	31.3	20.2	44.1
	≥38	64	20	31.3	20.2	44.1
	>38.5	64	12	18.8	10.1	30.5
	>39.0	64	8	12.5	5.6	23.2
	>39.5	64	2	3.1	0.4	10.8
	>40.0	64	0	0.0	0.0	5.6
	≥38 Related	64	12	18.8	10.1	30.5
	>38.5 Related	64	6	9.4	3.5	19.3
	>39.0 Related	64	2	3.1	0.4	10.8
	>39.5 Related	64	0	0.0	0.0	5.6
	>40.0 Related	64	0	0.0	0.0	5.6
	Medical advice	64	5	7.8	2.6	17.3

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.52 Incidence of fever reported during the 15-day (Days 0-14) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1190	326	27.4	24.9	30.0	1176	342	29.1	26.5	31.8	1200	339	28.3	25.7	30.9	3566	1007	28.2	26.8	29.7	1243	332	26.7	24.3	29.3
	≥38	1190	270	22.7	20.3	25.2	1176	289	24.6	22.1	27.1	1200	286	23.8	21.4	26.3	3566	845	23.7	22.3	25.1	1243	271	21.8	19.5	24.2
	>38.5	1190	133	11.2	9.4	13.1	1176	139	11.8	10.0	13.8	1200	138	11.5	9.7	13.4	3566	410	11.5	10.5	12.6	1243	128	10.3	8.7	12.1
	>39.0	1190	58	4.9	3.7	6.3	1176	53	4.5	3.4	5.9	1200	55	4.6	3.5	5.9	3566	166	4.7	4.0	5.4	1243	49	3.9	2.9	5.2
	>39.5	1190	19	1.6	1.0	2.5	1176	18	1.5	0.9	2.4	1200	19	1.6	1.0	2.5	3566	56	1.6	1.2	2.0	1243	18	1.4	0.9	2.3
	>40.0	1190	2	0.2	0.0	0.6	1176	6	0.5	0.2	1.1	1200	4	0.3	0.1	0.9	3566	12	0.3	0.2	0.6	1243	6	0.5	0.2	1.0
	≥38 Related	1190	202	17.0	14.9	19.2	1176	203	17.3	15.1	19.5	1200	200	16.7	14.6	18.9	3566	605	17.0	15.7	18.2	1243	194	15.6	13.6	17.7
	>38.5 Related	1190	94	7.9	6.4	9.6	1176	94	8.0	6.5	9.7	1200	103	8.6	7.1	10.3	3566	291	8.2	7.3	9.1	1243	93	7.5	6.1	9.1
	>39.0 Related	1190	38	3.2	2.3	4.4	1176	32	2.7	1.9	3.8	1200	43	3.6	2.6	4.8	3566	113	3.2	2.6	3.8	1243	32	2.6	1.8	3.6
	>39.5 Related	1190	13	1.1	0.6	1.9	1176	10	0.9	0.4	1.6	1200	16	1.3	0.8	2.2	3566	39	1.1	0.8	1.5	1243	12	1.0	0.5	1.7
	>40.0 Related	1190	1	0.1	0.0	0.5	1176	3	0.3	0.1	0.7	1200	4	0.3	0.1	0.9	3566	8	0.2	0.1	0.4	1243	5	0.4	0.1	0.9
	Medical advice	1190	60	5.0	3.9	6.4	1176	59	5.0	3.8	6.4	1200	72	6.0	4.7	7.5	3566	191	5.4	4.6	6.1	1243	68	5.5	4.3	6.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.53 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	123	35	28.5	20.7	37.3	125	42	33.6	25.4	42.6	125	46	36.8	28.4	45.9	373	123	33.0	28.2	38.0	127	32	25.2	17.9	33.7
	≥38	123	32	26.0	18.5	34.7	125	38	30.4	22.5	39.3	125	45	36.0	27.6	45.1	373	115	30.8	26.2	35.8	127	29	22.8	15.9	31.1
	>38.5	123	15	12.2	7.0	19.3	125	17	13.6	8.1	20.9	125	20	16.0	10.1	23.6	373	52	13.9	10.6	17.9	127	15	11.8	6.8	18.7
	>39.0	123	5	4.1	1.3	9.2	125	7	5.6	2.3	11.2	125	6	4.8	1.8	10.2	373	18	4.8	2.9	7.5	127	4	3.1	0.9	7.9
	>39.5	123	2	1.6	0.2	5.8	125	3	2.4	0.5	6.9	125	3	2.4	0.5	6.9	373	8	2.1	0.9	4.2	127	1	0.8	0.0	4.3
	>40.0	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	≥38 Related	123	18	14.6	8.9	22.1	125	13	10.4	5.7	17.1	125	15	12.0	6.9	19.0	373	46	12.3	9.2	16.1	127	13	10.2	5.6	16.9
	>38.5 Related	123	11	8.9	4.5	15.4	125	8	6.4	2.8	12.2	125	8	6.4	2.8	12.2	373	27	7.2	4.8	10.4	127	5	3.9	1.3	8.9
	>39.0 Related	123	3	2.4	0.5	7.0	125	3	2.4	0.5	6.9	125	1	0.8	0.0	4.4	373	7	1.9	0.8	3.8	127	0	0.0	0.0	2.9
	>39.5 Related	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	>40.0 Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	6	4.9	1.8	10.3	125	8	6.4	2.8	12.2	125	10	8.0	3.9	14.2	373	24	6.4	4.2	9.4	127	8	6.3	2.8	12.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.54 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	61	22	36.1	24.2	49.4	62	20	32.3	20.9	45.3	63	25	39.7	27.6	52.8	186	67	36.0	29.1	43.4	68	26	38.2	26.7	50.8
	≥38	61	19	31.1	19.9	44.3	62	20	32.3	20.9	45.3	63	20	31.7	20.6	44.7	186	59	31.7	25.1	38.9	68	25	36.8	25.4	49.3
	>38.5	61	10	16.4	8.2	28.1	62	9	14.5	6.9	25.8	63	6	9.5	3.6	19.6	186	25	13.4	8.9	19.2	68	10	14.7	7.3	25.4
	>39.0	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5	186	9	4.8	2.2	9.0	68	5	7.4	2.4	16.3
	>39.5	61	1	1.6	0.0	8.8	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>40.0	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	≥38 Related	61	8	13.1	5.8	24.2	62	10	16.1	8.0	27.7	63	10	15.9	7.9	27.3	186	28	15.1	10.2	21.0	68	13	19.1	10.6	30.5
	>38.5 Related	61	4	6.6	1.8	15.9	62	3	4.8	1.0	13.5	63	4	6.3	1.8	15.5	186	11	5.9	3.0	10.3	68	4	5.9	1.6	14.4
	>39.0 Related	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>39.5 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	>40.0 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	8	13.1	5.8	24.2	62	10	16.1	8.0	27.7	63	6	9.5	3.6	19.6	186	24	12.9	8.4	18.6	68	14	20.6	11.7	32.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.55 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	336	107	31.8	26.9	37.1	332	116	34.9	29.8	40.3	337	114	33.8	28.8	39.2	1005	337	33.5	30.6	36.5	340	97	28.5	23.8	33.6
	≥38	336	89	26.5	21.8	31.5	332	97	29.2	24.4	34.4	337	98	29.1	24.3	34.2	1005	284	28.3	25.5	31.2	340	81	23.8	19.4	28.7
	>38.5	336	38	11.3	8.1	15.2	332	47	14.2	10.6	18.4	337	47	13.9	10.4	18.1	1005	132	13.1	11.1	15.4	340	38	11.2	8.0	15.0
	>39.0	336	19	5.7	3.4	8.7	332	20	6.0	3.7	9.2	337	17	5.0	3.0	8.0	1005	56	5.6	4.2	7.2	340	15	4.4	2.5	7.2
	>39.5	336	6	1.8	0.7	3.8	332	6	1.8	0.7	3.9	337	3	0.9	0.2	2.6	1005	15	1.5	0.8	2.4	340	4	1.2	0.3	3.0
	>40.0	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	2	0.6	0.1	2.1
	≥38 Related	336	83	24.7	20.2	29.7	332	91	27.4	22.7	32.5	337	90	26.7	22.1	31.8	1005	264	26.3	23.6	29.1	340	73	21.5	17.2	26.2
	>38.5 Related	336	34	10.1	7.1	13.9	332	41	12.3	9.0	16.4	337	42	12.5	9.1	16.5	1005	117	11.6	9.7	13.8	340	34	10.0	7.0	13.7
	>39.0 Related	336	16	4.8	2.7	7.6	332	16	4.8	2.8	7.7	337	17	5.0	3.0	8.0	1005	49	4.9	3.6	6.4	340	11	3.2	1.6	5.7
	>39.5 Related	336	5	1.5	0.5	3.4	332	4	1.2	0.3	3.1	337	3	0.9	0.2	2.6	1005	12	1.2	0.6	2.1	340	2	0.6	0.1	2.1
	>40.0 Related	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	1	0.3	0.0	1.6
	Medical advice	336	9	2.7	1.2	5.0	332	5	1.5	0.5	3.5	337	12	3.6	1.9	6.1	1005	26	2.6	1.7	3.8	340	12	3.5	1.8	6.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.56 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	93	17	18.3	11.0	27.6	97	25	25.8	17.4	35.7	98	18	18.4	11.3	27.5	288	60	20.8	16.3	26.0	96	18	18.8	11.5	28.0
	≥38	93	16	17.2	10.2	26.4	97	22	22.7	14.8	32.3	98	18	18.4	11.3	27.5	288	56	19.4	15.0	24.5	96	17	17.7	10.7	26.8
	>38.5	93	4	4.3	1.2	10.6	97	10	10.3	5.1	18.1	98	8	8.2	3.6	15.5	288	22	7.6	4.8	11.3	96	2	2.1	0.3	7.3
	>39.0	93	0	0.0	0.0	3.9	97	4	4.1	1.1	10.2	98	3	3.1	0.6	8.7	288	7	2.4	1.0	4.9	96	0	0.0	0.0	3.8
	>39.5	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	1	1.0	0.0	5.6	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>40.0	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	≥38 Related	93	9	9.7	4.5	17.6	97	5	5.2	1.7	11.6	98	6	6.1	2.3	12.9	288	20	6.9	4.3	10.5	96	3	3.1	0.6	8.9
	>38.5 Related	93	3	3.2	0.7	9.1	97	0	0.0	0.0	3.7	98	4	4.1	1.1	10.1	288	7	2.4	1.0	4.9	96	1	1.0	0.0	5.7
	>39.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	2	2.0	0.2	7.2	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>39.5 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	>40.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	11	11.8	6.1	20.2	97	16	16.5	9.7	25.4	98	13	13.3	7.3	21.6	288	40	13.9	10.1	18.4	96	9	9.4	4.4	17.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.57 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	577	145	25.1	21.6	28.9	560	139	24.8	21.3	28.6	577	136	23.6	20.2	27.3	1714	420	24.5	22.5	26.6	612	159	26.0	22.5	29.6
	≥38	577	114	19.8	16.6	23.2	560	112	20.0	16.8	23.6	577	105	18.2	15.1	21.6	1714	331	19.3	17.5	21.3	612	119	19.4	16.4	22.8
	>38.5	577	66	11.4	9.0	14.3	560	56	10.0	7.6	12.8	577	57	9.9	7.6	12.6	1714	179	10.4	9.0	12.0	612	63	10.3	8.0	13.0
	>39.0	577	29	5.0	3.4	7.1	560	19	3.4	2.1	5.2	577	28	4.9	3.2	6.9	1714	76	4.4	3.5	5.5	612	25	4.1	2.7	6.0
	>39.5	577	10	1.7	0.8	3.2	560	7	1.3	0.5	2.6	577	12	2.1	1.1	3.6	1714	29	1.7	1.1	2.4	612	12	2.0	1.0	3.4
	>40.0	577	1	0.2	0.0	1.0	560	4	0.7	0.2	1.8	577	4	0.7	0.2	1.8	1714	9	0.5	0.2	1.0	612	4	0.7	0.2	1.7
	≥38 Related	577	84	14.6	11.8	17.7	560	84	15.0	12.1	18.2	577	79	13.7	11.0	16.8	1714	247	14.4	12.8	16.2	612	92	15.0	12.3	18.1
	>38.5 Related	577	42	7.3	5.3	9.7	560	42	7.5	5.5	10.0	577	45	7.8	5.7	10.3	1714	129	7.5	6.3	8.9	612	49	8.0	6.0	10.4
	>39.0 Related	577	18	3.1	1.9	4.9	560	13	2.3	1.2	3.9	577	22	3.8	2.4	5.7	1714	53	3.1	2.3	4.0	612	20	3.3	2.0	5.0
	>39.5 Related	577	6	1.0	0.4	2.2	560	5	0.9	0.3	2.1	577	11	1.9	1.0	3.4	1714	22	1.3	0.8	1.9	612	9	1.5	0.7	2.8
	>40.0 Related	577	1	0.2	0.0	1.0	560	3	0.5	0.1	1.6	577	4	0.7	0.2	1.8	1714	8	0.5	0.2	0.9	612	4	0.7	0.2	1.7
	Medical advice	577	26	4.5	3.0	6.5	560	20	3.6	2.2	5.5	577	31	5.4	3.7	7.5	1714	77	4.5	3.6	5.6	612	25	4.1	2.7	6.0

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.58 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1734	482	27.8	25.7	30.0	1832	525	28.7	26.6	30.8	598	166	27.8	24.2	31.5	645	166	25.7	22.4	29.3
	≥38	1734	407	23.5	21.5	25.5	1832	438	23.9	22.0	25.9	598	137	22.9	19.6	26.5	645	134	20.8	17.7	24.1
	>38.5	1734	208	12.0	10.5	13.6	1832	202	11.0	9.6	12.6	598	64	10.7	8.3	13.5	645	64	9.9	7.7	12.5
	>39.0	1734	69	4.0	3.1	5.0	1832	97	5.3	4.3	6.4	598	20	3.3	2.1	5.1	645	29	4.5	3.0	6.4
	>39.5	1734	24	1.4	0.9	2.1	1832	32	1.7	1.2	2.5	598	8	1.3	0.6	2.6	645	10	1.6	0.7	2.8
	>40.0	1734	7	0.4	0.2	0.8	1832	5	0.3	0.1	0.6	598	2	0.3	0.0	1.2	645	4	0.6	0.2	1.6
	≥38 Related	1734	301	17.4	15.6	19.2	1832	304	16.6	14.9	18.4	598	101	16.9	14.0	20.1	645	93	14.4	11.8	17.4
	>38.5 Related	1734	153	8.8	7.5	10.3	1832	138	7.5	6.4	8.8	598	50	8.4	6.3	10.9	645	43	6.7	4.9	8.9
	>39.0 Related	1734	48	2.8	2.0	3.7	1832	65	3.5	2.7	4.5	598	14	2.3	1.3	3.9	645	18	2.8	1.7	4.4
	>39.5 Related	1734	17	1.0	0.6	1.6	1832	22	1.2	0.8	1.8	598	6	1.0	0.4	2.2	645	6	0.9	0.3	2.0
	>40.0 Related	1734	5	0.3	0.1	0.7	1832	3	0.2	0.0	0.5	598	2	0.3	0.0	1.2	645	3	0.5	0.1	1.4
	Medical advice	1734	87	5.0	4.0	6.2	1832	104	5.7	4.7	6.8	598	30	5.0	3.4	7.1	645	38	5.9	4.2	8.0

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.59 Incidence of fever reported during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	2720	810	29.8	28.1	31.5	352	79	22.4	18.2	27.2	151	35	23.2	16.7	30.7	947	258	27.2	24.4	30.2	119	26	21.8	14.8	30.4
	≥38	2720	682	25.1	23.5	26.7	352	68	19.3	15.3	23.8	151	24	15.9	10.5	22.7	947	212	22.4	19.8	25.2	119	24	20.2	13.4	28.5
	>38.5	2720	324	11.9	10.7	13.2	352	31	8.8	6.1	12.3	151	12	7.9	4.2	13.5	947	104	11.0	9.1	13.1	119	6	5.0	1.9	10.7
	>39.0	2720	133	4.9	4.1	5.8	352	14	4.0	2.2	6.6	151	7	4.6	1.9	9.3	947	36	3.8	2.7	5.2	119	2	1.7	0.2	5.9
	>39.5	2720	43	1.6	1.1	2.1	352	4	1.1	0.3	2.9	151	3	2.0	0.4	5.7	947	13	1.4	0.7	2.3	119	0	0.0	0.0	3.1
	>40.0	2720	6	0.2	0.1	0.5	352	1	0.3	0.0	1.6	151	2	1.3	0.2	4.7	947	4	0.4	0.1	1.1	119	0	0.0	0.0	3.1
	≥38 Related	2720	494	18.2	16.7	19.7	352	28	8.0	5.4	11.3	151	20	13.2	8.3	19.7	947	156	16.5	14.2	19.0	119	8	6.7	2.9	12.8
	>38.5 Related	2720	229	8.4	7.4	9.5	352	12	3.4	1.8	5.9	151	12	7.9	4.2	13.5	947	75	7.9	6.3	9.8	119	3	2.5	0.5	7.2
	>39.0 Related	2720	90	3.3	2.7	4.1	352	6	1.7	0.6	3.7	151	7	4.6	1.9	9.3	947	24	2.5	1.6	3.7	119	0	0.0	0.0	3.1
	>39.5 Related	2720	29	1.1	0.7	1.5	352	2	0.6	0.1	2.0	151	3	2.0	0.4	5.7	947	9	1.0	0.4	1.8	119	0	0.0	0.0	3.1
	>40.0 Related	2720	3	0.1	0.0	0.3	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7	947	3	0.3	0.1	0.9	119	0	0.0	0.0	3.1
	Medical advice	2720	129	4.7	4.0	5.6	352	45	12.8	9.5	16.7	151	4	2.6	0.7	6.6	947	53	5.6	4.2	7.3	119	10	8.4	4.1	14.9

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	64	18	28.1	17.6	40.8
	≥38	64	14	21.9	12.5	34.0
	>38.5	64	8	12.5	5.6	23.2
	>39.0	64	4	6.3	1.7	15.2
	>39.5	64	2	3.1	0.4	10.8
	>40.0	64	0	0.0	0.0	5.6
	≥38 Related	64	11	17.2	8.9	28.7
	>38.5 Related	64	5	7.8	2.6	17.3
	>39.0 Related	64	1	1.6	0.0	8.4
	>39.5 Related	64	0	0.0	0.0	5.6
	>40.0 Related	64	0	0.0	0.0	5.6
	Medical advice	64	3	4.7	1.0	13.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.60 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	123	33	26.8	19.2	35.6	125	37	29.6	21.8	38.4	125	41	32.8	24.7	41.8	373	111	29.8	25.2	34.7	127	29	22.8	15.9	31.1
	≥38	123	30	24.4	17.1	33.0	125	34	27.2	19.6	35.9	125	39	31.2	23.2	40.1	373	103	27.6	23.1	32.5	127	25	19.7	13.2	27.7
	>38.5	123	13	10.6	5.7	17.4	125	15	12.0	6.9	19.0	125	17	13.6	8.1	20.9	373	45	12.1	8.9	15.8	127	12	9.4	5.0	15.9
	>39.0	123	4	3.3	0.9	8.1	125	5	4.0	1.3	9.1	125	6	4.8	1.8	10.2	373	15	4.0	2.3	6.5	127	4	3.1	0.9	7.9
	>39.5	123	1	0.8	0.0	4.4	125	3	2.4	0.5	6.9	125	3	2.4	0.5	6.9	373	7	1.9	0.8	3.8	127	1	0.8	0.0	4.3
	>40.0	123	0	0.0	0.0	3.0	125	1	0.8	0.0	4.4	125	0	0.0	0.0	2.9	373	1	0.3	0.0	1.5	127	0	0.0	0.0	2.9
	≥38 Related	123	17	13.8	8.3	21.2	125	11	8.8	4.5	15.2	125	13	10.4	5.7	17.1	373	41	11.0	8.0	14.6	127	12	9.4	5.0	15.9
	>38.5 Related	123	9	7.3	3.4	13.4	125	6	4.8	1.8	10.2	125	8	6.4	2.8	12.2	373	23	6.2	3.9	9.1	127	4	3.1	0.9	7.9
	>39.0 Related	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	4	1.1	0.3	2.7	127	0	0.0	0.0	2.9
	>39.5 Related	123	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	125	1	0.8	0.0	4.4	373	3	0.8	0.2	2.3	127	0	0.0	0.0	2.9
	>40.0 Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	6	4.9	1.8	10.3	125	8	6.4	2.8	12.2	125	9	7.2	3.3	13.2	373	23	6.2	3.9	9.1	127	5	3.9	1.3	8.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.61 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	61	21	34.4	22.7	47.7	62	17	27.4	16.9	40.2	63	20	31.7	20.6	44.7	186	58	31.2	24.6	38.4	68	25	36.8	25.4	49.3
	≥38	61	18	29.5	18.5	42.6	62	16	25.8	15.5	38.5	63	16	25.4	15.3	37.9	186	50	26.9	20.7	33.9	68	24	35.3	24.1	47.8
	>38.5	61	8	13.1	5.8	24.2	62	5	8.1	2.7	17.8	63	6	9.5	3.6	19.6	186	19	10.2	6.3	15.5	68	9	13.2	6.2	23.6
	>39.0	61	4	6.6	1.8	15.9	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5	186	7	3.8	1.5	7.6	68	5	7.4	2.4	16.3
	>39.5	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	1	1.5	0.0	7.9
	>40.0	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	≥38 Related	61	7	11.5	4.7	22.2	62	8	12.9	5.7	23.9	63	8	12.7	5.6	23.5	186	23	12.4	8.0	18.0	68	11	16.2	8.4	27.1
	>38.5 Related	61	3	4.9	1.0	13.7	62	1	1.6	0.0	8.7	63	4	6.3	1.8	15.5	186	8	4.3	1.9	8.3	68	3	4.4	0.9	12.4
	>39.0 Related	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	>39.5 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	1	1.5	0.0	7.9
	>40.0 Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	7	11.5	4.7	22.2	62	8	12.9	5.7	23.9	63	5	7.9	2.6	17.6	186	20	10.8	6.7	16.1	68	13	19.1	10.6	30.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.62 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	336	96	28.6	23.8	33.7	332	103	31.0	26.1	36.3	337	109	32.3	27.4	37.6	1005	308	30.6	27.8	33.6	340	88	25.9	21.3	30.9
	≥38	336	79	23.5	19.1	28.4	332	93	28.0	23.2	33.2	337	89	26.4	21.8	31.5	1005	261	26.0	23.3	28.8	340	75	22.1	17.8	26.8
	>38.5	336	33	9.8	6.9	13.5	332	45	13.6	10.1	17.7	337	42	12.5	9.1	16.5	1005	120	11.9	10.0	14.1	340	37	10.9	7.8	14.7
	>39.0	336	15	4.5	2.5	7.3	332	20	6.0	3.7	9.2	337	15	4.5	2.5	7.2	1005	50	5.0	3.7	6.5	340	15	4.4	2.5	7.2
	>39.5	336	6	1.8	0.7	3.8	332	5	1.5	0.5	3.5	337	3	0.9	0.2	2.6	1005	14	1.4	0.8	2.3	340	4	1.2	0.3	3.0
	>40.0	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	2	0.6	0.1	2.1
	≥38 Related	336	77	22.9	18.5	27.8	332	88	26.5	21.8	31.6	337	83	24.6	20.1	29.6	1005	248	24.7	22.0	27.5	340	70	20.6	16.4	25.3
	>38.5 Related	336	31	9.2	6.4	12.8	332	40	12.0	8.7	16.0	337	39	11.6	8.4	15.5	1005	110	10.9	9.1	13.0	340	33	9.7	6.8	13.4
	>39.0 Related	336	14	4.2	2.3	6.9	332	16	4.8	2.8	7.7	337	15	4.5	2.5	7.2	1005	45	4.5	3.3	5.9	340	11	3.2	1.6	5.7
	>39.5 Related	336	5	1.5	0.5	3.4	332	3	0.9	0.2	2.6	337	3	0.9	0.2	2.6	1005	11	1.1	0.5	1.9	340	2	0.6	0.1	2.1
	>40.0 Related	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	1	0.3	0.0	1.6
	Medical advice	336	6	1.8	0.7	3.8	332	5	1.5	0.5	3.5	337	12	3.6	1.9	6.1	1005	23	2.3	1.5	3.4	340	12	3.5	1.8	6.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.63 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	93	13	14.0	7.7	22.7	97	17	17.5	10.6	26.6	98	16	16.3	9.6	25.2	288	46	16.0	11.9	20.7	96	17	17.7	10.7	26.8
	≥38	93	13	14.0	7.7	22.7	97	16	16.5	9.7	25.4	98	16	16.3	9.6	25.2	288	45	15.6	11.6	20.3	96	16	16.7	9.8	25.6
	>38.5	93	3	3.2	0.7	9.1	97	7	7.2	3.0	14.3	98	8	8.2	3.6	15.5	288	18	6.3	3.7	9.7	96	2	2.1	0.3	7.3
	>39.0	93	0	0.0	0.0	3.9	97	3	3.1	0.6	8.8	98	3	3.1	0.6	8.7	288	6	2.1	0.8	4.5	96	0	0.0	0.0	3.8
	>39.5	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	1	1.0	0.0	5.6	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>40.0	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	≥38 Related	93	5	5.4	1.8	12.1	97	3	3.1	0.6	8.8	98	6	6.1	2.3	12.9	288	14	4.9	2.7	8.0	96	3	3.1	0.6	8.9
	>38.5 Related	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	4	4.1	1.1	10.1	288	5	1.7	0.6	4.0	96	1	1.0	0.0	5.7
	>39.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	2	2.0	0.2	7.2	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	>39.5 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	>40.0 Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	9	9.7	4.5	17.6	97	13	13.4	7.3	21.8	98	12	12.2	6.5	20.4	288	34	11.8	8.3	16.1	96	8	8.3	3.7	15.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.64 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	577	118	20.5	17.2	24.0	560	113	20.2	16.9	23.7	577	111	19.2	16.1	22.7	1714	342	20.0	18.1	21.9	612	125	20.4	17.3	23.8
	≥38	577	86	14.9	12.1	18.1	560	83	14.8	12.0	18.0	577	76	13.2	10.5	16.2	1714	245	14.3	12.7	16.0	612	86	14.1	11.4	17.1
	>38.5	577	46	8.0	5.9	10.5	560	44	7.9	5.8	10.4	577	41	7.1	5.1	9.5	1714	131	7.6	6.4	9.0	612	43	7.0	5.1	9.3
	>39.0	577	21	3.6	2.3	5.5	560	17	3.0	1.8	4.8	577	23	4.0	2.5	5.9	1714	61	3.6	2.7	4.5	612	15	2.5	1.4	4.0
	>39.5	577	8	1.4	0.6	2.7	560	7	1.3	0.5	2.6	577	10	1.7	0.8	3.2	1714	25	1.5	0.9	2.1	612	8	1.3	0.6	2.6
	>40.0	577	1	0.2	0.0	1.0	560	4	0.7	0.2	1.8	577	4	0.7	0.2	1.8	1714	9	0.5	0.2	1.0	612	3	0.5	0.1	1.4
	≥38 Related	577	58	10.1	7.7	12.8	560	57	10.2	7.8	13.0	577	55	9.5	7.3	12.2	1714	170	9.9	8.5	11.4	612	63	10.3	8.0	13.0
	>38.5 Related	577	27	4.7	3.1	6.7	560	31	5.5	3.8	7.8	577	32	5.5	3.8	7.7	1714	90	5.3	4.2	6.4	612	32	5.2	3.6	7.3
	>39.0 Related	577	12	2.1	1.1	3.6	560	11	2.0	1.0	3.5	577	18	3.1	1.9	4.9	1714	41	2.4	1.7	3.2	612	11	1.8	0.9	3.2
	>39.5 Related	577	5	0.9	0.3	2.0	560	5	0.9	0.3	2.1	577	9	1.6	0.7	2.9	1714	19	1.1	0.7	1.7	612	6	1.0	0.4	2.1
	>40.0 Related	577	1	0.2	0.0	1.0	560	3	0.5	0.1	1.6	577	4	0.7	0.2	1.8	1714	8	0.5	0.2	0.9	612	3	0.5	0.1	1.4
	Medical advice	577	21	3.6	2.3	5.5	560	19	3.4	2.1	5.2	577	24	4.2	2.7	6.1	1714	64	3.7	2.9	4.7	612	17	2.8	1.6	4.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.65 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	1734	411	23.7	21.7	25.8	1832	454	24.8	22.8	26.8	598	142	23.7	20.4	27.4	645	142	22.0	18.9	25.4
	≥38	1734	339	19.6	17.7	21.5	1832	365	19.9	18.1	21.8	598	112	18.7	15.7	22.1	645	114	17.7	14.8	20.8
	>38.5	1734	169	9.7	8.4	11.2	1832	164	9.0	7.7	10.4	598	49	8.2	6.1	10.7	645	54	8.4	6.4	10.8
	>39.0	1734	59	3.4	2.6	4.4	1832	80	4.4	3.5	5.4	598	14	2.3	1.3	3.9	645	25	3.9	2.5	5.7
	>39.5	1734	21	1.2	0.8	1.8	1832	28	1.5	1.0	2.2	598	5	0.8	0.3	1.9	645	9	1.4	0.6	2.6
	>40.0	1734	7	0.4	0.2	0.8	1832	5	0.3	0.1	0.6	598	1	0.2	0.0	0.9	645	4	0.6	0.2	1.6
	≥38 Related	1734	246	14.2	12.6	15.9	1832	250	13.6	12.1	15.3	598	82	13.7	11.1	16.7	645	77	11.9	9.5	14.7
	>38.5 Related	1734	127	7.3	6.1	8.7	1832	109	5.9	4.9	7.1	598	37	6.2	4.4	8.4	645	36	5.6	3.9	7.6
	>39.0 Related	1734	42	2.4	1.8	3.3	1832	52	2.8	2.1	3.7	598	8	1.3	0.6	2.6	645	15	2.3	1.3	3.8
	>39.5 Related	1734	15	0.9	0.5	1.4	1832	19	1.0	0.6	1.6	598	3	0.5	0.1	1.5	645	6	0.9	0.3	2.0
	>40.0 Related	1734	5	0.3	0.1	0.7	1832	3	0.2	0.0	0.5	598	1	0.2	0.0	0.9	645	3	0.5	0.1	1.4
	Medical advice	1734	78	4.5	3.6	5.6	1832	86	4.7	3.8	5.8	598	23	3.8	2.5	5.7	645	32	5.0	3.4	6.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

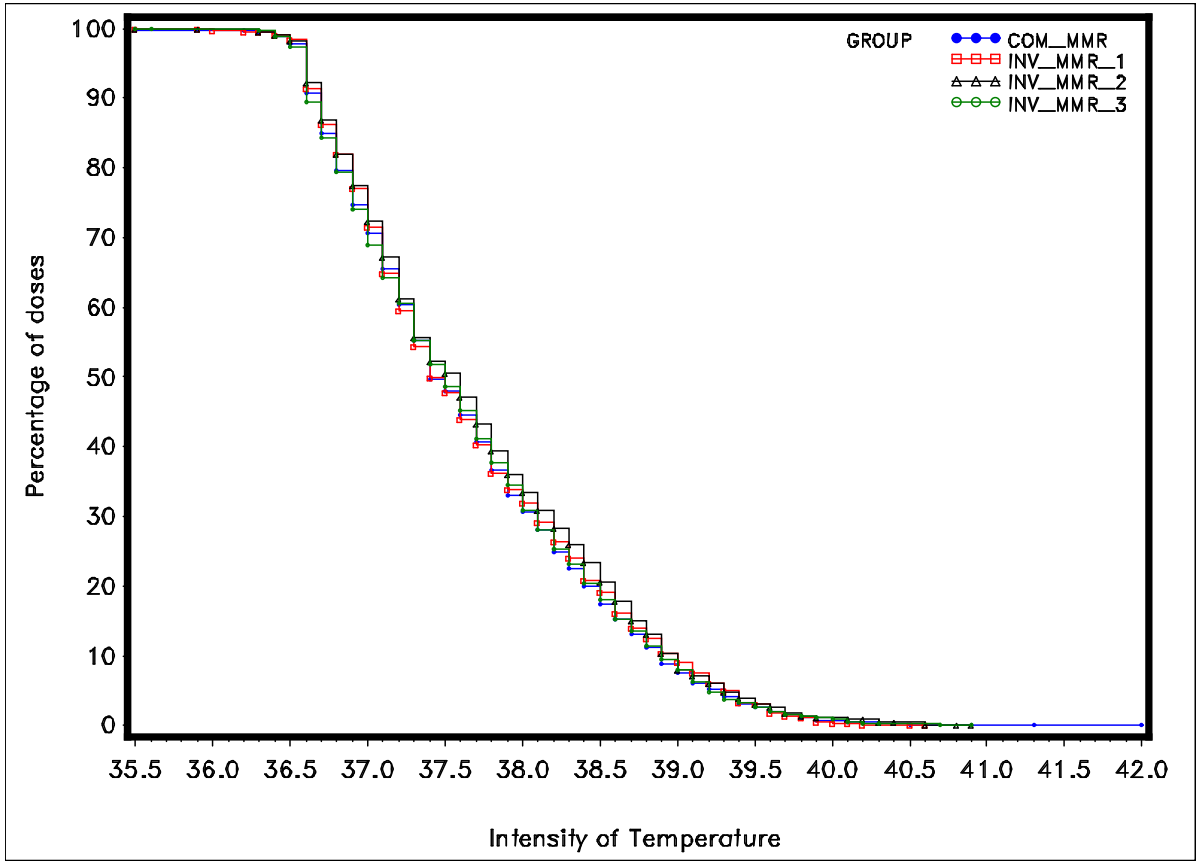
Table 8.66 Incidence of fever reported during the Day 5 to Day 12 post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	2720	712	26.2	24.5	27.9	352	62	17.6	13.8	22.0	151	23	15.2	9.9	22.0	947	225	23.8	21.1	26.6	119	24	20.2	13.4	28.5
	≥38	2720	590	21.7	20.2	23.3	352	53	15.1	11.5	19.2	151	10	6.6	3.2	11.8	947	183	19.3	16.9	22.0	119	21	17.6	11.3	25.7
	>38.5	2720	273	10.0	8.9	11.2	352	25	7.1	4.6	10.3	151	5	3.3	1.1	7.6	947	86	9.1	7.3	11.1	119	6	5.0	1.9	10.7
	>39.0	2720	116	4.3	3.5	5.1	352	12	3.4	1.8	5.9	151	4	2.6	0.7	6.6	947	31	3.3	2.2	4.6	119	2	1.7	0.2	5.9
	>39.5	2720	39	1.4	1.0	2.0	352	4	1.1	0.3	2.9	151	3	2.0	0.4	5.7	947	10	1.1	0.5	1.9	119	0	0.0	0.0	3.1
	>40.0	2720	6	0.2	0.1	0.5	352	1	0.3	0.0	1.6	151	2	1.3	0.2	4.7	947	3	0.3	0.1	0.9	119	0	0.0	0.0	3.1
	≥38 Related	2720	427	15.7	14.4	17.1	352	18	5.1	3.1	8.0	151	6	4.0	1.5	8.4	947	134	14.1	12.0	16.5	119	6	5.0	1.9	10.7
	>38.5 Related	2720	197	7.2	6.3	8.3	352	8	2.3	1.0	4.4	151	5	3.3	1.1	7.6	947	62	6.5	5.1	8.3	119	3	2.5	0.5	7.2
	>39.0 Related	2720	79	2.9	2.3	3.6	352	5	1.4	0.5	3.3	151	4	2.6	0.7	6.6	947	20	2.1	1.3	3.2	119	0	0.0	0.0	3.1
	>39.5 Related	2720	26	1.0	0.6	1.4	352	2	0.6	0.1	2.0	151	3	2.0	0.4	5.7	947	7	0.7	0.3	1.5	119	0	0.0	0.0	3.1
	>40.0 Related	2720	3	0.1	0.0	0.3	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7	947	2	0.2	0.0	0.8	119	0	0.0	0.0	3.1
	Medical advice	2720	113	4.2	3.4	5.0	352	39	11.1	8.0	14.8	151	2	1.3	0.2	4.7	947	44	4.6	3.4	6.2	119	9	7.6	3.5	13.9

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	64	12	18.8	10.1	30.5
	≥38	64	10	15.6	7.8	26.9
	>38.5	64	5	7.8	2.6	17.3
	>39.0	64	3	4.7	1.0	13.1
	>39.5	64	2	3.1	0.4	10.8
	>40.0	64	0	0.0	0.0	5.6
	≥38 Related	64	7	10.9	4.5	21.2
	>38.5 Related	64	2	3.1	0.4	10.8
	>39.0 Related	64	0	0.0	0.0	5.6
	>39.5 Related	64	0	0.0	0.0	5.6
	>40.0 Related	64	0	0.0	0.0	5.6
	Medical advice	64	1	1.6	0.0	8.4

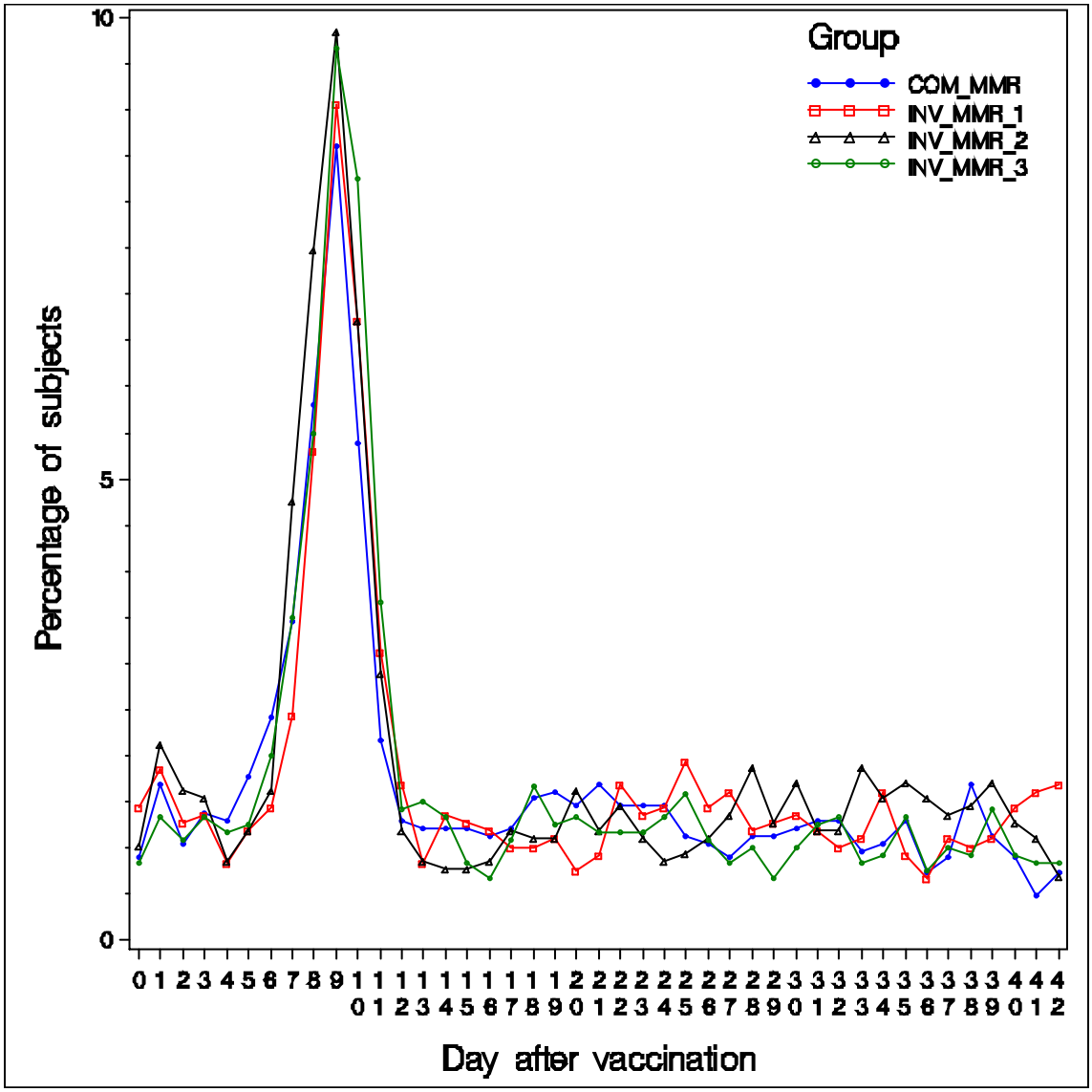
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Figure 8.1 Reverse cumulative distribution curve for Temperature (Total vaccinated cohort) (Dose : (1), during the whole follow-up period)



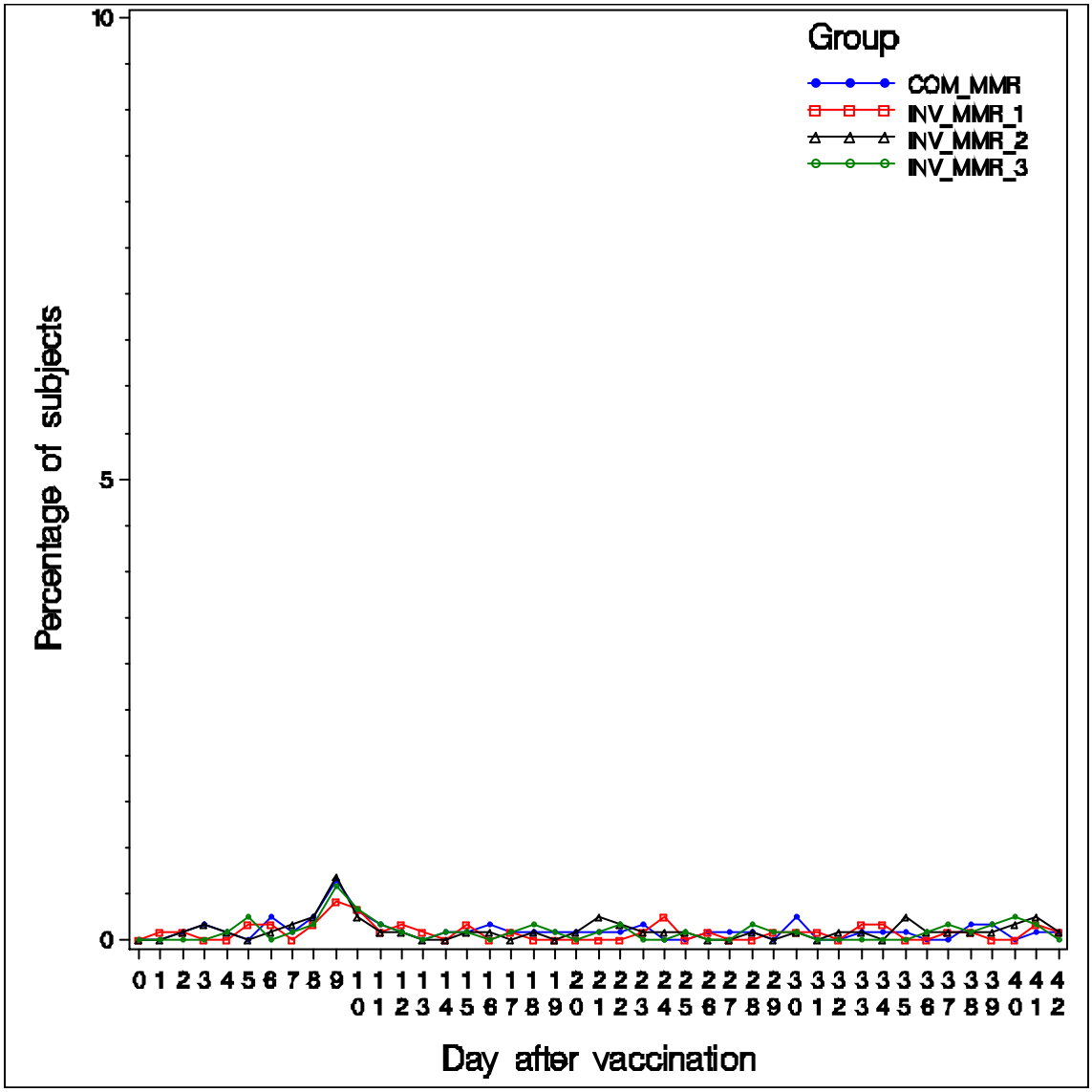
INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Percentage computed on documented dose

Figure 8.2 Daily prevalence of fever between Day 0 and Day 42 after vaccination (Total vaccinated cohort)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Percentage computed on documented dose

Figure 8.3 Daily prevalence of fever >39.5C between Day 0 and Day 42 after vaccination (Total vaccinated cohort)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR
Percentage computed on documented dose

Table 8.67 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 2 or 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
Parotid gland	All	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 2 or 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Grade 3	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Related	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9
	Medical advice	123	0	0.0	0.0	3.0	125	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	373	0	0.0	0.0	1.0	127	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.68 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 2 or 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
Parotid gland	All	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 2 or 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Medical advice	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.69 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	336	3	0.9	0.2	2.6	332	1	0.3	0.0	1.7	337	2	0.6	0.1	2.1	1005	6	0.6	0.2	1.3	340	2	0.6	0.1	2.1
	Grade 2 or 3	336	2	0.6	0.1	2.1	332	1	0.3	0.0	1.7	337	2	0.6	0.1	2.1	1005	5	0.5	0.2	1.2	340	1	0.3	0.0	1.6
	Grade 3	336	1	0.3	0.0	1.6	332	0	0.0	0.0	1.1	337	1	0.3	0.0	1.6	1005	2	0.2	0.0	0.7	340	0	0.0	0.0	1.1
	Related	336	1	0.3	0.0	1.6	332	1	0.3	0.0	1.7	337	0	0.0	0.0	1.1	1005	2	0.2	0.0	0.7	340	2	0.6	0.1	2.1
	Medical advice	336	3	0.9	0.2	2.6	332	1	0.3	0.0	1.7	337	2	0.6	0.1	2.1	1005	6	0.6	0.2	1.3	340	1	0.3	0.0	1.6
Parotid gland	All	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Grade 2 or 3	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Grade 3	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Related	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1
	Medical advice	336	0	0.0	0.0	1.1	332	0	0.0	0.0	1.1	337	0	0.0	0.0	1.1	1005	0	0.0	0.0	0.4	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.70 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Grade 2 or 3	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Grade 3	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	1	1.1	0.0	5.8	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
Parotid gland	All	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Grade 2 or 3	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Grade 3	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Related	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Medical advice	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.71 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	3	0.5	0.1	1.5	1714	3	0.2	0.0	0.5	612	1	0.2	0.0	0.9
	Grade 2 or 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	1	0.2	0.0	1.0	1714	1	0.1	0.0	0.3	612	0	0.0	0.0	0.6
	Grade 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	1	0.2	0.0	1.0	1714	1	0.1	0.0	0.3	612	0	0.0	0.0	0.6
	Related	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	2	0.3	0.0	1.2	1714	2	0.1	0.0	0.4	612	0	0.0	0.0	0.6
	Medical advice	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	2	0.3	0.0	1.2	1714	2	0.1	0.0	0.4	612	0	0.0	0.0	0.6
Parotid gland	All	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Grade 2 or 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Grade 3	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Related	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6
	Medical advice	577	0	0.0	0.0	0.6	560	0	0.0	0.0	0.7	577	0	0.0	0.0	0.6	1714	0	0.0	0.0	0.2	612	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.72 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR										COM_MMR									
		F					M					F					M				
					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	1734	5	0.3	0.1	0.7	1832	5	0.3	0.1	0.6	598	0	0.0	0.0	0.6	645	3	0.5	0.1	1.4
	Grade 2 or 3	1734	3	0.2	0.0	0.5	1832	4	0.2	0.1	0.6	598	0	0.0	0.0	0.6	645	1	0.2	0.0	0.9
	Grade 3	1734	2	0.1	0.0	0.4	1832	2	0.1	0.0	0.4	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Related	1734	2	0.1	0.0	0.4	1832	2	0.1	0.0	0.4	598	0	0.0	0.0	0.6	645	2	0.3	0.0	1.1
	Medical advice	1734	4	0.2	0.1	0.6	1832	5	0.3	0.1	0.6	598	0	0.0	0.0	0.6	645	1	0.2	0.0	0.9
Parotid gland	All	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Grade 2 or 3	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Grade 3	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Related	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6
	Medical advice	1734	0	0.0	0.0	0.2	1832	0	0.0	0.0	0.2	598	0	0.0	0.0	0.6	645	0	0.0	0.0	0.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.73 Incidence of MMR specific solicited general symptoms reported during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR															COM_MMR									
		WH					OT					AF					WH					OT				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	2720	8	0.3	0.1	0.6	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	3	0.3	0.1	0.9	119	0	0.0	0.0	3.1
	Grade 2 or 3	2720	5	0.2	0.1	0.4	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	1	0.1	0.0	0.6	119	0	0.0	0.0	3.1
	Grade 3	2720	2	0.1	0.0	0.3	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Related	2720	3	0.1	0.0	0.3	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	2	0.2	0.0	0.8	119	0	0.0	0.0	3.1
	Medical advice	2720	8	0.3	0.1	0.6	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4	947	1	0.1	0.0	0.6	119	0	0.0	0.0	3.1
Parotid gland	All	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Grade 2 or 3	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Grade 3	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Related	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1
	Medical advice	2720	0	0.0	0.0	0.1	352	0	0.0	0.0	1.0	151	0	0.0	0.0	2.4	947	0	0.0	0.0	0.4	119	0	0.0	0.0	3.1

		COM_MMR				
		AF				
					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**
Febrile convulsion	All	64	0	0.0	0.0	5.6
	Grade 2 or 3	64	0	0.0	0.0	5.6
	Grade 3	64	0	0.0	0.0	5.6
	Related	64	0	0.0	0.0	5.6
	Medical advice	64	0	0.0	0.0	5.6
Parotid gland	All	64	0	0.0	0.0	5.6
	Grade 2 or 3	64	0	0.0	0.0	5.6
	Grade 3	64	0	0.0	0.0	5.6
	Related	64	0	0.0	0.0	5.6
	Medical advice	64	0	0.0	0.0	5.6

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the documented dose
n/% = number/percentage of subjects reporting the symptom at least once
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.74 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	123	39	31.7	23.6	40.7	125	31	24.8	17.5	33.3	125	38	30.4	22.5	39.3
	With fever	123	11	8.9	4.6	15.4	125	14	11.2	6.3	18.1	125	19	15.2	9.4	22.7
	Varicella like	123	7	5.7	2.3	11.4	125	6	4.8	1.8	10.2	125	8	6.4	2.8	12.2
	Measles/Rubella like	123	6	4.9	1.8	10.3	125	2	1.6	0.2	5.7	125	4	3.2	0.9	8.0
	Grade 3	123	2	1.6	0.2	5.8	125	5	4.0	1.3	9.1	125	0	0.0	0.0	2.9
	Related	123	12	9.8	5.1	16.4	125	6	4.8	1.8	10.2	125	13	10.4	5.7	17.1
	Med adv	123	30	24.4	17.1	33.0	125	23	18.4	12.0	26.3	125	22	17.6	11.4	25.4
Localized	Any	123	26	21.1	14.3	29.4	125	21	16.8	10.7	24.5	125	29	23.2	16.1	31.6
	Administration site	123	1	0.8	0.0	4.5	125	0	0.0	0.0	2.9	125	1	0.8	0.0	4.4
	Other site	123	26	21.1	14.3	29.4	125	21	16.8	10.7	24.5	125	28	22.4	15.4	30.7
	With fever	123	3	2.4	0.5	7.0	125	6	4.8	1.8	10.2	125	13	10.4	5.7	17.1
	Varicella like	123	5	4.1	1.3	9.2	125	4	3.2	0.9	8.0	125	6	4.8	1.8	10.2
	Measles/Rubella like	123	2	1.6	0.2	5.8	125	1	0.8	0.0	4.4	125	2	1.6	0.2	5.7
	Grade 3	123	0	0.0	0.0	3.0	125	2	1.6	0.2	5.7	125	0	0.0	0.0	2.9
	Related	123	6	4.9	1.8	10.3	125	4	3.2	0.9	8.0	125	8	6.4	2.8	12.2
	Med adv	123	17	13.8	8.3	21.2	125	15	12.0	6.9	19.0	125	15	12.0	6.9	19.0
Generalized	Any	123	13	10.6	5.8	17.4	125	11	8.8	4.5	15.2	125	10	8.0	3.9	14.2
	With fever	123	8	6.5	2.9	12.4	125	9	7.2	3.4	13.2	125	6	4.8	1.8	10.2
	Varicella like	123	2	1.6	0.2	5.8	125	2	1.6	0.2	5.7	125	2	1.6	0.2	5.7
	Measles/Rubella like	123	4	3.3	0.9	8.1	125	1	0.8	0.0	4.4	125	2	1.6	0.2	5.7
	Grade 3	123	2	1.6	0.2	5.8	125	3	2.4	0.5	6.9	125	0	0.0	0.0	2.9
	Related	123	6	4.9	1.8	10.3	125	2	1.6	0.2	5.7	125	5	4.0	1.3	9.1
	Med adv	123	13	10.6	5.8	17.4	125	9	7.2	3.4	13.2	125	8	6.4	2.8	12.2

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	373	108	29.0	24.4	33.9	127	43	33.9	25.7	42.8
	With fever	373	44	11.8	8.7	15.5	127	15	11.8	6.8	18.7
	Varicella like	373	21	5.6	3.5	8.5	127	12	9.4	5.0	15.9
	Measles/Rubella like	373	12	3.2	1.7	5.6	127	5	3.9	1.3	9.0
	Grade 3	373	7	1.9	0.8	3.8	127	3	2.4	0.5	6.8
	Related	373	31	8.3	5.7	11.6	127	13	10.2	5.6	16.9
	Med adv	373	75	20.1	16.2	24.5	127	35	27.6	20.0	36.2
Localized	Any	373	76	20.4	16.4	24.8	127	25	19.7	13.2	27.7
	Administration site	373	2	0.5	0.1	1.9	127	2	1.6	0.2	5.6
	Other site	373	75	20.1	16.2	24.5	127	23	18.1	11.8	25.9
	With fever	373	22	5.9	3.7	8.8	127	4	3.1	0.9	7.9
	Varicella like	373	15	4.0	2.3	6.6	127	5	3.9	1.3	9.0
	Measles/Rubella like	373	5	1.3	0.4	3.1	127	0	0.0	0.0	2.9
	Grade 3	373	2	0.5	0.1	1.9	127	0	0.0	0.0	2.9
	Related	373	18	4.8	2.9	7.5	127	5	3.9	1.3	9.0
	Med adv	373	47	12.6	9.4	16.4	127	19	15.0	9.3	22.4
Generalized	Any	373	34	9.1	6.4	12.5	127	22	17.3	11.2	25.0
	With fever	373	23	6.2	4.0	9.1	127	11	8.7	4.4	15.0
	Varicella like	373	6	1.6	0.6	3.5	127	7	5.5	2.2	11.0
	Measles/Rubella like	373	7	1.9	0.8	3.8	127	5	3.9	1.3	9.0
	Grade 3	373	5	1.3	0.4	3.1	127	3	2.4	0.5	6.8
	Related	373	13	3.5	1.9	5.9	127	8	6.3	2.8	12.0
	Med adv	373	30	8.0	5.5	11.3	127	19	15.0	9.3	22.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.75 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	61	8	13.1	5.8	24.2	62	6	9.7	3.6	19.9	63	10	15.9	7.9	27.3
	With fever	61	2	3.3	0.4	11.4	62	3	4.8	1.0	13.5	63	6	9.5	3.6	19.6
	Varicella like	61	4	6.6	1.8	16.0	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5
	Measles/Rubella like	61	1	1.6	0.0	8.8	62	2	3.2	0.4	11.2	63	1	1.6	0.0	8.5
	Grade 3	61	0	0.0	0.0	5.9	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7
	Related	61	0	0.0	0.0	5.9	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5
	Med adv	61	4	6.6	1.8	16.0	62	6	9.7	3.6	19.9	63	6	9.5	3.6	19.6
Localized	Any	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	9	14.3	6.8	25.4
	Administration site	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5
	Other site	61	5	8.2	2.7	18.1	62	3	4.8	1.0	13.5	63	9	14.3	6.8	25.4
	With fever	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	5	7.9	2.6	17.6
	Varicella like	61	3	4.9	1.0	13.7	62	1	1.6	0.0	8.7	63	1	1.6	0.0	8.5
	Measles/Rubella like	61	1	1.6	0.0	8.8	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5
	Grade 3	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	0	0.0	0.0	5.7
	Related	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	63	1	1.6	0.0	8.5
	Med adv	61	2	3.3	0.4	11.4	62	3	4.8	1.0	13.5	63	5	7.9	2.6	17.6
Generalized	Any	61	3	4.9	1.0	13.7	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5
	With fever	61	1	1.6	0.0	8.8	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5
	Varicella like	61	1	1.6	0.0	8.8	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7
	Measles/Rubella like	61	0	0.0	0.0	5.9	62	2	3.2	0.4	11.2	63	0	0.0	0.0	5.7
	Grade 3	61	0	0.0	0.0	5.9	62	1	1.6	0.0	8.7	63	0	0.0	0.0	5.7
	Related	61	0	0.0	0.0	5.9	62	3	4.8	1.0	13.5	63	0	0.0	0.0	5.7
	Med adv	61	2	3.3	0.4	11.4	62	3	4.8	1.0	13.5	63	1	1.6	0.0	8.5

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	186	24	12.9	8.5	18.6	68	7	10.3	4.2	20.1
	With fever	186	11	5.9	3.0	10.3	68	3	4.4	0.9	12.4
	Varicella like	186	7	3.8	1.5	7.6	68	1	1.5	0.0	7.9
	Measles/Rubella like	186	4	2.2	0.6	5.4	68	1	1.5	0.0	7.9
	Grade 3	186	1	0.5	0.0	3.0	68	1	1.5	0.0	7.9
	Related	186	4	2.2	0.6	5.4	68	3	4.4	0.9	12.4
	Med adv	186	16	8.6	5.0	13.6	68	5	7.4	2.4	16.3
Localized	Any	186	17	9.1	5.4	14.2	68	4	5.9	1.6	14.4
	Administration site	186	1	0.5	0.0	3.0	68	0	0.0	0.0	5.3
	Other site	186	17	9.1	5.4	14.2	68	4	5.9	1.6	14.4
	With fever	186	6	3.2	1.2	6.9	68	1	1.5	0.0	7.9
	Varicella like	186	5	2.7	0.9	6.2	68	1	1.5	0.0	7.9
	Measles/Rubella like	186	2	1.1	0.1	3.8	68	0	0.0	0.0	5.3
	Grade 3	186	0	0.0	0.0	2.0	68	0	0.0	0.0	5.3
	Related	186	1	0.5	0.0	3.0	68	2	2.9	0.4	10.2
	Med adv	186	10	5.4	2.6	9.7	68	2	2.9	0.4	10.2
Generalized	Any	186	7	3.8	1.5	7.6	68	3	4.4	0.9	12.4
	With fever	186	5	2.7	0.9	6.2	68	2	2.9	0.4	10.2
	Varicella like	186	2	1.1	0.1	3.8	68	0	0.0	0.0	5.3
	Measles/Rubella like	186	2	1.1	0.1	3.8	68	1	1.5	0.0	7.9
	Grade 3	186	1	0.5	0.0	3.0	68	1	1.5	0.0	7.9
	Related	186	3	1.6	0.3	4.6	68	1	1.5	0.0	7.9
	Med adv	186	6	3.2	1.2	6.9	68	3	4.4	0.9	12.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.76 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	336	151	44.9	39.5	50.4	332	141	42.5	37.1	48.0	337	163	48.4	42.9	53.9
	With fever	336	46	13.7	10.2	17.8	332	53	16.0	12.2	20.4	337	59	17.5	13.6	22.0
	Varicella like	336	60	17.9	13.9	22.4	332	54	16.3	12.5	20.7	337	65	19.3	15.2	23.9
	Measles/Rubella like	336	38	11.3	8.1	15.2	332	45	13.6	10.1	17.7	337	34	10.1	7.1	13.8
	Grade 3	336	22	6.5	4.2	9.8	332	19	5.7	3.5	8.8	337	16	4.7	2.7	7.6
	Related	336	93	27.7	23.0	32.8	332	94	28.3	23.5	33.5	337	101	30.0	25.1	35.2
	Med adv	336	53	15.8	12.0	20.1	332	39	11.7	8.5	15.7	337	51	15.1	11.5	19.4
Localized	Any	336	98	29.2	24.4	34.3	332	101	30.4	25.5	35.7	337	111	32.9	27.9	38.2
	Administration site	336	4	1.2	0.3	3.0	332	9	2.7	1.3	5.1	337	5	1.5	0.5	3.4
	Other site	336	96	28.6	23.8	33.7	332	96	28.9	24.1	34.1	337	108	32.0	27.1	37.3
	With fever	336	21	6.3	3.9	9.4	332	31	9.3	6.4	13.0	337	29	8.6	5.8	12.1
	Varicella like	336	45	13.4	9.9	17.5	332	44	13.3	9.8	17.4	337	44	13.1	9.7	17.1
	Measles/Rubella like	336	10	3.0	1.4	5.4	332	14	4.2	2.3	7.0	337	14	4.2	2.3	6.9
	Grade 3	336	2	0.6	0.1	2.1	332	3	0.9	0.2	2.6	337	2	0.6	0.1	2.1
	Related	336	55	16.4	12.6	20.8	332	62	18.7	14.6	23.3	337	65	19.3	15.2	23.9
	Med adv	336	22	6.5	4.2	9.8	332	22	6.6	4.2	9.9	337	20	5.9	3.7	9.0
Generalized	Any	336	65	19.3	15.3	24.0	332	58	17.5	13.5	22.0	337	64	19.0	14.9	23.6
	With fever	336	30	8.9	6.1	12.5	332	27	8.1	5.4	11.6	337	32	9.5	6.6	13.1
	Varicella like	336	16	4.8	2.8	7.6	332	12	3.6	1.9	6.2	337	22	6.5	4.1	9.7
	Measles/Rubella like	336	28	8.3	5.6	11.8	332	31	9.3	6.4	13.0	337	20	5.9	3.7	9.0
	Grade 3	336	21	6.3	3.9	9.4	332	16	4.8	2.8	7.7	337	14	4.2	2.3	6.9
	Related	336	44	13.1	9.7	17.2	332	40	12.0	8.8	16.0	337	40	11.9	8.6	15.8
	Med adv	336	35	10.4	7.4	14.2	332	21	6.3	4.0	9.5	337	34	10.1	7.1	13.8

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	1005	455	45.3	42.2	48.4	340	160	47.1	41.7	52.5
	With fever	1005	158	15.7	13.5	18.1	340	40	11.8	8.5	15.7
	Varicella like	1005	179	17.8	15.5	20.3	340	58	17.1	13.2	21.5
	Measles/Rubella like	1005	117	11.6	9.7	13.8	340	38	11.2	8.0	15.0
	Grade 3	1005	57	5.7	4.3	7.3	340	10	2.9	1.4	5.3
	Related	1005	288	28.7	25.9	31.6	340	90	26.5	21.9	31.5
	Med adv	1005	143	14.2	12.1	16.5	340	48	14.1	10.6	18.3
Localized	Any	1005	310	30.8	28.0	33.8	340	116	34.1	29.1	39.4
	Administration site	1005	18	1.8	1.1	2.8	340	8	2.4	1.0	4.6
	Other site	1005	300	29.9	27.0	32.8	340	109	32.1	27.1	37.3
	With fever	1005	81	8.1	6.5	9.9	340	25	7.4	4.8	10.7
	Varicella like	1005	133	13.2	11.2	15.5	340	47	13.8	10.3	18.0
	Measles/Rubella like	1005	38	3.8	2.7	5.2	340	14	4.1	2.3	6.8
	Grade 3	1005	7	0.7	0.3	1.4	340	1	0.3	0.0	1.6
	Related	1005	182	18.1	15.8	20.6	340	62	18.2	14.3	22.8
	Med adv	1005	64	6.4	4.9	8.1	340	28	8.2	5.5	11.7
Generalized	Any	1005	187	18.6	16.3	21.2	340	62	18.2	14.3	22.8
	With fever	1005	89	8.9	7.2	10.8	340	19	5.6	3.4	8.6
	Varicella like	1005	50	5.0	3.7	6.5	340	12	3.5	1.8	6.1
	Measles/Rubella like	1005	79	7.9	6.3	9.7	340	24	7.1	4.6	10.3
	Grade 3	1005	51	5.1	3.8	6.6	340	9	2.6	1.2	5.0
	Related	1005	124	12.3	10.4	14.5	340	37	10.9	7.8	14.7
	Med adv	1005	90	9.0	7.3	10.9	340	25	7.4	4.8	10.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.77 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	93	23	24.7	16.4	34.8	97	18	18.6	11.4	27.7	98	10	10.2	5.0	18.0
	With fever	93	9	9.7	4.5	17.6	97	6	6.2	2.3	13.0	98	0	0.0	0.0	3.7
	Varicella like	93	4	4.3	1.2	10.7	97	3	3.1	0.6	8.8	98	1	1.0	0.0	5.6
	Measles/Rubella like	93	2	2.2	0.3	7.6	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Grade 3	93	1	1.1	0.0	5.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Related	93	12	12.9	6.9	21.5	97	6	6.2	2.3	13.0	98	4	4.1	1.1	10.1
	Med adv	93	15	16.1	9.3	25.2	97	17	17.5	10.6	26.6	98	7	7.1	2.9	14.2
Localized	Any	93	16	17.2	10.2	26.4	97	11	11.3	5.8	19.4	98	8	8.2	3.6	15.5
	Administration site	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	1	1.0	0.0	5.6
	Other site	93	16	17.2	10.2	26.4	97	11	11.3	5.8	19.4	98	7	7.1	2.9	14.2
	With fever	93	6	6.5	2.4	13.5	97	2	2.1	0.3	7.3	98	0	0.0	0.0	3.7
	Varicella like	93	4	4.3	1.2	10.7	97	2	2.1	0.3	7.3	98	1	1.0	0.0	5.6
	Measles/Rubella like	93	2	2.2	0.3	7.6	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Grade 3	93	1	1.1	0.0	5.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Related	93	8	8.6	3.8	16.3	97	3	3.1	0.6	8.8	98	3	3.1	0.6	8.7
	Med adv	93	10	10.8	5.3	18.9	97	11	11.3	5.8	19.4	98	5	5.1	1.7	11.5
Generalized	Any	93	7	7.5	3.1	14.9	97	8	8.2	3.6	15.6	98	3	3.1	0.6	8.7
	With fever	93	3	3.2	0.7	9.1	97	5	5.2	1.7	11.6	98	0	0.0	0.0	3.7
	Varicella like	93	0	0.0	0.0	3.9	97	1	1.0	0.0	5.6	98	0	0.0	0.0	3.7
	Measles/Rubella like	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Grade 3	93	0	0.0	0.0	3.9	97	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7
	Related	93	4	4.3	1.2	10.7	97	3	3.1	0.6	8.8	98	1	1.0	0.0	5.6
	Med adv	93	5	5.4	1.8	12.1	97	7	7.2	3.0	14.3	98	2	2.0	0.3	7.2

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	288	51	17.7	13.5	22.6	96	21	21.9	14.1	31.5
	With fever	288	15	5.2	2.9	8.4	96	4	4.2	1.2	10.3
	Varicella like	288	8	2.8	1.2	5.4	96	3	3.1	0.7	8.9
	Measles/Rubella like	288	2	0.7	0.1	2.5	96	1	1.0	0.0	5.7
	Grade 3	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Related	288	22	7.6	4.9	11.3	96	5	5.2	1.7	11.7
	Med adv	288	39	13.5	9.8	18.0	96	16	16.7	9.8	25.7
Localized	Any	288	35	12.2	8.6	16.5	96	16	16.7	9.8	25.7
	Administration site	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Other site	288	34	11.8	8.3	16.1	96	16	16.7	9.8	25.7
	With fever	288	8	2.8	1.2	5.4	96	2	2.1	0.3	7.3
	Varicella like	288	7	2.4	1.0	4.9	96	1	1.0	0.0	5.7
	Measles/Rubella like	288	2	0.7	0.1	2.5	96	0	0.0	0.0	3.8
	Grade 3	288	1	0.3	0.0	1.9	96	0	0.0	0.0	3.8
	Related	288	14	4.9	2.7	8.0	96	4	4.2	1.2	10.3
	Med adv	288	26	9.0	6.0	13.0	96	12	12.5	6.6	20.8
Generalized	Any	288	18	6.3	3.8	9.7	96	6	6.3	2.3	13.1
	With fever	288	8	2.8	1.2	5.4	96	2	2.1	0.3	7.3
	Varicella like	288	1	0.3	0.0	1.9	96	2	2.1	0.3	7.3
	Measles/Rubella like	288	0	0.0	0.0	1.3	96	1	1.0	0.0	5.7
	Grade 3	288	0	0.0	0.0	1.3	96	0	0.0	0.0	3.8
	Related	288	8	2.8	1.2	5.4	96	2	2.1	0.3	7.3
	Med adv	288	14	4.9	2.7	8.0	96	4	4.2	1.2	10.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.78 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1					INV_MMR_2					INV_MMR_3				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	577	131	22.7	19.4	26.3	560	135	24.1	20.6	27.9	577	139	24.1	20.7	27.8
	With fever	577	38	6.6	4.7	8.9	560	47	8.4	6.2	11.0	577	34	5.9	4.1	8.1
	Varicella like	577	12	2.1	1.1	3.6	560	13	2.3	1.2	3.9	577	10	1.7	0.8	3.2
	Measles/Rubella like	577	24	4.2	2.7	6.1	560	39	7.0	5.0	9.4	577	37	6.4	4.6	8.7
	Grade 3	577	8	1.4	0.6	2.7	560	12	2.1	1.1	3.7	577	20	3.5	2.1	5.3
	Related	577	36	6.2	4.4	8.5	560	56	10.0	7.6	12.8	577	52	9.0	6.8	11.7
	Med adv	577	58	10.1	7.7	12.8	560	51	9.1	6.9	11.8	577	64	11.1	8.7	13.9
Localized	Any	577	85	14.7	11.9	17.9	560	88	15.7	12.8	19.0	577	94	16.3	13.4	19.6
	Administration site	577	5	0.9	0.3	2.0	560	7	1.3	0.5	2.6	577	4	0.7	0.2	1.8
	Other site	577	82	14.2	11.5	17.3	560	82	14.6	11.8	17.9	577	90	15.6	12.7	18.8
	With fever	577	17	2.9	1.7	4.7	560	28	5.0	3.4	7.2	577	20	3.5	2.1	5.3
	Varicella like	577	11	1.9	1.0	3.4	560	6	1.1	0.4	2.3	577	3	0.5	0.1	1.5
	Measles/Rubella like	577	10	1.7	0.8	3.2	560	19	3.4	2.1	5.3	577	17	2.9	1.7	4.7
	Grade 3	577	3	0.5	0.1	1.5	560	5	0.9	0.3	2.1	577	7	1.2	0.5	2.5
	Related	577	18	3.1	1.9	4.9	560	32	5.7	3.9	8.0	577	24	4.2	2.7	6.1
	Med adv	577	33	5.7	4.0	7.9	560	26	4.6	3.1	6.7	577	35	6.1	4.3	8.3
Generalized	Any	577	55	9.5	7.3	12.2	560	58	10.4	8.0	13.2	577	55	9.5	7.3	12.2
	With fever	577	24	4.2	2.7	6.1	560	21	3.8	2.3	5.7	577	16	2.8	1.6	4.5
	Varicella like	577	1	0.2	0.0	1.0	560	7	1.3	0.5	2.6	577	7	1.2	0.5	2.5
	Measles/Rubella like	577	15	2.6	1.5	4.3	560	21	3.8	2.3	5.7	577	22	3.8	2.4	5.7
	Grade 3	577	6	1.0	0.4	2.3	560	7	1.3	0.5	2.6	577	13	2.3	1.2	3.8
	Related	577	20	3.5	2.1	5.3	560	26	4.6	3.1	6.7	577	29	5.0	3.4	7.1
	Med adv	577	28	4.9	3.3	6.9	560	28	5.0	3.4	7.2	577	31	5.4	3.7	7.5

		INV_MMR					COM_MMR				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	1714	405	23.6	21.6	25.7	612	147	24.0	20.7	27.6
	With fever	1714	119	6.9	5.8	8.3	612	42	6.9	5.0	9.2
	Varicella like	1714	35	2.0	1.4	2.8	612	11	1.8	0.9	3.2
	Measles/Rubella like	1714	100	5.8	4.8	7.1	612	32	5.2	3.6	7.3
	Grade 3	1714	40	2.3	1.7	3.2	612	11	1.8	0.9	3.2
	Related	1714	144	8.4	7.1	9.8	612	51	8.3	6.3	10.8
	Med adv	1714	173	10.1	8.7	11.6	612	60	9.8	7.6	12.4
Localized	Any	1714	267	15.6	13.9	17.4	612	105	17.2	14.3	20.4
	Administration site	1714	16	0.9	0.5	1.5	612	6	1.0	0.4	2.1
	Other site	1714	254	14.8	13.2	16.6	612	100	16.3	13.5	19.5
	With fever	1714	65	3.8	2.9	4.8	612	22	3.6	2.3	5.4
	Varicella like	1714	20	1.2	0.7	1.8	612	7	1.1	0.5	2.3
	Measles/Rubella like	1714	46	2.7	2.0	3.6	612	21	3.4	2.1	5.2
	Grade 3	1714	15	0.9	0.5	1.4	612	4	0.7	0.2	1.7
	Related	1714	74	4.3	3.4	5.4	612	30	4.9	3.3	6.9
	Med adv	1714	94	5.5	4.5	6.7	612	34	5.6	3.9	7.7
Generalized	Any	1714	168	9.8	8.4	11.3	612	50	8.2	6.1	10.6
	With fever	1714	61	3.6	2.7	4.6	612	21	3.4	2.1	5.2
	Varicella like	1714	15	0.9	0.5	1.4	612	4	0.7	0.2	1.7
	Measles/Rubella like	1714	58	3.4	2.6	4.4	612	11	1.8	0.9	3.2
	Grade 3	1714	26	1.5	1.0	2.2	612	7	1.1	0.5	2.3
	Related	1714	75	4.4	3.5	5.5	612	21	3.4	2.1	5.2
	Med adv	1714	87	5.1	4.1	6.2	612	29	4.7	3.2	6.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.79 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

		INV_MMR									
		F					M				
					95% CI					95% CI	
Symptom	rash type	N	n	%	LL	UL	N	n	%	LL	UL
Any	Localized or generalized	1734	517	29.8	27.7	32.0	1832	526	28.7	26.7	30.8
	With fever	1734	173	10.0	8.6	11.5	1832	174	9.5	8.2	10.9
	Varicella like	1734	127	7.3	6.1	8.7	1832	123	6.7	5.6	8.0
	Measles/Rubella like	1734	111	6.4	5.3	7.7	1832	124	6.8	5.7	8.0
	Grade 3	1734	54	3.1	2.4	4.0	1832	52	2.8	2.1	3.7
	Related	1734	239	13.8	12.2	15.5	1832	250	13.6	12.1	15.3
	Med adv	1734	235	13.6	12.0	15.3	1832	211	11.5	10.1	13.1
Localized	Any	1734	350	20.2	18.3	22.2	1832	355	19.4	17.6	21.3
	Administration site	1734	20	1.2	0.7	1.8	1832	18	1.0	0.6	1.6
	Other site	1734	338	19.5	17.7	21.4	1832	342	18.7	16.9	20.5
	With fever	1734	87	5.0	4.0	6.2	1832	95	5.2	4.2	6.3
	Varicella like	1734	85	4.9	3.9	6.0	1832	95	5.2	4.2	6.3
	Measles/Rubella like	1734	43	2.5	1.8	3.3	1832	50	2.7	2.0	3.6
	Grade 3	1734	11	0.6	0.3	1.1	1832	14	0.8	0.4	1.3
	Related	1734	136	7.8	6.6	9.2	1832	153	8.4	7.1	9.7
	Med adv	1734	123	7.1	5.9	8.4	1832	118	6.4	5.4	7.7
Generalized	Any	1734	209	12.1	10.6	13.7	1832	205	11.2	9.8	12.7
	With fever	1734	96	5.5	4.5	6.7	1832	90	4.9	4.0	6.0
	Varicella like	1734	45	2.6	1.9	3.5	1832	29	1.6	1.1	2.3
	Measles/Rubella like	1734	70	4.0	3.2	5.1	1832	76	4.1	3.3	5.2
	Grade 3	1734	45	2.6	1.9	3.5	1832	38	2.1	1.5	2.8
	Related	1734	117	6.7	5.6	8.0	1832	106	5.8	4.8	7.0
	Med adv	1734	127	7.3	6.1	8.7	1832	100	5.5	4.5	6.6

		COM_MMR									
		F					M				
					95% CI					95% CI	
Symptom	rash type	N	n	%	LL	UL	N	n	%	LL	UL
Any	Localized or generalized	598	179	29.9	26.3	33.8	645	199	30.9	27.3	34.6
	With fever	598	54	9.0	6.9	11.6	645	50	7.8	5.8	10.1
	Varicella like	598	35	5.9	4.1	8.1	645	50	7.8	5.8	10.1
	Measles/Rubella like	598	35	5.9	4.1	8.1	645	42	6.5	4.7	8.7
	Grade 3	598	13	2.2	1.2	3.7	645	12	1.9	1.0	3.2
	Related	598	76	12.7	10.2	15.7	645	86	13.3	10.8	16.2
	Med adv	598	77	12.9	10.3	15.8	645	87	13.5	11.0	16.4
Localized	Any	598	125	20.9	17.7	24.4	645	141	21.9	18.7	25.3
	Administration site	598	11	1.8	0.9	3.3	645	5	0.8	0.3	1.8
	Other site	598	116	19.4	16.3	22.8	645	136	21.1	18.0	24.4
	With fever	598	27	4.5	3.0	6.5	645	27	4.2	2.8	6.0
	Varicella like	598	26	4.3	2.9	6.3	645	35	5.4	3.8	7.5
	Measles/Rubella like	598	15	2.5	1.4	4.1	645	20	3.1	1.9	4.8
	Grade 3	598	2	0.3	0.0	1.2	645	3	0.5	0.1	1.4
	Related	598	44	7.4	5.4	9.8	645	59	9.1	7.0	11.6
	Med adv	598	46	7.7	5.7	10.1	645	49	7.6	5.7	9.9
Generalized	Any	598	65	10.9	8.5	13.6	645	78	12.1	9.7	14.9
	With fever	598	29	4.8	3.3	6.9	645	26	4.0	2.7	5.9
	Varicella like	598	9	1.5	0.7	2.8	645	16	2.5	1.4	4.0
	Measles/Rubella like	598	20	3.3	2.1	5.1	645	22	3.4	2.2	5.1
	Grade 3	598	11	1.8	0.9	3.3	645	9	1.4	0.6	2.6

		COM_MMR									
		F					M				
					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Related	598	33	5.5	3.8	7.7	645	36	5.6	3.9	7.6
	Med adv	598	34	5.7	4.0	7.9	645	46	7.1	5.3	9.4

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.80 Incidence of rash within the 43-day (Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

		INV_MMR														
		WH					OT					AF				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	2720	846	31.1	29.4	32.9	352	70	19.9	15.8	24.4	151	34	22.5	16.1	30.0
	With fever	2720	287	10.6	9.4	11.8	352	22	6.3	4.0	9.3	151	10	6.6	3.2	11.8
	Varicella like	2720	232	8.5	7.5	9.6	352	9	2.6	1.2	4.8	151	2	1.3	0.2	4.7
	Measles/Rubella like	2720	193	7.1	6.2	8.1	352	9	2.6	1.2	4.8	151	4	2.6	0.7	6.6
	Grade 3	2720	94	3.5	2.8	4.2	352	1	0.3	0.0	1.6	151	2	1.3	0.2	4.7
	Related	2720	402	14.8	13.5	16.2	352	32	9.1	6.3	12.6	151	7	4.6	1.9	9.3
	Med adv	2720	363	13.3	12.1	14.7	352	43	12.2	9.0	16.1	151	15	9.9	5.7	15.9
Localized	Any	2720	567	20.8	19.3	22.4	352	49	13.9	10.5	18.0	151	20	13.2	8.3	19.7
	Administration site	2720	29	1.1	0.7	1.5	352	3	0.9	0.2	2.5	151	3	2.0	0.4	5.7
	Other site	2720	549	20.2	18.7	21.7	352	46	13.1	9.7	17.0	151	17	11.3	6.7	17.4
	With fever	2720	144	5.3	4.5	6.2	352	13	3.7	2.0	6.2	151	5	3.3	1.1	7.6
	Varicella like	2720	169	6.2	5.3	7.2	352	7	2.0	0.8	4.1	151	2	1.3	0.2	4.7
	Measles/Rubella like	2720	67	2.5	1.9	3.1	352	7	2.0	0.8	4.1	151	2	1.3	0.2	4.7
	Grade 3	2720	19	0.7	0.4	1.1	352	1	0.3	0.0	1.6	151	0	0.0	0.0	2.4
	Related	2720	234	8.6	7.6	9.7	352	20	5.7	3.5	8.6	151	5	3.3	1.1	7.6
	Med adv	2720	189	6.9	6.0	8.0	352	28	8.0	5.4	11.3	151	6	4.0	1.5	8.5
Generalized	Any	2720	344	12.6	11.4	14.0	352	25	7.1	4.7	10.3	151	15	9.9	5.7	15.9
	With fever	2720	160	5.9	5.0	6.8	352	11	3.1	1.6	5.5	151	6	4.0	1.5	8.5
	Varicella like	2720	67	2.5	1.9	3.1	352	2	0.6	0.1	2.0	151	0	0.0	0.0	2.4
	Measles/Rubella like	2720	128	4.7	3.9	5.6	352	2	0.6	0.1	2.0	151	2	1.3	0.2	4.7
	Grade 3	2720	77	2.8	2.2	3.5	352	0	0.0	0.0	1.0	151	2	1.3	0.2	4.7
	Related	2720	189	6.9	6.0	8.0	352	12	3.4	1.8	5.9	151	2	1.3	0.2	4.7
	Med adv	2720	192	7.1	6.1	8.1	352	17	4.8	2.8	7.6	151	9	6.0	2.8	11.0

		COM_MMR														
		WH					OT					AF				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Any	Localized or generalized	947	303	32.0	29.0	35.1	119	28	23.5	16.2	32.2	64	16	25.0	15.0	37.4
	With fever	947	85	9.0	7.2	11.0	119	6	5.0	1.9	10.7	64	5	7.8	2.6	17.3
	Varicella like	947	78	8.2	6.6	10.2	119	3	2.5	0.5	7.2	64	1	1.6	0.0	8.4
	Measles/Rubella like	947	63	6.7	5.2	8.4	119	1	0.8	0.0	4.6	64	2	3.1	0.4	10.8
	Grade 3	947	23	2.4	1.6	3.6	119	0	0.0	0.0	3.1	64	0	0.0	0.0	5.6
	Related	947	136	14.4	12.2	16.8	119	5	4.2	1.4	9.5	64	6	9.4	3.5	19.3
	Med adv	947	133	14.0	11.9	16.4	119	17	14.3	8.6	21.9	64	6	9.4	3.5	19.3
Localized	Any	947	210	22.2	19.6	25.0	119	22	18.5	12.0	26.6	64	12	18.8	10.1	30.5
	Administration site	947	14	1.5	0.8	2.5	119	1	0.8	0.0	4.6	64	0	0.0	0.0	5.6
	Other site	947	198	20.9	18.4	23.6	119	21	17.6	11.3	25.7	64	12	18.8	10.1	30.5
	With fever	947	43	4.5	3.3	6.1	119	3	2.5	0.5	7.2	64	3	4.7	1.0	13.1
	Varicella like	947	57	6.0	4.6	7.7	119	1	0.8	0.0	4.6	64	1	1.6	0.0	8.4
	Measles/Rubella like	947	25	2.6	1.7	3.9	119	0	0.0	0.0	3.1	64	2	3.1	0.4	10.8
	Grade 3	947	5	0.5	0.2	1.2	119	0	0.0	0.0	3.1	64	0	0.0	0.0	5.6
	Related	947	84	8.9	7.1	10.9	119	4	3.4	0.9	8.4	64	5	7.8	2.6	17.3
	Med adv	947	76	8.0	6.4	9.9	119	12	10.1	5.3	17.0	64	3	4.7	1.0	13.1
Generalized	Any	947	121	12.8	10.7	15.1	119	7	5.9	2.4	11.7	64	4	6.3	1.7	15.2
	With fever	947	46	4.9	3.6	6.4	119	3	2.5	0.5	7.2	64	2	3.1	0.4	10.8
	Varicella like	947	22	2.3	1.5	3.5	119	2	1.7	0.2	5.9	64	0	0.0	0.0	5.6
	Measles/Rubella like	947	38	4.0	2.9	5.5	119	1	0.8	0.0	4.6	64	0	0.0	0.0	5.6
	Grade 3	947	18	1.9	1.1	3.0	119	0	0.0	0.0	3.1	64	0	0.0	0.0	5.6

		COM_MMR														
		WH					OT					AF				
					95% CI					95% CI					95% CI	
Symptom	**rash type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Related	947	61	6.4	5.0	8.2	119	2	1.7	0.2	5.9	64	1	1.6	0.0	8.4
	Med adv	947	67	7.1	5.5	8.9	119	5	4.2	1.4	9.5	64	3	4.7	1.0	13.1

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects having received the documented dose
n/% = number/percentage of subjects reporting a specified symptom
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.81 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		615	49.6	46.8	52.5	633	51.4	48.5	54.2	609	49.0	46.2	51.8	1857	50.0	48.4	51.6	618	47.9	45.2	50.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	4	0.3	0.1	0.8	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Leukocytosis (10024378)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Leukopenia (10024384)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lymphadenopathy (10025197)	5	0.4	0.1	0.9	5	0.4	0.1	0.9	2	0.2	0.0	0.6	12	0.3	0.2	0.6	4	0.3	0.1	0.8
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Deafness (10011878)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear pain (10014020)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	4	0.3	0.1	0.8	10	0.3	0.1	0.5	4	0.3	0.1	0.8
	Ear swelling (10014025)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Excessive cerumen production (10076897)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otorrhoea (10033101)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Dacryostenosis acquired (10053990)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye discharge (10015915)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye irritation (10015946)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye swelling (10015967)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eyelid oedema (10015993)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hypermetropia (10020675)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lacrimation increased (10023644)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lid sulcus deepened (10072716)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Strabismus (10042159)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain upper (10000087)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.8
	Anal fissure (10002153)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Aphthous ulcer (10002959)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Chapped lips (10049047)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Constipation (10010774)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	9	0.7	0.3	1.4	16	0.4	0.2	0.7	8	0.6	0.3	1.2
	Diarrhoea (10012735)	64	5.2	4.0	6.5	58	4.7	3.6	6.0	49	3.9	2.9	5.2	171	4.6	4.0	5.3	64	5.0	3.8	6.3
	Dyspepsia (10013946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Dysphagia (10013950)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Enterocolitis (10014893)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Faeces soft (10074859)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Flatulence (10016766)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Gastrooesophageal reflux disease (10017885)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Gingival hypertrophy (10018284)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival pain (10018286)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Haematochezia (10018836)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lip swelling (10024570)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Oral mucosal eruption (10030997)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Post-tussive vomiting (10066220)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Ranula (10037838)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Regurgitation (10067171)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Salivary gland enlargement (10039408)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Salivary gland pain (10039421)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salivary hypersecretion (10039424)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Stomatitis (10042128)	0	0.0	0.0	0.3	4	0.3	0.1	0.8	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Teething (10043183)	91	7.3	6.0	8.9	92	7.5	6.1	9.1	77	6.2	4.9	7.7	260	7.0	6.2	7.9	95	7.4	6.0	8.9
	Toothache (10044055)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	6	0.5	0.2	1.0
	Vomiting (10047700)	38	3.1	2.2	4.2	35	2.8	2.0	3.9	34	2.7	1.9	3.8	107	2.9	2.4	3.5	43	3.3	2.4	4.5
General disorders and administration site conditions (10018065)	Crying (10011469)	4	0.3	0.1	0.8	5	0.4	0.1	0.9	2	0.2	0.0	0.6	11	0.3	0.1	0.5	4	0.3	0.1	0.8
	Cyst (10011732)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Discomfort (10013082)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Feeling hot (10016334)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Influenza like illness (10022004)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site bruising (10022052)	4	0.3	0.1	0.8	5	0.4	0.1	0.9	1	0.1	0.0	0.4	10	0.3	0.1	0.5	2	0.2	0.0	0.6
	Injection site erosion (10022059)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site erythema (10022061)	31	2.5	1.7	3.5	29	2.4	1.6	3.4	32	2.6	1.8	3.6	92	2.5	2.0	3.0	26	2.0	1.3	2.9
	Injection site haematoma (10022066)	5	0.4	0.1	0.9	1	0.1	0.0	0.5	3	0.2	0.0	0.7	9	0.2	0.1	0.5	0	0.0	0.0	0.3
	Injection site haemorrhage (10022067)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Injection site induration (10022075)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	2	0.2	0.0	0.6	8	0.2	0.1	0.4	3	0.2	0.0	0.7
	Injection site mass (10022081)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Injection site nodule (10057880)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site pain (10022086)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Injection site papule (10066044)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	5	0.4	0.1	0.9
	Injection site swelling (10053425)	12	1.0	0.5	1.7	8	0.6	0.3	1.3	11	0.9	0.4	1.6	31	0.8	0.6	1.2	9	0.7	0.3	1.3
	Injection site vesicles (10022111)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oedema peripheral (10030124)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain (10033371)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Pyrexia (10037660)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Secretion discharge (10053459)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Swelling (10042674)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Vessel puncture site haematoma (10065902)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Food allergy (10016946)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.4	0.1	0.9	9	0.2	0.1	0.5	4	0.3	0.1	0.8
	Hypersensitivity (10020751)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Immunisation reaction (10021432)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Milk allergy (10027633)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seasonal allergy (10048908)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acute sinusitis (10001076)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Adenovirus infection (10060931)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body tinea (10005913)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchiolitis (10006448)	2	0.2	0.0	0.6	9	0.7	0.3	1.4	7	0.6	0.2	1.2	18	0.5	0.3	0.8	7	0.5	0.2	1.1
	Bronchitis (10006451)	10	0.8	0.4	1.5	13	1.1	0.6	1.8	10	0.8	0.4	1.5	33	0.9	0.6	1.2	12	0.9	0.5	1.6
	Bullous impetigo (10006563)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Candida nappy rash (10007135)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cellulitis (10007882)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Clostridium difficile infection (10054236)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	27	2.2	1.4	3.2	21	1.7	1.1	2.6	39	3.1	2.2	4.3	87	2.3	1.9	2.9	32	2.5	1.7	3.5
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Croup infectious (10011416)	4	0.3	0.1	0.8	11	0.9	0.4	1.6	8	0.6	0.3	1.3	23	0.6	0.4	0.9	6	0.5	0.2	1.0
	Ear infection (10014011)	9	0.7	0.3	1.4	14	1.1	0.6	1.9	4	0.3	0.1	0.8	27	0.7	0.5	1.1	13	1.0	0.5	1.7

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Enterovirus infection (10014909)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Epstein-barr virus infection (10015108)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exanthema subitum (10015586)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Eye infection (10015929)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Folliculitis (10016936)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Fungal infection (10017533)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis (10017888)	27	2.2	1.4	3.2	22	1.8	1.1	2.7	36	2.9	2.0	4.0	85	2.3	1.8	2.8	31	2.4	1.6	3.4
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastroenteritis viral (10017918)	3	0.2	0.0	0.7	6	0.5	0.2	1.1	6	0.5	0.2	1.0	15	0.4	0.2	0.7	6	0.5	0.2	1.0
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gingivitis (10018292)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand-foot-and-mouth disease (10019113)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	9	0.7	0.3	1.4	14	0.4	0.2	0.6	5	0.4	0.1	0.9
	Herpangina (10019936)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hordeolum (10020377)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Impetigo (10021531)	4	0.3	0.1	0.8	1	0.1	0.0	0.5	1	0.1	0.0	0.4	6	0.2	0.1	0.4	2	0.2	0.0	0.6
	Infected bite (10076911)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza (10022000)	2	0.2	0.0	0.6	5	0.4	0.1	0.9	1	0.1	0.0	0.4	8	0.2	0.1	0.4	10	0.8	0.4	1.4
	Injection site abscess (10022044)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Laryngitis (10023874)	1	0.1	0.0	0.4	8	0.6	0.3	1.3	2	0.2	0.0	0.6	11	0.3	0.1	0.5	6	0.5	0.2	1.0
	Lice infestation (10024424)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Localised infection (10024774)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lower respiratory tract infection (10024968)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6

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	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	74	6.0	4.7	7.4	75	6.1	4.8	7.6	74	6.0	4.7	7.4	223	6.0	5.3	6.8	65	5.0	3.9	6.4
	Oral candidiasis (10030963)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oral herpes (10067152)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Oral infection (10048685)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis externa (10033072)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	80	6.5	5.2	8.0	75	6.1	4.8	7.6	63	5.1	3.9	6.4	218	5.9	5.1	6.7	87	6.7	5.4	8.3
	Otitis media acute (10033079)	8	0.6	0.3	1.3	7	0.6	0.2	1.2	13	1.0	0.6	1.8	28	0.8	0.5	1.1	9	0.7	0.3	1.3
	Otitis media chronic (10033081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Paronychia (10034016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Periorbital cellulitis (10057182)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pharyngitis (10034835)	20	1.6	1.0	2.5	31	2.5	1.7	3.6	14	1.1	0.6	1.9	65	1.8	1.4	2.2	23	1.8	1.1	2.7
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pharyngotonsillitis (10049140)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	6	0.5	0.2	1.0	8	0.2	0.1	0.4	1	0.1	0.0	0.4
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia viral (10035737)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract infection (10062352)	8	0.6	0.3	1.3	11	0.9	0.4	1.6	9	0.7	0.3	1.4	28	0.8	0.5	1.1	7	0.5	0.2	1.1
	Respiratory tract infection viral (10062106)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	4	0.3	0.1	0.8
	Rhinitis (10039083)	46	3.7	2.7	4.9	49	4.0	3.0	5.2	38	3.1	2.2	4.2	133	3.6	3.0	4.2	41	3.2	2.3	4.3
	Roseola (10039222)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sinusitis (10040753)	9	0.7	0.3	1.4	3	0.2	0.1	0.7	4	0.3	0.1	0.8	16	0.4	0.2	0.7	3	0.2	0.0	0.7
	Skin bacterial infection (10052891)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin candida (10054152)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Staphylococcal infection (10058080)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Streptococcal infection (10061372)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.2	0.0	0.7	5	0.1	0.0	0.3	3	0.2	0.0	0.7
	Subcutaneous abscess (10042343)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tonsillitis (10044008)	21	1.7	1.1	2.6	9	0.7	0.3	1.4	9	0.7	0.3	1.4	39	1.1	0.7	1.4	15	1.2	0.7	1.9
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract infection (10046306)	106	8.6	7.1	10.3	124	10.1	8.4	11.9	122	9.8	8.2	11.6	352	9.5	8.6	10.5	122	9.5	7.9	11.2
	Urinary tract infection (10046571)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Viral infection (10047461)	15	1.2	0.7	2.0	21	1.7	1.1	2.6	24	1.9	1.2	2.9	60	1.6	1.2	2.1	15	1.2	0.7	1.9
	Viral pharyngitis (10047473)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Viral rash (10047476)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral tonsillitis (10047480)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Animal bite (10002515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Arthropod bite (10003399)	7	0.6	0.2	1.2	7	0.6	0.2	1.2	5	0.4	0.1	0.9	19	0.5	0.3	0.8	4	0.3	0.1	0.8
	Arthropod sting (10003402)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Bite (10004966)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Concussion (10010254)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Contusion (10050584)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	4	0.3	0.1	0.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Craniocerebral injury (10070976)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Ear canal injury (10056319)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear injury (10057446)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye contusion (10073354)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Face injury (10050392)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Fall (10016173)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gingival injury (10049300)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Head injury (10019196)	5	0.4	0.1	0.9	6	0.5	0.2	1.1	6	0.5	0.2	1.0	17	0.5	0.3	0.7	2	0.2	0.0	0.6
	Heat stroke (10019345)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Laceration (10023572)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	2	0.2	0.0	0.6	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Limb injury (10061225)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Lip injury (10055082)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Nail avulsion (10028686)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Upper limb fracture (10061394)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wound (10052428)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cold agglutinins positive (10009854)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight decreased (10047895)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	2	0.2	0.0	0.6	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Dehydration (10012174)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Lactose intolerance (10023681)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Knee deformity (10062061)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Synovial cyst (10042858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Drooling (10013642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Epilepsy (10015037)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exaggerated startle response (10066482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Febrile convulsion (10016284)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gross motor delay (10069118)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Headache (10019211)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Lethargy (10024264)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nystagmus (10029864)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	4	0.3	0.1	0.8	0	0.0	0.0	0.3	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Post-traumatic headache (10036313)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Somnolence (10041349)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Speech disorder developmental (10041467)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tremor (10044565)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Depressed mood (10012374)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Insomnia (10022437)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Irritability (10022998)	11	0.9	0.4	1.6	12	1.0	0.5	1.7	9	0.7	0.3	1.4	32	0.9	0.6	1.2	17	1.3	0.8	2.1
	Middle insomnia (10027590)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Restlessness (10038743)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Sleep disorder (10040984)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sleep terror (10041010)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tearfulness (10043169)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Terminal insomnia (10068932)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary tract disorder (10046566)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Balanoposthitis (10004078)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Bilateral breast buds (10004557)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Genital labial adhesions (10064162)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	5	0.4	0.1	0.9
	Bronchial hyperreactivity (10066091)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Bronchospasm (10006482)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Catarrh (10007774)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cough (10011224)	33	2.7	1.8	3.7	42	3.4	2.5	4.6	38	3.1	2.2	4.2	113	3.0	2.5	3.6	36	2.8	2.0	3.8
	Dyspnoea (10013968)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Epistaxis (10015090)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	1	0.1	0.0	0.4	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	10	0.8	0.4	1.5	11	0.9	0.4	1.6	5	0.4	0.1	0.9	26	0.7	0.5	1.0	11	0.9	0.4	1.5
	Nasal discomfort (10052437)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oropharyngeal pain (10068319)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory disorder (10038683)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.3	0.1	0.8	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract congestion (10052251)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rhinitis allergic (10039085)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	3	0.2	0.0	0.7	8	0.2	0.1	0.4	1	0.1	0.0	0.4
	Rhinorrhoea (10039101)	22	1.8	1.1	2.7	23	1.9	1.2	2.8	20	1.6	1.0	2.5	65	1.8	1.4	2.2	21	1.6	1.0	2.5
	Sinus congestion (10040742)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sneezing (10041232)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract congestion (10052252)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	6	0.5	0.2	1.0	14	0.4	0.2	0.6	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Blister (10005191)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis (10012431)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Dermatitis allergic (10012434)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis atopic (10012438)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	4	0.3	0.1	0.8	9	0.2	0.1	0.5	3	0.2	0.0	0.7
	Dermatitis contact (10012442)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	3	0.2	0.0	0.7	4	0.3	0.1	0.8	3	0.2	0.0	0.7	10	0.3	0.1	0.5	5	0.4	0.1	0.9
	Drug eruption (10013687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dry skin (10013786)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eczema (10014184)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.1	0.0	0.3	5	0.4	0.1	0.9
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Erythema (10015150)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Hyperhidrosis (10020642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hyperkeratosis (10020649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ingrowing nail (10022013)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Keratosis pilaris (10066295)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Macule (10025421)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Miliaria (10027627)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Papule (10033733)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prurigo (10037083)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Pruritus (10037087)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seborrhoea (10039792)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin irritation (10040880)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Skin mass (10067868)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin warm (10040952)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Solar dermatitis (10041303)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Swelling face (10042682)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Urticaria (10046735)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pallor (10033546)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.82 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		59	47.6	38.5	56.7	65	52.0	42.9	61.0	60	48.0	39.0	57.1	184	49.2	44.0	54.4	56	44.1	35.3	53.2
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Lymphadenopathy (10025197)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Eyelid oedema (10015993)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	7	5.6	2.3	11.3	4	3.2	0.9	8.0	4	3.2	0.9	8.0	15	4.0	2.3	6.5	7	5.5	2.2	11.0
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Flatulence (10016766)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival swelling (10018291)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Salivary hypersecretion (10039424)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Teething (10043183)	9	7.3	3.4	13.3	12	9.6	5.1	16.2	7	5.6	2.3	11.2	28	7.5	5.0	10.6	7	5.5	2.2	11.0
	Toothache (10044055)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Vomiting (10047700)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	3	2.4	0.5	6.9	8	2.1	0.9	4.2	3	2.4	0.5	6.7
General disorders and administration site conditions (10018065)	Injection site erosion (10022059)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site erythema (10022061)	9	7.3	3.4	13.3	5	4.0	1.3	9.1	7	5.6	2.3	11.2	21	5.6	3.5	8.5	9	7.1	3.3	13.0
	Injection site haematoma (10022066)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site pain (10022086)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Injection site papule (10066044)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site swelling (10053425)	4	3.2	0.9	8.1	1	0.8	0.0	4.4	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pyrexia (10037660)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Food allergy (10016946)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Infections and infestations (10021881)	Adenovirus infection (10060931)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Bronchitis (10006451)	1	0.8	0.0	4.4	4	3.2	0.9	8.0	1	0.8	0.0	4.4	6	1.6	0.6	3.5	2	1.6	0.2	5.6
	Conjunctivitis (10010741)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear infection (10014011)	3	2.4	0.5	6.9	5	4.0	1.3	9.1	1	0.8	0.0	4.4	9	2.4	1.1	4.5	6	4.7	1.8	10.0
	Enterovirus infection (10014909)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	0	0.0	0.0	2.9	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	1	0.8	0.0	4.4	4	1.1	0.3	2.7	3	2.4	0.5	6.7
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	1.6	0.2	5.7	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Influenza (10022000)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Nasopharyngitis (10028810)	4	3.2	0.9	8.1	7	5.6	2.3	11.2	3	2.4	0.5	6.9	14	3.7	2.1	6.2	2	1.6	0.2	5.6
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pneumonia (10035664)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Respiratory tract infection (10062352)	1	0.8	0.0	4.4	2	1.6	0.2	5.7	0	0.0	0.0	2.9	3	0.8	0.2	2.3	0	0.0	0.0	2.9
	Respiratory tract infection viral (10062106)	3	2.4	0.5	6.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	4	1.1	0.3	2.7	3	2.4	0.5	6.7
	Rhinitis (10039083)	13	10.5	5.7	17.3	17	13.6	8.1	20.9	15	12.0	6.9	19.0	45	12.0	8.9	15.8	12	9.4	5.0	15.9
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	7	1.9	0.8	3.8	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Viral infection (10047461)	3	2.4	0.5	6.9	9	7.2	3.3	13.2	8	6.4	2.8	12.2	20	5.3	3.3	8.1	5	3.9	1.3	8.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Nervous system disorders (10029205)	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Psychiatric disorders (10037175)	Sleep disorder (10040984)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Cough (10011224)	11	8.9	4.5	15.3	13	10.4	5.7	17.1	8	6.4	2.8	12.2	32	8.6	5.9	11.9	8	6.3	2.8	12.0
	Epistaxis (10015090)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rhinorrhoea (10039101)	2	1.6	0.2	5.7	2	1.6	0.2	5.7	2	1.6	0.2	5.7	6	1.6	0.6	3.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Eczema (10014184)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Erythema (10015150)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Hyperhidrosis (10020642)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.83 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		39	63.9	50.6	75.8	40	64.5	51.3	76.3	41	64.1	51.1	75.7	120	64.2	56.8	71.0	44	63.8	51.3	75.0
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	8	13.1	5.8	24.2	1	1.6	0.0	8.7	2	3.1	0.4	10.8	11	5.9	3.0	10.3	7	10.1	4.2	19.8
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Faeces soft (10074859)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Teething (10043183)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	3	4.3	0.9	12.2
	Toothache (10044055)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Vomiting (10047700)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	3	4.7	1.0	13.1	7	3.7	1.5	7.6	3	4.3	0.9	12.2
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oedema peripheral (10030124)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchitis (10006451)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	2	2.9	0.4	10.1
	Candida infection (10074170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Conjunctivitis (10010741)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	5	7.8	2.6	17.3	8	4.3	1.9	8.3	5	7.2	2.4	16.1
	Ear infection (10014011)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	3	4.7	1.0	13.1	7	3.7	1.5	7.6	3	4.3	0.9	12.2
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Impetigo (10021531)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Laryngitis (10023874)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Nasopharyngitis (10028810)	11	18.0	9.4	30.0	7	11.3	4.7	21.9	11	17.2	8.9	28.7	29	15.5	10.6	21.5	10	14.5	7.2	25.0
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Otitis media (10033078)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Otitis media acute (10033079)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	5	7.8	2.6	17.3	8	4.3	1.9	8.3	2	2.9	0.4	10.1
	Pharyngitis (10034835)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	1	1.4	0.0	7.8
	Pharyngotonsillitis (10049140)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Pneumonia (10035664)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Respiratory tract infection (10062352)	4	6.6	1.8	15.9	5	8.1	2.7	17.8	3	4.7	1.0	13.1	12	6.4	3.4	10.9	5	7.2	2.4	16.1
	Rhinitis (10039083)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Tonsillitis (10044008)	7	11.5	4.7	22.2	4	6.5	1.8	15.7	3	4.7	1.0	13.1	14	7.5	4.2	12.2	8	11.6	5.1	21.6
	Upper respiratory tract infection (10046306)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	2	3.1	0.4	10.8	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Viral infection (10047461)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	2	2.9	0.4	10.1
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	3	4.7	1.0	13.1	5	2.7	0.9	6.1	0	0.0	0.0	5.2
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	2	2.9	0.4	10.1
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Balanoposthitis (10004078)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchospasm (10006482)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	3	4.7	1.0	13.1	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Catarrh (10007774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Cough (10011224)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	2	2.9	0.4	10.1
	Epistaxis (10015090)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Nasal congestion (10028735)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Dermatitis atopic (10012438)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	3	4.7	1.0	13.1	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.84 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		201	59.5	54.0	64.7	197	58.8	53.3	64.1	206	61.1	55.7	66.4	604	59.8	56.7	62.8	184	54.1	48.7	59.5
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	2	0.6	0.1	2.1	8	0.8	0.3	1.6	1	0.3	0.0	1.6
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Ear swelling (10014025)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye irritation (10015946)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye swelling (10015967)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Aphthous ulcer (10002959)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Chapped lips (10049047)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	3	0.9	0.2	2.6
	Diarrhoea (10012735)	7	2.1	0.8	4.2	22	6.6	4.2	9.8	22	6.5	4.1	9.7	51	5.0	3.8	6.6	8	2.4	1.0	4.6
	Flatulence (10016766)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Haematochezia (10018836)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Regurgitation (10067171)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Salivary gland enlargement (10039408)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Salivary gland pain (10039421)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Salivary hypersecretion (10039424)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Teething (10043183)	56	16.6	12.8	21.0	38	11.3	8.2	15.2	46	13.6	10.2	17.8	140	13.9	11.8	16.1	47	13.8	10.3	18.0
	Toothache (10044055)	3	0.9	0.2	2.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	3	0.9	0.2	2.6
	Vomiting (10047700)	4	1.2	0.3	3.0	12	3.6	1.9	6.2	4	1.2	0.3	3.0	20	2.0	1.2	3.0	8	2.4	1.0	4.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
General disorders and administration site conditions (10018065)	Crying (10011469)	4	1.2	0.3	3.0	5	1.5	0.5	3.4	2	0.6	0.1	2.1	11	1.1	0.5	1.9	4	1.2	0.3	3.0
	Injection site bruising (10022052)	2	0.6	0.1	2.1	3	0.9	0.2	2.6	1	0.3	0.0	1.6	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Injection site erythema (10022061)	16	4.7	2.7	7.6	17	5.1	3.0	8.0	21	6.2	3.9	9.4	54	5.3	4.0	6.9	13	3.8	2.1	6.4
	Injection site haematoma (10022066)	4	1.2	0.3	3.0	1	0.3	0.0	1.7	3	0.9	0.2	2.6	8	0.8	0.3	1.6	0	0.0	0.0	1.1
	Injection site haemorrhage (10022067)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1
	Injection site induration (10022075)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Injection site nodule (10057880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Injection site pain (10022086)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	3	0.9	0.2	2.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
	Injection site papule (10066044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Injection site swelling (10053425)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	6	1.8	0.7	3.8	13	1.3	0.7	2.2	4	1.2	0.3	3.0
	Injection site vesicles (10022111)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pain (10033371)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Secretion discharge (10053459)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Swelling (10042674)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Infections and infestations (10021881)	Adenovirus infection (10060931)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchiolitis (10006448)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	2	0.6	0.1	2.1	7	0.7	0.3	1.4	6	1.8	0.7	3.8
	Conjunctivitis (10010741)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	12	3.6	1.9	6.1	19	1.9	1.1	2.9	5	1.5	0.5	3.4
	Ear infection (10014011)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	2	0.6	0.1	2.1
	Enterovirus infection (10014909)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Exanthema subitum (10015586)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gastroenteritis (10017888)	8	2.4	1.0	4.6	8	2.4	1.0	4.7	10	3.0	1.4	5.4	26	2.6	1.7	3.7	10	2.9	1.4	5.3
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	3	0.9	0.2	2.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Impetigo (10021531)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Influenza (10022000)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	4	1.2	0.3	3.0
	Injection site abscess (10022044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laryngitis (10023874)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	0	0.0	0.0	1.1	4	0.4	0.1	1.0	2	0.6	0.1	2.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Molluscum contagiosum (10027807)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nasopharyngitis (10028810)	9	2.7	1.2	5.0	5	1.5	0.5	3.4	7	2.1	0.8	4.2	21	2.1	1.3	3.2	8	2.4	1.0	4.6
	Oral candidiasis (10030963)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Oral herpes (10067152)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	35	10.4	7.3	14.1	45	13.4	10.0	17.6	32	9.5	6.6	13.1	112	11.1	9.2	13.2	37	10.9	7.8	14.7
	Pharyngitis (10034835)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	3	0.9	0.2	2.6	4	1.2	0.3	3.0	6	1.8	0.7	3.8	13	1.3	0.7	2.2	2	0.6	0.1	2.1
	Rhinitis (10039083)	28	8.3	5.6	11.8	24	7.2	4.6	10.5	20	5.9	3.7	9.0	72	7.1	5.6	8.9	21	6.2	3.9	9.3
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tonsillitis (10044008)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Upper respiratory tract infection (10046306)	65	19.2	15.2	23.8	72	21.5	17.2	26.3	74	22.0	17.7	26.8	211	20.9	18.4	23.5	58	17.1	13.2	21.5
	Urinary tract infection (10046571)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	1	0.3	0.0	1.6	7	0.7	0.3	1.4	1	0.3	0.0	1.6
	Arthropod sting (10003402)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Wound (10052428)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Nervous system disorders (10029205)	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Poor quality sleep (10062519)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Post-traumatic headache (10036313)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Somnolence (10041349)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Irritability (10022998)	5	1.5	0.5	3.4	7	2.1	0.8	4.3	7	2.1	0.8	4.2	19	1.9	1.1	2.9	10	2.9	1.4	5.3
	Restlessness (10038743)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Sleep disorder (10040984)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tearfulness (10043169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Terminal insomnia (10068932)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Cough (10011224)	4	1.2	0.3	3.0	10	3.0	1.4	5.4	6	1.8	0.7	3.8	20	2.0	1.2	3.0	8	2.4	1.0	4.6
	Dyspnoea (10013968)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Epistaxis (10015090)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nasal congestion (10028735)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Oropharyngeal pain (10068319)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rhinitis allergic (10039085)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Skin irritation (10040880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Swelling face (10042682)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.85 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		67	68.4	58.2	77.4	63	64.3	54.0	73.7	58	58.6	48.2	68.4	188	63.7	58.0	69.2	62	62.6	52.3	72.1
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Constipation (10010774)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Diarrhoea (10012735)	9	9.2	4.3	16.7	5	5.1	1.7	11.5	3	3.0	0.6	8.6	17	5.8	3.4	9.1	4	4.0	1.1	10.0
	Dyspepsia (10013946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	2	2.0	0.2	7.1
	Faeces soft (10074859)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Teething (10043183)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	3.7	4	4.1	1.1	10.1	3	3.0	0.6	8.6	7	2.4	1.0	4.8	2	2.0	0.2	7.1
	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Conjunctivitis (10010741)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	2	2.0	0.2	7.1	5	1.7	0.6	3.9	4	4.0	1.1	10.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	8	8.2	3.6	15.5	5	5.1	1.7	11.5	13	13.1	7.2	21.4	26	8.8	5.8	12.6	10	10.1	5.0	17.8
	Gastroenteritis viral (10017918)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Gingivitis (10018292)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Nasopharyngitis (10028810)	37	37.8	28.2	48.1	34	34.7	25.4	45.0	34	34.3	25.1	44.6	105	35.6	30.1	41.3	29	29.3	20.6	39.3
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media (10033078)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media acute (10033079)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	2	2.0	0.2	7.1	4	1.4	0.4	3.4	1	1.0	0.0	5.5
	Pharyngitis (10034835)	6	6.1	2.3	12.9	12	12.2	6.5	20.4	4	4.0	1.1	10.0	22	7.5	4.7	11.1	13	13.1	7.2	21.4

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngotonsillitis (10049140)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Pneumonia viral (10035737)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis (10039083)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	1	1.0	0.0	5.5	3	1.0	0.2	2.9	5	5.1	1.7	11.4
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	11	11.2	5.7	19.2	4	4.1	1.1	10.1	4	4.0	1.1	10.0	19	6.4	3.9	9.9	6	6.1	2.3	12.7
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	2	2.0	0.2	7.1	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	4	4.0	1.1	10.0	7	2.4	1.0	4.8	1	1.0	0.0	5.5
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Headache (10019211)	3	3.1	0.6	8.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Bronchospasm (10006482)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cough (10011224)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinorrhoea (10039101)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	2	2.0	0.2	7.1	4	1.4	0.4	3.4	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Miliaria (10027627)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Prurigo (10037083)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Solar dermatitis (10041303)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.86 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		249	40.3	36.4	44.3	268	43.8	39.8	47.8	244	39.5	35.6	43.5	761	41.2	38.9	43.5	272	41.6	37.8	45.5
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Leukocytosis (10024378)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Leukopenia (10024384)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphadenitis (10025188)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lymphadenopathy (10025197)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Deafness (10011878)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ear pain (10014020)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.5	0.1	1.4	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lid sulcus deepened (10072716)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abdominal pain upper (10000087)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Aphthous ulcer (10002959)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Constipation (10010774)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	7	1.1	0.5	2.3	14	0.8	0.4	1.3	4	0.6	0.2	1.6
	Diarrhoea (10012735)	33	5.3	3.7	7.4	26	4.2	2.8	6.2	18	2.9	1.7	4.6	77	4.2	3.3	5.2	38	5.8	4.1	7.9
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival pain (10018286)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival swelling (10018291)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Lip swelling (10024570)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Oral mucosal eruption (10030997)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Post-tussive vomiting (10066220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Teething (10043183)	22	3.6	2.2	5.3	39	6.4	4.6	8.6	21	3.4	2.1	5.1	82	4.4	3.5	5.5	38	5.8	4.1	7.9
	Toothache (10044055)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Vomiting (10047700)	26	4.2	2.8	6.1	20	3.3	2.0	5.0	24	3.9	2.5	5.7	70	3.8	3.0	4.8	29	4.4	3.0	6.3
General disorders and administration site conditions (10018065)	Cyst (10011732)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Discomfort (10013082)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Feeling hot (10016334)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Influenza like illness (10022004)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site bruising (10022052)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site erosion (10022059)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Injection site erythema (10022061)	6	1.0	0.4	2.1	6	1.0	0.4	2.1	4	0.6	0.2	1.6	16	0.9	0.5	1.4	4	0.6	0.2	1.6
	Injection site induration (10022075)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site mass (10022081)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site pain (10022086)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site papule (10066044)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Injection site swelling (10053425)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	4	0.6	0.2	1.6	12	0.6	0.3	1.1	4	0.6	0.2	1.6
	Injection site vesicles (10022111)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pain (10033371)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pyrexia (10037660)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Vessel puncture site haematoma (10065902)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Food allergy (10016946)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.6	0.2	1.6	7	0.4	0.2	0.8	2	0.3	0.0	1.1
	Hypersensitivity (10020751)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seasonal allergy (10048908)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acute sinusitis (10001076)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Adenovirus infection (10060931)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	2	0.3	0.0	1.2	4	0.7	0.2	1.7	3	0.5	0.1	1.4	9	0.5	0.2	0.9	5	0.8	0.2	1.8
	Bronchitis (10006451)	5	0.8	0.3	1.9	1	0.2	0.0	0.9	4	0.6	0.2	1.6	10	0.5	0.3	1.0	2	0.3	0.0	1.1
	Candida infection (10074170)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Cellulitis (10007882)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	20	3.2	2.0	5.0	15	2.5	1.4	4.0	19	3.1	1.9	4.8	54	2.9	2.2	3.8	18	2.8	1.6	4.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Croup infectious (10011416)	4	0.6	0.2	1.6	11	1.8	0.9	3.2	8	1.3	0.6	2.5	23	1.2	0.8	1.9	6	0.9	0.3	2.0
	Ear infection (10014011)	4	0.6	0.2	1.6	6	1.0	0.4	2.1	2	0.3	0.0	1.2	12	0.6	0.3	1.1	3	0.5	0.1	1.3
	Eye infection (10015929)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Folliculitis (10016936)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Fungal infection (10017533)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Gastroenteritis (10017888)	7	1.1	0.5	2.3	8	1.3	0.6	2.6	9	1.5	0.7	2.7	24	1.3	0.8	1.9	7	1.1	0.4	2.2

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	4	0.6	0.2	1.6	10	0.5	0.3	1.0	5	0.8	0.2	1.8
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand-foot-and-mouth disease (10019113)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.8	0.3	1.9	10	0.5	0.3	1.0	5	0.8	0.2	1.8
	Herpangina (10019936)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hordeolum (10020377)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Impetigo (10021531)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Influenza (10022000)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.3	0.1	0.6	5	0.8	0.2	1.8
	Lice infestation (10024424)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Nasopharyngitis (10028810)	13	2.1	1.1	3.6	22	3.6	2.3	5.4	19	3.1	1.9	4.8	54	2.9	2.2	3.8	16	2.4	1.4	3.9
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral herpes (10067152)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Otitis externa (10033072)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	43	7.0	5.1	9.3	29	4.7	3.2	6.7	31	5.0	3.4	7.0	103	5.6	4.6	6.7	48	7.3	5.5	9.6
	Otitis media acute (10033079)	6	1.0	0.4	2.1	4	0.7	0.2	1.7	6	1.0	0.4	2.1	16	0.9	0.5	1.4	6	0.9	0.3	2.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pharyngitis (10034835)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	7	1.1	0.5	2.3	26	1.4	0.9	2.1	7	1.1	0.4	2.2
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pneumonia (10035664)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.5	0.1	1.4	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis (10039083)	3	0.5	0.1	1.4	7	1.1	0.5	2.3	1	0.2	0.0	0.9	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Roseola (10039222)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Sinusitis (10040753)	8	1.3	0.6	2.5	3	0.5	0.1	1.4	4	0.6	0.2	1.6	15	0.8	0.5	1.3	3	0.5	0.1	1.3
	Skin candida (10054152)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Subcutaneous abscess (10042343)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tonsillitis (10044008)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	36	5.8	4.1	8.0	48	7.8	5.8	10.3	43	7.0	5.1	9.3	127	6.9	5.8	8.1	60	9.2	7.1	11.7
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	10	1.6	0.8	3.0	8	1.3	0.6	2.6	14	2.3	1.2	3.8	32	1.7	1.2	2.4	8	1.2	0.5	2.4
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral rash (10047476)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral upper respiratory tract infection (10047482)	4	0.6	0.2	1.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	6	0.3	0.1	0.7	2	0.3	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Animal bite (10002515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Contusion (10050584)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	0	0.0	0.0	0.6	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Craniocerebral injury (10070976)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gingival injury (10049300)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	3	0.5	0.1	1.4	4	0.7	0.2	1.7	2	0.3	0.0	1.2	9	0.5	0.2	0.9	1	0.2	0.0	0.8
	Laceration (10023572)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	7	0.4	0.2	0.8	1	0.2	0.0	0.8
	Limb injury (10061225)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Lip injury (10055082)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Nail avulsion (10028686)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Skin abrasion (10064990)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Thermal burn (10053615)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Upper limb fracture (10061394)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cold agglutinins positive (10009854)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Dehydration (10012174)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Lactose intolerance (10023681)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Nervous system disorders (10029205)	Drooling (10013642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gross motor delay (10069118)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Headache (10019211)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lethargy (10024264)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Poor quality sleep (10062519)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Speech disorder developmental (10041467)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tremor (10044565)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Depressed mood (10012374)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Insomnia (10022437)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Irritability (10022998)	6	1.0	0.4	2.1	5	0.8	0.3	1.9	2	0.3	0.0	1.2	13	0.7	0.4	1.2	7	1.1	0.4	2.2
	Middle insomnia (10027590)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Sleep disorder (10040984)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep terror (10041010)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Bronchial hyperreactivity (10066091)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Cough (10011224)	16	2.6	1.5	4.2	19	3.1	1.9	4.8	23	3.7	2.4	5.5	58	3.1	2.4	4.0	18	2.8	1.6	4.3
	Dyspnoea (10013968)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Epistaxis (10015090)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Nasal congestion (10028735)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	4	0.6	0.2	1.6	22	1.2	0.7	1.8	11	1.7	0.8	3.0
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory disorder (10038683)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.6	0.2	1.6	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Rhinorrhoea (10039101)	20	3.2	2.0	5.0	19	3.1	1.9	4.8	16	2.6	1.5	4.2	55	3.0	2.2	3.9	20	3.1	1.9	4.7
	Sinus congestion (10040742)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Sneezing (10041232)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	6	1.0	0.4	2.1	14	0.8	0.4	1.3	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Blister (10005191)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dermatitis (10012431)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dermatitis atopic (10012438)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Dermatitis contact (10012442)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	2	0.3	0.0	1.2	8	0.4	0.2	0.9	4	0.6	0.2	1.6
	Dry skin (10013786)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Eczema (10014184)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Erythema (10015150)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Keratosis pilaris (10066295)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Macule (10025421)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Papule (10033733)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Seborrhoea (10039792)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Skin mass (10067868)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin warm (10040952)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Swelling face (10042682)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Urticaria (10046735)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pallor (10033546)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.87 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		70	5.6	4.4	7.1	77	6.3	5.0	7.7	78	6.3	5.0	7.8	225	6.1	5.3	6.9	85	6.6	5.3	8.1
Ear and labyrinth disorders (10013993)	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otorrhoea (10033101)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Constipation (10010774)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Diarrhoea (10012735)	5	0.4	0.1	0.9	8	0.6	0.3	1.3	4	0.3	0.1	0.8	17	0.5	0.3	0.7	9	0.7	0.3	1.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Stomatitis (10042128)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Teething (10043183)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	6	0.5	0.2	1.0
	Vomiting (10047700)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	2	0.2	0.0	0.6	8	0.2	0.1	0.4	10	0.8	0.4	1.4
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Influenza like illness (10022004)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site erosion (10022059)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site erythema (10022061)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site pain (10022086)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site swelling (10053425)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	1	0.1	0.0	0.4
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Food allergy (10016946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Adenovirus infection (10060931)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchiolitis (10006448)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchitis (10006451)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Candida infection (10074170)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Conjunctivitis (10010741)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	3	0.2	0.0	0.7	10	0.3	0.1	0.5	4	0.3	0.1	0.8
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Croup infectious (10011416)	1	0.1	0.0	0.4	5	0.4	0.1	0.9	2	0.2	0.0	0.6	8	0.2	0.1	0.4	0	0.0	0.0	0.3
	Ear infection (10014011)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Exanthema subitum (10015586)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye infection (10015929)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Gastroenteritis (10017888)	5	0.4	0.1	0.9	2	0.2	0.0	0.6	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis viral (10017918)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Herpangina (10019936)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Impetigo (10021531)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza (10022000)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.8
	Laryngitis (10023874)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	2	0.2	0.0	0.6	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Nasopharyngitis (10028810)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Otitis externa (10033072)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otitis media (10033078)	22	1.8	1.1	2.7	22	1.8	1.1	2.7	20	1.6	1.0	2.5	64	1.7	1.3	2.2	27	2.1	1.4	3.0
	Otitis media acute (10033079)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Pharyngitis (10034835)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	2	0.2	0.0	0.6	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Respiratory tract infection (10062352)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Rhinitis (10039083)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Roseola (10039222)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tonsillitis (10044008)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract infection (10046306)	15	1.2	0.7	2.0	14	1.1	0.6	1.9	18	1.4	0.9	2.3	47	1.3	0.9	1.7	6	0.5	0.2	1.0
	Urinary tract infection (10046571)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Viral infection (10047461)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	6	0.5	0.2	1.0	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
Injury, poisoning and procedural complications (10022117)	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Craniocerebral injury (10070976)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Head injury (10019196)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Laceration (10023572)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Limb injury (10061225)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Thermal burn (10053615)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper limb fracture (10061394)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dehydration (10012174)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Lethargy (10024264)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Cough (10011224)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	4	0.3	0.1	0.8	7	0.2	0.1	0.4	5	0.4	0.1	0.9

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dyspnoea (10013968)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory disorder (10038683)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinorrhoea (10039101)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	3	0.2	0.0	0.7	6	0.2	0.1	0.4	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis contact (10012442)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Urticaria (10046735)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.88 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		3	2.4	0.5	6.9	2	1.6	0.2	5.7	4	3.2	0.9	8.0	9	2.4	1.1	4.5	4	3.1	0.9	7.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
General disorders and administration site conditions (10018065)	Injection site erosion (10022059)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site swelling (10053425)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Infections and infestations (10021881)	Eye infection (10015929)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pharyngitis (10034835)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Rhinitis (10039083)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral infection (10047461)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	2	1.6	0.2	5.7	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Injury, poisoning and procedural complications (10022117)	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	0	0.0	0.0	2.9	2	0.5	0.1	1.9	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.89 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	3	4.3	0.9	12.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Laryngitis (10023874)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Nasopharyngitis (10028810)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Otitis media (10033078)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.90 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		32	9.5	6.6	13.1	35	10.4	7.4	14.2	32	9.5	6.6	13.1	99	9.8	8.0	11.8	36	10.6	7.5	14.4
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	2	0.6	0.1	2.1	6	0.6	0.2	1.3	2	0.6	0.1	2.1
	Teething (10043183)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	4	1.2	0.3	3.0
	Vomiting (10047700)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Injection site erythema (10022061)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Injection site swelling (10053425)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Infections and infestations (10021881)	Adenovirus infection (10060931)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1
	Conjunctivitis (10010741)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Ear infection (10014011)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Exanthema subitum (10015586)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Gastroenteritis (10017888)	3	0.9	0.2	2.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Impetigo (10021531)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Laryngitis (10023874)	0	0.0	0.0	1.1	3	0.9	0.2	2.6	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Nasopharyngitis (10028810)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Otitis media (10033078)	12	3.6	1.8	6.1	18	5.4	3.2	8.4	13	3.9	2.1	6.5	43	4.3	3.1	5.7	18	5.3	3.2	8.2
	Pharyngitis (10034835)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Pneumonia (10035664)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Rhinitis (10039083)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tonsillitis (10044008)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Upper respiratory tract infection (10046306)	12	3.6	1.8	6.1	6	1.8	0.7	3.9	14	4.2	2.3	6.9	32	3.2	2.2	4.4	4	1.2	0.3	3.0
	Urinary tract infection (10046571)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Cough (10011224)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Dyspnoea (10013968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.91 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		2	2.0	0.2	7.2	4	4.1	1.1	10.1	3	3.0	0.6	8.6	9	3.1	1.4	5.7	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Conjunctivitis (10010741)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastroenteritis (10017888)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastroenteritis viral (10017918)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Nasopharyngitis (10028810)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngitis (10034835)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.92 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		32	5.2	3.6	7.2	36	5.9	4.2	8.1	38	6.1	4.4	8.3	106	5.7	4.7	6.9	42	6.4	4.7	8.6
Ear and labyrinth disorders (10013993)	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Otorrhoea (10033101)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Diarrhoea (10012735)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	2	0.3	0.0	1.2	10	0.5	0.3	1.0	7	1.1	0.4	2.2
	Gingival swelling (10018291)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Teething (10043183)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Vomiting (10047700)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	2	0.3	0.0	1.2	7	0.4	0.2	0.8	9	1.4	0.6	2.6
General disorders and administration site conditions (10018065)	Influenza like illness (10022004)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site pain (10022086)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site swelling (10053425)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Food allergy (10016946)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Adenovirus infection (10060931)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchitis (10006451)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Candida infection (10074170)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Conjunctivitis (10010741)	4	0.6	0.2	1.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Croup infectious (10011416)	1	0.2	0.0	0.9	5	0.8	0.3	1.9	2	0.3	0.0	1.2	8	0.4	0.2	0.9	0	0.0	0.0	0.6
	Ear infection (10014011)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Eye infection (10015929)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Gastroenteritis (10017888)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Herpangina (10019936)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Influenza (10022000)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	3	0.5	0.1	1.3
	Nasopharyngitis (10028810)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Otitis externa (10033072)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	7	1.1	0.5	2.3	20	1.1	0.7	1.7	9	1.4	0.6	2.6
	Otitis media acute (10033079)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Pharyngitis (10034835)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis (10039083)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Roseola (10039222)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillitis (10044008)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	3	0.5	0.1	1.4	8	1.3	0.6	2.6	4	0.6	0.2	1.6	15	0.8	0.5	1.3	2	0.3	0.0	1.1
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral infection (10047461)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.5	0.1	1.4	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Injury, poisoning and procedural complications (10022117)	Craniocerebral injury (10070976)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Hand fracture (10019114)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Head injury (10019196)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Laceration (10023572)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Limb injury (10061225)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Thermal burn (10053615)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper limb fracture (10061394)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dehydration (10012174)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
Nervous system disorders (10029205)	Lethargy (10024264)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory disorder (10038683)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinorrhoea (10039101)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis contact (10012442)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Urticaria (10046735)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.93 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		48	3.9	2.9	5.1	49	4.0	3.0	5.2	47	3.8	2.8	5.0	144	3.9	3.3	4.5	63	4.9	3.8	6.2
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
Eye disorders (10015919)	Lacrimation increased (10023644)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Diarrhoea (10012735)	6	0.5	0.2	1.1	7	0.6	0.2	1.2	15	1.2	0.7	2.0	28	0.8	0.5	1.1	15	1.2	0.7	1.9
	Flatulence (10016766)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Salivary gland enlargement (10039408)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Salivary gland pain (10039421)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vomiting (10047700)	8	0.6	0.3	1.3	10	0.8	0.4	1.5	7	0.6	0.2	1.2	25	0.7	0.4	1.0	11	0.9	0.4	1.5
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Feeling hot (10016334)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site bruising (10022052)	4	0.3	0.1	0.8	4	0.3	0.1	0.8	0	0.0	0.0	0.3	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Injection site erythema (10022061)	4	0.3	0.1	0.8	2	0.2	0.0	0.6	2	0.2	0.0	0.6	8	0.2	0.1	0.4	6	0.5	0.2	1.0
	Injection site haematoma (10022066)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Injection site haemorrhage (10022067)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Injection site induration (10022075)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site pain (10022086)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site papule (10066044)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injection site swelling (10053425)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oedema peripheral (10030124)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pain (10033371)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pyrexia (10037660)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Immune system disorders (10021428)	Hypersensitivity (10020751)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchitis (10006451)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastroenteritis (10017888)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Laryngitis (10023874)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Oral herpes (10067152)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pharyngitis (10034835)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	2	0.2	0.0	0.6	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Pneumonia (10035664)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinitis (10039083)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	2	0.2	0.0	0.6	6	0.2	0.1	0.4	3	0.2	0.0	0.7
	Upper respiratory tract infection (10046306)	4	0.3	0.1	0.8	7	0.6	0.2	1.2	6	0.5	0.2	1.0	17	0.5	0.3	0.7	9	0.7	0.3	1.3
	Viral infection (10047461)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Viral rash (10047476)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Irritability (10022998)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Restlessness (10038743)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Sleep disorder (10040984)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sleep terror (10041010)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Nasal congestion (10028735)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	0	0.0	0.0	0.3	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rhinorrhoea (10039101)	3	0.2	0.0	0.7	2	0.2	0.0	0.6	1	0.1	0.0	0.4	6	0.2	0.1	0.4	1	0.1	0.0	0.4
	Wheezing (10047924)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Erythema (10015150)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hyperhidrosis (10020642)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin warm (10040952)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Swelling face (10042682)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.94 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		3	2.4	0.5	6.9	2	1.6	0.2	5.7	1	0.8	0.0	4.4	6	1.6	0.6	3.5	5	3.9	1.3	8.9
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Vomiting (10047700)	2	1.6	0.2	5.7	0	0.0	0.0	2.9	0	0.0	0.0	2.9	2	0.5	0.1	1.9	1	0.8	0.0	4.3
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	3	2.4	0.5	6.7
	Injection site swelling (10053425)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Infections and infestations (10021881)	Pharyngitis (10034835)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Hyperhidrosis (10020642)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.95 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oedema peripheral (10030124)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.96 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		18	5.3	3.2	8.3	23	6.9	4.4	10.1	24	7.1	4.6	10.4	65	6.4	5.0	8.1	31	9.1	6.3	12.7
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Diarrhoea (10012735)	2	0.6	0.1	2.1	5	1.5	0.5	3.4	9	2.7	1.2	5.0	16	1.6	0.9	2.6	4	1.2	0.3	3.0
	Flatulence (10016766)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Salivary gland enlargement (10039408)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Salivary gland pain (10039421)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Vomiting (10047700)	1	0.3	0.0	1.6	6	1.8	0.7	3.9	2	0.6	0.1	2.1	9	0.9	0.4	1.7	3	0.9	0.2	2.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Injection site bruising (10022052)	2	0.6	0.1	2.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Injection site erythema (10022061)	3	0.9	0.2	2.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Injection site haematoma (10022066)	3	0.9	0.2	2.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Injection site haemorrhage (10022067)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Injection site induration (10022075)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Injection site swelling (10053425)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	2	0.6	0.1	2.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Pain (10033371)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Gastroenteritis (10017888)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Oral herpes (10067152)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Rhinitis (10039083)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Upper respiratory tract infection (10046306)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	1	0.3	0.0	1.6	8	0.8	0.3	1.6	6	1.8	0.7	3.8
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Restlessness (10038743)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Sleep disorder (10040984)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Swelling face (10042682)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.97 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		4	4.1	1.1	10.1	3	3.1	0.6	8.7	0	0.0	0.0	3.7	7	2.4	1.0	4.8	1	1.0	0.0	5.5
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Laryngitis (10023874)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Nasopharyngitis (10028810)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	4	1.4	0.4	3.4	1	1.0	0.0	5.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.98 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		23	3.7	2.4	5.5	19	3.1	1.9	4.8	22	3.6	2.2	5.3	64	3.5	2.7	4.4	26	4.0	2.6	5.8
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
Eye disorders (10015919)	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	6	1.0	0.4	2.1	11	0.6	0.3	1.1	10	1.5	0.7	2.8
	Vomiting (10047700)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	5	0.8	0.3	1.9	13	0.7	0.4	1.2	7	1.1	0.4	2.2
General disorders and administration site conditions (10018065)	Feeling hot (10016334)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site bruising (10022052)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site erythema (10022061)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site pain (10022086)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Injection site papule (10066044)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pain (10033371)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pyrexia (10037660)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Immune system disorders (10021428)	Hypersensitivity (10020751)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis (10017888)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Nasopharyngitis (10028810)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Oral herpes (10067152)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Pharyngitis (10034835)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Pneumonia (10035664)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	0	0.0	0.0	0.6	4	0.7	0.2	1.7	5	0.8	0.3	1.9	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Viral infection (10047461)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral rash (10047476)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Viral upper respiratory tract infection (10047482)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Nervous system disorders (10029205)	Poor quality sleep (10062519)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Irritability (10022998)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep disorder (10040984)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep terror (10041010)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Nasal congestion (10028735)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Rhinorrhoea (10039101)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	1	0.2	0.0	0.9	6	0.3	0.1	0.7	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Skin warm (10040952)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.99 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		350	28.2	25.8	30.8	357	29.0	26.5	31.6	339	27.3	24.8	29.8	1046	28.2	26.7	29.6	356	27.6	25.2	30.1
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	4	0.3	0.1	0.8	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Leukocytosis (10024378)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Leukopenia (10024384)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	3	0.2	0.0	0.7
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Deafness (10011878)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear pain (10014020)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	4	0.3	0.1	0.8	8	0.2	0.1	0.4	2	0.2	0.0	0.6
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Excessive cerumen production (10076897)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Otorrhoea (10033101)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dacryostenosis acquired (10053990)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye discharge (10015915)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Eye inflammation (10015943)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eyelid oedema (10015993)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hypermetropia (10020675)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lacrimation increased (10023644)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Strabismus (10042159)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Abdominal pain (10000081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain upper (10000087)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Anal fissure (10002153)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Constipation (10010774)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	5	0.4	0.1	0.9	8	0.2	0.1	0.4	3	0.2	0.0	0.7
	Diarrhoea (10012735)	24	1.9	1.2	2.9	14	1.1	0.6	1.9	12	1.0	0.5	1.7	50	1.3	1.0	1.8	27	2.1	1.4	3.0
	Dyspepsia (10013946)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Dysphagia (10013950)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Enterocolitis (10014893)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastrooesophageal reflux disease (10017885)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	3	0.2	0.0	0.7
	Gingival hypertrophy (10018284)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival pain (10018286)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gingival swelling (10018291)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nausea (10028813)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Oral contusion (10078170)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Ranula (10037838)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Stomatitis (10042128)	0	0.0	0.0	0.3	4	0.3	0.1	0.8	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Teething (10043183)	4	0.3	0.1	0.8	6	0.5	0.2	1.1	5	0.4	0.1	0.9	15	0.4	0.2	0.7	8	0.6	0.3	1.2
	Toothache (10044055)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vomiting (10047700)	8	0.6	0.3	1.3	4	0.3	0.1	0.8	6	0.5	0.2	1.0	18	0.5	0.3	0.8	12	0.9	0.5	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Influenza like illness (10022004)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Injection site erythema (10022061)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	0	0.0	0.0	0.3	5	0.1	0.0	0.3	1	0.1	0.0	0.4
	Injection site swelling (10053425)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyrexia (10037660)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Food allergy (10016946)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	3	0.2	0.0	0.7	6	0.2	0.1	0.4	4	0.3	0.1	0.8
	Hypersensitivity (10020751)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Immunisation reaction (10021432)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Milk allergy (10027633)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Seasonal allergy (10048908)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acute sinusitis (10001076)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Adenovirus infection (10060931)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Body tinea (10005913)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bronchiolitis (10006448)	2	0.2	0.0	0.6	8	0.6	0.3	1.3	7	0.6	0.2	1.2	17	0.5	0.3	0.7	7	0.5	0.2	1.1
	Bronchitis (10006451)	10	0.8	0.4	1.5	13	1.1	0.6	1.8	10	0.8	0.4	1.5	33	0.9	0.6	1.2	12	0.9	0.5	1.6
	Bullous impetigo (10006563)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Candida infection (10074170)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Candida nappy rash (10007135)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Cellulitis (10007882)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Clostridium difficile infection (10054236)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Conjunctivitis (10010741)	20	1.6	1.0	2.5	17	1.4	0.8	2.2	28	2.3	1.5	3.2	65	1.8	1.4	2.2	28	2.2	1.4	3.1
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Croup infectious (10011416)	4	0.3	0.1	0.8	11	0.9	0.4	1.6	6	0.5	0.2	1.0	21	0.6	0.4	0.9	6	0.5	0.2	1.0
	Ear infection (10014011)	8	0.6	0.3	1.3	14	1.1	0.6	1.9	4	0.3	0.1	0.8	26	0.7	0.5	1.0	13	1.0	0.5	1.7
	Enterovirus infection (10014909)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Epstein-barr virus infection (10015108)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Exanthema subitum (10015586)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye infection (10015929)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	0	0.0	0.0	0.3	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Folliculitis (10016936)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Fungal infection (10017533)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis (10017888)	19	1.5	0.9	2.4	13	1.1	0.6	1.8	23	1.9	1.2	2.8	55	1.5	1.1	1.9	18	1.4	0.8	2.2
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastroenteritis rotavirus (10017913)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Gastroenteritis viral (10017918)	2	0.2	0.0	0.6	3	0.2	0.1	0.7	3	0.2	0.0	0.7	8	0.2	0.1	0.4	3	0.2	0.0	0.7
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gingivitis (10018292)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand-foot-and-mouth disease (10019113)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	6	0.5	0.2	1.0	10	0.3	0.1	0.5	5	0.4	0.1	0.9
	Herpangina (10019936)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	2	0.2	0.0	0.6	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Hordeolum (10020377)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Impetigo (10021531)	3	0.2	0.0	0.7	1	0.1	0.0	0.5	1	0.1	0.0	0.4	5	0.1	0.0	0.3	2	0.2	0.0	0.6
	Infected bite (10076911)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Influenza (10022000)	2	0.2	0.0	0.6	4	0.3	0.1	0.8	0	0.0	0.0	0.3	6	0.2	0.1	0.4	6	0.5	0.2	1.0
	Laryngitis (10023874)	1	0.1	0.0	0.4	7	0.6	0.2	1.2	2	0.2	0.0	0.6	10	0.3	0.1	0.5	5	0.4	0.1	0.9
	Localised infection (10024774)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Molluscum contagiosum (10027807)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Nasopharyngitis (10028810)	50	4.0	3.0	5.3	45	3.7	2.7	4.9	50	4.0	3.0	5.3	145	3.9	3.3	4.6	37	2.9	2.0	3.9
	Oral candidiasis (10030963)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Oral herpes (10067152)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Oral infection (10048685)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis externa (10033072)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Otitis media (10033078)	80	6.5	5.2	8.0	75	6.1	4.8	7.6	63	5.1	3.9	6.4	218	5.9	5.1	6.7	86	6.7	5.4	8.2
	Otitis media acute (10033079)	6	0.5	0.2	1.1	7	0.6	0.2	1.2	13	1.0	0.6	1.8	26	0.7	0.5	1.0	9	0.7	0.3	1.3
	Otitis media chronic (10033081)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Paronychia (10034016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Periorbital cellulitis (10057182)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4

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	Pharyngitis (10034835)	20	1.6	1.0	2.5	31	2.5	1.7	3.6	14	1.1	0.6	1.9	65	1.8	1.4	2.2	23	1.8	1.1	2.7
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.3	3	0.2	0.1	0.7	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Pharyngotonsillitis (10049140)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumonia (10035664)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	6	0.5	0.2	1.0	8	0.2	0.1	0.4	1	0.1	0.0	0.4
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia viral (10035737)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract infection (10062352)	4	0.3	0.1	0.8	6	0.5	0.2	1.1	7	0.6	0.2	1.2	17	0.5	0.3	0.7	5	0.4	0.1	0.9
	Respiratory tract infection viral (10062106)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Rhinitis (10039083)	9	0.7	0.3	1.4	14	1.1	0.6	1.9	6	0.5	0.2	1.0	29	0.8	0.5	1.1	13	1.0	0.5	1.7
	Roseola (10039222)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	0	0.0	0.0	0.3
	Rotavirus infection (10067470)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Salmonellosis (10039447)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Scarlet fever (10039587)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Sinusitis (10040753)	9	0.7	0.3	1.4	3	0.2	0.1	0.7	4	0.3	0.1	0.8	16	0.4	0.2	0.7	3	0.2	0.0	0.7
	Skin bacterial infection (10052891)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin candida (10054152)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Staphylococcal infection (10058080)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Streptococcal infection (10061372)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.2	0.0	0.7	5	0.1	0.0	0.3	3	0.2	0.0	0.7
	Subcutaneous abscess (10042343)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tonsillitis (10044008)	21	1.7	1.1	2.6	9	0.7	0.3	1.4	9	0.7	0.3	1.4	39	1.1	0.7	1.4	15	1.2	0.7	1.9
	Tooth abscess (10044016)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract infection (10046306)	48	3.9	2.9	5.1	65	5.3	4.1	6.7	57	4.6	3.5	5.9	170	4.6	3.9	5.3	63	4.9	3.8	6.2
	Urinary tract infection (10046571)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Viral diarrhoea (10051511)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.2	1	0.1	0.0	0.4
	Viral infection (10047461)	12	1.0	0.5	1.7	17	1.4	0.8	2.2	17	1.4	0.8	2.2	46	1.2	0.9	1.6	13	1.0	0.5	1.7
	Viral pharyngitis (10047473)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	0	0.0	0.0	0.3	4	0.1	0.0	0.3	1	0.1	0.0	0.4
	Viral rash (10047476)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral tonsillitis (10047480)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral upper respiratory tract infection (10047482)	3	0.2	0.0	0.7	3	0.2	0.1	0.7	4	0.3	0.1	0.8	10	0.3	0.1	0.5	3	0.2	0.0	0.7
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Animal bite (10002515)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Arthropod bite (10003399)	4	0.3	0.1	0.8	3	0.2	0.1	0.7	4	0.3	0.1	0.8	11	0.3	0.1	0.5	3	0.2	0.0	0.7
	Arthropod sting (10003402)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Bite (10004966)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chemical poisoning (10008428)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Clavicle fracture (10009245)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Concussion (10010254)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Contusion (10050584)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	1	0.1	0.0	0.4	4	0.1	0.0	0.3	4	0.3	0.1	0.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Craniocerebral injury (10070976)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	2	0.2	0.0	0.6
	Ear canal injury (10056319)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ear injury (10057446)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Eye contusion (10073354)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Face injury (10050392)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Femur fracture (10016454)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Hand fracture (10019114)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Head injury (10019196)	3	0.2	0.0	0.7	4	0.3	0.1	0.8	3	0.2	0.0	0.7	10	0.3	0.1	0.5	2	0.2	0.0	0.6
	Heat stroke (10019345)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Laceration (10023572)	5	0.4	0.1	0.9	0	0.0	0.0	0.3	1	0.1	0.0	0.4	6	0.2	0.1	0.4	2	0.2	0.0	0.6
	Limb injury (10061225)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Lip injury (10055082)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Radial head dislocation (10073749)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Road traffic accident (10039203)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Scratch (10039737)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Skin abrasion (10064990)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	1	0.1	0.0	0.4	3	0.1	0.0	0.2	0	0.0	0.0	0.3
	Superficial injury of eye (10042530)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thermal burn (10053615)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Tibia fracture (10043827)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tongue injury (10059924)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Upper limb fracture (10061394)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wound (10052428)	0	0.0	0.0	0.3	2	0.2	0.0	0.6	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Weight decreased (10047895)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.2	2	0.2	0.0	0.6
	Lactose intolerance (10023681)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Polydipsia (10036067)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Knee deformity (10062061)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Synovial cyst (10042858)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Nervous system disorders (10029205)	Epilepsy (10015037)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

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	Exaggerated startle response (10066482)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Febrile convulsion (10016284)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gross motor delay (10069118)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Headache (10019211)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nystagmus (10029864)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Poor quality sleep (10062519)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Seizure (10039906)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Speech disorder developmental (10041467)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Tremor (10044565)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	Insomnia (10022437)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Irritability (10022998)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	1	0.1	0.0	0.4	5	0.1	0.0	0.3	1	0.1	0.0	0.4
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Polyuria (10036142)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary tract disorder (10046566)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Balanoposthitis (10004078)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	2	0.2	0.0	0.6	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Bilateral breast buds (10004557)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Genital labial adhesions (10064162)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	2	0.2	0.0	0.6	5	0.1	0.0	0.3	5	0.4	0.1	0.9
	Bronchial hyperreactivity (10066091)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	2	0.2	0.0	0.6
	Bronchospasm (10006482)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Catarrh (10007774)	2	0.2	0.0	0.6	1	0.1	0.0	0.5	0	0.0	0.0	0.3	3	0.1	0.0	0.2	2	0.2	0.0	0.6

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	Cough (10011224)	13	1.0	0.6	1.8	16	1.3	0.7	2.1	12	1.0	0.5	1.7	41	1.1	0.8	1.5	16	1.2	0.7	2.0
	Dyspnoea (10013968)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	2	0.2	0.0	0.6
	Hypoxia (10021143)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	3	0.2	0.0	0.7
	Nasal discomfort (10052437)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rales (10037833)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory disorder (10038683)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory distress (10038687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Rhinitis allergic (10039085)	3	0.2	0.0	0.7	0	0.0	0.0	0.3	3	0.2	0.0	0.7	6	0.2	0.1	0.4	0	0.0	0.0	0.3
	Rhinorrhoea (10039101)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	0	0.0	0.0	0.3	3	0.1	0.0	0.2	1	0.1	0.0	0.4
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Upper respiratory tract congestion (10052252)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Wheezing (10047924)	2	0.2	0.0	0.6	6	0.5	0.2	1.1	6	0.5	0.2	1.0	14	0.4	0.2	0.6	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	1	0.1	0.0	0.4	4	0.1	0.0	0.3	2	0.2	0.0	0.6
	Dermatitis atopic (10012438)	1	0.1	0.0	0.4	3	0.2	0.1	0.7	3	0.2	0.0	0.7	7	0.2	0.1	0.4	2	0.2	0.0	0.6
	Dermatitis contact (10012442)	1	0.1	0.0	0.4	2	0.2	0.0	0.6	2	0.2	0.0	0.6	5	0.1	0.0	0.3	0	0.0	0.0	0.3
	Dermatitis diaper (10012444)	2	0.2	0.0	0.6	2	0.2	0.0	0.6	3	0.2	0.0	0.7	7	0.2	0.1	0.4	3	0.2	0.0	0.7
	Drug eruption (10013687)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eczema (10014184)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.2	0.0	0.6	2	0.1	0.0	0.2	5	0.4	0.1	0.9
	Eczema nummular (10014201)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Erythema (10015150)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hyperkeratosis (10020649)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ingrowing nail (10022013)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Keratosis pilaris (10066295)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Miliaria (10027627)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Prurigo (10037083)	2	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.3	2	0.1	0.0	0.2	0	0.0	0.0	0.3
	Seborrhoea (10039792)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

		INV_MMR_1 N = 1239				INV_MMR_2 N = 1232				INV_MMR_3 N = 1243				INV_MMR N = 3714				COM_MMR N = 1289			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Skin irritation (10040880)	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urticaria (10046735)	1	0.1	0.0	0.4	1	0.1	0.0	0.5	1	0.1	0.0	0.4	3	0.1	0.0	0.2	1	0.1	0.0	0.4
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	0.3	0	0.0	0.0	0.3	1	0.1	0.0	0.4	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.3	1	0.1	0.0	0.5	0	0.0	0.0	0.3	1	0.0	0.0	0.1	0	0.0	0.0	0.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.100 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		23	18.5	12.1	26.5	27	21.6	14.7	29.8	24	19.2	12.7	27.2	74	19.8	15.9	24.2	26	20.5	13.8	28.5
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	1	0.8	0.0	4.4	2	1.6	0.2	5.7	0	0.0	0.0	2.9	3	0.8	0.2	2.3	0	0.0	0.0	2.9
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Teething (10043183)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyrexia (10037660)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Immune system disorders (10021428)	Food allergy (10016946)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Infections and infestations (10021881)	Bronchitis (10006451)	1	0.8	0.0	4.4	4	3.2	0.9	8.0	1	0.8	0.0	4.4	6	1.6	0.6	3.5	2	1.6	0.2	5.6
	Ear infection (10014011)	3	2.4	0.5	6.9	5	4.0	1.3	9.1	1	0.8	0.0	4.4	9	2.4	1.1	4.5	6	4.7	1.8	10.0
	Enterovirus infection (10014909)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	0	0.0	0.0	2.9	3	0.8	0.2	2.3	2	1.6	0.2	5.6
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Laryngitis (10023874)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Nasopharyngitis (10028810)	0	0.0	0.0	2.9	2	1.6	0.2	5.7	0	0.0	0.0	2.9	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pneumonia (10035664)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Respiratory tract infection (10062352)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Respiratory tract infection viral (10062106)	3	2.4	0.5	6.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Rhinitis (10039083)	2	1.6	0.2	5.7	5	4.0	1.3	9.1	2	1.6	0.2	5.7	9	2.4	1.1	4.5	4	3.1	0.9	7.9
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	2	1.6	0.2	5.7	2	1.6	0.2	5.7	2	1.6	0.2	5.7	6	1.6	0.6	3.5	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Viral infection (10047461)	1	0.8	0.0	4.4	5	4.0	1.3	9.1	3	2.4	0.5	6.9	9	2.4	1.1	4.5	3	2.4	0.5	6.7
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Nervous system disorders (10029205)	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Cough (10011224)	5	4.0	1.3	9.2	4	3.2	0.9	8.0	1	0.8	0.0	4.4	10	2.7	1.3	4.9	1	0.8	0.0	4.3
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose

n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.101 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		38	62.3	49.0	74.4	36	58.1	44.8	70.5	37	57.8	44.8	70.1	111	59.4	51.9	66.5	43	62.3	49.8	73.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	7	11.5	4.7	22.2	1	1.6	0.0	8.7	2	3.1	0.4	10.8	10	5.3	2.6	9.6	5	7.2	2.4	16.1
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Teething (10043183)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Toothache (10044055)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Vomiting (10047700)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	2	3.1	0.4	10.8	5	2.7	0.9	6.1	2	2.9	0.4	10.1
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchitis (10006451)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	2	2.9	0.4	10.1
	Candida infection (10074170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Conjunctivitis (10010741)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	4	6.3	1.7	15.2	7	3.7	1.5	7.6	5	7.2	2.4	16.1
	Ear infection (10014011)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	2	3.1	0.4	10.8	6	3.2	1.2	6.9	3	4.3	0.9	12.2
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Impetigo (10021531)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Laryngitis (10023874)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Nasopharyngitis (10028810)	10	16.4	8.2	28.1	6	9.7	3.6	19.9	10	15.6	7.8	26.9	26	13.9	9.3	19.7	10	14.5	7.2	25.0
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Otitis media (10033078)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Otitis media acute (10033079)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	5	7.8	2.6	17.3	7	3.7	1.5	7.6	2	2.9	0.4	10.1
	Pharyngitis (10034835)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	1	1.4	0.0	7.8
	Pharyngotonsillitis (10049140)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Pneumonia (10035664)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Respiratory tract infection (10062352)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	3	4.7	1.0	13.1	11	5.9	3.0	10.3	5	7.2	2.4	16.1
	Rhinitis (10039083)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Tonsillitis (10044008)	7	11.5	4.7	22.2	4	6.5	1.8	15.7	3	4.7	1.0	13.1	14	7.5	4.2	12.2	8	11.6	5.1	21.6
	Upper respiratory tract infection (10046306)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	2	3.1	0.4	10.8	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Viral infection (10047461)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	2	2.9	0.4	10.1
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	3	4.7	1.0	13.1	5	2.7	0.9	6.1	0	0.0	0.0	5.2
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	2	2.9	0.4	10.1
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Balanoposthitis (10004078)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchospasm (10006482)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	3	4.7	1.0	13.1	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Catarrh (10007774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Cough (10011224)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	2	2.9	0.4	10.1
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Dermatitis atopic (10012438)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	3	4.7	1.0	13.1	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.102 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		75	22.2	17.9	27.0	78	23.3	18.9	28.2	70	20.8	16.6	25.5	223	22.1	19.6	24.8	71	20.9	16.7	25.6
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Diarrhoea (10012735)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Teething (10043183)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Vomiting (10047700)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Injection site erythema (10022061)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Infections and infestations (10021881)	Adenovirus infection (10060931)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchiolitis (10006448)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	2	0.6	0.1	2.1	7	0.7	0.3	1.4	6	1.8	0.7	3.8
	Conjunctivitis (10010741)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	6	1.8	0.7	3.8	12	1.2	0.6	2.1	4	1.2	0.3	3.0
	Ear infection (10014011)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	2	0.6	0.1	2.1
	Enterovirus infection (10014909)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gastroenteritis (10017888)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Impetigo (10021531)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Laryngitis (10023874)	0	0.0	0.0	1.1	3	0.9	0.2	2.6	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Nasopharyngitis (10028810)	3	0.9	0.2	2.6	0	0.0	0.0	1.1	3	0.9	0.2	2.6	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	35	10.4	7.3	14.1	45	13.4	10.0	17.6	32	9.5	6.6	13.1	112	11.1	9.2	13.2	37	10.9	7.8	14.7
	Pharyngitis (10034835)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	4	1.2	0.3	3.0	5	0.5	0.2	1.2	0	0.0	0.0	1.1
	Rhinitis (10039083)	3	0.9	0.2	2.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	7	0.7	0.3	1.4	2	0.6	0.1	2.1
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tonsillitis (10044008)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Upper respiratory tract infection (10046306)	18	5.3	3.2	8.3	17	5.1	3.0	8.0	20	5.9	3.7	9.0	55	5.4	4.1	7.0	14	4.1	2.3	6.8
	Urinary tract infection (10046571)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Wound (10052428)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Cough (10011224)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	5	0.5	0.2	1.2	5	1.5	0.5	3.4
	Dyspnoea (10013968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.103 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		62	63.3	52.9	72.8	61	62.2	51.9	71.8	55	55.6	45.2	65.5	178	60.3	54.5	66.0	58	58.6	48.2	68.4
Eye disorders (10015919)	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Constipation (10010774)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Diarrhoea (10012735)	4	4.1	1.1	10.1	4	4.1	1.1	10.1	3	3.0	0.6	8.6	11	3.7	1.9	6.6	3	3.0	0.6	8.6
	Dyspepsia (10013946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	2	2.0	0.2	7.1
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	3.7	4	4.1	1.1	10.1	3	3.0	0.6	8.6	7	2.4	1.0	4.8	2	2.0	0.2	7.1
	Bronchitis (10006451)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Conjunctivitis (10010741)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	2	2.0	0.2	7.1	4	1.4	0.4	3.4	4	4.0	1.1	10.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	8	8.2	3.6	15.5	5	5.1	1.7	11.5	13	13.1	7.2	21.4	26	8.8	5.8	12.6	10	10.1	5.0	17.8
	Gastroenteritis viral (10017918)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Gingivitis (10018292)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Nasopharyngitis (10028810)	34	34.7	25.4	45.0	32	32.7	23.5	42.9	32	32.3	23.3	42.5	98	33.2	27.9	38.9	24	24.2	16.2	33.9
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media (10033078)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Otitis media acute (10033079)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	2	2.0	0.2	7.1	4	1.4	0.4	3.4	1	1.0	0.0	5.5
	Pharyngitis (10034835)	6	6.1	2.3	12.9	12	12.2	6.5	20.4	4	4.0	1.1	10.0	22	7.5	4.7	11.1	13	13.1	7.2	21.4
	Pharyngotonsillitis (10049140)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Pneumonia viral (10035737)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis (10039083)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	5	5.1	1.7	11.4

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	11	11.2	5.7	19.2	4	4.1	1.1	10.1	4	4.0	1.1	10.0	19	6.4	3.9	9.9	6	6.1	2.3	12.7
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	2	2.0	0.2	7.1	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	3	3.0	0.6	8.6	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Bronchospasm (10006482)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cough (10011224)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Miliaria (10027627)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Prurigo (10037083)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled

COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.104 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, within the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		152	24.6	21.2	28.2	155	25.3	21.9	29.0	153	24.8	21.4	28.4	460	24.9	22.9	26.9	158	24.2	20.9	27.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Iron deficiency anaemia (10022972)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Leukocytosis (10024378)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Leukopenia (10024384)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphadenopathy (10025197)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Deafness (10011878)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ear pain (10014020)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.8	0.3	1.9	8	0.4	0.2	0.9	2	0.3	0.0	1.1
	Diarrhoea (10012735)	11	1.8	0.9	3.2	4	0.7	0.2	1.7	5	0.8	0.3	1.9	20	1.1	0.7	1.7	18	2.8	1.6	4.3
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival swelling (10018291)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Teething (10043183)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	2	0.3	0.0	1.2	10	0.5	0.3	1.0	4	0.6	0.2	1.6
	Vomiting (10047700)	6	1.0	0.4	2.1	3	0.5	0.1	1.4	4	0.6	0.2	1.6	13	0.7	0.4	1.2	9	1.4	0.6	2.6
General disorders and administration site conditions (10018065)	Influenza like illness (10022004)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site erythema (10022061)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site swelling (10053425)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyrexia (10037660)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Food allergy (10016946)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Hypersensitivity (10020751)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seasonal allergy (10048908)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acute sinusitis (10001076)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	3	0.5	0.1	1.4	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Bronchitis (10006451)	5	0.8	0.3	1.9	1	0.2	0.0	0.9	4	0.6	0.2	1.6	10	0.5	0.3	1.0	2	0.3	0.0	1.1
	Candida infection (10074170)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cellulitis (10007882)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	14	2.3	1.2	3.8	12	2.0	1.0	3.4	16	2.6	1.5	4.2	42	2.3	1.6	3.1	15	2.3	1.3	3.8
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Croup infectious (10011416)	4	0.6	0.2	1.6	11	1.8	0.9	3.2	6	1.0	0.4	2.1	21	1.1	0.7	1.7	6	0.9	0.3	2.0
	Ear infection (10014011)	3	0.5	0.1	1.4	6	1.0	0.4	2.1	2	0.3	0.0	1.2	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Folliculitis (10016936)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Fungal infection (10017533)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis (10017888)	6	1.0	0.4	2.1	6	1.0	0.4	2.1	6	1.0	0.4	2.1	18	1.0	0.6	1.5	5	0.8	0.2	1.8
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand-foot-and-mouth disease (10019113)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.6	0.2	1.6	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Herpangina (10019936)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hordeolum (10020377)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Impetigo (10021531)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Influenza (10022000)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.3	0.1	0.6	4	0.6	0.2	1.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Nasopharyngitis (10028810)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	5	0.8	0.3	1.9	13	0.7	0.4	1.2	1	0.2	0.0	0.8
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral herpes (10067152)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Otitis externa (10033072)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otitis media (10033078)	43	7.0	5.1	9.3	29	4.7	3.2	6.7	31	5.0	3.4	7.0	103	5.6	4.6	6.7	47	7.2	5.3	9.4

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Otitis media acute (10033079)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	6	1.0	0.4	2.1	15	0.8	0.5	1.3	6	0.9	0.3	2.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pharyngitis (10034835)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	7	1.1	0.5	2.3	26	1.4	0.9	2.1	7	1.1	0.4	2.2
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pneumonia (10035664)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.5	0.1	1.4	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis (10039083)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	1	0.2	0.0	0.9	9	0.5	0.2	0.9	2	0.3	0.0	1.1
	Roseola (10039222)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Sinusitis (10040753)	8	1.3	0.6	2.5	3	0.5	0.1	1.4	4	0.6	0.2	1.6	15	0.8	0.5	1.3	3	0.5	0.1	1.3
	Skin candida (10054152)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Subcutaneous abscess (10042343)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tonsillitis (10044008)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	26	4.2	2.8	6.1	44	7.2	5.3	9.5	32	5.2	3.6	7.2	102	5.5	4.5	6.7	45	6.9	5.1	9.1
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	9	1.5	0.7	2.7	8	1.3	0.6	2.6	12	1.9	1.0	3.4	29	1.6	1.1	2.2	8	1.2	0.5	2.4

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral rash (10047476)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral upper respiratory tract infection (10047482)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	2	0.3	0.0	1.2	5	0.3	0.1	0.6	2	0.3	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Animal bite (10002515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Contusion (10050584)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Craniocerebral injury (10070976)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Laceration (10023572)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Limb injury (10061225)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Lip injury (10055082)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Skin abrasion (10064990)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Upper limb fracture (10061394)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Lactose intolerance (10023681)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Musculoskeletal and connective tissue disorders (10028395)	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Nervous system disorders (10029205)	Gross motor delay (10069118)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Speech disorder developmental (10041467)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tremor (10044565)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Insomnia (10022437)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Irritability (10022998)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Renal and urinary disorders (10038359)	Dysuria (10013990)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Bronchial hyperreactivity (10066091)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Cough (10011224)	5	0.8	0.3	1.9	10	1.6	0.8	3.0	9	1.5	0.7	2.7	24	1.3	0.8	1.9	8	1.2	0.5	2.4
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Oropharyngeal pain (10068319)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory disorder (10038683)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinorrhoea (10039101)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	6	1.0	0.4	2.1	14	0.8	0.4	1.3	0	0.0	0.0	0.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dermatitis atopic (10012438)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Dermatitis contact (10012442)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Eczema (10014184)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Erythema (10015150)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Keratosis pilaris (10066295)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seborrhoea (10039792)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urticaria (10046735)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

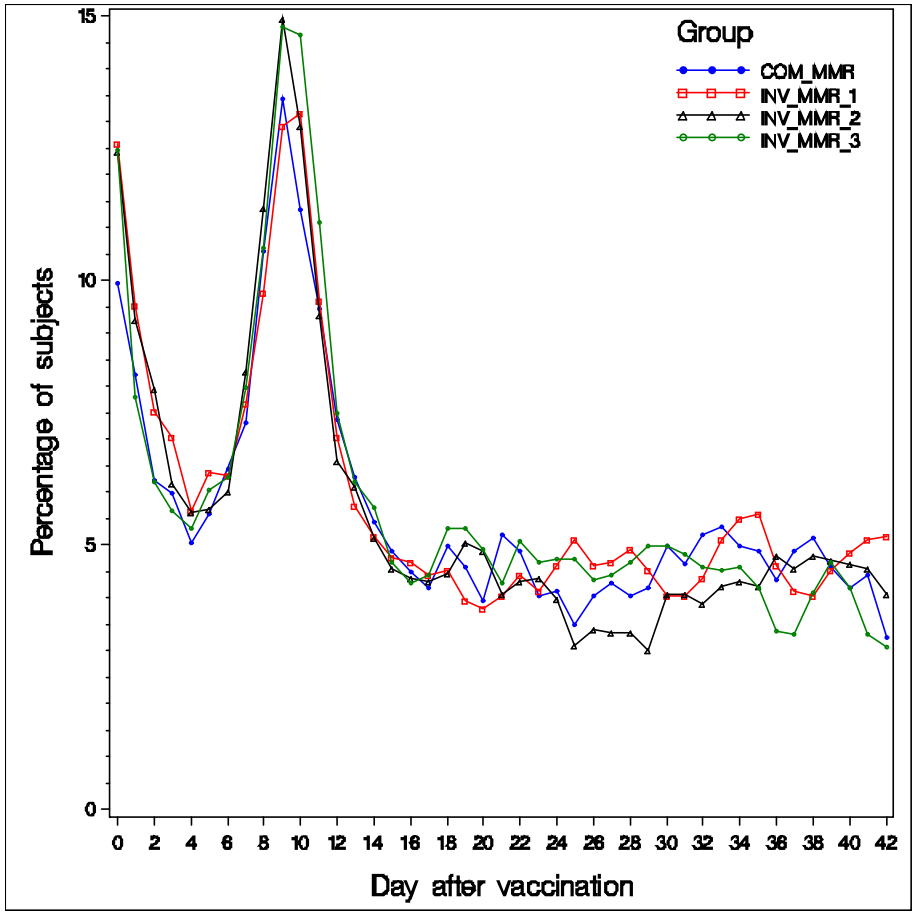
INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.105 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1239	845	68.2	65.5	70.8	1232	837	67.9	65.3	70.5	1243	833	67.0	64.3	69.6	3714	2515	67.7	66.2	69.2	1289	879	68.2	65.6	70.7
Any antipyretic	1239	632	51.0	48.2	53.8	1232	641	52.0	49.2	54.9	1243	610	49.1	46.3	51.9	3714	1883	50.7	49.1	52.3	1289	667	51.7	49.0	54.5
Prophylactic antipyretic	1239	40	3.2	2.3	4.4	1232	47	3.8	2.8	5.0	1243	38	3.1	2.2	4.2	3714	125	3.4	2.8	4.0	1289	36	2.8	2.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Figure 8.4 Percentage of subjects who took antipyretics by day (Day 0 to Day 42) (Total vaccinated cohort)



INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR

Table 8.106 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Estonia)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	124	72	58.1	48.9	66.9	125	69	55.2	46.0	64.1	125	64	51.2	42.1	60.2	374	205	54.8	49.6	59.9	127	68	53.5	44.5	62.4
Any antipyretic	124	44	35.5	27.1	44.6	125	46	36.8	28.4	45.9	125	37	29.6	21.8	38.4	374	127	34.0	29.2	39.0	127	41	32.3	24.3	41.2
Prophylactic antipyretic	124	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	125	1	0.8	0.0	4.4	374	1	0.3	0.0	1.5	127	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.107 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Spain)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	61	37	60.7	47.3	72.9	62	41	66.1	53.0	77.7	64	42	65.6	52.7	77.1	187	120	64.2	56.8	71.0	69	39	56.5	44.0	68.4
Any antipyretic	61	29	47.5	34.6	60.7	62	28	45.2	32.5	58.3	64	24	37.5	25.7	50.5	187	81	43.3	36.1	50.7	69	31	44.9	32.9	57.4
Prophylactic antipyretic	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	64	0	0.0	0.0	5.6	187	0	0.0	0.0	2.0	69	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.108 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Finland)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	338	313	92.6	89.3	95.2	335	300	89.6	85.8	92.6	337	305	90.5	86.9	93.4	1010	918	90.9	88.9	92.6	340	308	90.6	87.0	93.5
Any antipyretic	338	220	65.1	59.7	70.2	335	211	63.0	57.6	68.2	337	204	60.5	55.1	65.8	1010	635	62.9	59.8	65.9	340	206	60.6	55.2	65.8
Prophylactic antipyretic	338	4	1.2	0.3	3.0	335	3	0.9	0.2	2.6	337	4	1.2	0.3	3.0	1010	11	1.1	0.5	1.9	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.109 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, Mexico)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	98	65	66.3	56.1	75.6	98	65	66.3	56.1	75.6	99	59	59.6	49.3	69.3	295	189	64.1	58.3	69.5	99	64	64.6	54.4	74.0
Any antipyretic	98	57	58.2	47.8	68.1	98	54	55.1	44.7	65.2	99	49	49.5	39.3	59.7	295	160	54.2	48.4	60.0	99	51	51.5	41.3	61.7
Prophylactic antipyretic	98	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	99	0	0.0	0.0	3.7	295	0	0.0	0.0	1.2	99	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.110 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, United States)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	618	358	57.9	53.9	61.9	612	362	59.2	55.1	63.1	618	363	58.7	54.7	62.7	1848	1083	58.6	56.3	60.9	654	400	61.2	57.3	64.9
Any antipyretic	618	282	45.6	41.7	49.7	612	302	49.3	45.3	53.4	618	296	47.9	43.9	51.9	1848	880	47.6	45.3	49.9	654	338	51.7	47.8	55.6
Prophylactic antipyretic	618	36	5.8	4.1	8.0	612	44	7.2	5.3	9.5	618	33	5.3	3.7	7.4	1848	113	6.1	5.1	7.3	654	35	5.4	3.8	7.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.111 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by gender)

	INV_MMR										COM_MMR									
	F					M					F					M				
				95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1816	1194	65.7	63.5	67.9	1898	1321	69.6	67.5	71.7	618	422	68.3	64.5	71.9	671	457	68.1	64.4	71.6
Any antipyretic	1816	891	49.1	46.7	51.4	1898	992	52.3	50.0	54.5	618	306	49.5	45.5	53.5	671	361	53.8	49.9	57.6
Prophylactic antipyretic	1816	65	3.6	2.8	4.5	1898	60	3.2	2.4	4.1	618	11	1.8	0.9	3.2	671	25	3.7	2.4	5.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.112 Number and percentage of subjects taking a concomitant medication during the 43-day(Days 0-42) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

	INV_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	2814	2004	71.2	69.5	72.9	364	229	62.9	57.7	67.9	169	84	49.7	41.9	57.5
Any antipyretic	2814	1480	52.6	50.7	54.5	364	191	52.5	47.2	57.7	169	57	33.7	26.6	41.4
Prophylactic antipyretic	2814	99	3.5	2.9	4.3	364	7	1.9	0.8	3.9	169	9	5.3	2.5	9.9

	COM_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	970	700	72.2	69.2	75.0	124	79	63.7	54.6	72.2	70	36	51.4	39.2	63.6
Any antipyretic	970	519	53.5	50.3	56.7	124	63	50.8	41.7	59.9	70	29	41.4	29.8	53.8
Prophylactic antipyretic	970	25	2.6	1.7	3.8	124	4	3.2	0.9	8.1	70	2	2.9	0.3	9.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.113 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1239	680	54.9	52.1	57.7	1232	676	54.9	52.0	57.7	1243	669	53.8	51.0	56.6	3714	2025	54.5	52.9	56.1	1289	697	54.1	51.3	56.8
Any antipyretic	1239	479	38.7	35.9	41.4	1232	473	38.4	35.7	41.2	1243	465	37.4	34.7	40.2	3714	1417	38.2	36.6	39.7	1289	493	38.2	35.6	41.0
Prophylactic antipyretic	1239	40	3.2	2.3	4.4	1232	47	3.8	2.8	5.0	1243	38	3.1	2.2	4.2	3714	125	3.4	2.8	4.0	1289	36	2.8	2.0	3.8

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.114 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Estonia)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	124	47	37.9	29.3	47.1	125	52	41.6	32.9	50.8	125	44	35.2	26.9	44.2	374	143	38.2	33.3	43.4	127	55	43.3	34.5	52.4
Any antipyretic	124	30	24.2	17.0	32.7	125	32	25.6	18.2	34.2	125	27	21.6	14.7	29.8	374	89	23.8	19.6	28.4	127	31	24.4	17.2	32.8
Prophylactic antipyretic	124	0	0.0	0.0	2.9	125	0	0.0	0.0	2.9	125	1	0.8	0.0	4.4	374	1	0.3	0.0	1.5	127	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.115 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Spain)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	61	25	41.0	28.6	54.3	62	23	37.1	25.2	50.3	64	23	35.9	24.3	48.9	187	71	38.0	31.0	45.3	69	22	31.9	21.2	44.2
Any antipyretic	61	20	32.8	21.3	46.0	62	16	25.8	15.5	38.5	64	14	21.9	12.5	34.0	187	50	26.7	20.5	33.7	69	16	23.2	13.9	34.9
Prophylactic antipyretic	61	0	0.0	0.0	5.9	62	0	0.0	0.0	5.8	64	0	0.0	0.0	5.6	187	0	0.0	0.0	2.0	69	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.116 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Finland)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	338	298	88.2	84.2	91.4	335	284	84.8	80.5	88.4	337	290	86.1	81.9	89.6	1010	872	86.3	84.1	88.4	340	284	83.5	79.2	87.3
Any antipyretic	338	177	52.4	46.9	57.8	335	161	48.1	42.6	53.6	337	161	47.8	42.3	53.3	1010	499	49.4	46.3	52.5	340	155	45.6	40.2	51.0
Prophylactic antipyretic	338	4	1.2	0.3	3.0	335	3	0.9	0.2	2.6	337	4	1.2	0.3	3.0	1010	11	1.1	0.5	1.9	340	0	0.0	0.0	1.1

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.117 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, Mexico)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	98	36	36.7	27.2	47.1	98	45	45.9	35.8	56.3	99	39	39.4	29.7	49.7	295	120	40.7	35.0	46.5	99	38	38.4	28.8	48.7
Any antipyretic	98	26	26.5	18.1	36.4	98	32	32.7	23.5	42.9	99	30	30.3	21.5	40.4	295	88	29.8	24.7	35.4	99	31	31.3	22.4	41.4
Prophylactic antipyretic	98	0	0.0	0.0	3.7	98	0	0.0	0.0	3.7	99	0	0.0	0.0	3.7	295	0	0.0	0.0	1.2	99	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.118 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, United States)

	INV_MMR_1					INV_MMR_2					INV_MMR_3					INV_MMR					COM_MMR				
				95% CI					95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	618	274	44.3	40.4	48.4	612	272	44.4	40.5	48.5	618	273	44.2	40.2	48.2	1848	819	44.3	42.0	46.6	654	298	45.6	41.7	49.5
Any antipyretic	618	226	36.6	32.8	40.5	612	232	37.9	34.0	41.9	618	233	37.7	33.9	41.7	1848	691	37.4	35.2	39.6	654	260	39.8	36.0	43.6
Prophylactic antipyretic	618	36	5.8	4.1	8.0	612	44	7.2	5.3	9.5	618	33	5.3	3.7	7.4	1848	113	6.1	5.1	7.3	654	35	5.4	3.8	7.4

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.119 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by gender)

	INV_MMR										COM_MMR									
	F					M					F					M				
				95% CI					95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	1816	959	52.8	50.5	55.1	1898	1066	56.2	53.9	58.4	618	328	53.1	49.1	57.1	671	369	55.0	51.1	58.8
Any antipyretic	1816	670	36.9	34.7	39.2	1898	747	39.4	37.2	41.6	618	217	35.1	31.3	39.0	671	276	41.1	37.4	45.0
Prophylactic antipyretic	1816	65	3.6	2.8	4.5	1898	60	3.2	2.4	4.1	618	11	1.8	0.9	3.2	671	25	3.7	2.4	5.5

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
F = Female
M = Male
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.120 Number and percentage of subjects taking a concomitant medication during the 15-day(Days 0-14) post-vaccination period (Total vaccinated cohort, by geographic ancestry)

	INV_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	2814	1665	59.2	57.3	61.0	364	152	41.8	36.6	47.0	169	58	34.3	27.2	42.0
Any antipyretic	2814	1137	40.4	38.6	42.2	364	116	31.9	27.1	36.9	169	45	26.6	20.1	34.0
Prophylactic antipyretic	2814	99	3.5	2.9	4.3	364	7	1.9	0.8	3.9	169	9	5.3	2.5	9.9

	COM_MMR														
	WH					OT					AF				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	970	577	59.5	56.3	62.6	124	47	37.9	29.3	47.1	70	23	32.9	22.1	45.1
Any antipyretic	970	395	40.7	37.6	43.9	124	38	30.6	22.7	39.6	70	20	28.6	18.4	40.6
Prophylactic antipyretic	970	25	2.6	1.7	3.8	124	4	3.2	0.9	8.1	70	2	2.9	0.3	9.9

INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
WH = White Caucasian/European heritage
OT = Other - American Hispanic or Latino
AF = African Heritage/African American
N = number of subjects with the administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.121 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		74	59.7	50.5	68.4	78	62.4	53.3	70.9	74	59.2	50.1	67.9	226	60.4	55.3	65.4	67	52.8	43.7	61.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Lymphadenopathy (10025197)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Auricular swelling (10003800)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear pain (10014020)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Eyelid oedema (10015993)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Diarrhoea (10012735)	8	6.5	2.8	12.3	6	4.8	1.8	10.2	6	4.8	1.8	10.2	20	5.3	3.3	8.1	7	5.5	2.2	11.0
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Flatulence (10016766)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival swelling (10018291)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Nausea (10028813)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Salivary hypersecretion (10039424)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Stomatitis (10042128)	0	0.0	0.0	2.9	4	3.2	0.9	8.0	1	0.8	0.0	4.4	5	1.3	0.4	3.1	0	0.0	0.0	2.9
	Teething (10043183)	9	7.3	3.4	13.3	13	10.4	5.7	17.1	7	5.6	2.3	11.2	29	7.8	5.3	10.9	7	5.5	2.2	11.0
	Toothache (10044055)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Vomiting (10047700)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	3	2.4	0.5	6.9	8	2.1	0.9	4.2	4	3.1	0.9	7.9
General disorders and administration site conditions (10018065)	Injection site erosion (10022059)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site erythema (10022061)	9	7.3	3.4	13.3	5	4.0	1.3	9.1	7	5.6	2.3	11.2	21	5.6	3.5	8.5	9	7.1	3.3	13.0
	Injection site haematoma (10022066)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site pain (10022086)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Injection site papule (10066044)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Injection site swelling (10053425)	4	3.2	0.9	8.1	1	0.8	0.0	4.4	1	0.8	0.0	4.4	6	1.6	0.6	3.5	1	0.8	0.0	4.3
	Pyrexia (10037660)	4	3.2	0.9	8.1	6	4.8	1.8	10.2	2	1.6	0.2	5.7	12	3.2	1.7	5.5	1	0.8	0.0	4.3
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Food allergy (10016946)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	1	0.8	0.0	4.4	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Infections and infestations (10021881)	Adenovirus infection (10060931)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Bronchitis (10006451)	4	3.2	0.9	8.1	4	3.2	0.9	8.0	4	3.2	0.9	8.0	12	3.2	1.7	5.5	5	3.9	1.3	8.9
	Conjunctivitis (10010741)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear infection (10014011)	6	4.8	1.8	10.2	12	9.6	5.1	16.2	8	6.4	2.8	12.2	26	7.0	4.6	10.0	11	8.7	4.4	15.0
	Enterovirus infection (10014909)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	0	0.0	0.0	2.9	2	0.5	0.1	1.9	2	1.6	0.2	5.6
	Exanthema subitum (10015586)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	2	1.6	0.2	5.7	5	1.3	0.4	3.1	4	3.1	0.9	7.9
	Fungal skin infection (10017543)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gastroenteritis rotavirus (10017913)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	4	1.1	0.3	2.7	1	0.8	0.0	4.3
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Impetigo (10021531)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Influenza (10022000)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	2	1.6	0.2	5.7	5	1.3	0.4	3.1	2	1.6	0.2	5.6
	Nasopharyngitis (10028810)	5	4.0	1.3	9.2	9	7.2	3.3	13.2	3	2.4	0.5	6.9	17	4.5	2.7	7.2	3	2.4	0.5	6.7
	Neutropenic infection (10059482)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	2	1.6	0.2	5.7	1	0.8	0.0	4.4	5	4.0	1.3	9.1	8	2.1	0.9	4.2	4	3.1	0.9	7.9
	Otitis media acute (10033079)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	7	1.9	0.8	3.8	2	1.6	0.2	5.6
	Pneumonia (10035664)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	1	0.8	0.0	4.4	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyelonephritis acute (10037597)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Respiratory tract infection (10062352)	1	0.8	0.0	4.4	2	1.6	0.2	5.7	0	0.0	0.0	2.9	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Respiratory tract infection viral (10062106)	4	3.2	0.9	8.1	1	0.8	0.0	4.4	0	0.0	0.0	2.9	5	1.3	0.4	3.1	6	4.7	1.8	10.0

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis (10039083)	16	12.9	7.6	20.1	18	14.4	8.8	21.8	16	12.8	7.5	20.0	50	13.4	10.1	17.2	15	11.8	6.8	18.7
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	2	1.6	0.2	5.6
	Tracheitis (10044302)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	7	5.6	2.3	11.3	4	3.2	0.9	8.0	4	3.2	0.9	8.0	15	4.0	2.3	6.5	0	0.0	0.0	2.9
	Urinary tract infection (10046571)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Varicella (10046980)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	2	1.6	0.2	5.6
	Viral infection (10047461)	8	6.5	2.8	12.3	11	8.8	4.5	15.2	11	8.8	4.5	15.2	30	8.0	5.5	11.3	8	6.3	2.8	12.0
	Viral pharyngitis (10047473)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral rash (10047476)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Burns second degree (10006802)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Concussion (10010254)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Head injury (10019196)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Psychiatric disorders (10037175)	Sleep disorder (10040984)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Cough (10011224)	17	13.7	8.2	21.0	17	13.6	8.1	20.9	14	11.2	6.3	18.1	48	12.8	9.6	16.7	10	7.9	3.8	14.0
	Epistaxis (10015090)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Rhinorrhoea (10039101)	2	1.6	0.2	5.7	2	1.6	0.2	5.7	2	1.6	0.2	5.7	6	1.6	0.6	3.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dermatitis allergic (10012434)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	4	3.2	0.9	8.0	5	1.3	0.4	3.1	1	0.8	0.0	4.3
	Dermatitis atopic (10012438)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Eczema (10014184)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Erythema (10015150)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Hyperhidrosis (10020642)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rash (10037844)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	1.6	0.2	5.7	3	0.8	0.2	2.3	2	1.6	0.2	5.6
	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.122 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		55	90.2	79.8	96.3	57	91.9	82.2	97.3	59	92.2	82.7	97.4	171	91.4	86.5	95.0	64	92.8	83.9	97.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	3	4.7	1.0	13.1	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Iron deficiency anaemia (10022972)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lymphadenitis (10025188)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Congenital, familial and genetic disorders (10010331)	Talipes (10043101)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eye discharge (10015915)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Eyelid oedema (10015993)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Lacrimation increased (10023644)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Anal fissure (10002153)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Aphthous ulcer (10002959)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Colitis (10009887)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Constipation (10010774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Diarrhoea (10012735)	15	24.6	14.5	37.3	9	14.5	6.9	25.8	11	17.2	8.9	28.7	35	18.7	13.4	25.1	21	30.4	19.9	42.7
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Faeces soft (10074859)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Inguinal hernia (10022016)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral contusion (10078170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral disorder (10067621)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Stomatitis (10042128)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Teething (10043183)	4	6.6	1.8	15.9	6	9.7	3.6	19.9	4	6.3	1.7	15.2	14	7.5	4.2	12.2	4	5.8	1.6	14.2
	Toothache (10044055)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	2	2.9	0.4	10.1
	Vomiting (10047700)	5	8.2	2.7	18.1	6	9.7	3.6	19.9	6	9.4	3.5	19.3	17	9.1	5.4	14.2	6	8.7	3.3	18.0

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
General disorders and administration site conditions (10018065)	Asthenia (10003549)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oedema peripheral (10030124)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pain (10033371)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pyrexia (10037660)	6	9.8	3.7	20.2	2	3.2	0.4	11.2	3	4.7	1.0	13.1	11	5.9	3.0	10.3	4	5.8	1.6	14.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Selective iga immunodeficiency (10039915)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Adenoiditis (10051223)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Bronchiolitis (10006448)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	1	1.6	0.0	8.4	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Bronchitis (10006451)	8	13.1	5.8	24.2	9	14.5	6.9	25.8	12	18.8	10.1	30.5	29	15.5	10.6	21.5	10	14.5	7.2	25.0
	Burn infection (10051548)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Candida infection (10074170)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	4	5.8	1.6	14.2
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cellulitis (10007882)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Cellulitis orbital (10007918)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Conjunctivitis (10010741)	8	13.1	5.8	24.2	11	17.7	9.2	29.5	15	23.4	13.8	35.7	34	18.2	12.9	24.5	14	20.3	11.6	31.7
	Coxsackie viral infection (10011261)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	3	4.7	1.0	13.1	7	3.7	1.5	7.6	0	0.0	0.0	5.2
	Cystitis (10011781)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Ear infection (10014011)	5	8.2	2.7	18.1	7	11.3	4.7	21.9	4	6.3	1.7	15.2	16	8.6	5.0	13.5	4	5.8	1.6	14.2
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Erythema infectiosum (10015214)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	15	24.6	14.5	37.3	11	17.7	9.2	29.5	12	18.8	10.1	30.5	38	20.3	14.8	26.8	14	20.3	11.6	31.7
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hand-foot-and-mouth disease (10019113)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Herpangina (10019936)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	3	4.7	1.0	13.1	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Herpes simplex (10019948)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Hordeolum (10020377)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Impetigo (10021531)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Laryngitis (10023874)	6	9.8	3.7	20.2	6	9.7	3.6	19.9	6	9.4	3.5	19.3	18	9.6	5.8	14.8	9	13.0	6.1	23.3
	Nasopharyngitis (10028810)	24	39.3	27.1	52.7	17	27.4	16.9	40.2	20	31.3	20.2	44.1	61	32.6	26.0	39.8	24	34.8	23.7	47.2
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Oral herpes (10067152)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Otitis externa (10033072)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Otitis media (10033078)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	4	6.3	1.7	15.2	9	4.8	2.2	8.9	5	7.2	2.4	16.1
	Otitis media acute (10033079)	7	11.5	4.7	22.2	3	4.8	1.0	13.5	11	17.2	8.9	28.7	21	11.2	7.1	16.7	8	11.6	5.1	21.6
	Pharyngitis (10034835)	12	19.7	10.6	31.8	15	24.2	14.2	36.7	11	17.2	8.9	28.7	38	20.3	14.8	26.8	14	20.3	11.6	31.7
	Pharyngotonsillitis (10049140)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Pneumonia (10035664)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Respiratory tract infection (10062352)	10	16.4	8.2	28.1	12	19.4	10.4	31.4	7	10.9	4.5	21.2	29	15.5	10.6	21.5	13	18.8	10.4	30.1
	Rhinitis (10039083)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	1	1.6	0.0	8.4	4	2.1	0.6	5.4	2	2.9	0.4	10.1
	Rotavirus infection (10067470)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Tonsillitis (10044008)	15	24.6	14.5	37.3	12	19.4	10.4	31.4	16	25.0	15.0	37.4	43	23.0	17.2	29.7	21	30.4	19.9	42.7
	Upper respiratory tract infection (10046306)	7	11.5	4.7	22.2	5	8.1	2.7	17.8	10	15.6	7.8	26.9	22	11.8	7.5	17.3	10	14.5	7.2	25.0
	Viral diarrhoea (10051511)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Viral infection (10047461)	4	6.6	1.8	15.9	9	14.5	6.9	25.8	5	7.8	2.6	17.3	18	9.6	5.8	14.8	9	13.0	6.1	23.3
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1
	Viral rash (10047476)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	1	1.6	0.0	8.4	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	6	9.4	3.5	19.3	14	7.5	4.2	12.2	4	5.8	1.6	14.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	4	6.6	1.8	15.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eyelid injury (10069200)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Fall (10016173)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Head injury (10019196)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Injury (10022116)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lip injury (10055082)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Poisoning (10061355)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Skull fracture (10061365)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Wound (10052428)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	1	1.6	0.0	8.4	4	2.1	0.6	5.4	0	0.0	0.0	5.2
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cardiac murmur functional (10007587)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Iron deficiency (10022970)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	0	0.0	0.0	5.6	4	2.1	0.6	5.4	1	1.4	0.0	7.8
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Synovitis (10042868)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Mycosis fungoides (10028483)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Balanoposthitis (10004078)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Oedema genital (10030104)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Perineal cyst (10066058)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchitis chronic (10006458)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchospasm (10006482)	3	4.9	1.0	13.7	6	9.7	3.6	19.9	6	9.4	3.5	19.3	15	8.0	4.6	12.9	6	8.7	3.3	18.0
	Catarrh (10007774)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	1	1.6	0.0	8.4	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Cough (10011224)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Epistaxis (10015090)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Increased bronchial secretion (10062530)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Nasal congestion (10028735)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	3	4.3	0.9	12.2
	Dermatitis atopic (10012438)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	5	7.8	2.6	17.3	9	4.8	2.2	8.9	4	5.8	1.6	14.2
	Dermatitis contact (10012442)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	3	4.7	1.0	13.1	11	5.9	3.0	10.3	6	8.7	3.3	18.0
	Dyshidrotic eczema (10013913)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	5	7.2	2.4	16.1
	Lichen striatus (10066945)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Miliaria (10027627)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	1	1.6	0.0	8.4	5	2.7	0.9	6.1	2	2.9	0.4	10.1
	Onychomalacia (10058673)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Rash (10037844)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	7	10.9	4.5	21.2	13	7.0	3.8	11.6	2	2.9	0.4	10.1
	Seborrhoeic dermatitis (10039793)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Urticaria (10046735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	3	4.7	1.0	13.1	4	2.1	0.6	5.4	4	5.8	1.6	14.2
Vascular disorders (10047065)	Haematoma (10018852)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.123 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		261	77.2	72.4	81.6	248	74.0	69.0	78.6	249	73.9	68.9	78.5	758	75.0	72.3	77.7	238	70.0	64.8	74.8
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenitis (10025188)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	2	0.6	0.1	2.1	8	0.8	0.3	1.6	1	0.3	0.0	1.6
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Ear swelling (10014025)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Endocrine disorders (10014698)	Hypothyroidism (10021114)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Blepharitis (10005148)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Conjunctivitis allergic (10010744)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye irritation (10015946)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye swelling (10015967)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Panophthalmitis (10033683)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Aphthous ulcer (10002959)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Chapped lips (10049047)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Coeliac disease (10009839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	4	1.2	0.3	3.0
	Diarrhoea (10012735)	9	2.7	1.2	5.0	22	6.6	4.2	9.8	24	7.1	4.6	10.4	55	5.4	4.1	7.0	10	2.9	1.4	5.3
	Flatulence (10016766)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Gastrooesophageal reflux disease (10017885)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Haematochezia (10018836)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Regurgitation (10067171)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Salivary gland enlargement (10039408)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Salivary gland pain (10039421)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Salivary hypersecretion (10039424)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Stomatitis (10042128)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Teething (10043183)	56	16.6	12.8	21.0	38	11.3	8.2	15.2	48	14.2	10.7	18.4	142	14.1	12.0	16.4	49	14.4	10.9	18.6
	Tongue ulceration (10043991)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Toothache (10044055)	3	0.9	0.2	2.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	3	0.9	0.2	2.6
	Vomiting (10047700)	4	1.2	0.3	3.0	12	3.6	1.9	6.2	4	1.2	0.3	3.0	20	2.0	1.2	3.0	8	2.4	1.0	4.6
General disorders and administration site conditions (10018065)	Crying (10011469)	4	1.2	0.3	3.0	5	1.5	0.5	3.4	2	0.6	0.1	2.1	11	1.1	0.5	1.9	4	1.2	0.3	3.0
	Developmental delay (10012559)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fatigue (10016256)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Feeling hot (10016334)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gait disturbance (10017577)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Ill-defined disorder (10061520)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza like illness (10022004)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Injection site bruising (10022052)	2	0.6	0.1	2.1	3	0.9	0.2	2.6	1	0.3	0.0	1.6	6	0.6	0.2	1.3	1	0.3	0.0	1.6
	Injection site erythema (10022061)	16	4.7	2.7	7.6	17	5.1	3.0	8.0	21	6.2	3.9	9.4	54	5.3	4.0	6.9	13	3.8	2.1	6.4
	Injection site haematoma (10022066)	4	1.2	0.3	3.0	1	0.3	0.0	1.7	3	0.9	0.2	2.6	8	0.8	0.3	1.6	0	0.0	0.0	1.1
	Injection site haemorrhage (10022067)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	2	0.6	0.1	2.1
	Injection site induration (10022075)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Injection site nodule (10057880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Injection site pain (10022086)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	3	0.9	0.2	2.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
	Injection site papule (10066044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Injection site swelling (10053425)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	6	1.8	0.7	3.8	13	1.3	0.7	2.2	4	1.2	0.3	3.0
	Injection site vesicles (10022111)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pain (10033371)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pyrexia (10037660)	6	1.8	0.7	3.8	8	2.4	1.0	4.7	3	0.9	0.2	2.6	17	1.7	1.0	2.7	9	2.6	1.2	5.0
	Secretion discharge (10053459)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Swelling (10042674)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Drug hypersensitivity (10013700)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Hypersensitivity (10020751)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Milk allergy (10027633)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Seasonal allergy (10048908)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Adenovirus infection (10060931)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Borrelia infection (10061591)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Bronchiolitis (10006448)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	1	0.3	0.0	1.6	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Bronchitis (10006451)	11	3.3	1.6	5.7	15	4.5	2.5	7.3	13	3.9	2.1	6.5	39	3.9	2.8	5.2	18	5.3	3.2	8.2
	Conjunctivitis (10010741)	21	6.2	3.9	9.3	26	7.8	5.1	11.2	24	7.1	4.6	10.4	71	7.0	5.5	8.8	23	6.8	4.3	10.0
	Ear infection (10014011)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	1	0.3	0.0	1.6	8	0.8	0.3	1.6	4	1.2	0.3	3.0
	Enterovirus infection (10014909)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	7	0.7	0.3	1.4	4	1.2	0.3	3.0
	Exanthema subitum (10015586)	5	1.5	0.5	3.4	6	1.8	0.7	3.9	3	0.9	0.2	2.6	14	1.4	0.8	2.3	6	1.8	0.7	3.8
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fungal skin infection (10017543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Gastroenteritis (10017888)	11	3.3	1.6	5.7	9	2.7	1.2	5.0	11	3.3	1.6	5.8	31	3.1	2.1	4.3	12	3.5	1.8	6.1
	Gastroenteritis norovirus (10068189)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Gingivitis (10018292)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	2	0.6	0.1	2.1	5	1.5	0.5	3.4	5	1.5	0.5	3.4	12	1.2	0.6	2.1	2	0.6	0.1	2.1
	Herpes zoster (10019974)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Impetigo (10021531)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	5	0.5	0.2	1.2	1	0.3	0.0	1.6
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	1	0.3	0.0	1.6	5	0.5	0.2	1.2	4	1.2	0.3	3.0
	Injection site abscess (10022044)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laryngitis (10023874)	8	2.4	1.0	4.6	13	3.9	2.1	6.5	12	3.6	1.9	6.1	33	3.3	2.3	4.6	6	1.8	0.7	3.8

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Localised infection (10024774)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Lyme disease (10025169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Molluscum contagiosum (10027807)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	3	0.9	0.2	2.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Nasopharyngitis (10028810)	12	3.6	1.8	6.1	9	2.7	1.2	5.0	10	3.0	1.4	5.4	31	3.1	2.1	4.3	11	3.2	1.6	5.7
	Oral candidiasis (10030963)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Oral herpes (10067152)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	98	29.0	24.2	34.1	105	31.3	26.4	36.6	87	25.8	21.2	30.8	290	28.7	25.9	31.6	104	30.6	25.7	35.8
	Otitis media acute (10033079)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Pharyngitis (10034835)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	3	0.9	0.2	2.6	7	0.7	0.3	1.4	3	0.9	0.2	2.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	3	0.9	0.2	2.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	8	0.8	0.3	1.6	2	0.6	0.1	2.1
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pyelonephritis (10037596)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus infection (10061603)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	5	1.5	0.5	3.4	6	1.8	0.7	3.9	9	2.7	1.2	5.0	20	2.0	1.2	3.0	2	0.6	0.1	2.1
	Respiratory tract infection viral (10062106)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinitis (10039083)	29	8.6	5.8	12.1	24	7.2	4.6	10.5	22	6.5	4.1	9.7	75	7.4	5.9	9.2	22	6.5	4.1	9.6
	Roseola (10039222)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin infection (10040872)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Tonsillitis (10044008)	6	1.8	0.7	3.8	3	0.9	0.2	2.6	2	0.6	0.1	2.1	11	1.1	0.5	1.9	3	0.9	0.2	2.6
	Upper respiratory tract infection (10046306)	87	25.7	21.2	30.7	90	26.9	22.2	32.0	90	26.7	22.1	31.8	267	26.4	23.7	29.3	70	20.6	16.4	25.3
	Urinary tract infection (10046571)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	3	0.9	0.2	2.6
	Varicella (10046980)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	5	1.5	0.5	3.4	3	0.9	0.2	2.6	1	0.3	0.0	1.6	9	0.9	0.4	1.7	2	0.6	0.1	2.1
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye injury (10061128)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Ligament sprain (10024453)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Post vaccination syndrome (10036242)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Post-traumatic pain (10065016)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Radial head dislocation (10073749)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin wound (10072170)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Splinter (10041662)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Thermal burn (10053615)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	1	0.3	0.0	1.6	4	0.4	0.1	1.0	0	0.0	0.0	1.1
	Wound (10052428)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	5	0.5	0.2	1.2	1	0.3	0.0	1.6
Investigations (10022891)	Cardiac murmur (10007586)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hypoglycaemia (10020993)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Overweight (10033307)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Skin papilloma (10040907)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Poor quality sleep (10062519)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Post-traumatic headache (10036313)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Somnolence (10041349)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Irritability (10022998)	5	1.5	0.5	3.4	7	2.1	0.8	4.3	7	2.1	0.8	4.2	19	1.9	1.1	2.9	10	2.9	1.4	5.3
	Restlessness (10038743)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Sleep disorder (10040984)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Tearfulness (10043169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Terminal insomnia (10068932)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Testicular retraction (10043348)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Apnoea (10002974)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Bronchitis chronic (10006458)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Cough (10011224)	9	2.7	1.2	5.0	11	3.3	1.7	5.8	9	2.7	1.2	5.0	29	2.9	1.9	4.1	16	4.7	2.7	7.5
	Dyspnoea (10013968)	1	0.3	0.0	1.6	3	0.9	0.2	2.6	1	0.3	0.0	1.6	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Epistaxis (10015090)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Nasal congestion (10028735)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Oropharyngeal pain (10068319)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rhinitis allergic (10039085)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Dermatitis atopic (10012438)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	3	0.9	0.2	2.6	9	0.9	0.4	1.7	4	1.2	0.3	3.0
	Dermatitis diaper (10012444)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	2	0.6	0.1	2.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Dry skin (10013786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eczema (10014184)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash (10037844)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash erythematous (10037855)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rash macular (10037867)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rash papular (10037876)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash vesicular (10037898)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin burning sensation (10054786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Skin irritation (10040880)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Swelling face (10042682)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Urticaria (10046735)	5	1.5	0.5	3.4	1	0.3	0.0	1.7	0	0.0	0.0	1.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.124 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		87	88.8	80.8	94.3	89	90.8	83.3	95.7	93	93.9	87.3	97.7	269	91.2	87.4	94.2	88	88.9	81.0	94.3
Cardiac disorders (10007541)	Supraventricular extrasystoles (10042602)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Congenital, familial and genetic disorders (10010331)	Congenital cardiovascular anomaly (10061054)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Eye disorders (10015919)	Blepharitis (10005148)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	2.0	0.2	7.1	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Entropion (10061842)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Colitis (10009887)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Constipation (10010774)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Diarrhoea (10012735)	17	17.3	10.4	26.3	8	8.2	3.6	15.5	11	11.1	5.7	19.0	36	12.2	8.7	16.5	6	6.1	2.3	12.7
	Dyspepsia (10013946)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Faeces soft (10074859)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastritis (10017853)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Teething (10043183)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tongue ulceration (10043991)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	4	4.1	1.1	10.1	0	0.0	0.0	3.7	0	0.0	0.0	3.7	4	1.4	0.4	3.4	2	2.0	0.2	7.1
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	4	4.1	1.1	10.1	1	1.0	0.0	5.6	1	1.0	0.0	5.5	6	2.0	0.7	4.4	3	3.0	0.6	8.6
Immune system disorders (10021428)	Allergy to animal (10001742)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Drug hypersensitivity (10013700)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Milk allergy (10027633)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Infections and infestations (10021881)	Bronchiolitis (10006448)	4	4.1	1.1	10.1	9	9.2	4.3	16.7	6	6.1	2.3	12.7	19	6.4	3.9	9.9	5	5.1	1.7	11.4
	Bronchitis (10006451)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Candida nappy rash (10007135)	5	5.1	1.7	11.5	2	2.0	0.2	7.2	1	1.0	0.0	5.5	8	2.7	1.2	5.3	3	3.0	0.6	8.6

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Conjunctivitis (10010741)	6	6.1	2.3	12.9	6	6.1	2.3	12.9	4	4.0	1.1	10.0	16	5.4	3.1	8.7	8	8.1	3.6	15.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cutaneous larva migrans (10059547)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Ear infection (10014011)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	22	22.4	14.6	32.0	20	20.4	12.9	29.7	28	28.3	19.7	38.2	70	23.7	19.0	29.0	22	22.2	14.5	31.7
	Gastroenteritis viral (10017918)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Gingivitis (10018292)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Nasopharyngitis (10028810)	69	70.4	60.3	79.2	68	69.4	59.3	78.3	73	73.7	63.9	82.1	210	71.2	65.7	76.3	67	67.7	57.5	76.7
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Oral herpes (10067152)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Otitis externa (10033072)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Otitis media (10033078)	2	2.0	0.2	7.2	4	4.1	1.1	10.1	2	2.0	0.2	7.1	8	2.7	1.2	5.3	2	2.0	0.2	7.1
	Otitis media acute (10033079)	3	3.1	0.6	8.7	3	3.1	0.6	8.7	4	4.0	1.1	10.0	10	3.4	1.6	6.1	5	5.1	1.7	11.4
	Parasitic gastroenteritis (10067720)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngitis (10034835)	22	22.4	14.6	32.0	19	19.4	12.1	28.6	22	22.2	14.5	31.7	63	21.4	16.8	26.5	21	21.2	13.6	30.6
	Pharyngitis bacterial (10057869)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngotonsillitis (10049140)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	2	2.0	0.2	7.1	6	2.0	0.7	4.4	4	4.0	1.1	10.0
	Pneumonia (10035664)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia viral (10035737)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Rhinitis (10039083)	7	7.1	2.9	14.2	2	2.0	0.2	7.2	3	3.0	0.6	8.6	12	4.1	2.1	7.0	11	11.1	5.7	19.0
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	1	1.0	0.0	5.5	4	1.4	0.4	3.4	3	3.0	0.6	8.6
	Tonsillitis (10044008)	17	17.3	10.4	26.3	13	13.3	7.3	21.6	9	9.1	4.2	16.6	39	13.2	9.6	17.6	10	10.1	5.0	17.8
	Tracheitis (10044302)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Urinary tract infection (10046571)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Varicella (10046980)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	2	2.0	0.2	7.2	1	1.0	0.0	5.5	5	1.7	0.6	3.9	0	0.0	0.0	3.7
	Viral rash (10047476)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	3	3.0	0.6	8.6	6	2.0	0.7	4.4	1	1.0	0.0	5.5
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	1	1.0	0.0	5.6	5	5.1	1.7	11.5	2	2.0	0.2	7.1	8	2.7	1.2	5.3	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Burns second degree (10006802)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Eye burns (10015911)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	3	3.1	0.6	8.7	6	6.1	2.3	12.9	6	6.1	2.3	12.7	15	5.1	2.9	8.2	5	5.1	1.7	11.4
	Limb injury (10061225)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Lip injury (10055082)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Malnutrition (10061273)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Headache (10019211)	3	3.1	0.6	8.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Seizure (10039906)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	3	3.1	0.6	8.7	4	4.1	1.1	10.1	4	4.0	1.1	10.0	11	3.7	1.9	6.6	6	6.1	2.3	12.7
	Bronchospasm (10006482)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5
	Cough (10011224)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Productive cough (10036790)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Rhinorrhoea (10039101)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	2	2.0	0.2	7.1	5	1.7	0.6	3.9	0	0.0	0.0	3.7
	Vasomotor rhinitis (10047145)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Wheezing (10047924)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	2.0	0.2	7.2	3	3.1	0.6	8.7	1	1.0	0.0	5.5	6	2.0	0.7	4.4	2	2.0	0.2	7.1
	Dermatitis allergic (10012434)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Dermatitis atopic (10012438)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	4	4.0	1.1	10.0	7	2.4	1.0	4.8	4	4.0	1.1	10.0
	Dermatitis contact (10012442)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	2	2.0	0.2	7.1	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Dermatitis diaper (10012444)	4	4.1	1.1	10.1	2	2.0	0.2	7.2	6	6.1	2.3	12.7	12	4.1	2.1	7.0	1	1.0	0.0	5.5
	Miliaria (10027627)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Prurigo (10037083)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	2	2.0	0.2	7.1	5	1.7	0.6	3.9	2	2.0	0.2	7.1
	Rash (10037844)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Rash erythematous (10037855)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Skin disorder (10040831)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Solar dermatitis (10041303)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Urticaria (10046735)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Urticaria vesiculosa (10046755)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vitiligo (10047642)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	4	4.0	1.1	10.0	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.125 Percentage of subjects reporting new onset of chronic diseases classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		428	69.3	65.5	72.9	432	70.6	66.8	74.2	430	69.6	65.8	73.2	1290	69.8	67.7	71.9	475	72.6	69.0	76.0
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	6	0.3	0.1	0.7	4	0.6	0.2	1.6
	Iron deficiency anaemia (10022972)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Leukocytosis (10024378)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	5	0.8	0.2	1.8
	Leukopenia (10024384)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Lymphadenitis (10025188)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lymphadenopathy (10025197)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	4	0.6	0.2	1.6
	Thrombocytopenia (10043554)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Congenital, familial and genetic disorders (10010331)	Ankyloglossia congenital (10049244)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Atrial septal defect (10003664)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cerebral palsy (10008129)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cleft uvula (10053507)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cryptorchism (10011498)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Imperforate hymen (10021529)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Microcephaly (10027534)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Phimosis (10034878)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Supernumerary nipple (10042571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Talipes (10043101)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tibial torsion (10064515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Conductive deafness (10010280)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Deafness (10011878)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Ear pain (10014020)	11	1.8	0.9	3.2	4	0.7	0.2	1.7	11	1.8	0.9	3.2	26	1.4	0.9	2.1	10	1.5	0.7	2.8
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Middle ear effusion (10062545)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Eye disorders (10015919)	Astigmatism (10003569)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Conjunctivitis allergic (10010744)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Eye swelling (10015967)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Eyelid oedema (10015993)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lid sulcus deepened (10072716)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pseudostrabismus (10072123)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Scleral haemorrhage (10050508)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Strabismus (10042159)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Abdominal distension (10000060)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Abdominal pain upper (10000087)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Anal skin tags (10002172)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Aphthous ulcer (10002959)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Chapped lips (10049047)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chronic gastritis (10008882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Colitis (10009887)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	8	1.3	0.6	2.5	8	1.3	0.6	2.6	16	2.6	1.5	4.2	32	1.7	1.2	2.4	11	1.7	0.8	3.0
	Dental caries (10012318)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Diarrhoea (10012735)	53	8.6	6.5	11.1	43	7.0	5.1	9.3	37	6.0	4.3	8.2	133	7.2	6.1	8.5	56	8.6	6.5	11.0
	Dysphagia (10013950)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Faeces discoloured (10016100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gastritis (10017853)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gingival pain (10018286)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gingival swelling (10018291)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Haematochezia (10018836)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Inguinal hernia (10022016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lip swelling (10024570)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Melaena (10027141)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mouth cyst (10028020)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mucous stools (10028140)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral mucosal eruption (10030997)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Post-tussive vomiting (10066220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Proctitis (10036774)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	1	0.2	0.0	0.9	6	1.0	0.4	2.1	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Teething (10043183)	29	4.7	3.2	6.7	48	7.8	5.8	10.3	31	5.0	3.4	7.0	108	5.8	4.8	7.0	45	6.9	5.1	9.1
	Tooth discolouration (10044032)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Toothache (10044055)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Umbilical hernia (10045458)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Vomiting (10047700)	43	7.0	5.1	9.3	28	4.6	3.1	6.5	40	6.5	4.7	8.7	111	6.0	5.0	7.2	43	6.6	4.8	8.8
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cyst (10011732)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Developmental delay (10012559)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Discomfort (10013082)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Fatigue (10016256)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Feeling hot (10016334)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Gait disturbance (10017577)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Gait inability (10017581)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Influenza like illness (10022004)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Injection site bruising (10022052)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site erosion (10022059)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Injection site erythema (10022061)	6	1.0	0.4	2.1	6	1.0	0.4	2.1	4	0.6	0.2	1.6	16	0.9	0.5	1.4	4	0.6	0.2	1.6
	Injection site induration (10022075)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site mass (10022081)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Injection site pain (10022086)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Injection site papule (10066044)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Injection site rash (10022094)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Injection site swelling (10053425)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	4	0.6	0.2	1.6	12	0.6	0.3	1.1	4	0.6	0.2	1.6
	Injection site vesicles (10022111)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Mucosal inflammation (10028116)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pain (10033371)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pyrexia (10037660)	44	7.1	5.2	9.4	49	8.0	6.0	10.4	37	6.0	4.3	8.2	130	7.0	5.9	8.3	45	6.9	5.1	9.1
	Vessel puncture site bruise (10063881)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vessel puncture site haematoma (10065902)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Immune system disorders (10021428)	Allergy to animal (10001742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Drug hypersensitivity (10013700)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.6	0.2	1.6	6	0.3	0.1	0.7	6	0.9	0.3	2.0
	Food allergy (10016946)	4	0.6	0.2	1.6	5	0.8	0.3	1.9	8	1.3	0.6	2.5	17	0.9	0.5	1.5	5	0.8	0.2	1.8
	Hypersensitivity (10020751)	2	0.3	0.0	1.2	4	0.7	0.2	1.7	3	0.5	0.1	1.4	9	0.5	0.2	0.9	2	0.3	0.0	1.1
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Multiple allergies (10028164)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Seasonal allergy (10048908)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	0	0.0	0.0	0.6	8	0.4	0.2	0.9	2	0.3	0.0	1.1
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Abscess limb (10050473)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Abscess neck (10053576)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acarodermatitis (10063409)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Acute sinusitis (10001076)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	6	1.0	0.4	2.1	16	0.9	0.5	1.4	2	0.3	0.0	1.1
	Adenovirus infection (10060931)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Bronchiolitis (10006448)	15	2.4	1.4	4.0	15	2.5	1.4	4.0	11	1.8	0.9	3.2	41	2.2	1.6	3.0	18	2.8	1.6	4.3
	Bronchitis (10006451)	7	1.1	0.5	2.3	7	1.1	0.5	2.3	14	2.3	1.2	3.8	28	1.5	1.0	2.2	9	1.4	0.6	2.6
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchitis viral (10053160)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Candida infection (10074170)	7	1.1	0.5	2.3	5	0.8	0.3	1.9	3	0.5	0.1	1.4	15	0.8	0.5	1.3	8	1.2	0.5	2.4
	Candida nappy rash (10007135)	6	1.0	0.4	2.1	5	0.8	0.3	1.9	3	0.5	0.1	1.4	14	0.8	0.4	1.3	6	0.9	0.3	2.0
	Cellulitis (10007882)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	7	1.1	0.5	2.3	16	0.9	0.5	1.4	3	0.5	0.1	1.3
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	44	7.1	5.2	9.4	49	8.0	6.0	10.4	54	8.7	6.6	11.2	147	8.0	6.8	9.3	53	8.1	6.1	10.5
	Conjunctivitis bacterial (10061784)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	3	0.5	0.1	1.4	13	0.7	0.4	1.2	4	0.6	0.2	1.6
	Croup infectious (10011416)	28	4.5	3.0	6.5	37	6.0	4.3	8.2	33	5.3	3.7	7.4	98	5.3	4.3	6.4	33	5.0	3.5	7.0
	Cutaneous larva migrans (10059547)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Diarrhoea infectious (10012742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Ear infection (10014011)	14	2.3	1.2	3.8	12	2.0	1.0	3.4	6	1.0	0.4	2.1	32	1.7	1.2	2.4	15	2.3	1.3	3.8
	Eczema herpeticum (10014197)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema infected (10014199)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Enteritis infectious (10058839)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Erythema infectiosum (10015214)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Escherichia urinary tract infection (10052238)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Exanthema subitum (10015586)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	External ear cellulitis (10015729)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye infection (10015929)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Folliculitis (10016936)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	1.0	0.4	2.1	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Fungal infection (10017533)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Fungal skin infection (10017543)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	4	0.6	0.2	1.6
	Gastroenteritis (10017888)	27	4.4	2.9	6.3	28	4.6	3.1	6.5	22	3.6	2.2	5.3	77	4.2	3.3	5.2	22	3.4	2.1	5.0
	Gastroenteritis enteroviral (10017901)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	6	1.0	0.4	2.1	19	1.0	0.6	1.6	7	1.1	0.4	2.2
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hand-foot-and-mouth disease (10019113)	16	2.6	1.5	4.2	19	3.1	1.9	4.8	17	2.8	1.6	4.4	52	2.8	2.1	3.7	21	3.2	2.0	4.9
	Herpangina (10019936)	5	0.8	0.3	1.9	5	0.8	0.3	1.9	4	0.6	0.2	1.6	14	0.8	0.4	1.3	2	0.3	0.0	1.1
	Herpes dermatitis (10062639)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hordeolum (10020377)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Impetigo (10021531)	11	1.8	0.9	3.2	5	0.8	0.3	1.9	3	0.5	0.1	1.4	19	1.0	0.6	1.6	7	1.1	0.4	2.2
	Infected bite (10076911)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Influenza (10022000)	5	0.8	0.3	1.9	8	1.3	0.6	2.6	4	0.6	0.2	1.6	17	0.9	0.5	1.5	8	1.2	0.5	2.4
	Lice infestation (10024424)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.5	0.1	1.4	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Mycoplasma infection (10061300)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Nasopharyngitis (10028810)	24	3.9	2.5	5.7	30	4.9	3.3	6.9	28	4.5	3.0	6.5	82	4.4	3.5	5.5	26	4.0	2.6	5.8
	Neonatal candida infection (10028924)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Onychomycosis (10030338)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Oral herpes (10067152)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Otitis externa (10033072)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Otitis media (10033078)	111	18.0	15.0	21.2	110	18.0	15.0	21.2	98	15.9	13.1	19.0	319	17.3	15.6	19.1	133	20.3	17.3	23.6
	Otitis media acute (10033079)	20	3.2	2.0	5.0	12	2.0	1.0	3.4	23	3.7	2.4	5.5	55	3.0	2.2	3.9	26	4.0	2.6	5.8
	Otitis media chronic (10033081)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Otosalpingitis (10033102)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Parotitis (10034038)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pertussis (10034738)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pharyngitis (10034835)	29	4.7	3.2	6.7	32	5.2	3.6	7.3	28	4.5	3.0	6.5	89	4.8	3.9	5.9	28	4.3	2.9	6.1
	Pharyngitis streptococcal (10034839)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	7	1.1	0.5	2.3	15	0.8	0.5	1.3	6	0.9	0.3	2.0
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Pneumonia (10035664)	8	1.3	0.6	2.5	14	2.3	1.3	3.8	6	1.0	0.4	2.1	28	1.5	1.0	2.2	5	0.8	0.2	1.8
	Pyoderma (10037632)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Respiratory tract infection (10062352)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Rhinitis (10039083)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	8	1.3	0.6	2.5	27	1.5	1.0	2.1	11	1.7	0.8	3.0
	Roseola (10039222)	5	0.8	0.3	1.9	6	1.0	0.4	2.1	7	1.1	0.5	2.3	18	1.0	0.6	1.5	1	0.2	0.0	0.8
	Salmonellosis (10039447)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Scarlet fever (10039587)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Sinusitis (10040753)	22	3.6	2.2	5.3	10	1.6	0.8	3.0	12	1.9	1.0	3.4	44	2.4	1.7	3.2	15	2.3	1.3	3.8
	Skin candida (10054152)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	3	0.5	0.1	1.4	9	0.5	0.2	0.9	1	0.2	0.0	0.8

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	2	0.3	0.0	1.2	8	1.3	0.6	2.6	4	0.6	0.2	1.6	14	0.8	0.4	1.3	8	1.2	0.5	2.4
	Subcutaneous abscess (10042343)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	0	0.0	0.0	0.6	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Tinea capitis (10043866)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea cruris (10043868)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea infection (10060889)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tinea nigra (10043871)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillitis (10044008)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	10	0.5	0.3	1.0	6	0.9	0.3	2.0
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	114	18.4	15.5	21.7	131	21.4	18.2	24.9	125	20.2	17.1	23.6	370	20.0	18.2	21.9	145	22.2	19.0	25.6
	Urethritis (10046480)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Vaginal infection (10046914)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	44	7.1	5.2	9.4	32	5.2	3.6	7.3	43	7.0	5.1	9.3	119	6.4	5.4	7.7	33	5.0	3.5	7.0
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral rash (10047476)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	11	1.8	0.9	3.2	29	1.6	1.1	2.2	9	1.4	0.6	2.6
	Viral upper respiratory tract infection (10047482)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	7	1.1	0.5	2.3	17	0.9	0.5	1.5	7	1.1	0.4	2.2
	Vulvovaginitis (10047794)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Animal bite (10002515)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Animal scratch (10002519)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	5	0.8	0.3	1.9	6	1.0	0.4	2.1	10	1.6	0.8	3.0	21	1.1	0.7	1.7	7	1.1	0.4	2.2
	Burns first degree (10006797)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Burns second degree (10006802)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chemical eye injury (10055116)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Clavicle fracture (10009245)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Concussion (10010254)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Contusion (10050584)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	4	0.6	0.2	1.6	13	0.7	0.4	1.2	10	1.5	0.7	2.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Craniocerebral injury (10070976)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye contusion (10073354)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Eyelid injury (10069200)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Face injury (10050392)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Foot fracture (10016970)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in eye (10017012)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Gingival injury (10049300)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	8	1.3	0.6	2.5	11	1.8	0.9	3.2	7	1.1	0.5	2.3	26	1.4	0.9	2.1	5	0.8	0.2	1.8
	Humerus fracture (10020462)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Joint dislocation (10023204)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Joint injury (10060820)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Laceration (10023572)	8	1.3	0.6	2.5	2	0.3	0.0	1.2	10	1.6	0.8	3.0	20	1.1	0.7	1.7	9	1.4	0.6	2.6
	Ligament sprain (10024453)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Limb crushing injury (10064031)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Limb injury (10061225)	5	0.8	0.3	1.9	3	0.5	0.1	1.4	3	0.5	0.1	1.4	11	0.6	0.3	1.1	3	0.5	0.1	1.3
	Lip injury (10055082)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.8	0.3	1.9	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Mouth injury (10049294)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	0	0.0	0.0	0.6	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Nail avulsion (10028686)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Procedural pain (10064882)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	2	0.3	0.0	1.2	7	0.4	0.2	0.8	5	0.8	0.2	1.8
	Radius fracture (10037802)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Scar (10039580)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin abrasion (10064990)	0	0.0	0.0	0.6	6	1.0	0.4	2.1	1	0.2	0.0	0.9	7	0.4	0.2	0.8	3	0.5	0.1	1.3
	Splinter (10041662)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sunburn (10042496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Thermal burn (10053615)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	3	0.5	0.1	1.4	7	0.4	0.2	0.8	3	0.5	0.1	1.3
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Upper limb fracture (10061394)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Wrist fracture (10048049)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Investigations (10022891)	Blood lead increased (10005642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Blood urine present (10018870)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body height below normal (10056811)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cardiac murmur (10007586)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Cold agglutinins positive (10009854)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Dehydration (10012174)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	3	0.5	0.1	1.4	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Failure to thrive (10016165)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hypoglycaemia (10020993)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Iron deficiency (10022970)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lactose intolerance (10023681)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Overweight (10033307)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight gain poor (10047897)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foot deformity (10061159)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Limb asymmetry (10070670)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Muscular weakness (10028372)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pain in extremity (10033425)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	4	0.6	0.2	1.6	11	0.6	0.3	1.1	1	0.2	0.0	0.8
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Toe walking (10068872)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Trigger finger (10044654)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma of skin (10018823)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphangioma (10025219)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Skin papilloma (10040907)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Drooling (10013642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Febrile convulsion (10016284)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	9	0.5	0.2	0.9	4	0.6	0.2	1.6
	Gross motor delay (10069118)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Headache (10019211)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lethargy (10024264)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Loss of consciousness (10024855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Motor developmental delay (10070302)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Poor quality sleep (10062519)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Seizure (10039906)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder (10041466)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder developmental (10041467)	4	0.6	0.2	1.6	3	0.5	0.1	1.4	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Tremor (10044565)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Psychiatric disorders (10037175)	Aggression (10001488)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Breath holding (10006322)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Depressed mood (10012374)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Insomnia (10022437)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Irritability (10022998)	11	1.8	0.9	3.2	9	1.5	0.7	2.8	4	0.6	0.2	1.6	24	1.3	0.8	1.9	9	1.4	0.6	2.6
	Middle insomnia (10027590)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pica (10035001)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep disorder (10040984)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Sleep terror (10041010)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	2	0.3	0.0	1.1
Renal and urinary disorders (10038359)	Dysuria (10013990)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Haematuria (10018867)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pollakiuria (10036018)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Genital labial adhesions (10064162)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Penile adhesion (10059636)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Prepuce redundant (10036624)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulval disorder (10047754)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulvovaginal discomfort (10047786)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Respiratory, thoracic and mediastinal disorders (10038738)	Adenoidal hypertrophy (10001229)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Aspiration (10003504)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Asthma (10003553)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	11	1.8	0.9	3.2	19	1.0	0.6	1.6	10	1.5	0.7	2.8
	Bronchial hyperreactivity (10066091)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	5	0.8	0.3	1.9	14	0.8	0.4	1.3	5	0.8	0.2	1.8
	Bronchospasm (10006482)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cough (10011224)	36	5.8	4.1	8.0	37	6.0	4.3	8.2	38	6.1	4.4	8.3	111	6.0	5.0	7.2	42	6.4	4.7	8.6
	Dyspnoea (10013968)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Epistaxis (10015090)	1	0.2	0.0	0.9	6	1.0	0.4	2.1	1	0.2	0.0	0.9	8	0.4	0.2	0.9	2	0.3	0.0	1.1
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	11	1.8	0.9	3.2	11	1.8	0.9	3.2	11	1.8	0.9	3.2	33	1.8	1.2	2.5	15	2.3	1.3	3.8
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Nasal obstruction (10028748)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Oropharyngeal pain (10068319)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Respiratory disorder (10038683)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	1.0	0.4	2.1	11	0.6	0.3	1.1	2	0.3	0.0	1.1
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	14	2.3	1.2	3.8	9	1.5	0.7	2.8	8	1.3	0.6	2.5	31	1.7	1.1	2.4	13	2.0	1.1	3.4
	Rhinorrhoea (10039101)	23	3.7	2.4	5.5	22	3.6	2.3	5.4	21	3.4	2.1	5.1	66	3.6	2.8	4.5	23	3.5	2.2	5.2
	Sinus congestion (10040742)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Sneezing (10041232)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Stridor (10042241)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tachypnoea (10043089)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	5	0.8	0.3	1.9	18	2.9	1.8	4.6	9	1.5	0.7	2.7	32	1.7	1.2	2.4	6	0.9	0.3	2.0
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Blister (10005191)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Dermatitis (10012431)	10	1.6	0.8	3.0	3	0.5	0.1	1.4	5	0.8	0.3	1.9	18	1.0	0.6	1.5	5	0.8	0.2	1.8
	Dermatitis allergic (10012434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Dermatitis atopic (10012438)	5	0.8	0.3	1.9	13	2.1	1.1	3.6	17	2.8	1.6	4.4	35	1.9	1.3	2.6	5	0.8	0.2	1.8
	Dermatitis contact (10012442)	3	0.5	0.1	1.4	7	1.1	0.5	2.3	4	0.6	0.2	1.6	14	0.8	0.4	1.3	3	0.5	0.1	1.3
	Dermatitis diaper (10012444)	25	4.0	2.6	5.9	23	3.8	2.4	5.6	26	4.2	2.8	6.1	74	4.0	3.2	5.0	40	6.1	4.4	8.2
	Drug eruption (10013687)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dry skin (10013786)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ecchymosis (10014080)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema (10014184)	9	1.5	0.7	2.7	5	0.8	0.3	1.9	8	1.3	0.6	2.5	22	1.2	0.7	1.8	15	2.3	1.3	3.8
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Erythema (10015150)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Erythema multiforme (10015218)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Granuloma annulare (10018692)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hair disorder (10019037)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Henoch-schonlein purpura (10019617)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Keratosis pilaris (10066295)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Lichen sclerosus (10024434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Macule (10025421)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Miliaria (10027627)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Nail disorder (10028694)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Papule (10033733)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pityriasis (10035110)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pityriasis rosea (10035114)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Rash (10037844)	18	2.9	1.7	4.6	12	2.0	1.0	3.4	12	1.9	1.0	3.4	42	2.3	1.6	3.1	11	1.7	0.8	3.0
	Rash erythematous (10037855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash generalised (10037858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash macular (10037867)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash maculo-papular (10037868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash papular (10037876)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash scarlatiniform (10037890)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seborrhoea (10039792)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Seborrhoeic dermatitis (10039793)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Skin fissures (10040849)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Skin hypopigmentation (10040868)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Skin lesion (10040882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin mass (10067868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Skin warm (10040952)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Swelling face (10042682)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Urticaria (10046735)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	3	0.5	0.1	1.4	16	0.9	0.5	1.4	4	0.6	0.2	1.6
Surgical and medical procedures (10042613)	Myringotomy (10028662)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pallor (10033546)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.126 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	0.8	0.0	4.4	2	1.6	0.2	5.7	1	0.8	0.0	4.4	4	1.1	0.3	2.7	5	3.9	1.3	8.9
Gastrointestinal disorders (10017947)	Stomatitis (10042128)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Enterovirus infection (10014909)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Pneumonia (10035664)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral infection (10047461)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Injury, poisoning and procedural complications (10022117)	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Concussion (10010254)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.127 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		25	41.0	28.6	54.3	21	33.9	22.3	47.0	29	45.3	32.8	58.3	75	40.1	33.0	47.5	25	36.2	25.0	48.7
Blood and lymphatic system disorders (10005329)	Lymphadenitis (10025188)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Colitis (10009887)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Constipation (10010774)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Diarrhoea (10012735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	3	4.3	0.9	12.2
	Oral contusion (10078170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Teething (10043183)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Vomiting (10047700)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	0	0.0	0.0	5.2
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	1	1.6	0.0	8.4	3	1.6	0.3	4.6	2	2.9	0.4	10.1
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchiolitis (10006448)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Bronchitis (10006451)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	2	3.1	0.4	10.8	7	3.7	1.5	7.6	1	1.4	0.0	7.8
	Burn infection (10051548)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Cellulitis orbital (10007918)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Conjunctivitis (10010741)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	2	3.1	0.4	10.8	6	3.2	1.2	6.9	1	1.4	0.0	7.8
	Coxsackie viral infection (10011261)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Ear infection (10014011)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Gastroenteritis (10017888)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	4	6.3	1.7	15.2	8	4.3	1.9	8.3	4	5.8	1.6	14.2
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Hand-foot-and-mouth disease (10019113)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Herpangina (10019936)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Impetigo (10021531)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Laryngitis (10023874)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	2	3.1	0.4	10.8	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Nasopharyngitis (10028810)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	3	4.7	1.0	13.1	9	4.8	2.2	8.9	2	2.9	0.4	10.1
	Oral herpes (10067152)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Otitis media (10033078)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Otitis media acute (10033079)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	2	3.1	0.4	10.8	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Pharyngitis (10034835)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	0	0.0	0.0	5.6	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Pharyngotonsillitis (10049140)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Pneumonia (10035664)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Respiratory tract infection (10062352)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Tonsillitis (10044008)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	3	4.7	1.0	13.1	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Upper respiratory tract infection (10046306)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	1	1.6	0.0	8.4	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Viral diarrhoea (10051511)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Viral infection (10047461)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	2	3.1	0.4	10.8	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Contusion (10050584)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	3	4.3	0.9	12.2
	Head injury (10019196)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Lip injury (10055082)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Poisoning (10061355)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Wound (10052428)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Reproductive system and breast disorders (10038604)	Perineal cyst (10066058)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchospasm (10006482)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	3	4.7	1.0	13.1	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Catarrh (10007774)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cough (10011224)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Miliaria (10027627)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rash (10037844)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	3	4.7	1.0	13.1	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Urticaria (10046735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	2	2.9	0.4	10.1
Vascular disorders (10047065)	Haematoma (10018852)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.128 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		27	8.0	5.3	11.4	23	6.9	4.4	10.1	23	6.8	4.4	10.1	73	7.2	5.7	9.0	26	7.6	5.1	11.0
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Teething (10043183)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Pyrexia (10037660)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	3	0.9	0.2	2.6
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Hypersensitivity (10020751)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Bronchitis (10006451)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	3	0.9	0.2	2.6	5	0.5	0.2	1.2	3	0.9	0.2	2.6
	Conjunctivitis (10010741)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Ear infection (10014011)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Exanthema subitum (10015586)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Gastroenteritis (10017888)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Influenza (10022000)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laryngitis (10023874)	2	0.6	0.1	2.1	3	0.9	0.2	2.6	2	0.6	0.1	2.1	7	0.7	0.3	1.4	1	0.3	0.0	1.6
	Otitis media (10033078)	6	1.8	0.7	3.8	13	3.9	2.1	6.5	9	2.7	1.2	5.0	28	2.8	1.8	4.0	5	1.5	0.5	3.4
	Pneumonia (10035664)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pyelonephritis (10037596)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinitis (10039083)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Tonsillitis (10044008)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Upper respiratory tract infection (10046306)	7	2.1	0.8	4.2	5	1.5	0.5	3.4	4	1.2	0.3	3.0	16	1.6	0.9	2.6	7	2.1	0.8	4.2
	Urinary tract infection (10046571)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Eye injury (10061128)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Radial head dislocation (10073749)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Respiratory, thoracic and mediastinal disorders (10038738)	Cough (10011224)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Skin and subcutaneous tissue disorders (10040785)	Skin burning sensation (10054786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.129 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	1.0	0.0	5.6	5	5.1	1.7	11.5	5	5.1	1.7	11.4	11	3.7	1.9	6.6	0	0.0	0.0	3.7
Infections and infestations (10021881)	Gastroenteritis (10017888)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Nasopharyngitis (10028810)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Otitis media acute (10033079)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Tonsillitis (10044008)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Injury, poisoning and procedural complications (10022117)	Head injury (10019196)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	2.0	0.2	7.1	2	0.7	0.1	2.4	0	0.0	0.0	3.7
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Urticaria vesiculosa (10046755)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.130 Percentage of subjects reporting with AEs prompting emergency room visits classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		69	11.2	8.8	13.9	65	10.6	8.3	13.3	78	12.6	10.1	15.5	212	11.5	10.1	13.0	78	11.9	9.5	14.7
Blood and lymphatic system disorders (10005329)	Lymphadenopathy (10025197)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Diarrhoea (10012735)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	8	0.4	0.2	0.9	7	1.1	0.4	2.2
	Gastritis (10017853)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Stomatitis (10042128)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Teething (10043183)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Vomiting (10047700)	6	1.0	0.4	2.1	2	0.3	0.0	1.2	4	0.6	0.2	1.6	12	0.6	0.3	1.1	9	1.4	0.6	2.6
General disorders and administration site conditions (10018065)	Gait disturbance (10017577)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyrexia (10037660)	11	1.8	0.9	3.2	5	0.8	0.3	1.9	6	1.0	0.4	2.1	22	1.2	0.7	1.8	12	1.8	1.0	3.2
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Food allergy (10016946)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Hypersensitivity (10020751)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Seasonal allergy (10048908)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Infections and infestations (10021881)	Abscess limb (10050473)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abscess neck (10053576)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchiolitis (10006448)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Bronchitis (10006451)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Candida infection (10074170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Candida nappy rash (10007135)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cellulitis (10007882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Conjunctivitis (10010741)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Croup infectious (10011416)	3	0.5	0.1	1.4	12	2.0	1.0	3.4	5	0.8	0.3	1.9	20	1.1	0.7	1.7	8	1.2	0.5	2.4
	Ear infection (10014011)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Fungal skin infection (10017543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis (10017888)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	5	0.8	0.2	1.8
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand-foot-and-mouth disease (10019113)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Herpangina (10019936)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Impetigo (10021531)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Influenza (10022000)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasopharyngitis (10028810)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Otitis externa (10033072)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Otitis media (10033078)	11	1.8	0.9	3.2	8	1.3	0.6	2.6	12	1.9	1.0	3.4	31	1.7	1.1	2.4	13	2.0	1.1	3.4
	Otitis media acute (10033079)	2	0.3	0.0	1.2	4	0.7	0.2	1.7	1	0.2	0.0	0.9	7	0.4	0.2	0.8	3	0.5	0.1	1.3
	Pharyngitis (10034835)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.6	0.2	1.6	8	0.4	0.2	0.9	2	0.3	0.0	1.1
	Pharyngitis streptococcal (10034839)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pneumonia (10035664)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	3	0.5	0.1	1.4	7	0.4	0.2	0.8	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinitis (10039083)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Scarlet fever (10039587)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Sinusitis (10040753)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Skin candida (10054152)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Streptococcal infection (10061372)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Upper respiratory tract infection (10046306)	5	0.8	0.3	1.9	8	1.3	0.6	2.6	8	1.3	0.6	2.5	21	1.1	0.7	1.7	8	1.2	0.5	2.4
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral infection (10047461)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.6	0.2	1.6	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Viral rash (10047476)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	2	0.3	0.0	1.2	6	0.3	0.1	0.7	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral upper respiratory tract infection (10047482)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	3	0.5	0.1	1.4	7	0.4	0.2	0.8	2	0.3	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Animal bite (10002515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Arthropod bite (10003399)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Chemical eye injury (10055116)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Clavicle fracture (10009245)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Concussion (10010254)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Contusion (10050584)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Craniocerebral injury (10070976)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Eyelid injury (10069200)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Foreign body in eye (10017012)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	2	0.3	0.0	1.2	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Humerus fracture (10020462)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Joint dislocation (10023204)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Laceration (10023572)	7	1.1	0.5	2.3	2	0.3	0.0	1.2	7	1.1	0.5	2.3	16	0.9	0.5	1.4	3	0.5	0.1	1.3
	Limb injury (10061225)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Lip injury (10055082)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Mouth injury (10049294)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Skin abrasion (10064990)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	2	0.3	0.0	1.1
	Thermal burn (10053615)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
Investigations (10022891)	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	3	0.5	0.1	1.3
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Pyogenic granuloma (10037649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Nervous system disorders (10029205)	Febrile convulsion (10016284)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	7	0.4	0.2	0.8	0	0.0	0.0	0.6
	Seizure (10039906)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tremor (10044565)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Breath holding (10006322)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Irritability (10022998)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Renal and urinary disorders (10038359)	Pollakiuria (10036018)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Respiratory, thoracic and mediastinal disorders (10038738)	Aspiration (10003504)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Asthma (10003553)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchospasm (10006482)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cough (10011224)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	3	0.5	0.1	1.4	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Dyspnoea (10013968)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Rhinitis allergic (10039085)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinorrhoea (10039101)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stridor (10042241)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Dermatitis contact (10012442)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Dermatitis diaper (10012444)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pityriasis (10035110)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rash (10037844)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Rash generalised (10037858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash scarlatiniform (10037890)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urticaria (10046735)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.131 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Estonia)

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		46	37.1	28.6	46.2	47	37.6	29.1	46.7	44	35.2	26.9	44.2	137	36.6	31.7	41.7	46	36.2	27.9	45.2
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Ear and labyrinth disorders (10013993)	Auricular swelling (10003800)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Ear pain (10014020)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Eye disorders (10015919)	Eye inflammation (10015943)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Diarrhoea (10012735)	2	1.6	0.2	5.7	5	4.0	1.3	9.1	2	1.6	0.2	5.7	9	2.4	1.1	4.5	0	0.0	0.0	2.9
	Enterocolitis (10014893)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gingival pain (10018286)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Stomatitis (10042128)	0	0.0	0.0	2.9	4	3.2	0.9	8.0	1	0.8	0.0	4.4	5	1.3	0.4	3.1	0	0.0	0.0	2.9
	Teething (10043183)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
General disorders and administration site conditions (10018065)	Injection site erythema (10022061)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyrexia (10037660)	4	3.2	0.9	8.1	6	4.8	1.8	10.2	2	1.6	0.2	5.7	12	3.2	1.7	5.5	1	0.8	0.0	4.3
Immune system disorders (10021428)	Food allergy (10016946)	1	0.8	0.0	4.4	1	0.8	0.0	4.4	1	0.8	0.0	4.4	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Hypersensitivity (10020751)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Infections and infestations (10021881)	Bronchitis (10006451)	4	3.2	0.9	8.1	4	3.2	0.9	8.0	4	3.2	0.9	8.0	12	3.2	1.7	5.5	5	3.9	1.3	8.9
	Ear infection (10014011)	6	4.8	1.8	10.2	12	9.6	5.1	16.2	8	6.4	2.8	12.2	26	7.0	4.6	10.0	11	8.7	4.4	15.0
	Enterovirus infection (10014909)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6
	Exanthema subitum (10015586)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Eye infection (10015929)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	1	0.8	0.0	4.4	4	1.1	0.3	2.7	3	2.4	0.5	6.7
	Fungal skin infection (10017543)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Gastroenteritis (10017888)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Gastroenteritis adenovirus (10017889)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Gastroenteritis rotavirus (10017913)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Gastroenteritis viral (10017918)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Herpes simplex (10019948)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Impetigo (10021531)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Laryngitis (10023874)	0	0.0	0.0	2.9	3	2.4	0.5	6.9	2	1.6	0.2	5.7	5	1.3	0.4	3.1	2	1.6	0.2	5.6
	Nasopharyngitis (10028810)	1	0.8	0.0	4.4	4	3.2	0.9	8.0	0	0.0	0.0	2.9	5	1.3	0.4	3.1	2	1.6	0.2	5.6
	Neutropenic infection (10059482)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Oral candidiasis (10030963)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Oral infection (10048685)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Otitis media (10033078)	2	1.6	0.2	5.7	1	0.8	0.0	4.4	4	3.2	0.9	8.0	7	1.9	0.8	3.8	4	3.1	0.9	7.9
	Otitis media acute (10033079)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6
	Pharyngitis (10034835)	3	2.4	0.5	6.9	2	1.6	0.2	5.7	2	1.6	0.2	5.7	7	1.9	0.8	3.8	2	1.6	0.2	5.6
	Pneumonia (10035664)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	1	0.8	0.0	4.3
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Pyelonephritis acute (10037597)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Respiratory tract infection (10062352)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Respiratory tract infection viral (10062106)	4	3.2	0.9	8.1	0	0.0	0.0	2.9	0	0.0	0.0	2.9	4	1.1	0.3	2.7	4	3.1	0.9	7.9
	Rhinitis (10039083)	5	4.0	1.3	9.2	6	4.8	1.8	10.2	4	3.2	0.9	8.0	15	4.0	2.3	6.5	7	5.5	2.2	11.0
	Rotavirus infection (10067470)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Skin bacterial infection (10052891)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Tonsillitis (10044008)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	2	1.6	0.2	5.6
	Tracheitis (10044302)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Upper respiratory tract infection (10046306)	5	4.0	1.3	9.2	4	3.2	0.9	8.0	4	3.2	0.9	8.0	13	3.5	1.9	5.9	0	0.0	0.0	2.9
	Urinary tract infection (10046571)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Varicella (10046980)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Viral diarrhoea (10051511)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	2	1.6	0.2	5.6
	Viral infection (10047461)	6	4.8	1.8	10.2	7	5.6	2.3	11.2	6	4.8	1.8	10.2	19	5.1	3.1	7.8	6	4.7	1.8	10.0
	Viral pharyngitis (10047473)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Viral rash (10047476)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Injury, poisoning and procedural complications (10022117)	Arthropod sting (10003402)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9

		INV_MMR_1 N = 124				INV_MMR_2 N = 125				INV_MMR_3 N = 125				INV_MMR N = 374				COM_MMR N = 127			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Burns second degree (10006802)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
	Chemical poisoning (10008428)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Concussion (10010254)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Head injury (10019196)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Heat stroke (10019345)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	1	0.8	0.0	4.3
	Poor quality sleep (10062519)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	1	0.8	0.0	4.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	1	0.8	0.0	4.3
	Cough (10011224)	11	8.9	4.5	15.3	9	7.2	3.3	13.2	7	5.6	2.3	11.2	27	7.2	4.8	10.3	4	3.1	0.9	7.9
	Rhinitis allergic (10039085)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.8	0.0	4.4	2	0.5	0.1	1.9	0	0.0	0.0	2.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.8	0.0	4.4	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Dermatitis allergic (10012434)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	3	2.4	0.5	6.9	3	0.8	0.2	2.3	1	0.8	0.0	4.3
	Dermatitis atopic (10012438)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	1	0.8	0.0	4.4	1	0.3	0.0	1.5	0	0.0	0.0	2.9
	Rash (10037844)	0	0.0	0.0	2.9	1	0.8	0.0	4.4	2	1.6	0.2	5.7	3	0.8	0.2	2.3	2	1.6	0.2	5.6
	Urticaria (10046735)	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	2.9	0	0.0	0.0	1.0	2	1.6	0.2	5.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.132 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Spain)

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		55	90.2	79.8	96.3	56	90.3	80.1	96.4	59	92.2	82.7	97.4	170	90.9	85.8	94.6	64	92.8	83.9	97.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	3	4.7	1.0	13.1	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Iron deficiency anaemia (10022972)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lymphadenitis (10025188)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Congenital, familial and genetic disorders (10010331)	Talipes (10043101)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	2	3.3	0.4	11.3	0	0.0	0.0	5.8	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eye discharge (10015915)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Eyelid oedema (10015993)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Lacrimation increased (10023644)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Anal fissure (10002153)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Aphthous ulcer (10002959)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Colitis (10009887)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Constipation (10010774)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	2	2.9	0.4	10.1
	Diarrhoea (10012735)	14	23.0	13.2	35.5	9	14.5	6.9	25.8	11	17.2	8.9	28.7	34	18.2	12.9	24.5	19	27.5	17.5	39.6
	Dysphagia (10013950)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Inguinal hernia (10022016)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral contusion (10078170)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Oral disorder (10067621)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Stomatitis (10042128)	0	0.0	0.0	5.9	2	3.2	0.4	11.2	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Teething (10043183)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	3	4.7	1.0	13.1	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Toothache (10044055)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Vomiting (10047700)	4	6.6	1.8	15.9	6	9.7	3.6	19.9	5	7.8	2.6	17.3	15	8.0	4.6	12.9	5	7.2	2.4	16.1
General disorders and administration site conditions (10018065)	Asthenia (10003549)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Injection site erythema (10022061)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pain (10033371)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Pyrexia (10037660)	6	9.8	3.7	20.2	1	1.6	0.0	8.7	2	3.1	0.4	10.8	9	4.8	2.2	8.9	4	5.8	1.6	14.2
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Selective iga immunodeficiency (10039915)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Adenoiditis (10051223)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Bronchiolitis (10006448)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	1	1.6	0.0	8.4	6	3.2	1.2	6.9	2	2.9	0.4	10.1
	Bronchitis (10006451)	8	13.1	5.8	24.2	9	14.5	6.9	25.8	12	18.8	10.1	30.5	29	15.5	10.6	21.5	10	14.5	7.2	25.0
	Burn infection (10051548)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Candida infection (10074170)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	0	0.0	0.0	5.6	3	1.6	0.3	4.6	4	5.8	1.6	14.2
	Candida nappy rash (10007135)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cellulitis (10007882)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Cellulitis orbital (10007918)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Conjunctivitis (10010741)	8	13.1	5.8	24.2	11	17.7	9.2	29.5	14	21.9	12.5	34.0	33	17.6	12.5	23.9	14	20.3	11.6	31.7
	Coxsackie viral infection (10011261)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	3	4.7	1.0	13.1	7	3.7	1.5	7.6	0	0.0	0.0	5.2
	Cystitis (10011781)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Ear infection (10014011)	5	8.2	2.7	18.1	7	11.3	4.7	21.9	3	4.7	1.0	13.1	15	8.0	4.6	12.9	4	5.8	1.6	14.2
	Epstein-barr virus infection (10015108)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Erythema infectiosum (10015214)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Folliculitis (10016936)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Gastroenteritis (10017888)	15	24.6	14.5	37.3	11	17.7	9.2	29.5	11	17.2	8.9	28.7	37	19.8	14.3	26.2	13	18.8	10.4	30.1
	Gastrointestinal infection (10017964)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Hand-foot-and-mouth disease (10019113)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Herpangina (10019936)	2	3.3	0.4	11.3	3	4.8	1.0	13.5	3	4.7	1.0	13.1	8	4.3	1.9	8.3	3	4.3	0.9	12.2

		INV_MMR_1 N = 61				INV_MMR_2 N = 62				INV_MMR_3 N = 64				INV_MMR N = 187				COM_MMR N = 69			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Herpes simplex (10019948)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Hordeolum (10020377)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Impetigo (10021531)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Laryngitis (10023874)	6	9.8	3.7	20.2	6	9.7	3.6	19.9	6	9.4	3.5	19.3	18	9.6	5.8	14.8	9	13.0	6.1	23.3
	Nasopharyngitis (10028810)	24	39.3	27.1	52.7	17	27.4	16.9	40.2	20	31.3	20.2	44.1	61	32.6	26.0	39.8	24	34.8	23.7	47.2
	Oral candidiasis (10030963)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Oral herpes (10067152)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	0	0.0	0.0	5.6	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Otitis externa (10033072)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Otitis media (10033078)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	4	6.3	1.7	15.2	9	4.8	2.2	8.9	5	7.2	2.4	16.1
	Otitis media acute (10033079)	6	9.8	3.7	20.2	3	4.8	1.0	13.5	11	17.2	8.9	28.7	20	10.7	6.7	16.0	8	11.6	5.1	21.6
	Pharyngitis (10034835)	12	19.7	10.6	31.8	15	24.2	14.2	36.7	10	15.6	7.8	26.9	37	19.8	14.3	26.2	14	20.3	11.6	31.7
	Pharyngotonsillitis (10049140)	3	4.9	1.0	13.7	4	6.5	1.8	15.7	1	1.6	0.0	8.4	8	4.3	1.9	8.3	3	4.3	0.9	12.2
	Pneumonia (10035664)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	1	1.6	0.0	8.4	3	1.6	0.3	4.6	1	1.4	0.0	7.8
	Respiratory tract infection (10062352)	9	14.8	7.0	26.2	12	19.4	10.4	31.4	7	10.9	4.5	21.2	28	15.0	10.2	20.9	13	18.8	10.4	30.1
	Rhinitis (10039083)	3	4.9	1.0	13.7	0	0.0	0.0	5.8	1	1.6	0.0	8.4	4	2.1	0.6	5.4	2	2.9	0.4	10.1
	Rotavirus infection (10067470)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Scarlet fever (10039587)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Tonsillitis (10044008)	15	24.6	14.5	37.3	12	19.4	10.4	31.4	16	25.0	15.0	37.4	43	23.0	17.2	29.7	21	30.4	19.9	42.7
	Upper respiratory tract infection (10046306)	7	11.5	4.7	22.2	5	8.1	2.7	17.8	10	15.6	7.8	26.9	22	11.8	7.5	17.3	10	14.5	7.2	25.0
	Viral diarrhoea (10051511)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Viral infection (10047461)	4	6.6	1.8	15.9	9	14.5	6.9	25.8	5	7.8	2.6	17.3	18	9.6	5.8	14.8	8	11.6	5.1	21.6
	Viral pharyngitis (10047473)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	2	2.9	0.4	10.1
	Viral rash (10047476)	2	3.3	0.4	11.3	1	1.6	0.0	8.7	1	1.6	0.0	8.4	4	2.1	0.6	5.4	1	1.4	0.0	7.8
	Vulvovaginal candidiasis (10047784)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	6	9.4	3.5	19.3	14	7.5	4.2	12.2	4	5.8	1.6	14.2
	Bite (10004966)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Contusion (10050584)	4	6.6	1.8	15.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	5	2.7	0.9	6.1	3	4.3	0.9	12.2
	Eye contusion (10073354)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

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Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Eyelid injury (10069200)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Fall (10016173)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Head injury (10019196)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Injury (10022116)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Lip injury (10055082)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Poisoning (10061355)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Skull fracture (10061365)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Thermal burn (10053615)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Wound (10052428)	1	1.6	0.0	8.8	2	3.2	0.4	11.2	1	1.6	0.0	8.4	4	2.1	0.6	5.4	0	0.0	0.0	5.2
Investigations (10022891)	Cardiac murmur (10007586)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	1	1.6	0.0	8.4	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Cardiac murmur functional (10007587)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	2	3.1	0.4	10.8	2	1.1	0.1	3.8	1	1.4	0.0	7.8
	Iron deficiency (10022970)	2	3.3	0.4	11.3	2	3.2	0.4	11.2	0	0.0	0.0	5.6	4	2.1	0.6	5.4	1	1.4	0.0	7.8
Musculoskeletal and connective tissue disorders (10028395)	Elbow deformity (10061833)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	1	1.4	0.0	7.8
	Synovitis (10042868)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Mycosis fungoides (10028483)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Reproductive system and breast disorders (10038604)	Acquired phimosis (10068625)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Balanoposthitis (10004078)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	2	3.1	0.4	10.8	3	1.6	0.3	4.6	0	0.0	0.0	5.2
	Bilateral breast buds (10004557)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Genital labial adhesions (10064162)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Oedema genital (10030104)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Perineal cyst (10066058)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchitis chronic (10006458)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Bronchospasm (10006482)	3	4.9	1.0	13.7	6	9.7	3.6	19.9	6	9.4	3.5	19.3	15	8.0	4.6	12.9	6	8.7	3.3	18.0

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Catarrh (10007774)	3	4.9	1.0	13.7	2	3.2	0.4	11.2	1	1.6	0.0	8.4	6	3.2	1.2	6.9	4	5.8	1.6	14.2
	Cough (10011224)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	2	3.1	0.4	10.8	4	2.1	0.6	5.4	4	5.8	1.6	14.2
	Epistaxis (10015090)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Increased bronchial secretion (10062530)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Nasal congestion (10028735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	1	1.4	0.0	7.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	3.3	0.4	11.3	4	6.5	1.8	15.7	1	1.6	0.0	8.4	7	3.7	1.5	7.6	3	4.3	0.9	12.2
	Dermatitis atopic (10012438)	1	1.6	0.0	8.8	3	4.8	1.0	13.5	5	7.8	2.6	17.3	9	4.8	2.2	8.9	4	5.8	1.6	14.2
	Dermatitis contact (10012442)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	1	1.4	0.0	7.8
	Dermatitis diaper (10012444)	3	4.9	1.0	13.7	5	8.1	2.7	17.8	3	4.7	1.0	13.1	11	5.9	3.0	10.3	6	8.7	3.3	18.0
	Dyshidrotic eczema (10013913)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Eczema (10014184)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	0	0.0	0.0	5.6	0	0.0	0.0	2.0	5	7.2	2.4	16.1
	Lichen striatus (10066945)	0	0.0	0.0	5.9	1	1.6	0.0	8.7	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Miliaria (10027627)	3	4.9	1.0	13.7	1	1.6	0.0	8.7	1	1.6	0.0	8.4	5	2.7	0.9	6.1	2	2.9	0.4	10.1
	Onychomalacia (10058673)	0	0.0	0.0	5.9	0	0.0	0.0	5.8	1	1.6	0.0	8.4	1	0.5	0.0	2.9	0	0.0	0.0	5.2
	Rash (10037844)	3	4.9	1.0	13.7	3	4.8	1.0	13.5	7	10.9	4.5	21.2	13	7.0	3.8	11.6	2	2.9	0.4	10.1
	Seborrhoeic dermatitis (10039793)	1	1.6	0.0	8.8	1	1.6	0.0	8.7	0	0.0	0.0	5.6	2	1.1	0.1	3.8	0	0.0	0.0	5.2
	Urticaria (10046735)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	3	4.7	1.0	13.1	4	2.1	0.6	5.4	4	5.8	1.6	14.2
Vascular disorders (10047065)	Haematoma (10018852)	1	1.6	0.0	8.8	0	0.0	0.0	5.8	0	0.0	0.0	5.6	1	0.5	0.0	2.9	0	0.0	0.0	5.2

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.133 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Finland)

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		187	55.3	49.9	60.7	177	52.8	47.3	58.3	159	47.2	41.7	52.7	523	51.8	48.6	54.9	170	50.0	44.6	55.4
Blood and lymphatic system disorders (10005329)	Leukopenia (10024384)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lymphadenopathy (10025197)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Endocrine disorders (10014698)	Hypothyroidism (10021114)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Eye disorders (10015919)	Blepharitis (10005148)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye swelling (10015967)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eyelid oedema (10015993)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Panophthalmitis (10033683)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Strabismus (10042159)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Coeliac disease (10009839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Diarrhoea (10012735)	2	0.6	0.1	2.1	4	1.2	0.3	3.0	4	1.2	0.3	3.0	10	1.0	0.5	1.8	3	0.9	0.2	2.6
	Gastrooesophageal reflux disease (10017885)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Stomatitis (10042128)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Teething (10043183)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Tongue ulceration (10043991)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Vomiting (10047700)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	2	0.6	0.1	2.1
	Developmental delay (10012559)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fatigue (10016256)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gait disturbance (10017577)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ill-defined disorder (10061520)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza like illness (10022004)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Injection site erythema (10022061)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Pyrexia (10037660)	6	1.8	0.7	3.8	8	2.4	1.0	4.7	3	0.9	0.2	2.6	17	1.7	1.0	2.7	8	2.4	1.0	4.6
Immune system disorders (10021428)	Allergy to arthropod bite (10058285)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Drug hypersensitivity (10013700)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Food allergy (10016946)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Hypersensitivity (10020751)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Milk allergy (10027633)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Seasonal allergy (10048908)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Infections and infestations (10021881)	Adenovirus infection (10060931)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Borrelia infection (10061591)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Bronchiolitis (10006448)	1	0.3	0.0	1.6	4	1.2	0.3	3.0	1	0.3	0.0	1.6	6	0.6	0.2	1.3	3	0.9	0.2	2.6
	Bronchitis (10006451)	11	3.3	1.6	5.7	15	4.5	2.5	7.3	13	3.9	2.1	6.5	39	3.9	2.8	5.2	18	5.3	3.2	8.2
	Conjunctivitis (10010741)	21	6.2	3.9	9.3	25	7.5	4.9	10.8	19	5.6	3.4	8.7	65	6.4	5.0	8.1	22	6.5	4.1	9.6
	Ear infection (10014011)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	1	0.3	0.0	1.6	8	0.8	0.3	1.6	4	1.2	0.3	3.0
	Enterovirus infection (10014909)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	7	0.7	0.3	1.4	3	0.9	0.2	2.6
	Exanthema subitum (10015586)	5	1.5	0.5	3.4	6	1.8	0.7	3.9	3	0.9	0.2	2.6	14	1.4	0.8	2.3	5	1.5	0.5	3.4
	Eye infection (10015929)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Fungal skin infection (10017543)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Gastroenteritis (10017888)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	2	0.6	0.1	2.1	8	0.8	0.3	1.6	2	0.6	0.1	2.1
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Gingivitis (10018292)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Hand-foot-and-mouth disease (10019113)	2	0.6	0.1	2.1	5	1.5	0.5	3.4	3	0.9	0.2	2.6	10	1.0	0.5	1.8	2	0.6	0.1	2.1
	Herpes zoster (10019974)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Impetigo (10021531)	2	0.6	0.1	2.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Infected bite (10076911)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Influenza (10022000)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	0	0.0	0.0	1.1	4	0.4	0.1	1.0	2	0.6	0.1	2.1
	Laryngitis (10023874)	8	2.4	1.0	4.6	12	3.6	1.9	6.2	12	3.6	1.9	6.1	32	3.2	2.2	4.4	5	1.5	0.5	3.4

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Localised infection (10024774)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	2	0.6	0.1	2.1
	Lyme disease (10025169)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Molluscum contagiosum (10027807)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nasopharyngitis (10028810)	6	1.8	0.7	3.8	4	1.2	0.3	3.0	7	2.1	0.8	4.2	17	1.7	1.0	2.7	4	1.2	0.3	3.0
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Otitis media (10033078)	98	29.0	24.2	34.1	105	31.3	26.4	36.6	87	25.8	21.2	30.8	290	28.7	25.9	31.6	104	30.6	25.7	35.8
	Otitis media acute (10033079)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Pharyngitis (10034835)	0	0.0	0.0	1.1	4	1.2	0.3	3.0	3	0.9	0.2	2.6	7	0.7	0.3	1.4	3	0.9	0.2	2.6
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumococcal sepsis (10054047)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pneumonia (10035664)	3	0.9	0.2	2.6	3	0.9	0.2	2.6	2	0.6	0.1	2.1	8	0.8	0.3	1.6	2	0.6	0.1	2.1
	Pneumonia respiratory syncytial viral (10035732)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Pyelonephritis (10037596)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6
	Respiratory syncytial virus infection (10061603)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	1	0.3	0.0	1.6	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Respiratory tract infection (10062352)	4	1.2	0.3	3.0	2	0.6	0.1	2.1	7	2.1	0.8	4.2	13	1.3	0.7	2.2	1	0.3	0.0	1.6
	Respiratory tract infection viral (10062106)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rhinitis (10039083)	4	1.2	0.3	3.0	3	0.9	0.2	2.6	3	0.9	0.2	2.6	10	1.0	0.5	1.8	3	0.9	0.2	2.6
	Roseola (10039222)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	2	0.6	0.1	2.1	4	0.4	0.1	1.0	1	0.3	0.0	1.6
	Scarlet fever (10039587)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin infection (10040872)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Streptococcal infection (10061372)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Tonsillitis (10044008)	6	1.8	0.7	3.8	3	0.9	0.2	2.6	2	0.6	0.1	2.1	11	1.1	0.5	1.9	3	0.9	0.2	2.6
	Upper respiratory tract infection (10046306)	46	13.6	10.1	17.7	40	11.9	8.7	15.9	44	13.1	9.6	17.1	130	12.9	10.9	15.1	32	9.4	6.5	13.0
	Urinary tract infection (10046571)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	3	0.9	0.2	2.6
	Viral infection (10047461)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.6	0.1	2.1	2	0.2	0.0	0.7	1	0.3	0.0	1.6
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Arthropod bite (10003399)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	5	0.5	0.2	1.2	2	0.6	0.1	2.1
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Clavicle fracture (10009245)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Concussion (10010254)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Ear canal injury (10056319)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eye injury (10061128)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Femur fracture (10016454)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Head injury (10019196)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Laceration (10023572)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Ligament sprain (10024453)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Post vaccination syndrome (10036242)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Radial head dislocation (10073749)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Scratch (10039737)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin wound (10072170)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Splinter (10041662)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Superficial injury of eye (10042530)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Thermal burn (10053615)	1	0.3	0.0	1.6	1	0.3	0.0	1.7	1	0.3	0.0	1.6	3	0.3	0.1	0.9	0	0.0	0.0	1.1
	Wound (10052428)	0	0.0	0.0	1.1	2	0.6	0.1	2.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Investigations (10022891)	Cardiac murmur (10007586)	2	0.6	0.1	2.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	2	0.2	0.0	0.7	0	0.0	0.0	1.1
Metabolism and nutrition disorders (10027433)	Hypoglycaemia (10020993)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Overweight (10033307)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Skin papilloma (10040907)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Exaggerated startle response (10066482)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Febrile convulsion (10016284)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	3	0.9	0.2	2.6
	Headache (10019211)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Nystagmus (10029864)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Seizure (10039906)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Irritability (10022998)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Genital labial adhesions (10064162)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Testicular retraction (10043348)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Apnoea (10002974)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Asthma (10003553)	2	0.6	0.1	2.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	3	0.3	0.1	0.9	1	0.3	0.0	1.6
	Bronchitis chronic (10006458)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Cough (10011224)	6	1.8	0.7	3.8	4	1.2	0.3	3.0	5	1.5	0.5	3.4	15	1.5	0.8	2.4	14	4.1	2.3	6.8
	Dyspnoea (10013968)	1	0.3	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.1	3	0.3	0.1	0.9	3	0.9	0.2	2.6
	Rales (10037833)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Wheezing (10047924)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis allergic (10012434)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Dermatitis atopic (10012438)	3	0.9	0.2	2.6	2	0.6	0.1	2.1	2	0.6	0.1	2.1	7	0.7	0.3	1.4	4	1.2	0.3	3.0
	Dermatitis diaper (10012444)	0	0.0	0.0	1.1	1	0.3	0.0	1.7	1	0.3	0.0	1.6	2	0.2	0.0	0.7	0	0.0	0.0	1.1
	Drug eruption (10013687)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6

		INV_MMR_1 N = 338				INV_MMR_2 N = 335				INV_MMR_3 N = 337				INV_MMR N = 1010				COM_MMR N = 340			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dry skin (10013786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Eczema (10014184)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash (10037844)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash macular (10037867)	1	0.3	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Rash papular (10037876)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Rash vesicular (10037898)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	1	0.3	0.0	1.6	1	0.1	0.0	0.6	0	0.0	0.0	1.1
	Skin burning sensation (10054786)	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	1.1	0	0.0	0.0	0.4	1	0.3	0.0	1.6
	Urticaria (10046735)	5	1.5	0.5	3.4	1	0.3	0.0	1.7	0	0.0	0.0	1.1	6	0.6	0.2	1.3	3	0.9	0.2	2.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.134 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, Mexico)

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		83	84.7	76.0	91.2	89	90.8	83.3	95.7	91	91.9	84.7	96.4	263	89.2	85.0	92.5	86	86.9	78.6	92.8
Cardiac disorders (10007541)	Supraventricular extrasystoles (10042602)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Congenital, familial and genetic disorders (10010331)	Congenital cardiovascular anomaly (10061054)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Eye disorders (10015919)	Blepharitis (10005148)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Conjunctivitis allergic (10010744)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	2.0	0.2	7.1	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Entropion (10061842)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Gastrointestinal disorders (10017947)	Abdominal pain (10000081)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Colitis (10009887)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Constipation (10010774)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Diarrhoea (10012735)	12	12.2	6.5	20.4	7	7.1	2.9	14.2	11	11.1	5.7	19.0	30	10.2	7.0	14.2	5	5.1	1.7	11.4
	Dyspepsia (10013946)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Gastritis (10017853)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Gastrooesophageal reflux disease (10017885)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Gingival hypertrophy (10018284)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Tongue ulceration (10043991)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vomiting (10047700)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	2	2.0	0.2	7.1
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	4	4.1	1.1	10.1	1	1.0	0.0	5.6	1	1.0	0.0	5.5	6	2.0	0.7	4.4	3	3.0	0.6	8.6
Immune system disorders (10021428)	Allergy to animal (10001742)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Drug hypersensitivity (10013700)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Milk allergy (10027633)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Infections and infestations (10021881)	Bronchiolitis (10006448)	4	4.1	1.1	10.1	9	9.2	4.3	16.7	6	6.1	2.3	12.7	19	6.4	3.9	9.9	5	5.1	1.7	11.4
	Bronchitis (10006451)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Bullous impetigo (10006563)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Candida nappy rash (10007135)	5	5.1	1.7	11.5	2	2.0	0.2	7.2	1	1.0	0.0	5.5	8	2.7	1.2	5.3	3	3.0	0.6	8.6

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Conjunctivitis (10010741)	5	5.1	1.7	11.5	6	6.1	2.3	12.9	4	4.0	1.1	10.0	15	5.1	2.9	8.2	8	8.1	3.6	15.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Cutaneous larva migrans (10059547)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Ear infection (10014011)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Exanthema subitum (10015586)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Gastroenteritis (10017888)	22	22.4	14.6	32.0	20	20.4	12.9	29.7	28	28.3	19.7	38.2	70	23.7	19.0	29.0	22	22.2	14.5	31.7
	Gastroenteritis viral (10017918)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Gingivitis (10018292)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Herpangina (10019936)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
	Laryngitis (10023874)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	0	0.0	0.0	3.7	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Nasopharyngitis (10028810)	65	66.3	56.1	75.6	67	68.4	58.2	77.4	72	72.7	62.9	81.2	204	69.2	63.5	74.4	64	64.6	54.4	74.0
	Oral candidiasis (10030963)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Oral herpes (10067152)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Otitis externa (10033072)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Otitis media (10033078)	2	2.0	0.2	7.2	4	4.1	1.1	10.1	2	2.0	0.2	7.1	8	2.7	1.2	5.3	2	2.0	0.2	7.1
	Otitis media acute (10033079)	3	3.1	0.6	8.7	3	3.1	0.6	8.7	4	4.0	1.1	10.0	10	3.4	1.6	6.1	5	5.1	1.7	11.4
	Parasitic gastroenteritis (10067720)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngitis (10034835)	22	22.4	14.6	32.0	19	19.4	12.1	28.6	22	22.2	14.5	31.7	63	21.4	16.8	26.5	21	21.2	13.6	30.6
	Pharyngitis bacterial (10057869)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pharyngotonsillitis (10049140)	3	3.1	0.6	8.7	1	1.0	0.0	5.6	2	2.0	0.2	7.1	6	2.0	0.7	4.4	4	4.0	1.1	10.0
	Pneumonia (10035664)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Pneumonia viral (10035737)	1	1.0	0.0	5.6	2	2.0	0.2	7.2	1	1.0	0.0	5.5	4	1.4	0.4	3.4	0	0.0	0.0	3.7
	Rhinitis (10039083)	7	7.1	2.9	14.2	1	1.0	0.0	5.6	3	3.0	0.6	8.6	11	3.7	1.9	6.6	11	11.1	5.7	19.0
	Salmonellosis (10039447)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Sinusitis (10040753)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	1	1.0	0.0	5.5	4	1.4	0.4	3.4	3	3.0	0.6	8.6
	Tonsillitis (10044008)	17	17.3	10.4	26.3	13	13.3	7.3	21.6	9	9.1	4.2	16.6	39	13.2	9.6	17.6	10	10.1	5.0	17.8
	Tracheitis (10044302)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	2	2.0	0.2	7.1
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Urinary tract infection (10046571)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	3	3.0	0.6	8.6
	Varicella (10046980)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	2	2.0	0.2	7.1
	Viral pharyngitis (10047473)	2	2.0	0.2	7.2	2	2.0	0.2	7.2	1	1.0	0.0	5.5	5	1.7	0.6	3.9	0	0.0	0.0	3.7
	Viral rash (10047476)	0	0.0	0.0	3.7	3	3.1	0.6	8.7	3	3.0	0.6	8.6	6	2.0	0.7	4.4	1	1.0	0.0	5.5
	Viral tonsillitis (10047480)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Viral upper respiratory tract infection (10047482)	1	1.0	0.0	5.6	5	5.1	1.7	11.5	2	2.0	0.2	7.1	8	2.7	1.2	5.3	1	1.0	0.0	5.5
Injury, poisoning and procedural complications (10022117)	Animal bite (10002515)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Arthropod bite (10003399)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Burns second degree (10006802)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Contusion (10050584)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Craniocerebral injury (10070976)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Eye burns (10015911)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Face injury (10050392)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Head injury (10019196)	2	2.0	0.2	7.2	6	6.1	2.3	12.9	5	5.1	1.7	11.4	13	4.4	2.4	7.4	5	5.1	1.7	11.4
	Limb injury (10061225)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Lip injury (10055082)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Metabolism and nutrition disorders (10027433)	Lactose intolerance (10023681)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Malnutrition (10061273)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	0	0.0	0.0	3.7	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Nervous system disorders (10029205)	Epilepsy (10015037)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	0	0.0	0.0	3.7	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Seizure (10039906)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Pregnancy, puerperium and perinatal conditions (10036585)	Cephalhaematoma (10008014)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
Psychiatric disorders (10037175)	Breath holding (10006322)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	1.0	0.0	5.5	2	0.7	0.1	2.4	1	1.0	0.0	5.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	3	3.1	0.6	8.7	4	4.1	1.1	10.1	4	4.0	1.1	10.0	11	3.7	1.9	6.6	6	6.1	2.3	12.7
	Bronchospasm (10006482)	0	0.0	0.0	3.7	2	2.0	0.2	7.2	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5
	Cough (10011224)	2	2.0	0.2	7.2	0	0.0	0.0	3.7	1	1.0	0.0	5.5	3	1.0	0.2	2.9	1	1.0	0.0	5.5
	Productive cough (10036790)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7

		INV_MMR_1 N = 98				INV_MMR_2 N = 98				INV_MMR_3 N = 99				INV_MMR N = 295				COM_MMR N = 99			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis allergic (10039085)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	1	1.0	0.0	5.5	2	0.7	0.1	2.4	0	0.0	0.0	3.7
	Rhinorrhoea (10039101)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vasomotor rhinitis (10047145)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Wheezing (10047924)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	2.0	0.2	7.2	3	3.1	0.6	8.7	1	1.0	0.0	5.5	6	2.0	0.7	4.4	2	2.0	0.2	7.1
	Dermatitis allergic (10012434)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	3.7	0	0.0	0.0	1.2	1	1.0	0.0	5.5
	Dermatitis atopic (10012438)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	4	4.0	1.1	10.0	7	2.4	1.0	4.8	4	4.0	1.1	10.0
	Dermatitis contact (10012442)	1	1.0	0.0	5.6	1	1.0	0.0	5.6	2	2.0	0.2	7.1	4	1.4	0.4	3.4	2	2.0	0.2	7.1
	Dermatitis diaper (10012444)	4	4.1	1.1	10.1	2	2.0	0.2	7.2	6	6.1	2.3	12.7	12	4.1	2.1	7.0	1	1.0	0.0	5.5
	Miliaria (10027627)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	0	0.0	0.0	3.7	3	1.0	0.2	2.9	0	0.0	0.0	3.7
	Prurigo (10037083)	2	2.0	0.2	7.2	1	1.0	0.0	5.6	2	2.0	0.2	7.1	5	1.7	0.6	3.9	2	2.0	0.2	7.1
	Rash (10037844)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Rash erythematous (10037855)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Skin disorder (10040831)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Urticaria (10046735)	1	1.0	0.0	5.6	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	0.3	0.0	1.9	1	1.0	0.0	5.5
	Urticaria vesiculosa (10046755)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
	Vitiligo (10047642)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7
Social circumstances (10041244)	Diet noncompliance (10072373)	0	0.0	0.0	3.7	1	1.0	0.0	5.6	4	4.0	1.1	10.0	5	1.7	0.6	3.9	1	1.0	0.0	5.5
Surgical and medical procedures (10042613)	Finger amputation (10016678)	0	0.0	0.0	3.7	0	0.0	0.0	3.7	1	1.0	0.0	5.5	1	0.3	0.0	1.9	0	0.0	0.0	3.7

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.135 Percentage of subjects reporting with AEs leading to a medically attended visit classified by MedDRA Primary System Organ Class and Preferred Term from Day 0 through the end of the study (Total vaccinated cohort, United States)

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		372	60.2	56.2	64.1	367	60.0	56.0	63.9	374	60.5	56.5	64.4	1113	60.2	58.0	62.5	413	63.1	59.3	66.9
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	4	0.6	0.2	1.6	5	0.3	0.1	0.6	2	0.3	0.0	1.1
	Iron deficiency anaemia (10022972)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Leukocytosis (10024378)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	5	0.8	0.2	1.8
	Leukopenia (10024384)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Lymphadenopathy (10025197)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	4	0.6	0.2	1.6
	Thrombocytopenia (10043554)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
Cardiac disorders (10007541)	Cardiomegaly (10007632)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Congenital, familial and genetic disorders (10010331)	Ankyloglossia congenital (10049244)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Atrial septal defect (10003664)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Cerebral palsy (10008129)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cleft uvula (10053507)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Cryptorchism (10011498)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Imperforate hymen (10021529)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Microcephaly (10027534)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Phimosis (10034878)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Supernumerary nipple (10042571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Talipes (10043101)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tibial torsion (10064515)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Conductive deafness (10010280)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Deafness (10011878)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Ear pain (10014020)	10	1.6	0.8	3.0	3	0.5	0.1	1.4	11	1.8	0.9	3.2	24	1.3	0.8	1.9	9	1.4	0.6	2.6
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Excessive cerumen production (10076897)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Middle ear effusion (10062545)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Otorrhoea (10033101)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Eye disorders (10015919)	Astigmatism (10003569)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Conjunctivitis allergic (10010744)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye discharge (10015915)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Eye swelling (10015967)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eyelid oedema (10015993)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hypermetropia (10020675)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Lacrimation increased (10023644)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pseudostrabismus (10072123)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Scleral haemorrhage (10050508)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Strabismus (10042159)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Abdominal distension (10000060)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Abdominal pain (10000081)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Anal fissure (10002153)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Anal skin tags (10002172)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Aphthous ulcer (10002959)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Chapped lips (10049047)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chronic gastritis (10008882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Colitis (10009887)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Constipation (10010774)	7	1.1	0.5	2.3	6	1.0	0.4	2.1	14	2.3	1.2	3.8	27	1.5	1.0	2.1	9	1.4	0.6	2.6
	Dental caries (10012318)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Diarrhoea (10012735)	29	4.7	3.2	6.7	20	3.3	2.0	5.0	23	3.7	2.4	5.5	72	3.9	3.1	4.9	35	5.4	3.8	7.4
	Dysphagia (10013950)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Gastritis (10017853)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Gingival swelling (10018291)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Haematochezia (10018836)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Inguinal hernia (10022016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Melaena (10027141)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mouth cyst (10028020)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mucous stools (10028140)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nausea (10028813)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.3	0.0	1.2	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Oral contusion (10078170)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Proctitis (10036774)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ranula (10037838)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Stomatitis (10042128)	1	0.2	0.0	0.9	6	1.0	0.4	2.1	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Teething (10043183)	8	1.3	0.6	2.5	14	2.3	1.3	3.8	10	1.6	0.8	3.0	32	1.7	1.2	2.4	8	1.2	0.5	2.4
	Tooth discolouration (10044032)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Umbilical hernia (10045458)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Vomiting (10047700)	23	3.7	2.4	5.5	11	1.8	0.9	3.2	15	2.4	1.4	4.0	49	2.7	2.0	3.5	21	3.2	2.0	4.9
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Developmental delay (10012559)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Feeling hot (10016334)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gait disturbance (10017577)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Gait inability (10017581)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Influenza like illness (10022004)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Injection site erythema (10022061)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site rash (10022094)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Injection site swelling (10053425)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Mucosal inflammation (10028116)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pain (10033371)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyrexia (10037660)	35	5.7	4.0	7.8	38	6.2	4.4	8.4	33	5.3	3.7	7.4	106	5.7	4.7	6.9	36	5.5	3.9	7.5
Immune system disorders (10021428)	Allergy to animal (10001742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Drug hypersensitivity (10013700)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.6	0.2	1.6	6	0.3	0.1	0.7	6	0.9	0.3	2.0

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Food allergy (10016946)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	6	1.0	0.4	2.1	14	0.8	0.4	1.3	5	0.8	0.2	1.8
	Hypersensitivity (10020751)	1	0.2	0.0	0.9	4	0.7	0.2	1.7	3	0.5	0.1	1.4	8	0.4	0.2	0.9	1	0.2	0.0	0.8
	Immunisation reaction (10021432)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Milk allergy (10027633)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Multiple allergies (10028164)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Seasonal allergy (10048908)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
Infections and infestations (10021881)	Abscess (10000269)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Abscess limb (10050473)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Abscess neck (10053576)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Acarodermatitis (10063409)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	3	0.5	0.1	1.3
	Acute sinusitis (10001076)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	6	1.0	0.4	2.1	16	0.9	0.5	1.4	2	0.3	0.0	1.1
	Beta haemolytic streptococcal infection (10052100)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body tinea (10005913)	3	0.5	0.1	1.4	0	0.0	0.0	0.6	2	0.3	0.0	1.2	5	0.3	0.1	0.6	1	0.2	0.0	0.8
	Bronchiolitis (10006448)	15	2.4	1.4	4.0	14	2.3	1.3	3.8	11	1.8	0.9	3.2	40	2.2	1.6	2.9	17	2.6	1.5	4.1
	Bronchitis (10006451)	7	1.1	0.5	2.3	7	1.1	0.5	2.3	14	2.3	1.2	3.8	28	1.5	1.0	2.2	9	1.4	0.6	2.6
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Bronchitis viral (10053160)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Candida infection (10074170)	7	1.1	0.5	2.3	5	0.8	0.3	1.9	3	0.5	0.1	1.4	15	0.8	0.5	1.3	8	1.2	0.5	2.4
	Candida nappy rash (10007135)	6	1.0	0.4	2.1	5	0.8	0.3	1.9	3	0.5	0.1	1.4	14	0.8	0.4	1.3	6	0.9	0.3	2.0
	Cellulitis (10007882)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	7	1.1	0.5	2.3	16	0.9	0.5	1.4	3	0.5	0.1	1.3
	Clostridium difficile infection (10054236)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Conjunctivitis (10010741)	37	6.0	4.3	8.2	46	7.5	5.6	9.9	49	7.9	5.9	10.3	132	7.1	6.0	8.4	49	7.5	5.6	9.8
	Conjunctivitis bacterial (10061784)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	1	0.2	0.0	0.9	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Coxsackie viral infection (10011261)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	2	0.3	0.0	1.2	12	0.6	0.3	1.1	4	0.6	0.2	1.6
	Croup infectious (10011416)	28	4.5	3.0	6.5	37	6.0	4.3	8.2	31	5.0	3.4	7.0	96	5.2	4.2	6.3	33	5.0	3.5	7.0
	Cutaneous larva migrans (10059547)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Diarrhoea infectious (10012742)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Ear infection (10014011)	13	2.1	1.1	3.6	12	2.0	1.0	3.4	6	1.0	0.4	2.1	31	1.7	1.1	2.4	15	2.3	1.3	3.8

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Eczema herpeticum (10014197)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema infected (10014199)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Enteritis infectious (10058839)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Erythema infectiosum (10015214)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Escherichia urinary tract infection (10052238)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Exanthema subitum (10015586)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	External ear cellulitis (10015729)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye infection (10015929)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Folliculitis (10016936)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	5	0.8	0.3	1.9	10	0.5	0.3	1.0	3	0.5	0.1	1.3
	Fungal infection (10017533)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Fungal skin infection (10017543)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	4	0.6	0.2	1.6
	Gastroenteritis (10017888)	26	4.2	2.8	6.1	24	3.9	2.5	5.8	19	3.1	1.9	4.8	69	3.7	2.9	4.7	21	3.2	2.0	4.9
	Gastroenteritis enteroviral (10017901)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Gastroenteritis rotavirus (10017913)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Gastroenteritis viral (10017918)	7	1.1	0.5	2.3	2	0.3	0.0	1.2	3	0.5	0.1	1.4	12	0.6	0.3	1.1	5	0.8	0.2	1.8
	Gingivitis (10018292)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Hand-foot-and-mouth disease (10019113)	16	2.6	1.5	4.2	18	2.9	1.8	4.6	15	2.4	1.4	4.0	49	2.7	2.0	3.5	21	3.2	2.0	4.9
	Herpangina (10019936)	5	0.8	0.3	1.9	5	0.8	0.3	1.9	4	0.6	0.2	1.6	14	0.8	0.4	1.3	2	0.3	0.0	1.1
	Herpes dermatitis (10062639)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Herpes simplex (10019948)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hordeolum (10020377)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	1	0.2	0.0	0.9	3	0.2	0.0	0.5	2	0.3	0.0	1.1
	Impetigo (10021531)	11	1.8	0.9	3.2	5	0.8	0.3	1.9	3	0.5	0.1	1.4	19	1.0	0.6	1.6	6	0.9	0.3	2.0
	Infected bite (10076911)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Influenza (10022000)	5	0.8	0.3	1.9	8	1.3	0.6	2.6	4	0.6	0.2	1.6	17	0.9	0.5	1.5	6	0.9	0.3	2.0
	Lice infestation (10024424)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Localised infection (10024774)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lower respiratory tract infection (10024968)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Molluscum contagiosum (10027807)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.3	0.0	1.2	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Mycoplasma infection (10061300)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Nasopharyngitis (10028810)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	7	1.1	0.5	2.3	25	1.4	0.9	2.0	4	0.6	0.2	1.6
	Neonatal candida infection (10028924)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Onychomycosis (10030338)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Oral candidiasis (10030963)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Oral herpes (10067152)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	3	0.5	0.1	1.3
	Otitis externa (10033072)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	3	0.5	0.1	1.3
	Otitis media (10033078)	111	18.0	15.0	21.2	108	17.6	14.7	20.9	98	15.9	13.1	19.0	317	17.2	15.5	19.0	132	20.2	17.2	23.5
	Otitis media acute (10033079)	19	3.1	1.9	4.8	12	2.0	1.0	3.4	23	3.7	2.4	5.5	54	2.9	2.2	3.8	26	4.0	2.6	5.8
	Otitis media chronic (10033081)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Otosalpingitis (10033102)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Paronychia (10034016)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Parotitis (10034038)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Periorbital cellulitis (10057182)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Pertussis (10034738)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pharyngitis (10034835)	28	4.5	3.0	6.5	32	5.2	3.6	7.3	28	4.5	3.0	6.5	88	4.8	3.8	5.8	28	4.3	2.9	6.1
	Pharyngitis streptococcal (10034839)	2	0.3	0.0	1.2	6	1.0	0.4	2.1	7	1.1	0.5	2.3	15	0.8	0.5	1.3	6	0.9	0.3	2.0
	Pharyngotonsillitis (10049140)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Pneumonia (10035664)	8	1.3	0.6	2.5	14	2.3	1.3	3.8	6	1.0	0.4	2.1	28	1.5	1.0	2.2	5	0.8	0.2	1.8
	Pyoderma (10037632)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Respiratory syncytial virus bronchiolitis (10038718)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	1	0.2	0.0	0.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Respiratory tract infection (10062352)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Respiratory tract infection viral (10062106)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	2	0.3	0.0	1.1

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis (10039083)	7	1.1	0.5	2.3	10	1.6	0.8	3.0	8	1.3	0.6	2.5	25	1.4	0.9	2.0	10	1.5	0.7	2.8
	Roseola (10039222)	4	0.6	0.2	1.6	5	0.8	0.3	1.9	4	0.6	0.2	1.6	13	0.7	0.4	1.2	1	0.2	0.0	0.8
	Salmonellosis (10039447)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Scarlet fever (10039587)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	2	0.3	0.0	1.2	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Sinusitis (10040753)	21	3.4	2.1	5.1	10	1.6	0.8	3.0	11	1.8	0.9	3.2	42	2.3	1.6	3.1	14	2.1	1.2	3.6
	Skin candida (10054152)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	3	0.5	0.1	1.4	9	0.5	0.2	0.9	1	0.2	0.0	0.8
	Staphylococcal infection (10058080)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Streptococcal infection (10061372)	2	0.3	0.0	1.2	8	1.3	0.6	2.6	4	0.6	0.2	1.6	14	0.8	0.4	1.3	8	1.2	0.5	2.4
	Subcutaneous abscess (10042343)	2	0.3	0.0	1.2	2	0.3	0.0	1.2	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Tinea capitis (10043866)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea cruris (10043868)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tinea infection (10060889)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Tinea nigra (10043871)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillitis (10044008)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	4	0.6	0.2	1.6	10	0.5	0.3	1.0	6	0.9	0.3	2.0
	Tooth abscess (10044016)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Upper respiratory tract infection (10046306)	97	15.7	12.9	18.8	125	20.4	17.3	23.8	110	17.8	14.9	21.0	332	18.0	16.2	19.8	132	20.2	17.2	23.5
	Urethritis (10046480)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urinary tract infection (10046571)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Vaginal infection (10046914)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral diarrhoea (10051511)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Viral infection (10047461)	43	7.0	5.1	9.3	32	5.2	3.6	7.3	42	6.8	4.9	9.1	117	6.3	5.3	7.5	32	4.9	3.4	6.8
	Viral pharyngitis (10047473)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Viral rash (10047476)	9	1.5	0.7	2.7	9	1.5	0.7	2.8	11	1.8	0.9	3.2	29	1.6	1.1	2.2	9	1.4	0.6	2.6
	Viral upper respiratory tract infection (10047482)	6	1.0	0.4	2.1	3	0.5	0.1	1.4	7	1.1	0.5	2.3	16	0.9	0.5	1.4	7	1.1	0.4	2.2
	Vulvovaginitis (10047794)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
Injury, poisoning and procedural complications (10022117)	Accidental exposure to product (10073317)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.5	0.1	1.4	4	0.2	0.1	0.6	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Animal bite (10002515)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Arthropod bite (10003399)	3	0.5	0.1	1.4	3	0.5	0.1	1.4	10	1.6	0.8	3.0	16	0.9	0.5	1.4	5	0.8	0.2	1.8
	Burns first degree (10006797)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Burns second degree (10006802)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Chemical eye injury (10055116)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Clavicle fracture (10009245)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Concussion (10010254)	0	0.0	0.0	0.6	2	0.3	0.0	1.2	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Contusion (10050584)	4	0.6	0.2	1.6	4	0.7	0.2	1.7	4	0.6	0.2	1.6	12	0.6	0.3	1.1	10	1.5	0.7	2.8
	Corneal abrasion (10010984)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Craniocerebral injury (10070976)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	3	0.5	0.1	1.3
	Ear injury (10057446)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eye contusion (10073354)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Eyelid injury (10069200)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Face injury (10050392)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Fall (10016173)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Foot fracture (10016970)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Foreign body in eye (10017012)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foreign body in gastrointestinal tract (10079846)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	0	0.0	0.0	0.6
	Gingival injury (10049300)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hand fracture (10019114)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Head injury (10019196)	6	1.0	0.4	2.1	8	1.3	0.6	2.6	5	0.8	0.3	1.9	19	1.0	0.6	1.6	5	0.8	0.2	1.8
	Humerus fracture (10020462)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Joint dislocation (10023204)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Joint injury (10060820)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Laceration (10023572)	8	1.3	0.6	2.5	2	0.3	0.0	1.2	9	1.5	0.7	2.7	19	1.0	0.6	1.6	9	1.4	0.6	2.6
	Ligament sprain (10024453)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Limb crushing injury (10064031)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Limb injury (10061225)	4	0.6	0.2	1.6	2	0.3	0.0	1.2	3	0.5	0.1	1.4	9	0.5	0.2	0.9	3	0.5	0.1	1.3
	Lip injury (10055082)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	5	0.8	0.3	1.9	8	0.4	0.2	0.9	3	0.5	0.1	1.3
	Mouth injury (10049294)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Nail avulsion (10028686)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Procedural pain (10064882)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Radial head dislocation (10073749)	3	0.5	0.1	1.4	2	0.3	0.0	1.2	2	0.3	0.0	1.2	7	0.4	0.2	0.8	5	0.8	0.2	1.8
	Radius fracture (10037802)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Road traffic accident (10039203)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Skin abrasion (10064990)	0	0.0	0.0	0.6	5	0.8	0.3	1.9	1	0.2	0.0	0.9	6	0.3	0.1	0.7	3	0.5	0.1	1.3
	Splinter (10041662)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sunburn (10042496)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Thermal burn (10053615)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	3	0.5	0.1	1.4	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Tibia fracture (10043827)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Tongue injury (10059924)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	1	0.2	0.0	0.8
	Upper limb fracture (10061394)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Wrist fracture (10048049)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Investigations (10022891)	Blood lead increased (10005642)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Body height below normal (10056811)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cardiac murmur (10007586)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Otic examination normal (10056833)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight decreased (10047895)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Dehydration (10012174)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	3	0.5	0.1	1.4	8	0.4	0.2	0.9	5	0.8	0.2	1.8
	Failure to thrive (10016165)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Hypoglycaemia (10020993)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Iron deficiency (10022970)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Lactose intolerance (10023681)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Polydipsia (10036067)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Weight gain poor (10047897)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Foot deformity (10061159)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8

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				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Knee deformity (10062061)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Limb asymmetry (10070670)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pain in extremity (10033425)	5	0.8	0.3	1.9	2	0.3	0.0	1.2	4	0.6	0.2	1.6	11	0.6	0.3	1.1	1	0.2	0.0	0.8
	Synovial cyst (10042858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Toe walking (10068872)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Trigger finger (10044654)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma of skin (10018823)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Lymphangioma (10025219)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Seborrhoeic keratosis (10039796)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Skin papilloma (10040907)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Nervous system disorders (10029205)	Dizziness (10013573)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Febrile convulsion (10016284)	5	0.8	0.3	1.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	9	0.5	0.2	0.9	4	0.6	0.2	1.6
	Gross motor delay (10069118)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Lethargy (10024264)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Loss of consciousness (10024855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Motor developmental delay (10070302)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	2	0.3	0.0	1.1
	Seizure (10039906)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder (10041466)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Speech disorder developmental (10041467)	4	0.6	0.2	1.6	3	0.5	0.1	1.4	5	0.8	0.3	1.9	12	0.6	0.3	1.1	2	0.3	0.0	1.1
	Tremor (10044565)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
Psychiatric disorders (10037175)	Breath holding (10006322)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Insomnia (10022437)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Irritability (10022998)	7	1.1	0.5	2.3	3	0.5	0.1	1.4	3	0.5	0.1	1.4	13	0.7	0.4	1.2	2	0.3	0.0	1.1
	Pica (10035001)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Sleep disorder (10040984)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Sleep terror (10041010)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
Renal and urinary disorders (10038359)	Dysuria (10013990)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	4	0.6	0.2	1.6	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Haematuria (10018867)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pollakiuria (10036018)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Polyuria (10036142)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	2	0.3	0.0	1.1
	Urinary tract disorder (10046566)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	0.3	0.0	1.2	3	0.5	0.1	1.4	1	0.2	0.0	0.9	6	0.3	0.1	0.7	2	0.3	0.0	1.1
	Genital labial adhesions (10064162)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	1	0.2	0.0	0.9	4	0.2	0.1	0.6	1	0.2	0.0	0.8
	Penile adhesion (10059636)	3	0.5	0.1	1.4	1	0.2	0.0	0.9	1	0.2	0.0	0.9	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Prepuce redundant (10036624)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Vaginal mucosal blistering (10048904)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulval disorder (10047754)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Vulvovaginal discomfort (10047786)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
Respiratory, thoracic and mediastinal disorders (10038738)	Adenoidal hypertrophy (10001229)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Aspiration (10003504)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Asthma (10003553)	3	0.5	0.1	1.4	5	0.8	0.3	1.9	11	1.8	0.9	3.2	19	1.0	0.6	1.6	10	1.5	0.7	2.8
	Bronchial hyperreactivity (10066091)	5	0.8	0.3	1.9	4	0.7	0.2	1.7	5	0.8	0.3	1.9	14	0.8	0.4	1.3	5	0.8	0.2	1.8
	Bronchospasm (10006482)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Cough (10011224)	24	3.9	2.5	5.7	24	3.9	2.5	5.8	22	3.6	2.2	5.3	70	3.8	3.0	4.8	32	4.9	3.4	6.8
	Dyspnoea (10013968)	1	0.2	0.0	0.9	1	0.2	0.0	0.9	1	0.2	0.0	0.9	3	0.2	0.0	0.5	0	0.0	0.0	0.6
	Epistaxis (10015090)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Hypoxia (10021143)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nasal congestion (10028735)	3	0.5	0.1	1.4	4	0.7	0.2	1.7	6	1.0	0.4	2.1	13	0.7	0.4	1.2	4	0.6	0.2	1.6
	Nasal discomfort (10052437)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Nasal obstruction (10028748)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Oropharyngeal pain (10068319)	2	0.3	0.0	1.2	1	0.2	0.0	0.9	0	0.0	0.0	0.6	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Respiratory disorder (10038683)	0	0.0	0.0	0.6	3	0.5	0.1	1.4	1	0.2	0.0	0.9	4	0.2	0.1	0.6	2	0.3	0.0	1.1
	Respiratory distress (10038687)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Respiratory tract congestion (10052251)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rhinitis allergic (10039085)	14	2.3	1.2	3.8	8	1.3	0.6	2.6	8	1.3	0.6	2.5	30	1.6	1.1	2.3	12	1.8	1.0	3.2
	Rhinorrhoea (10039101)	2	0.3	0.0	1.2	5	0.8	0.3	1.9	3	0.5	0.1	1.4	10	0.5	0.3	1.0	2	0.3	0.0	1.1
	Stridor (10042241)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tachypnoea (10043089)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Tonsillar hypertrophy (10044003)	1	0.2	0.0	0.9	3	0.5	0.1	1.4	0	0.0	0.0	0.6	4	0.2	0.1	0.6	0	0.0	0.0	0.6
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Wheezing (10047924)	5	0.8	0.3	1.9	18	2.9	1.8	4.6	9	1.5	0.7	2.7	32	1.7	1.2	2.4	5	0.8	0.2	1.8
Skin and subcutaneous tissue disorders (10040785)	Blister (10005191)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Dermatitis (10012431)	10	1.6	0.8	3.0	3	0.5	0.1	1.4	5	0.8	0.3	1.9	18	1.0	0.6	1.5	5	0.8	0.2	1.8
	Dermatitis allergic (10012434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Dermatitis atopic (10012438)	5	0.8	0.3	1.9	13	2.1	1.1	3.6	17	2.8	1.6	4.4	35	1.9	1.3	2.6	4	0.6	0.2	1.6
	Dermatitis contact (10012442)	3	0.5	0.1	1.4	7	1.1	0.5	2.3	4	0.6	0.2	1.6	14	0.8	0.4	1.3	3	0.5	0.1	1.3
	Dermatitis diaper (10012444)	21	3.4	2.1	5.1	21	3.4	2.1	5.2	25	4.0	2.6	5.9	67	3.6	2.8	4.6	36	5.5	3.9	7.5
	Drug eruption (10013687)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ecchymosis (10014080)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Eczema (10014184)	9	1.5	0.7	2.7	4	0.7	0.2	1.7	8	1.3	0.6	2.5	21	1.1	0.7	1.7	14	2.1	1.2	3.6
	Eczema nummular (10014201)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.3	0.0	1.2	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Erythema (10015150)	2	0.3	0.0	1.2	0	0.0	0.0	0.6	0	0.0	0.0	0.6	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Erythema multiforme (10015218)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Granuloma annulare (10018692)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hair disorder (10019037)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Henoch-schonlein purpura (10019617)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Hyperkeratosis (10020649)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Ingrowing nail (10022013)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	2	0.3	0.0	1.1

		INV_MMR_1 N = 618				INV_MMR_2 N = 612				INV_MMR_3 N = 618				INV_MMR N = 1848				COM_MMR N = 654			
				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Keratosis pilaris (10066295)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	2	0.3	0.0	1.2	3	0.2	0.0	0.5	1	0.2	0.0	0.8
	Lichen sclerosus (10024434)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Miliaria (10027627)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Nail disorder (10028694)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.6	0	0.0	0.0	0.2	1	0.2	0.0	0.8
	Pityriasis (10035110)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Pityriasis rosea (10035114)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Pruritus (10037087)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash (10037844)	14	2.3	1.2	3.8	10	1.6	0.8	3.0	10	1.6	0.8	3.0	34	1.8	1.3	2.6	8	1.2	0.5	2.4
	Rash erythematous (10037855)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash generalised (10037858)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash macular (10037867)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash maculo-papular (10037868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	1	0.2	0.0	0.8
	Rash papular (10037876)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Rash scarlatiniform (10037890)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Seborrhoea (10039792)	1	0.2	0.0	0.9	2	0.3	0.0	1.2	2	0.3	0.0	1.2	5	0.3	0.1	0.6	0	0.0	0.0	0.6
	Seborrhoeic dermatitis (10039793)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.1	0.0	0.3	3	0.5	0.1	1.3
	Skin fissures (10040849)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin hypopigmentation (10040868)	0	0.0	0.0	0.6	0	0.0	0.0	0.6	1	0.2	0.0	0.9	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin irritation (10040880)	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.2	0.0	0.9	2	0.1	0.0	0.4	0	0.0	0.0	0.6
	Skin lesion (10040882)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Skin mass (10067868)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
	Urticaria (10046735)	6	1.0	0.4	2.1	4	0.7	0.2	1.7	3	0.5	0.1	1.4	13	0.7	0.4	1.2	3	0.5	0.1	1.3
Surgical and medical procedures (10042613)	Myringotomy (10028662)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6
Vascular disorders (10047065)	Haematoma (10018852)	0	0.0	0.0	0.6	1	0.2	0.0	0.9	0	0.0	0.0	0.6	1	0.1	0.0	0.3	0	0.0	0.0	0.6

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
INV_MMR = GSK MMR Pooled
COM_MMR = Merck MMR

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with the administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.136 Listings of SAEs (Total vaccinated cohort)

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
INV_MMR_1	PPD	M	United States	Ot	62	Wheezing with upper respiratory infection	Upper respiratory tract infection	Infections and infestations	HO	1	62	28	2	N	Recovered/resolved
		F	United States	Wh	59	Escherichia coli urinary tract infection	Escherichia urinary tract infection	Infections and infestations	HO	1	48	32	3	N	Recovered/resolved
		F	United States	Wh	74	Pneumonia	Pneumonia	Infections and infestations	HO	1	121	5	3	N	Recovered/resolved
		F	United States	As	72	Respiratory syncytial virus bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	125	11	3	N	Recovered/resolved
		F	United States	Wh	57	Viral upper respiratory infection	Viral upper respiratory tract infection	Infections and infestations	HO	1	34	10	2	N	Recovered/resolved
					58	Hypoxia	Hypoxia	Respiratory, thoracic and mediastinal disorders	HO	1	38	2	3	N	Recovered/resolved
		M	United States	Af	69	Pneumonia	Pneumonia	Infections and infestations	HO	1	98	8	3	N	Recovered/resolved
		F	United States	Af	58	Cellulitis	Cellulitis	Infections and infestations	HO	1	3	25	2	N	Recovered/resolved
					58	Conjunctivitis	Conjunctivitis	Infections and infestations	HO	1	3	25	2	N	Recovered/resolved
		M	United States	Wh	70	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	ER	1	122	8	3	N	Recovered/resolved
					71	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	129	5	3	N	Recovered/resolved
		M	United States	Ot	56	Scalp abscess	Subcutaneous abscess	Infections and infestations	HO	1	18	5	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	F	Estonia	Wh	66	Pyelonephritis acute	Pyelonephritis acute	Infections and infestations	HO	1	96	9	2	N	Recovered/resolved
		M	Estonia	Wh	81	Superficial injury of head	Head injury	Injury, poisoning and procedural complications	HO	1	176	3	2	N	Recovered/resolved
		M	Estonia	Wh	61	Rotavirus infection	Rotavirus infection	Infections and infestations	HO	1	3	8	3	N	Recovered/resolved
		M	Finland	Wh	67	Concussion of the brain	Concussion	Injury, poisoning and procedural complications	HO	1	91	4	2	N	Recovered/resolved
		F	Finland	Wh	86	Acute obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	184	14	2	N	Recovered/resolved
		F	Finland	Wh	66	Acute obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	94	42	2	N	Recovered/resolved
		M	Finland	Wh	61	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	33	19	3	N	Recovered/resolved
		F	Finland	Wh	80	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	172	5	2	N	Recovered/resolved
		F	Finland	Wh	66	Gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	78	8	3	N	Recovered/resolved
		F	Spain	Wh	64	Pharyngitis	Pharyngitis	Infections and infestations	HO	1	74	10	3	N	Recovered/resolved
		F	Mexico	Ot	61	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	58	6	2	N	Recovered/resolved
		M	Mexico	Ot	61	Epilepsy	Epilepsy	Nervous system disorders	MD	1	10	.	2	N	Not recovered/not resolved
					84	Gastritis per medication	Gastritis	Gastrointestinal disorders	HO	1	173	2	2	N	Recovered/resolved
					84	Head trauma	Head injury	Injury, poisoning and procedural complications	HO	1	172	3	1	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
INV_MMR_2	PPD	F	United States	As	72	Croup	Croup infectious	Infections and infestations	HO	1	120	8	3	N	Recovered/resolved
		M	United States	Wh	56	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	21	2	2	N	Recovered/resolved
					56	Leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	19	4	2	N	Recovered/resolved
		F	United States	Wh	75	Mycoplasma pneumoniae	Mycoplasma infection	Infections and infestations	HO	1	147	16	2	N	Recovered/resolved
		M	United States	Af	78	Concussion	Concussion	Injury, poisoning and procedural complications	HO	1	176	14	2	N	Recovered/resolved
					78	Fractured right foot	Foot fracture	Injury, poisoning and procedural complications	HO	1	176	14	2	N	Recovered/resolved
		F	United States	Wh	79	Reactive airways disease exacerbation	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	190	8	3	N	Recovered/resolved
		F	United States	Wh	71	Bronchiolitis due to respiratory syncytial virus	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	128	11	3	N	Recovered/resolved
		M	United States	Wh	55	Reactive airway disease	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	22	5	2	N	Recovered/resolved
					65	Asthma exacerbation	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	92	9	2	N	Recovered/resolved
		M	United States	Ot	54	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	8	6	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD				54	Rotavirus gastroenteritis	Gastroenteritis rotavirus	Infections and infestations	HO	1	8	6	2	N	Recovered/resolved
		M	Estonia	Wh	72	Viral intestinal infection, unspecified	Gastroenteritis viral	Infections and infestations	HO	1	47	7	2	N	Recovered/resolved
		F	Estonia	Wh	88	Acute upper respiratory infection of multiple and unspecified sites	Upper respiratory tract infection	Infections and infestations	HO	1	157	15	2	N	Recovered/resolved
		F	Estonia	Wh	57	Pharyngitis acute	Pharyngitis	Infections and infestations	HO	1	7	5	2	N	Recovered/resolved
		M	Estonia	Wh	61	Laryngitis	Laryngitis	Infections and infestations	HO	1	18	10	2	N	Recovered/resolved
		M	Estonia	Wh	75	Body burns level ii	Burns second degree	Injury, poisoning and procedural complications	HO	1	143	40	2	N	Recovered/resolved
		M	Estonia	Wh	76	Viral pharyngitis	Viral pharyngitis	Infections and infestations	HO	1	144	15	2	N	Recovered/resolved
		M	Estonia	Wh	64	Rhinopharyngitis acute	Nasopharyngitis	Infections and infestations	HO	1	73	3	2	N	Recovered/resolved
		M	Finland	Wh	70	Acute asthma exacerbation	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	27	6	3	N	Recovered/resolved
		F	Finland	Wh	55	Gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	0	14	2	Y	Recovered/resolved
		F	Finland	Wh	62	Fracture of femur	Femur fracture	Injury, poisoning and procedural complications	HO	1	39	26	3	N	Recovered/resolved
		M	Finland	Wh	58	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	37	12	3	N	Recovered/resolved
		F	Finland	Wh	65	Streptococcus pneumoniae septicemia	Pneumococcal sepsis	Infections and infestations	HO	1	40	23	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	M	Finland	Wh	76	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	171	7	2	N	Recovered/resolved
		M	Finland	Wh	58	Type 1 diabetes	Type 1 diabetes mellitus	Metabolism and nutrition disorders	HO	1	44	.	3	N	Not recovered/not resolved
		F	Finland	Wh	73	Respiratory syncytial virus (rsv) pneumonia	Pneumonia respiratory syncytial viral	Infections and infestations	HO	1	139	6	3	N	Recovered/resolved
					73	Respiratory tract infection (rhino virus)	Respiratory tract infection viral	Infections and infestations	HO	1	139	6	3	N	Recovered/resolved
		F	Mexico	Ot	60	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	29	12	2	N	Recovered/resolved
		M	Mexico	Ot	58	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	33	11	2	N	Recovered/resolved
		M	Mexico	Ot	69	Bronchial hyperreactivity	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	114	14	2	N	Recovered/resolved
					69	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	114	14	2	N	Recovered/resolved
		F	Mexico	Ot	62	Community acquired pneumonia	Pneumonia	Infections and infestations	HO	1	69	16	2	N	Recovered/resolved
		F	United States	Wh	80	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	115	11	3	N	Recovered/resolved
INV_MMR_3		F	United States	Af	60	Pneumonia	Pneumonia	Infections and infestations	HO	1	53	23	3	N	Recovered/resolved
		F	United States	Af	55	Pneumonia	Pneumonia	Infections and infestations	HO	1	26	25	1	N	Recovered/resolved
		M	United States	Wh	75	Loss of consciousness	Loss of consciousness	Nervous system disorders	HO	1	162	2	3	N	Recovered/resolved
					75	Seizure	Seizure	Nervous system disorders	HO	1	162	2	3	N	Recovered/resolved
		F	United States	Af	56	herpangina	Herpangina	Infections and infestations	HO	1	24	27	3	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	F	United States	Wh	68	Respiratory syncitail virus bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	111	9	2	N	Recovered/resolved
		F	United States	Wh	60	Cellulitis	Cellulitis	Infections and infestations	HO	1	57	10	2	N	Recovered/resolved
					60	Left conjunctivitis	Conjunctivitis	Infections and infestations	ER	1	57	5	2	N	Recovered/resolved
					61	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	60	2	2	N	Recovered/resolved
					61	Left otitis media	Otitis media	Infections and infestations	HO	1	59	9	2	N	Recovered/resolved
		M	United States	Ot	77	Abscess	Abscess	Infections and infestations	HO	1	97	9	3	N	Recovered/resolved
		F	Estonia	Wh	84	Pyelonephritis acute	Pyelonephritis acute	Infections and infestations	HO	1	150	12	2	N	Recovered/resolved
		M	Estonia	Wh	52	Enterocolitis acutae	Enterocolitis	Gastrointestinal disorders	HO	1	4	9	2	N	Recovered/resolved
		M	Estonia	Wh	73	Bronchitis	Bronchitis	Infections and infestations	HO	1	143	14	1	N	Recovered/resolved
		M	Estonia	Wh	77	Second-degree burns	Burns second degree	Injury, poisoning and procedural complications	HO	1	130	24	2	N	Recovered/resolved
		F	Estonia	Wh	57	Adenoviral enteritis	Gastroenteritis adenovirus	Infections and infestations	HO	1	25	6	2	N	Recovered/resolved
		M	Finland	Wh	76	Pneumonia	Pneumonia	Infections and infestations	HO	1	152	13	2	N	Recovered/resolved
		F	Finland	Wh	75	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	144	9	2	N	Recovered/resolved
		F	Finland	Wh	57	febrile seizure	Febrile convulsion	Nervous system disorders	ER	1	9	1	2	Y	Recovered/resolved
		M	Finland	Wh	80	Otitis media	Otitis media	Infections and infestations	HO	1	183	3	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	M	Finland	Wh	76	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	159	18	2	N	Recovered/resolved
		F	Finland	Wh	56	Viral infection	Viral infection	Infections and infestations	HO	1	24	19	3	N	Recovered/resolved
					57	Otitis media	Otitis media	Infections and infestations	HO	1	31	12	3	N	Recovered/resolved
					57	Cerebral convulsions	Seizure	Nervous system disorders	HO	1	34	1	3	N	Recovered/resolved
		F	Spain	Wh	66	Fever	Pyrexia	General disorders and administration site conditions	HO	1	93	17	2	N	Recovered/resolved
					66	Acute tonsillitis	Tonsillitis	Infections and infestations	MD	1	93	6	2	N	Recovered/resolved
					67	Diarrhea	Diarrhoea	Gastrointestinal disorders	HO	1	102	11	2	N	Recovered/resolved
					67	Otitis media	Otitis media	Infections and infestations	MD	1	98	5	2	N	Recovered/resolved
		M	Spain	Wh	67	Cellulitis	Cellulitis	Infections and infestations	HO	1	90	35	3	N	Recovered/resolved
		F	Mexico	Ot	68	Viral pneumonia	Pneumonia viral	Infections and infestations	HO	1	112	12	2	N	Recovered/resolved
		F	Mexico	Ot	73	Phalanx amputation	Finger amputation	Surgical and medical procedures	HO	1	151	47	3	N	Recovered/resolved with sequelae
		F	Mexico	Ot	75	Community acquired bacterial pneumonia	Pneumonia bacterial	Infections and infestations	HO	1	151	51	2	N	Recovered/resolved
		M	Mexico	Ot	67	Gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	90	3	2	N	Recovered/resolved
		M	United States	Wh	78	Unspecified viral infection	Viral infection	Infections and infestations	HO	1	167	3	2	N	Recovered/resolved
		F	United States	Wh	57	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	31	4	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD				57	Acute gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	31	4	2	N	Recovered/resolved
		F	United States	Wh	70	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	57	17	2	N	Recovered/resolved
		F	United States	Af	77	Acute bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	169	12	1	N	Recovered/resolved
COM_MMR		F	United States	As	71	Febrile seizure	Febrile convulsion	Nervous system disorders	HO	1	128	2	3	N	Recovered/resolved
		F	United States	Wh	79	Bronchiolitis	Bronchiolitis	Infections and infestations	HO	1	183	13	3	N	Recovered/resolved
					79	Conjunctivitis	Conjunctivitis	Infections and infestations	MD	1	182	7	3	N	Recovered/resolved
					80	Leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	188	8	3	N	Recovered/resolved
		F	United States	Wh	59	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	17	12	3	N	Recovered/resolved
					59	Rsv bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	1	16	13	3	N	Recovered/resolved
		F	United States	Wh	59	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	51	5	3	N	Recovered/resolved
					59	Leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	51	5	2	N	Recovered/resolved
					59	Acute otits media	Otitis media acute	Infections and infestations	MD	1	50	6	3	N	Recovered/resolved
		F	United States	Wh	82	Febrile seizure	Febrile convulsion	Nervous system disorders	HO	1	171	1	2	N	Recovered/resolved
		F	Estonia	Wh	69	Respiratory syncytial virus pneumonia	Pneumonia respiratory syncytial viral	Infections and infestations	HO	1	19	20	2	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD				70	Otitis media bilateral ears	Otitis media	Infections and infestations	HO	1	30	9	1	N	Recovered/resolved
		F	Estonia	Wh	61	Urticaria	Urticaria	Skin and subcutaneous tissue disorders	HO	1	4	16	2	N	Recovered/resolved
		F	Estonia	Wh	62	Acute rotavirus gastroenteritis	Gastroenteritis rotavirus	Infections and infestations	HO	1	72	6	2	N	Recovered/resolved
		F	Estonia	Wh	62	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	1	57	4	2	N	Recovered/resolved
					62	Adenovirus gastroenteritis	Gastroenteritis adenovirus	Infections and infestations	HO	1	57	4	2	N	Recovered/resolved
					74	Tonsillitis acuta	Tonsillitis	Infections and infestations	HO	1	142	14	2	N	Recovered/resolved
					75	Otitis media bilateralis	Otitis media	Infections and infestations	HO	1	145	9	2	N	Recovered/resolved
					80	Neutropenia parainfection	Neutropenic infection	Infections and infestations	HO	1	181	8	2	N	Recovered/resolved
					80	Infection viral	Viral infection	Infections and infestations	HO	1	179	7	2	N	Recovered/resolved
		F	Estonia	Wh	66	Febrile convulsions	Febrile convulsion	Nervous system disorders	HO	1	87	1	2	N	Recovered/resolved
					66	Unspecified viral infection	Viral infection	Infections and infestations	HO	1	87	2	2	N	Recovered/resolved
		M	Finland	Wh	65	Urticaria	Urticaria	Skin and subcutaneous tissue disorders	HO	1	52	16	3	N	Recovered/resolved
		M	Finland	Wh	57	Asthma infectious	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	37	15	2	N	Recovered/resolved
		M	Finland	Wh	59	Obtructive bronchitis	Bronchitis	Infections and infestations	HO	1	44	44	3	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	M	Finland	Wh	60	Febrile convulsions	Febrile convulsion	Nervous system disorders	HO	1	51	2	2	N	Recovered/resolved
		M	Finland	Wh	81	Diarrhea	Diarrhoea	Gastrointestinal disorders	HO	1	192	3	1	N	Recovered/resolved
					81	Hypoglycemia	Hypoglycaemia	Metabolism and nutrition disorders	HO	1	193	5	3	N	Recovered/resolved
		F	Finland	Wh	64	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	80	6	2	N	Recovered/resolved
					79	Obstructive bronchitis	Bronchitis	Infections and infestations	HO	1	189	15	2	N	Recovered/resolved
		F	Finland	Wh	75	Infection viral	Viral infection	Infections and infestations	HO	1	152	20	3	N	Recovered/resolved
		M	Spain	Wh	73	Acute gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	136	4	2	N	Recovered/resolved
		F	Mexico	Ot	61	Bronchial hyperreactor	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	58	7	2	N	Recovered/resolved
					63	Milk allergy	Milk allergy	Immune system disorders	HO	1	71	8	1	N	Recovered/resolved
		F	Mexico	Ot	70	Bronchial hyperreactivity	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	104	26	2	N	Recovered/resolved
		F	Mexico	Ot	70	Acute gastroenteritis	Gastroenteritis	Infections and infestations	HO	1	113	12	2	N	Recovered/resolved
		F	United States	Wh	52	Bronchiolitis exacerbation	Bronchiolitis	Infections and infestations	HO	1	1	18	2	N	Recovered/resolved
		M	United States	Af	80	Reactive airway disease	Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	HO	1	173	7	3	N	Recovered/resolved

Group	Sub. No.	Sex	Country	Race	Age at onset (Week)	Verbatim	Preferred term	Primary System Organ Class	MED type	Dose	Day of onset	Duration	Intensity	Causality	Outcome
	PPD	F	United States	Wh	74	Complex febrile seizure	Febrile convulsion	Nervous system disorders	HO	1	98	2	3	N	Recovered/resolved
		M	United States	Ot	88	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	HO	1	192	10	3	N	Recovered/resolved

INV_MMR_1 = GSK MMR LOT 1
INV_MMR_2 = GSK MMR LOT 2
INV_MMR_3 = GSK MMR LOT 3
COM_MMR = Merck MMR

List of investigators, IEC/IRB and distribution of subjects

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
Estonia						
PPD			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	43	0.9
			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	319	6.4
			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	24	0.5
			PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	60	1.2

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD Estonia,	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	48	1.0
			PPD PPD PPD Estonia.	Research Ethics Committee of the University of Tartu (UT REC), Office of Research and Development Lossi 3 51003, Tartu, Estonia.	7	0.1
Finland						
PPD (Co-ordinating Investigator)	-	All Centres	PPD PPD PPD PPD Finland	-		
PPD PPD PPD (Former PI)	PPD		PPD PPD PPD PPD Finland.	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530, Helsinki	127	2.5
PPD			PPD PPD PPD PPD Finland.	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	96	1.9

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	102	2.0
			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	48	1.0
			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	104	2.1
PPD PPD PPD (Former PI)	PPD		PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	142	2.8
PPD			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	103	2.1
PPD PPD (Former PI) PPD (Former PI)			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	144	2.9

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD	PPD		PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	172	3.4
PPD PPD (Former PI) PPD (Former PI)			PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	113	2.3
PPD			PPD PPD PPD PPD PPD Finland	National Committee on Medical Research Ethics TUKIJA Lintulahdentie 4, 00530 Helsinki	199	4.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
Mexico						
PPD			PPD PPD PPD PPD PPD Mexico	Instituto Nacional de Pediatria, Comite de Investigacion y Comite de Etica en Investigacion, Av. Insurgentes Sur 3700-C, Insurgentes Cuiculco, Delegacion Coyoacan,Ciudad de Mexico, C.P. 04530, Mexico	330	6.6
			PPD PPD PPD Mexico	HOSPITAL GENERAL DE DURANGO, Comite de Investigacion y Comite de Etica en Investigacion, 5 de Febrero y Norman Fuentes s/n, Zona Centro, Durango, Durango, C.P., 34000, Mexico	64	1.3

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
Puerto Rico						
PPD			PPD PPD PPD PPD PPD PPD PPD Puerto Rico	Western Institutional Review Board 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115 Western Institutional Review Board, 3535 7th Avenue SW, Olympia, WA 98502-5010	16	0.3
Spain						
PPD			PPD PPD , Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	21	0.4
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	30	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	10	0.2
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	24	0.5
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	38	0.8
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	56	1.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	50	1.0
			PPD PPD , Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	7	0.1
			PPD PPD PPD Spain	Comité Ético de Investigación Clínica de la Dirección General de Salud Pública y Centro Superior de Investigación en Salud Pública (CEIC-DGSP/CSISP) Avda. de Cataluña, 21 46020 Valencia	20	0.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
United States						
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc. 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	40	0.8
			PPD PPD United States	St. Luke's Health System Institutional Review Board 190 E. Bannock Street, Denver Way,Boise, ID, 83712	40	0.8
			PPD PPD PPD	Chesapeake IRB 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	2	0.0
			PPD PPD PPD United States	Chesapeake Research Review, Inc. 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	18	0.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc. 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	8	0.2
			PPD PPD PPD United States	Inova Human Research Protection Program (HRPP) Claude Moore Health Education & Research Building - 3rd Floor Inova Fairfax Hospital 3300 Gallows Road Falls Church, Virginia 22042-3300	40	0.8

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	4	0.1
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	29	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD						
			PPD PPD PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	18	0.4
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	21	0.4
			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	150	3.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD PPD (Former PI)	PPD		PPD PPD PPD , PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.4
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	30	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.4
			PPD PPD PPD PPD USA	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	54	1.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD		**	PPD PPD PPD USA, PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	--	--
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	48	1.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	32	0.6
			PPD PPD PPD , United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	59	1.2
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	134	2.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States, PPD	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	14	0.3
			PPD PPD PPD United States, PPD	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	13	0.3
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	25	0.5
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	118	2.4
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	83	1.7
			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	169	3.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Kaiser Foundation Research Institute 1800 Harrison Street 16th Floor Oakland, CA 94612	57	1.1
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	29	0.6
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	1	0.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	103	2.1
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	27	0.5

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD PPD	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	45	0.9
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	80	1.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD PPD (Former PI) PPD (Former PI)	PPD		PPD PPD PPD United States	Biomedical Research Alliance of New York, LLC Institutional Review Board (BRANY), 1981 Marcus Avenue, Suite 210, Lake Success, NY 11042	13	0.3
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	44	0.9

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Boston University Medical Center, Office of the Institutional Review Board, 560 Harrison Ave, Suite 300 Boston, Massachusetts,02118-2526	83	1.7
	PPD (formerly PPD	**	PPD PPD PPD United States	University of Louisville, Human Subjects Protection Program Office MedCenter One – Suite 200 501 E. Broadway Louisville, KY 40202-1798	--	--
PPD			PPD PPD PPD United States	University of Louisville, Human Subjects Protection Program Office MedCenter One – Suite 200 501 E. Broadway Louisville, KY 40202-1798	37	0.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD	PPD PPD PPD (formerly					
			PPD PPD PPD PPD PPD United States	Western Institutional Review Board 3535 7th Avenue SW, Olympia, WA 98502-5010 Western Institutional Review Board 1019 39th Avenue SE Suite 120 ,Puyallup, WA 98374-2115	5	0.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	63	1.3
			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	50	1.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	1	0.0
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	34	0.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	10	0.2
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	8	0.2

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	87	1.7
			PPD PPD PPD United States	Marshfield Clinic Research Foundation INSTITUTIONAL REVIEW BOARD 1000 North Oak Avenue Marshfield, WI 54449-5790	33	0.7
			PPD PPD PPD United States, PPD	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	26	0.5

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD PPD (Former PI)	PPD		PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	20	0.6
PPD			PPD PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	31	0.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	54	1.1
			PPD PPD PPD PPD United States	UTMB Health, Institutional Review Board 301 University Blvd. Galveston, TX 77550-0158	33	0.7
			PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	1	0.0

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	39	0.8
			PPD PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	24	0.5
			PPD PPD PPD United States	7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	35	0.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	27	0.5
			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403	5	0.1
			PPD PPD PPD United States	Western Institutional Review Board 3535 Seventh Ave SW Olympia WA 98502-5010 Western Institutional Review Board 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115	9	0.2
			PPD PPD PPD PPD United States	Upstate Medical University, Institutional Review Board for the Protection of Human Subjects, 750 East Adams Street, Syracruse, NY 13210	17	0.3

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Upstate Medical University, Institutional Review Board for the Protection of Human Subjects, 750 East Adams Street, Syracruse, NY 13210	37	0.7
			PPD PPD PPD , United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	63	1.3

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects*	% of Subjects*
PPD			PPD PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403 Chesapeake Research Review, Inc 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	42	0.8
			PPD PPD United States	Chesapeake Research Review, Inc 7063 Columbia Gateway Drive, Suite 110 Columbia, MD 21046-3403	4	0.1

* Number and percentage of subjects per center reflects the number of subjects effectively taken into account for the end of study statistical analysis.
** 32 Subjects, enrolled in center PPD were transferred to center PPD 14 subjects enrolled in center PPD were transferred to center PPD

Representative written information for patient and sample consent forms

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

Non-US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 01 (replace with Version of Local ICF)

Date: 06/AUG/2012 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is licensed in over 100 countries. More than 240

million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been licensed in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet licensed for sale. [Note to local team: Delete the previous 2 sentences if GSK MMR (Priorix) is licensed in your country.]

In this study the MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well when given at the same time as other licensed vaccines that your child normally receives.

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II, also called MMR VaxPro®). [Note to local team: Decide which product name to use and adjust as needed.]

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed]. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II/MMR VaxPro® vaccine.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the either the GSK MMR or the MMR®II/MMR VaxPro® [local team to delete vaccine name as needed].vaccination was not the best possible. If the study doctor believes your child would benefit from another shot of the MMR®II/MMR VaxPro® vaccine, he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive two additional shots at the first visit.

- *Havrix* which prevents hepatitis A virus
- *Varivax* which prevents chicken pox (varicella)

In some countries, these are common childhood vaccines that your child may normally get at this age, together with MMR vaccine.

In some countries where *Havrix* and varicella vaccination are not routinely given, GSK will offer your child a second shot of these two childhood vaccines, at the end of the study.

Here is a summary of what will happen at each visit:

	Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:

Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study.
	• You answer questions about your child's health.
	• The study doctor and/or nurse will:
	– Give your child a physical examination, including height and weight.
	– Take a blood sample (about a teaspoon).
	– Take your child's body temperature.
	– Give your child the vaccines and have you wait for 30 minutes after the shots.
	– Give you a diary card to write down safety information until the next visit.
	  – Day 0-3: write down any redness, pain or swelling at the site of the shots.
	  – Day 0-14: write down any drowsiness, loss of appetite and/or irritability your child experiences.
	  – Day 0-42: measure and write down your child's temperature. You will get a thermometer and will be shown how to do this.
	  – Day 0-42: write down other specific symptoms. These include rash, swollen glands and jerking movements or staring into space. We will explain these to you in detail. You will have to contact us if any of these specific symptoms occur.
	  – Day 0-42: write down any medication or other vaccines your child receives.
	• If you take your child to a doctor or nurse you will also need to write down this information on the diary card.

Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • Physical examination, only if needed. • Take a blood sample (about a teaspoon). • Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if you need emergency

care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

<u>Optional tests on your samples:</u>

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. The study staff may give your child medicine to help lessen side effects. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are **common**:

- Redness, pain or swelling at the site of the shot or of the limb where the shot is given
- Fever
- Common cold
- Rash

The following side effects are **less common**:

- Ear infection
- Swollen glands in the armpit, groins or any place on the body
- Loss of appetite or altered taste
- Fussiness and/or drowsiness
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Painful swelling of the salivary glands
- Diarrhea
- Vomiting
- Headache
- Stomach pain or nausea
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **rare**:

- Febrile convulsion (also called a “fit” with fever)
- Inflammation and/or infection of the gut leading to loss of body water and increased body salts
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)
- Stroke

- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord
- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness. It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol®) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution to persons with a history or family history of convulsions.

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash
- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not optimal.

If the tests results for measles, mumps, or rubella show that your child's response to the vaccine was not optimal, the study doctor will offer you another shot for your child, of MMR®II (or *Priorix* where the vaccine is licensed) at no cost to you.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you decide not to continue vaccination, study visits, etc.

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.
3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.
6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study

What happens if your child gets hurt while taking part in this study?

Note to local team: The type of compensation offered to research subjects who are injured during a clinical study differs in each country. It is the responsibility of GSK Biologicals' staff in each country to ensure that Local ICFs include the correct compensation-for-injury terms applicable to their country (see GUI_51905).

For phase II -III clinical research studies, GSK Biologicals' will comply with the ABPI Clinical Trials Compensation Guidelines (1991). The following wording should be used:

If your child is hurt by a vaccine or a clinical procedure that your child would not have been given outside this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For studies in which the GSK Biologicals' investigational vaccine is already marketed for the relevant indication and the protocol requires the subject to undergo a procedure that they would not otherwise undergo (e.g. sample collection), the following wording should be used:

If your child is hurt by clinical procedures needed only because your child is taking part in this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For GSK sponsored studies in Other Regions: In other countries where there is local compensation for injury requirements, the CMD staff preparing the Local ICF must apply the rules and conventions required locally.

Signing this consent form does not change any legal rights you or your child may have.

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) for study MMR-161, Version 01, dated: 06-AUG-2012, 14 pages [ICF version, date and number of pages, (to be updated locally)] including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- [For the US LOC only: **understand that by signing this form any of my identifiable medical information given to someone that is not a health care provider is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.**]
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

- I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent:

_____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

- I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

Non-US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 02 (replace with Version of Local ICF)

Date: 13/MAY/2014 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is approved for use in over 100 countries. More than

240 million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been approved for use in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet approved for use. [Note to local team: Delete the previous 2 sentences if GSK MMR (Priorix) is licensed in your country.]

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II, also called MMR VaxPro®). [Note to local team: Decide which product name to use and adjust as needed.]

The MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well when given at the same time as other approved vaccines that your child normally receives.

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future. You will not be paid for any part of this.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed]. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed]. Neither the doctor nor you, the parent/legally acceptable representative (LAR) will know or be able to choose which vaccine your child receives. The study doctor will be able to tell you what your child was given after the whole study is finished or in case of a medical emergency.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the either the GSK MMR or the MMR®II/MMR VaxPro® [local team to delete vaccine name as needed].vaccination was not good enough. If the study doctor believes your child would benefit from another shot of the MMR®II/MMR VaxPro® vaccine [local team to delete vaccine name as needed], he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive two additional shots at the first visit.

- *Havrix* which prevents hepatitis A virus
- *Varivax* which prevents chicken pox (varicella)

Havrix and varicella vaccinations are common childhood vaccines that your child may normally get at this age, together with MMR vaccine. [Note to local team: Delete if this does not apply to your country],

Since *Havrix* and varicella vaccinations are not routinely given in your country, GSK will offer your child a second shot of these two childhood vaccines, at the end of the study or shortly after the study, depending on vaccines availability. [Note to local team: Delete if this does not apply to your country]

Here is a summary of what will happen at each visit:

	Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:
Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study. • You answer questions about your child's health. • The study doctor and/or nurse will: – Give your child a physical examination, including height and weight. – Take a blood sample (about a teaspoon). – Take your child's body temperature. – Give your child the vaccines and have you wait for 30 minutes after the shots. – Give you a diary card to write down safety information until the next visit and instruct you to call the clinic if your child has specific signs or symptoms. • If you take your child to a doctor or nurse you will also need to write down this information on the diary card.
Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • The study doctor and/or nurse will: • Give your child a physical examination, only if needed. • Take a blood sample (about a teaspoon). • Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if your child needs emergency care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

Optional tests on your samples:

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are very common (one in 10 or more doses):

- Redness/tenderness/swelling where the shot is given
- Low fever (37.5°C/99.5°F or more)
- Fussiness/irritability
- Fatigue
- Headache

The following side effects are **common (**events ≥1/100 to <1/10**)**:

- High fever (more than 39°C/102.2°F)
- Common cold
- Rash
- Feeling of general discomfort or uneasiness, not feeling well
- Drowsiness
- Loss of appetite
- Swelling of glands in the cheeks or neck
- Diarrhea, nausea, vomiting
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **less common (**events ≥1/1,000 to <1/100):

- Ear infection
- Rhinitis
- Abnormal crying
- Swollen glands in the armpit, groins or any place on the body
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Dizziness
- Stomach pain
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Flu- like illness

The following side effects are **rare** (events ≥1/10,000 to <1/1,000) and include side effects reported with the use of the vaccines after being approved:

- Convulsion (also called a “fit”) with or without fever
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)
- Stroke

- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord
- Inability to coordinate balance, gait, extremity and eye movements
- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination
- In rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination
- Joint inflammation/swelling
- Itchy pink-red blotches (usually on hands, legs)
- Damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage
- Rapid swelling of the skin of the face and possibly the hands that can be itchy or painful
- Low blood count (very rare)

Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

There may be other side effects that are not known now.

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness.

It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol® or Paracetamol) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution should be employed in administration of M-M-R II to persons with an individual or family history of seizures

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash
- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not good enough.

If the tests results for measles, mumps, or rubella show that your child's response to the vaccine was not good enough, the study doctor will offer you another shot for your child, of MMR®II (or *Priorix* where the vaccine is approved for use) at no cost to you.

When your child has blood taken, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you do not withdraw your consent but decide to leave the study (i.e., decide not to continue vaccination, study visits, etc.):

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's personal and medical information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.
3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.

6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study

What happens if your child gets hurt while taking part in this study?

Note to local team: The type of compensation offered to research subjects who are injured during a clinical study differs in each country. It is the responsibility of

GSK Biologicals' staff in each country to ensure that Local ICFs include the correct compensation-for-injury terms applicable to their country (see GUI_51905).

For phase II -III clinical research studies, GSK Biologicals' will comply with the ABPI Clinical Trials Compensation Guidelines (1991). The following wording should be used:

If your child is hurt by a vaccine or a clinical procedure that your child would not have been given outside this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For studies in which the GSK Biologicals' investigational vaccine is already marketed for the relevant indication and the protocol requires the subject to undergo a procedure that they would not otherwise undergo (e.g. sample collection), the following wording should be used:

If your child is hurt by clinical procedures needed only because your child is taking part in this study, you will be compensated. Your study doctor can give you information about the compensation guidelines for this kind of hurt.

For GSK sponsored studies in Other Regions: In other countries where there is local compensation for injury requirements, the CMD staff preparing the Local ICF must apply the rules and conventions required locally.

Signing this consent form does not change any legal rights you or your child may have.

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) within this document for the 115648 (MMR-160) study, including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- know what will happen to my child's blood samples.
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No** ☐ **N/A**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Relationship of legally acceptable representative to the subject _____

_____

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent: _____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

Information letter for parents/guardians

CONFIDENTIAL

Study Identification: 115648 (MMR-160)

INFORMATION LETTER

to the Informed Consent Form for Parents/Guardians

Non US Sub-cohort

[Country to be inserted]

Study Identification:	115648 (MMR-160)
Study Title:	Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.
Version and Date:	Version 01: 13 May 2014
Company Name:	**GlaxoSmithKline (GSK) Biologicals S.A.**
Subject Identification:	**Insert subject ID here** _____

This document should be presented to parents/guardians of subjects who are currently enrolled in study MMR-160 but completed the study vaccination, or who have now either completed or withdrawn from the study.

This document should be presented to the subject's parent / guardian in full; no page(s) or section(s) should be omitted.

Purpose of this document

Recently, new information became available in the study MMR-160, the study that your child is enrolled in or he/she has completed or withdrawn from. We would like to share this new information with you.

The purpose of this document is to provide you with new information on the side effects that may occur after each blood draw, the side effects or risks your child may experience after vaccination, and new information about the timing of the second dose of varicella and hepatitis A (*Havrix*) vaccines.

When your child gives blood, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.

Changes have been made in the list of side effects seen after the vaccines given in this study:

- The following side effects were added:
  - **very common:** fatigue.
  - **common:** high fever (more than 39°C/102.2°F); feeling of general discomfort or uneasiness, not feeling well.

- **less common:** rhinitis; abnormal crying; dizziness; flu-like illness.
- **rare:** convulsions (also called a "fit") with or without fever; in rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination; joint inflammation/swelling; itchy pink-red blotches (usually on hands, legs); damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage; rapid swelling of the skin of the face and possibly the hands that can be itchy or painful; inability to coordinate balance, gait, extremity and eye movements; low blood count (very rare).
- Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

➢ Inflammation and/or infection of the gut leading to loss of body water and increased body salts is not a risk associated with any of the vaccines received as part of this study.

➢ The following side effects were included in the original risk section of the ICF; however, the frequency of occurrence was changed:

- **From common to very common**: redness/tenderness/swelling where the shot is given; low fever (37.5°C/99.5°F or more).
- **From less common to very common:** fussiness/irritability; headache.
- **From less common to common:** drowsiness; loss of appetite; dryness of skin; difficulty or infrequent passing of stool; swelling of glands in the cheeks or neck; diarrhea, nausea, vomiting.

Since *Havrix* and varicella vaccinations are not routinely given in your country, GSK will offer your child a second shot of these two childhood vaccines, at the end of the study or shortly after the study, depending on vaccine availability.

If you have any questions, please contact your child's physician.

Investigator Name _____

Investigator signature _____

Date _____

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 01 (replace with Version of Local ICF)

Date: 06/AUG/2012 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is licensed in over 100 countries. More than 240

million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been licensed in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet licensed for sale.

In this study the MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well, when given at the same time as other licensed vaccines.

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II).

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.
- Has already received 3 shots of a pneumococcal vaccine, Prevnar 13® (not *Prevnar* or *Prevenar*), with no doses given at least 60 days prior to study entry.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II vaccine. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II vaccine.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the MMR vaccine (either the GSK MMR or MMR®II) or varicella vaccination was not the best possible. If the study doctor believes your child would benefit from another shot of the MMR®II or varicella vaccine, he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive three additional shots at the first visit.

- *Havrix* which prevents against hepatitis A virus
- *Varivax* which prevents against chicken pox (varicella)
- *Prevnar 13* which prevents pneumococcal (certain bacterial) infections

These are common childhood vaccines that your child would normally get at this age, together with MMR vaccine.

Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:

	What will happen at this visit

Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study.
	• You answer questions about your child's health.
	• The study doctor and/or nurse will:
	– Give your child a physical examination, including height and weight.
	– Take a blood sample (about a teaspoon).
	– Take your child's body temperature.
	– Give your child the vaccines and have you wait for 30 minutes after the shots.
	– Give you a diary card to write down safety information until the next visit.
	  – Day 0-3: write down any redness, pain or swelling at the site of the shots.
	  – Day 0-14: write down any drowsiness, loss of appetite and/or irritability your child experiences.
	  – Day 0-42: measure and write down your child's temperature. You will get a thermometer and will be shown how to do this.
	  – Day 0-42: write down other specific symptoms. These include rash, swollen glands and jerking movements or staring into space. We will explain these to you in detail. You will have to contact us if any of these specific symptoms occur.
	  – Day 0-42: write down any medication or other vaccines your child receives.
	• If you take your child to a doctor or nurse you will also need to write down this information on the diary card.

Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • Physical examination, only if needed. • Take a blood sample (about a teaspoon). • Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if you need emergency care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

Optional tests on your samples:

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. The study staff may give your child medicine to help lessen side effects. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are **common**:

- Redness, pain or swelling at the site of the shot or of the limb where the shot is given
- Fever
- Common cold
- Rash

The following side effects are **less common**:

- Ear infection
- Swollen glands in the armpit, groins or any place on the body
- Loss of appetite or altered taste
- Fussiness and/or drowsiness
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Painful swelling of the salivary glands
- Diarrhea
- Vomiting
- Headache
- Stomach pain or nausea
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **rare**:

- Febrile convulsion (also called a “fit” with fever)
- Inflammation and/or infection of the gut leading to loss of body water and increased body salts
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)
- Stroke
- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord

- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Bleeding or bruising more easily than normal due to a drop in number of a type of blood cells called platelets
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness. It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol®) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution to persons with a history or family history of convulsions.

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash

- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not optimal.

If the tests results for measles, mumps, rubella, or varicella show that your child's response to the vaccines were not optimal, the study doctor will offer you another shot for your child, of MMR®II or Varivax® at no cost to you.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

By letting your child be in this study, you will contribute to developing a second MMR vaccine available in the US. This will reduce the risk of having a shortage of this important vaccine in the future.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you decide not to continue vaccination, study visits, etc.

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies for example, the FDA in the US. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.
3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.
6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study.

You should know that once identifiable medical information about your child is given to someone that is not a health care provider, it is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.

What happens if your child gets hurt while taking part in this study?

GSK will help pay for your care if your child is hurt by the study vaccine or a procedure done to you as part of the study. GSK will pay for reasonable and necessary care for the injury that is not covered by the National Vaccine Injury Compensation Fund. GSK will not pay for any other expenses. To pay these medical expenses, GSK will need to know some information about you like your child's name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because GSK has to check to see if your child receives Medicare and if you do, report the payment it makes to Medicare. GSK will not use this information for any other purpose.

Signing this consent form does not change any legal rights you may have.]

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) for study MMR-160, Version 01, dated: 06-AUG-2012, 14 pages [ICF version, date and number of pages, (to be updated locally)] including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- **understand that by signing this form any of my identifiable medical information given to someone that is not a health care provider is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.**]
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study.

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

- I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent:

_____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

- I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

Instructions for Local ICF development

The LOC should ensure that all local legal regulatory requirements are satisfied before finalizing the Local ICF. It is strongly recommended to align the content of the Local ICF with the content of the Model ICF and this template.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Note: In the final Local ICF all text should be in the same format i.e. any bold text must be in normal font and red hidden text must not be retained.

Refer to INS_51928, SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.

(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

US Sub-cohort

Study Identification: 115648 (MMR-160)

Study Title: Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.

Model ICF Version Number: 02 (replace with Version of Local ICF)

Date: 13/MAY/2014 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: Insert subject ID here

This form describes a type of research study called a clinical trial. The study staff will explain the study to you. The study will only include people who choose to take part.

Some of the information in this form is required by law. This form has been reviewed and approved by an Ethics Committee. This committee reviews research studies to protect the rights and wellbeing of the people in the study.

What is consent?

Consent means agreeing to be in this research study. You can decide if you want your child to take part in this study or not. Please take time to read the following information and ask the study doctor or study staff if you have any questions. They will explain the study fully to you. You can talk in private with family, friends and your doctor to help you make a decision. If you decide to have your child join this study, you must sign the Consent page at the end of this form. This is called "giving consent". A copy of this form will be given to you. You should make your decision only after:

1. A study staff person has explained the study to you
2. You know the purpose of the study and the risks, and
3. You/your child are willing to do what is asked of you in the study.

Why is this study being done?

This study involves research about vaccines. Vaccines help protect against diseases. We want to find out if the measles-mumps-rubella (MMR) vaccine works well when given during a child's second year of life. The way to check if the vaccine works well is to take and test a blood sample before and after the shot is given.

This MMR vaccine is made by GlaxoSmithKline Biologicals (also known as GSK MMR vaccine). The GSK MMR vaccine is approved for use in over 100 countries. More than

240 million doses of GSK MMR vaccine have been given. But in this study, since the GSK MMR vaccine has not been approved for use in your country, it is considered an "investigational" vaccine. An investigational vaccine is a vaccine that is still being tested and is not yet approved for use.

In this study, the GSK MMR vaccine will be compared against another MMR vaccine (MMR®II).

The MMR vaccine will be given once during this study. A blood sample (about a teaspoon) will be taken, before the shot and about six weeks after the shot is given, to measure how well the vaccine works. The study will also see if the GSK MMR vaccine works well, when given at the same time as other approved vaccines.

How is GSK involved?

GSK is a company that studies and makes vaccines, medicines and other health products. GSK planned and organized this study. GSK pays the study doctor and the institution to run this study.

GSK will be the owner of the study results. GSK plans to sell the vaccine in the future. You will not be paid for any of this.

The information and materials we give you about this study are confidential and belong to GSK. We ask that you keep it private. However, you can share information with your doctor, family or friends when discussing about your child's participation in this study and your healthcare.

Who can join this study?

About 5000 healthy children will take part in this study. Once we have 5000 children enrolled, we will stop inviting any more to join.

To decide if your child can be in study, we will ask you questions about your child's health.

Your child can be in this study if he or she:

- Is between 12 and 15 months old.
- Is in good health.
- Is not taking certain medications or had previous vaccinations against MMR or chicken pox (varicella).
- Has no history of allergy to any part of the vaccine including gelatin and neomycin.
- Has already received 3 shots of a pneumococcal vaccine, Prevnar 13® (not *Prevnar* or *Prevenar*), with no doses given at least 60 days prior to study entry.

The study doctor will also check some other aspects before you can join this study.

You can ask your study doctor for more details.

What does this study involve?

Your child will be given one shot of either the GSK MMR vaccine or the MMR®II vaccine. The choice of which vaccine your child will get will be made by chance, like flipping a coin. Your child will have a 6 out of 8 chance of receiving the GSK MMR vaccine and a 2 out of 8 chance of receiving the MMR®II vaccine. Neither the doctor nor you, the parent/legally acceptable representative (LAR) will know or be able to choose which vaccine your child receives. The study doctor will be able to tell you what your child was given after the whole study is finished or in case of a medical emergency.

Two blood samples will be taken and tested.

In some cases the testing may show that your child's response to the MMR vaccine (either the GSK MMR or MMR®II) or varicella vaccination was not good enough. If the study doctor believes your child would benefit from another shot of the MMR®II or varicella vaccine, he or she will contact you.

The study will last 6 months.

Besides the MMR vaccine, your child will also receive three additional shots at the first visit.

- *Havrix* which prevents against hepatitis A virus
- *Varivax* which prevents against chicken pox (varicella)
- *Prevnar 13* which prevents pneumococcal (certain bacterial) infections

These are common childhood vaccines that your child would normally get at this age, together with MMR vaccine.

Here is a summary of what will happen at each visit. It is important that you follow all study activities as described below:

	What will happen at this visit
Visit 1 (Day 0)	• You sign this consent form if you agree to take part in this study. • You answer questions about your child's health. • The study doctor and/or nurse will: – Give your child a physical examination, including height and weight. – Take a blood sample (about a teaspoon). – Take your child's body temperature. – Give your child the vaccines and have you wait for 30 minutes after the shots. – Give you a diary card to write down safety information until the next visit and instruct you to call the clinic if your child has specific signs or symptoms. • If you take your child to a doctor or nurse you will also need to write down this information on the diary card.
Visit 2 (Day 42)	• Return the diary card. • Answer questions about your child's health. • The study doctor and/or nurse will: – Give your child a physical examination, only if needed. – Take a blood sample (about a teaspoon). – Give you a 2nd set of diary cards to write down events your child might experience, including any doctor visits and medications or other vaccines your child receives between Visits 2 and 3.
Visit 3 (Day 180)	• Return the diary card. • The study staff will ask questions about your child's health including any new illness, medications or vaccines your child receives and any emergency room visits. • Physical examination, only if needed

Note to local team: This paragraph is mandatory standard text not to be changed

You will receive a card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if your child needs emergency care during the study. The medical staff can then contact your study doctor if needed to ask about the vaccine or product your child received.

What will happen to samples taken in this study?

Note to local team: The content of this section needs to be aligned with the Use of Human Samples form. Any request to changes in this section must be discussed with the central study team and the GSK Biologicals' ICF taskforce prior to finalization of the ICF.

As part of the study, you will be asked to give samples of your child's blood. **Your** child's blood **samples may be sent to GSK or other laboratories working with GSK including those outside [insert name of country] to**:

- measure how your child's body reacts to the study vaccine,
- **ensure the quality of the tests we use for the study vaccine and/ or disease(s),**
- **improve tests and develop new tests linked to the study vaccine and/or disease(s). These tests will never include testing related to your** child's **genes (hereditary characteristics).**

In case IEC/IRB or Regulatory Authorities do not accept the above wording, the clarification paper on future use of biospecimens (in the Process Documents Repository under Laboratory Activities) can be consulted to formulate responses to IEC/IRB or Regulatory Authorities comments or requests for removal of this type of testing.

or

In case the IEC/IRB or Regulatory Authorities can still not be convinced, then the following wording can be proposed.

- **improve tests and develop new tests linked to the study vaccine(s) and/or disease(s). These tests will never include testing related to your genes' hereditary characteristics. GSK will always ask in advance approval for this research to an independent ethics committee or review board.**

Your child's blood **samples will be given a code so that it does not directly identify** them**.**

Your child's **samples will be kept for a maximum of** 20 **years from the end of the study**. **Any sample remaining at that time will be destroyed**.

Optional tests on your samples:

If you agree, your child's blood **sample(s) may also be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board.**

You can choose not to allow these optional tests and still be in the study.

What side effects or risks can you expect in this study?

Your child may have some side effects while in this study. The study staff will watch for these.

Side effects may be mild or serious. Some side effects will go away within a few days. Some side effects can be serious, long lasting or may never go away.

The following side effects are very common (one in 10 or more doses):

- Redness/tenderness/swelling where the shot is given
- Low fever (37.5°C/99.5°F or more)
- Drowsiness
- Loss of appetite
- Fussiness/irritability
- Fatigue
- Headache

The following side effects are **common (**events ≥1/100 to <1/10**)**:

- High fever (more than 39°C/102.2°F)
- Common cold
- Rash
- Feeling of general discomfort or uneasiness, not feeling well
- Swelling of glands in the cheeks or neck
- Diarrhea, nausea, vomiting
- Dryness of the skin
- Difficult or infrequent passing of stool

The following side effects are **less common (**events ≥1/1,000 to <1/100):

- Ear infection
- Rhinitis
- Abnormal crying
- Swollen glands in the armpit, groins or any place on the body
- Trouble sleeping
- Redness, inflammation or infection of the eye
- Eye sensitivity to light
- Cough
- Pneumonia
- Bronchitis
- Dizziness
- Stomach pain
- Chills
- Muscle pain or stiff neck
- Joint pain
- Itching
- Flu- like illness

The following side effects are **rare** (events ≥1/10,000 to <1/1000) and include side effects reported with the use of the vaccines after being approved:

- Convulsion (also called a “fit”) with or without fever
- Severe allergic reactions
- Low blood cells called platelets (could have no symptoms or could cause bruising, gum and/or nose bleeding and/or tiredness)

- Stroke
- Fever which lasts for more than five days, associated with a rash on the chest, stomach or back sometimes followed by peeling of the skin on the hands, fingers, palms and soles, swollen glands in the neck, red eyes, lips, throat and tongue
- Inflammation around and/or of the brain or spinal cord
- Inability to coordinate balance, gait, extremity and eye movements
- Inflammation of some nerves, possibly with the feeling of pins and needles in the fingers or toes
- Impaired or loss of sensation or difficulty with movement
- Hard time breathing
- Hepatitis and jaundice
- Bleeding or bruising more easily than normal due to a drop in number of a type of blood cells called platelets
- Severe condition of the skin that may affect the skin or lining of the mouth, palms, soles and other parts of the body
- Fainting may occur following, or even before, giving the shot because of fear of shots or needles
- In rare cases, measles-like symptoms have been reported following MMR vaccination
- In rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination
- Joint inflammation/swelling
- Itchy pink-red blotches (usually on hands, legs)
- Damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage
- Rapid swelling of the skin of the face and possibly the hands that can be itchy or painful
- Low blood count (very rare)

Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

There may be other side effects that are not known now

Cautions

The measles and mumps part of the vaccine are made in chicken egg cells and may have small amounts of egg protein. Some children get a severe allergic reaction or other immediate reaction after eating eggs (a drop in blood pressure, itching, swelling, difficulty breathing). If your child does, the risk of an allergic reaction after vaccination could be higher. This is very rare. People with a severe allergic reaction after eating eggs should be watched very carefully after being given the shot.

You should not give any aspirin or medicine with aspirin to your child for six weeks after the shots. The reason for this is that a condition called Reye's syndrome could occur. This is a sudden and sometimes deadly disease of the brain and liver. It may occur in

children (most cases 4-12 years of age). It can happen after chickenpox or flu-like illness. It is also associated with taking aspirin. Medicines containing acetaminophen (like Tylenol®) do not have this effect.

In the 6 weeks after your child receives the vaccine, he or she should avoid close contact with people who have a weak immune system (that is people who cannot fight off infections).

Your child should also keep away from pregnant women and the newborns of mothers who have never had chickenpox or chickenpox vaccine. These people may get chickenpox by such contacts.

Caution should be employed in administration of M-M-R II to persons with an individual or family history of seizures.

If your child needs a test for tuberculosis (TB) it should be done before the shots. Talk to the doctor if this is the case.

Sometimes people have allergic reactions to vaccines. These are rare but can be serious or even life threatening if not treated promptly. These kinds of reactions usually happen within a few minutes to a few hours after the shot. Some things that happen during an allergic reaction are:

- appearance of a rash
- having a hard time breathing
- wheezing
- sudden drop in blood pressure (dizziness, paleness)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

The prefilled syringes used for *Havrix* may contain latex and so shots of *Havrix* with these syringes may cause allergic reactions in some people that are sensitive to latex.

The study staff will observe your child for at least 30 minutes at the study center. If an allergic reaction happens, treatment will be available.

It is possible that the study vaccine can cause problems and side effects that nobody knows about. If there is any new information about the vaccine that could affect your child, the study staff will tell you about it. You can then decide if your child should continue in the study.

The vaccines in this study may not protect all people who get them. Your child's response to the vaccines in this study will be tested. In some cases, the test results may show that your child's response to the vaccination/s was not good enough.

If the tests results for measles, mumps, rubella, or varicella show that your child's response to the vaccines were not good enough, the study doctor will offer you another shot for your child, of MMR®II or Varivax® at no cost to you.

When your child has blood taken, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.

What benefits can your child expect in this study?

There may or may not be direct benefit for your child.

Your child will receive the vaccines, all the study tests and procedures and follow-up at no cost to you.

By letting your child be in this study, you will contribute to developing a second MMR vaccine available in the US. This will reduce the risk of having a shortage of this important vaccine in the future.

Are there other products or treatment?

Note to local team: This section should be completed locally using the most current information regarding the treatments/ vaccines/ products that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

You may choose for your child to receive another vaccine (routinely given) outside of this study.

Talk with your doctor before you decide to take part in this study. The study doctor can give you more information.

Does your child have to stay in the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject/patient withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

You may choose to have your child leave the study at any time, without giving a reason. If you do give a reason, then it may be recorded. Your choice will not change the medical care or other benefits your child receives outside of this study.

Tell the study doctor if you no longer want your child to take part in this study.

The study staff will share with you as soon as possible any new information that may change your choice to stay in the study.

GSK (the study sponsor) may choose to stop the study or the study doctor may choose to stop your child's participation in the study at any time. The study staff will then tell you why. You may be asked that your child leave the study if:

- You do not follow study instructions for treatment or follow-up visits.
- The study doctor thinks it is in your child's best interest to stop.

What happens if your child leaves the study?

Note to local team: Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in the Local ICF compared to the Model ICF, in response to a request from any source, these should be discussed with the central study team and GSK Biologicals ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account.

If you decide to withdraw consent

No more information about your child will be collected after leaving the study. All the information and samples collected before your child left the study will still be used.

If you do not withdraw your consent but decide to leave the study (i.e., decide not to continue vaccination, study visits, etc.):

If the doctor becomes aware of any relevant safety information about your child after leaving the study, this will be collected.

We may also contact you later for safety information. This is to help us better understand the safety of the vaccine.

What about your child's personal and medical information?

Note to local team: If changes are made to this text it needs to be checked with the local Legal team that this is aligned with local rules and regulations.

It is very important to us that your child's personal and medical information stay confidential and secure. GSK will protect your child's personal and medical information in accordance with the law.

When you sign this consent form you agree that we can use your child's personal and medical information as described here.

1. Your child's personal and medical information may be checked by GSK and others (like agencies that approve and monitor studies for example, the FDA in the US. This is to make sure that the study is being run properly.
2. Besides that, only the researchers at this study site can use information that identifies your child (such as name and address) and only for the purpose of the study.

3. Study information will be labeled with a code number (for example, PPD It will not include your child's name or address. The study doctor has the link between your child's name and the code number.
4. The link between your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
5. GSK will use your child's coded information for research only.
6. GSK may:

- keep it electronically, and analyse it by computer to find out what the study is telling us,
- share it with regulatory agencies that approve new vaccines and medicines,
- share it with people who check that the study is done properly (like the independent ethics committee or review boards),
- combine it with results from other studies to learn more about the vaccine and other vaccines. This may help us to assess the risks and benefits of GSK (or other) vaccines or medicines, or to improve disease understanding,
- publish study results in medical journals, for meetings and on the internet for other researchers to use.
- share coded information with other companies, organisations or universities to carry out research.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or any other country where GSK or those working with GSK work.

Use of this information may take place in countries with lower data protection rules than the country you live in. GSK will make sure that if your data is moved to another country, it will still be treated as stated in this Informed Consent Form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

A description of this clinical trial will be available on the GSK Clinical Study Register http://www.gsk-clinicalstudyregister.com/ and may also appear in clinical trial registries in countries in which the clinical study is conducted.

If you withdraw your consent for us to use your child's personal information your child will no longer be able to continue in the study.

At any time, you may ask to see your child's personal information and correct it if necessary. Please contact the person responsible for your child's rights in this study. This contact information is given in this consent form.

In some circumstances we may not be able to share your child's study information with you while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child's health during the course of the study.

You should know that once identifiable medical information about your child is given to someone that is not a health care provider, it is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.

What happens if your child gets hurt while taking part in this study?

GSK will help pay for your child's care if your child is hurt by the study vaccine or a procedure done to your child as part of the study. GSK will pay for reasonable and necessary care for the injury that is not covered by the National Vaccine Injury Compensation Fund. GSK will not pay for any other expenses. To pay these medical expenses, GSK will need to know some information about your child like your child's name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because GSK has to check to see if your child receives Medicare and if you do, report the payment it makes to Medicare. GSK will not use this information for any other purpose.

Signing this consent form does not change any legal rights you may have.]

Will you be paid for your child being in the study?

This section should be completed locally.

You will not be paid for taking part in this study. **OR**

We will reimburse you for the cost of travelling to your study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to be in the study?

This section is optional. This section should be completed locally.

Your child will get all the study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

This section may be completed at Country Level. Identify who the subject/ legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries.

Person to contact for any questions: **name, address, telephone number.**

Person to contact about your rights: **name, address, telephone number.**

Person to contact in case of injury: **name, address, telephone number.**

Consent statement

I,

_____
(Printed name of the Legally acceptable representative)

Legally acceptable representative of:

_____
(Printed name of the Child)

- confirm that I have read the written information (or have had the information read to me) within this document for the 115648 (MMR-160) study, including signature pages and the study procedures have been explained to me by study staff during the consent process for this study.
- confirm that I have had the chance to ask questions about this study and I am satisfied with the answers and explanations that have been given.
- know what will happen to my child's blood samples.
- understand that I give access to data about my child to authorized persons described in this information sheet.
- **understand that by signing this form any of my identifiable medical information given to someone that is not a health care provider is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.]**
- have been given time and opportunity to consider allowing my child to take part in this study.

Tick as appropriate (this decision will not affect your child's ability to enter the study):

I agree that my family doctor will be told that my child is taking part in this study. <Note: Not applicable if investigator is family doctor or if is there is no family doctor.>

☐ **Yes** ☐ **No** ☐ **N/A**

Tick as appropriate

I agree that my son's / daughter's / ward's biological sample(s) may be used for future research. GSK will always ask approval for this research to an independent ethics committee or independent review board. I understand that if I select "No", my son / daughter / ward can still take part in the study.

☐ **Yes** ☐ **No**

I agree to have my child take part in this study.

Relationship of legally acceptable representative to the subject _____

_____

Signature of legally acceptable representative _____ Date: _____ day/ month/ year

I confirm that I have conducted the consent process according to applicable regulations.

Printed name of person conducting consent: _____ Date: _____ day/ month/ year

Signature of person conducting consent: _____ Date: _____ day/ month/ year

I confirm that I am independent of the study, that I attended the informed consent process and that I have read the written information for the study. *< add if applicable >*

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the child's legally acceptable representative(s) is/are unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Biologicals Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Biologicals internally approved model ICF and is adapted according to country or local requirements.

The model ICF is the recommended content and structure which contains all ICH and GSK required elements and is aligned with the study protocol.

The content of the local ICF should be aligned with the Model ICF and any local specifications and regulations included.

The local GSK approved version should be submitted for ethical/regulatory approval and should be presented to the subject and/or their legally acceptable representative.

It is essential that the version of the local ICF is accurately tracked, with a unique version number, date and reference to the model ICF on which it is based, to ensure that the correct version of the ICF is used and can be identified if needed.

It is strongly recommended to have a final local ICF, back-translated in English, available in the Investigator's study file to ensure site readiness in case of audits and/or inspections.

Objective

These best practices are intended to give adequate support and to ensure consistency while developing the local ICF from the model ICF.

It is a tool to know what changes are not permitted and what changes can be justified and/or are required per local regulations and site specific information.

The development of the accurate and complete local ICF is a local responsibility and alignment with the model ICF is essential to study conduct.

Any changes made to the local ICF from the model ICF must be documented at local level.

Human Sample Management

The collection of human tissue samples, the intended use, and secondary use, if retained, and how the subject's confidentiality would be maintained for the retained samples, must be reported in the ICF.

The content of this section must be fully aligned with the Use of Human Samples form. This form allows the central project team to track the actual testing at GSK (or

laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. To avoid ethical and legal implications and invalidating the study data, any changes made to this section must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF.

Subject data after withdrawal

The retention of samples collected and data recorded before withdrawal and the continued collection of safety information after withdrawal must be reported in the ICF. Check local regulations and seek local legal advice for the use of data after subject withdrawal. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection and sample destruction can be taken into account

Type of changes

Changes to the local ICF can be classified into 3 categories:

'Not permitted' changes

BOLD BLACK mandatory text in the model ICF should not be changed.

'Required' changes

Required changes must be made in the local ICF to add country-specific or center-specific information. (Indicated as **BOLD RED** text in the model ICF e.g. investigator details).

'Justified' changes

Justified changes may be necessary in some countries to comply with local requirements / regulations or to comply with a specific template e.g. country specific compensation guidance text.

In addition, some text can be clarified / simplified, provided the meaning remains the same as in the model ICF and does not contradict or change the intended meaning of the model ICF.

Changes that require a specific rationale or justification, that may be necessary in specific situations e.g. storage duration of samples, or changes required by the relevant Ethics Committees, can also be justified.

Best Practices per ICF Section

This table describes the type of changes (not permitted, required or justified) for each ICF section of the local ICF compared to the model ICF.

ICF section	Type of changes	Rationale/Impact
Study Identification		
Check if study identification is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Study Title		
Check if study title is identical to Model ICF.	Not permitted	The study title allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
ICF Version Number and Date		
Update with version and date of Local ICF and check if reference to the Model ICF version and date is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
Company Name		
Check if company name is GlaxoSmithKline (GSK) Biologicals S.A. or the local GSK affiliate if this is required	Justified	A change to this section is permitted if it is justified by local regulations.

ICF section	Type of changes	Rationale/Impact
by local regulations.		For some countries, the local GSK affiliate should be indicated as Company Name.
Subject Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject ID should be mentioned on the ICF to be able to link the subject ID with the corresponding source documents and RDE entries.
Header		
Check if study identification in header is identical to Model ICF.	Not permitted	The study identification and study number allows us to link the document to the study protocol, the corresponding IRB/IEC approvals, all relevant study documentation and ensures that the subject is linked to the correct study.
Footer		
Indicate version of Local ICF and check if reference to the Model ICF version is included. Specify country and subset if applicable.	Required	It is mandatory to include an ICF version number, the date of the final version, the page number and the total number of pages (for the Local and Model ICF). Each ICF type has to be uniquely identified and must include a reference to the source. The version of the local ICF allows us to link the ICF to the corresponding approval documents. If the version is omitted in the local ICF, the subject may not receive the most up to date ICF and thus may not receive the complete information required to make an informed consent.
What is consent?		
Explain the consent process and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	Freely given and written informed consent must be obtained from each subject/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
		the potential subject. How the process of consenting looks like, needs to be explained in the ICF. The text can be simplified, if necessary.
Why is this study being done?		
Describe the study aim and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
How is GSK involved?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The role of the sponsor should be explained in this section. The text can be simplified if necessary.
Who can join this study?		
Summarize the main inclusion and exclusion criteria. Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What does this study involve?		
Explain the approximate number of subjects involved in the study, the study design and groups, the study procedures and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary
If subject cards are used, check if the text is identical to the Model ICF.	Not permitted	Subject cards provide information about the study which can be used in the event of a medical emergency. Provision of this information in the ICF ensures that

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
		the subject is aware of the use of the subject card. This information will also indicate to the ethics committee that it is provided to the subject.
What about pregnancy and breastfeeding?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
What will happen to samples taken in this study?		
Check if all mandatory wording from the Model ICF is present in the Local ICF.	Not permitted	If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… .
Check if the content of this section is aligned with the Use of Human samples form (UHSF).	Not permitted	The text in the ICF should match 100% with the information documented in the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject’s consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject‘s consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
Check if the QA (Quality Assurance) on protocol tests (type 2 testing) is reported in the Local ICF.	Not permitted	QA testing will be done at all times, assuming it is allowed as per individual subject's consent. If QA testing is not mentioned in the ICF, there is a risk that GSK will be unable to perform the protocol tests and therefore this type of testing cannot be omitted.
Check local regulations regarding tests related to the product/disease under study (type 3a and 3b testing). [If there are concerns regarding this text then this should be discussed with the central team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since type 3a or 3b should be chosen according to local regulations. However, the wording of the text itself, should not be changed! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording. So if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss of company reputation, lack of confidence, invalid study data, etc….

GlaxoSmithKline Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
Check Local regulations regarding storage duration. Check if the wording "up to 15 years" is not changed into "for 15 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	It is necessary to put a defined storage period in the ICF. As a standard, GSK proposes to store samples for "up to"15 years. Attention should be paid to the used wording "**Up to**" 15 years. This wording allows for GSK to covers different situations (e.g. to keep samples for maximum 15 years, to destroy samples when GSK no longer wants to store them or no longer is interested in testing, when physical integrity of some type of samples does not permit such long storage, etc). Any changes to this section should be captured in the UHSF. This will allow the laboratory to take the appropriate measures for sample storage, "up to 15" years or as defined in the ICF and documented in the UHSF section called "other".
Check local regulations regarding additional research NOT related to the product/disease under study. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. However, <u>the wording of the text itself, should not be changed</u>! We capture this info in the CRF/eCRF by the mean of the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF. This form allows the central project team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's consent and local regulations. If this text is changed, there is a risk to use human samples outside the subject's consent. This has major ethical and legal implications and can lead to a loss

ICF section	Type of changes	Rationale/Impact
		of company reputation, lack of confidence, invalid study data, etc….
What side effects or risks can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably foreseeable risks or inconveniences to the subject should be mentioned in the ICF. If any of this information is omitted in the local ICF, the subject may not receive the complete information required to make an informed consent. Text can be simplified if necessary.
Check if the text on autoimmune diseases (applicable if product/vaccine contains an adjuvant) is identical to the Model ICF.	Not permitted	The text on autoimmune diseases has been approved by GSK upper management following feedback from Authorities. The AID wording should remain consistent in all projects and countries. There is a reputational risk associated to the fact that GSK might seem to be sharing different information with Subjects/Externally on AID.
Check if the text on Rotarix, if applicable, is identical to the Model ICF.	Not permitted	This text has been approved by GSK upper management following feedback from Authorities.

ICF section	Type of changes	Rationale/Impact
What benefits can you expect in the study?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. The reasonably expected benefits or indirect benefits or if there is no direct clinical benefit for the subjects must be included in the local ICF. Text can be simplified if necessary
Are there other products or treatment?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	It is an ICH-GCP requirement to provide to the subject information on alternative procedures or treatment that may be available and their important potential benefits and risks. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
Add currently available local alternatives, if applicable.	Required	This information must be added locally to the ICF using the most current information regarding the treatments that are available in the country.
Do you have to stay in the study?		
Explain voluntary participation and check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The content of this section is required by ICH-GCP. Omitting any of this information would be violating the rights of the subject to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.
What happens if you leave the study?		
Check if the text on the use of data after subject withdrawal is identical to the Model ICF.	Justified	The bold text in this section has been approved by Medical Governance. Changes to this

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
[Check local regulations and seek local legal advice] [If the text needs to be changed it should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]		section in response to a request from any source, can have an impact for database collection and sample handling and should therefore be discussed with the central teams for alignment.
What about your personal and medical information?		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary). [If the text needs to be changed, it should be reviewed by the local legal team]	Justified	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. Omitting this information would be violating the confidentiality and the data privacy of the subject and could have legal implications. Text can be simplified if necessary.
What happens if you get hurt while taking part in this study?		
- For UK, US and countries without special local regulations, check if compensation section is not changed compared to the section in the Model ICF. [If changes are made, the CMD (Country Medical Department) should ensure that all local legal regulatory requirements are satisfied.]	Justified	The content of this section is required by ICH-GCP. In the UK and in countries where there is no local scheme, GSK will apply the Clinical Trial Compensation guidelines set down by the UK Association of British Pharmaceutical Industry (ABPI) to compensate subjects for GSK sponsored clinical study related injury
- For other countries where there is compensation for injury, the CMD (Country Medical Department) should ensure that the rules and conventions required locally are applied.	Justified	The content of this section is required by ICH-GCP and must be completed so that the subject is well informed before consenting to participation.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
Will you be paid for being in the study?		
Information related to this section is added at a regional or country level.	Required	The content of this section is required by ICH-GCP and must be included in the ICF so that the subject is well informed before consenting to participation. The anticipated prorated payment or other financial benefit, if any, to the subject for participating in the study should be mentioned in the ICF. Explain if expenses incurred by subjects for clinical visits made because of their participation in the study will be reimbursed or not.
Do you have to pay anything to be in the study?		
This section is optional. Information related to this section is added at a regional or country level when it is appropriate for a study and/or is required by local practice.	Justified	If appropriate for a study, include here information on cost/expenses that subject will have to bear for taking part in the study i.e., whether the subject or the subject's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject for participating in the study should be mentioned.
Who should you contact if you have questions?		
Add local contact details.	Required	The content of this section is required by ICH-GCP. The subject must have a contact person for further information regarding the study, his rights and who to contact in the event of trial- related injury.
Consent statement		
Check if the meaning of the text is not changed compared to the Model ICF (Text can be simplified if necessary).	Justified	The consent statement should be aligned with ICH-GCP requirements. Omitting any of the information can have legal implications

ICF section	Type of changes	Rationale/Impact
Check local regulations regarding further research (type 4 testing). Check if the wording is identical to the wording in the body of the ICF. [If there are concerns regarding this text then this should be discussed with the central project team and GSK Biologicals' central ICF taskforce for alignment prior to the finalization of the local ICF]	Justified	A change to this section is justified, since depending on local regulations, this type of testing is allowed or not. This type of testing is optional for the subject, meaning that if this testing is mentioned in the body of the ICF, a tickbox should be available in the consent statement. The wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF by using the UHSF, which contains standard wording so if the wording in the ICF is changed, this will not be matching with the UHSF.

References

SOP_54823, Development and implementation of Informed Consent for clinical studies.

INS_51928, Instructions for the content of the Informed Consent Form.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

INFORMATION LETTER

to the Informed Consent Form for Parents/Guardians

US Sub-cohort

Study Identification:	115648 (MMR-160)
Study Title:	Consistency study of GSK Biologicals' MMR vaccine (209762) (Priorix®) comparing immunogenicity and safety to Merck & Co., Inc.'s MMR vaccine (M-M-R®II), in healthy children 12 to 15 months of age.
Version and Date:	Version 01: 13 May 2014
Company Name:	**GlaxoSmithKline (GSK) Biologicals S.A.**
Subject Identification:	**Insert subject ID here**

This document should be presented to parents/guardians of subjects who are currently enrolled in study MMR-160 but completed the study vaccination, or who have now either completed or withdrawn from the study.

This document should be presented to the subject's parent / guardian in full; no page(s) or section(s) should be omitted.

Purpose of this document

Recently, new information became available in the study MMR-160, the study that your child is enrolled in or he/she has completed or withdrawn from. We would like to share this new information with you.

The purpose of this document is to provide you with new information on the side effects that may occur after each blood draw and the side effects or risks your child may experience after vaccination.

- When your child gives blood, he/she may feel faint, or locally experience mild pain, bruising, irritation or redness.
- Changes have been made in the list of side effects seen after the vaccines given in this study:

➢ The following side effects were added:

- **very common:** fatigue.
- **common:** high fever (more than 39°C/102.2°F); feeling of general discomfort or uneasiness, not feeling well.
- **less common:** rhinitis; abnormal crying; dizziness; flu-like illness.

- **rare:** convulsions (also called a "fit") with or without fever; in rare cases, mumps like syndrome including testicular swelling has been reported following MMR vaccination; joint inflammation/swelling; itchy pink-red blotches (usually on hands, legs); damage to the blood vessel walls that can lead to damage of different organs and include symptoms like fever, rash, weight loss, or more serious problems including heart or kidney damage; rapid swelling of the skin of the face and possibly the hands that can be itchy or painful; inability to coordinate balance, gait, extremity and eye movements; low blood count (very rare).
- Other very rare but severe problems have been known to occur after a child gets MMR or chickenpox vaccine. These very rare problems are: deafness, long term seizures, severe brain reactions (like coma or lowered consciousness) and permanent brain damage.

➢ Inflammation and/or infection of the gut leading to loss of body water and increased body salts is not a risk associated with any of the vaccines received as part of this study.

➢ The following side effects were included in the original risk section of the ICF; however, the frequency of occurrence was changed:

- **From common to very common**: redness/tenderness/swelling where the shot is given; low fever (37.5°C/99.5°F or more).
- **From less common to very common:** drowsiness; loss of appetite; fussiness/irritability; headache.
- **From less common to common:** dryness of skin; difficulty or infrequent passing of stool; swelling of glands in the cheeks or neck; diarrhea, nausea, vomiting.

If you have any questions, please contact your child/ward's physician.

Investigator Name _____

Investigator signature _____

Date _____

Investigator CVs or equivalent summaries of training and experience relevant to the performance of the clinical study

Pages 1201 to 1395 have been removed - Out of Scope of phase 1 of Policy 0070 - Investigator CVs

Signature of principal or coordinating investigator

GlaxoSmithKline Biologicals
Vaccines R&D
Investigator Approval Page

STUDY TITLE: A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Study: 115648 (MMR-160) Development Phase: IIIa

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Investigator:	Mercedes Macias Parra
Affiliation /investigational centre:	Instituto Nacional de Pediatria, Av. Insurgentes Sur 3700-C, Insurgentes Cuicuilco, Mexico City, Mexico, 04530
Signature of Investigator:	_____
Date:	_____

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GlaxoSmithKline Biologicals
Vaccines R&D
Sponsor Signatory Approval Page

Please note that by signing this page, you take responsibility for the content of the Study Report, including appendices

STUDY TITLE: A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Study: 115648 (MMR-160) Development Phase: IIIa

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Sponsor Signatory:	Paul Gillard
Title of Sponsor Signatory:	Clinical and Epidemiology Project Lead, GlaxoSmithKline Biologicals, SA

Signature: _____

Date: _____

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f2c0032eef0631fd00346d817376ba3e30f79b53 1.0 9/27/2018 3:17:12 PM - -
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Listings of patients receiving test drug(s) /investigational product(s) from specific batches, where more than one batch was used

Not applicable.

Audit Certificates

AUDIT CERTIFICATE

Study Number: 115648

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Clinical studies are conducted by or on behalf of GlaxoSmithKline in accordance with Standard Operating Procedures, which conform to the requirements of international GCP guidelines (ICH Harmonised Tripartite Guidelines E6 for Good Clinical Practice, FDA 21CFR parts 50, 56 and 312).

During the conduct and reporting of this study, the following independent audits were performed by or on behalf of GlaxoSmithKline.

Study Number	Type	Conducted by	Centre number	Country	Audit Date
115648	Investigator Site	Falcon-US	PPD	Estonia	14-15 August 2013
115648	Investigator Site	GSK-CDQA-US		USA	14-16 August 2013
115648	Investigator Site	GSK-CDQA-UK		Finland	21-23 August 2013
115648	Investigator Site	GSK-CDQA-US		USA	6-8 August 2014
115648	Investigator Site	GSK-CDQA-US		USA	13-15 August 2014

Clinical Development Quality Assurance hereby confirm that the audits detailed above were carried out in accordance with appropriate regulatory requirements and guidelines in order to assess compliance with the study protocol, ICH GCP, FDA 21CFR parts 314.50 and 601.2, appropriate standard operating procedures and policies.

Name: PPD **Date:** 30 November 2016

Role: Manager

Clinical Development Quality Assurance
GlaxoSmithKline Research and Development

Documentation of statistical methods

Documentation of inter-laboratory standardization methods and quality assurance procedures

Not Applicable

Publications based on the study

Not Applicable

Important publications referenced in the report

No key references have been identified and the other ones will be available on request.

CRF /eCRFs for deaths, other SAEs and withdrawals due to adverse events

Pages 1602 to 10848 have been removed - Out of Scope of phase 1 of Policy 0070 - CRF/eCRFs

GlaxoSmithKline Biologicals
Vaccines R&D
Sponsor Signatory Approval Page

Please note that by signing this page, you take responsibility for the content of the Study Report, including appendices

STUDY TITLE: A phase IIIA, randomized, observer-blind, controlled, multinational consistency study to evaluate the immunogenicity and safety of GSK Biologicals' MMR Vaccine (209762) (Priorix®) compared to Merck & Co., Inc.'s MMR Vaccine (M-M-R®II), as a first dose, both co-administered with Varivax®, Havrix® and Prevnar 13® (subset of children) to healthy children 12 to 15 months of age

Study: 115648 (MMR-160) Development Phase: IIIa

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Sponsor Signatory: Paul Gillard

Title of Sponsor Signatory: Clinical and Epidemiology Project Lead, GlaxoSmithKline Biologicals, SA

PPD

Signature:

Date: 11 OCT 2018

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