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*

GlaxoSmithKline Biologicals, SA

Study detailed title

A Phase III, randomized, open-label, controlled, multi-center study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Abridged Interim Clinical Study Report for Study 117119 (DTPA-HBV-IPV-135)

This abridged report provides all results available at the time of the database freeze (19 June 2015) which include safety data and immunogenicity data against Polyribosyl-Ribitol-Phosphate (PRP) antigen assessed till Visit 4.

Development Phase III

IND Number: BB-IND 006687

EUDRACT Number: 2013-004304-19

Name of Investigational Product: Infanrix hexa™

Indication Studied: Active immunization against diphtheria, tetanus, pertussis, infection caused by all known subtypes of hepatitis B virus, poliomyelitis, and invasive disease caused by *Haemophilus influenzae* type B (Hib) in infants.

Study initiation date:	16-April-2014
Study completion date:	31-March-2015 (Visit 4)
Data lock point (Date of database freeze):	19-June-2015
Date of report:	Final: 19-October-2015

Sponsor Signatory: Narcisa Elena Mesaros, MD
Project level Clinical Research and Development Lead,
DTP/Polio Vaccines,
Late Clinical Development,
Vaccine Discovery and Development,
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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LIST OF ABBREVIATIONS

AE	Adverse Event
ATP	According-To-Protocol
CBER	Center for Biologics Evaluation and Research
CDQA	Clinical Development Quality Assurance
CRDL	Clinical Research and Development Lead
CI	Confidence Interval
D	Diphtheria
DBF	Data Base Freeze
DTPa-HBV-IPV/Hib	Combined diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus and *Haemophilus influenzae* type b vaccine (*Infanrix hexa*).
DT	Diphtheria Toxoid
eCRF:	electronic Case Report Form
FHA	Filamentous Haemagglutinin
GCP	Good Clinical Practice
GMC	Geometric Mean Concentration
GMT	Geometric Mean Titer
GSK	GlaxoSmithKline
GQC	Global Quality Compliance
HBs	Recombinant hepatitis B surface antigen
Hib	*Haemophilus influenzae* (*H. influenzae*) type b
ICF	Informed Consent Form
IM	Intramuscular
IND	Investigational New Drug
IRB	Institutional Review Board

LAR	Legally Acceptable Representative
MedDRA:	Medical Dictionary for Regulatory Activities
NOCD	New-onset Chronic Disease
PRN	Pertactin
PRP	Polyribosyl-Ribitol-Phosphate
PT	Pertussis Toxoid
RCC	Reverse Cumulative Curve
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SBIR	Central Randomization System on Internet
SOP	Standard Operating Procedure
T	Tetanus
TT	Tetanus Toxoid
TVC	Total Vaccinated Cohort

GLOSSARY OF TERMS

According-To-Protocol:	Included all subjects enrolled in the study who met the criteria defined in the protocol for the considered analysis (reactogenicity or immunogenicity).
Adverse event:	Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An adverse event was therefore any unfavourable 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.
Eligible:	Qualified for enrolment into the study based upon strict adherence to inclusion/exclusion criteria.
Epoch:	An epoch is a self-contained set of consecutive timepoints or a single timepoint from a single protocol. Self-contained means that data collected for all subjects at all timepoints within that epoch allowed to draw a complete conclusion to define or precise the targeted label of the product. Typical examples of epochs are primary vaccinations, boosters, yearly immunogenicity follow-ups, and surveillance periods for efficacy or safety.
Investigational vaccine/product: **(Synonym of Investigational Medicinal Product)**	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Legally Acceptable Representative:	ICH GCP defines Legally Accepted Representative as an individual or juridical or other body authorised under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Randomization:	Process of random attribution of treatment to subjects in order to reduce bias of selection.

Solicited adverse event:	Adverse events recorded as endpoints in the clinical study. The presence/occurrence/intensity of these events was 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 was contacted in order to participate or participates in the clinical study, either as a recipient of the product(s) or as a control.
Total Vaccinated Cohort:	The Total vaccinated cohort included all subjects with at least one study vaccine administration documented.
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 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 was reported as an unsolicited adverse event.

TRADEMARKS

The following trademarks are used in the present report.

In the body of the Study Report, (including the synopsis), the names of the vaccines have been written without the superscript symbol ™ or ® and in *italics*.

Trademarks of the GlaxoSmithKline group of companies	Generic description
Engerix-B®	Hepatitis B vaccine (recombinant)
Hiberix™	*Haemophilus* b conjugate vaccine (tetanus toxoid conjugate)
Infanrix®	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed
Infanrix hexa™	Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine
Pediarix®	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine
Rotarix®	Rotavirus Vaccine, Live, Oral

Trademarks not owned by the GlaxoSmithKline group of companies	Generic description
ActHIB® (Sanofi Pasteur SA)	*Haemophilus* type b conjugate vaccine (tetanus toxoid conjugate)
Pentacel® (Sanofi Pasteur SA)	Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus* b conjugate (tetanus toxoid conjugate)
Prevnar13® (Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)	Pneumoccocal 13-valent conjugate vaccine (diphtheria CRM_{197} protein)

ABRIDGED INTERIM REPORT BODY

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Study No.: 117119 (DTPA-HBV-IPV-135)

Title of the study: A Phase III, randomized, open-label, controlled, multi-center study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Investigators and study centers: This study was conducted by 32 investigators at multiple centers in the United States of America.

Ethics: The study protocol, amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national IRB.
Overall this study was to be 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/or preventive actions where possible were taken.
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. Electronic Case report forms (eCRFs) were provided for each subject's data to be recorded.
Hepatitis B vaccination history of the subjects, their eligibility criteria and confirmation on Informed Consent Form (ICF) sign off was used in order to ensure the subject's entry and/or randomization in the in the Randomization System on Internet (SBIR). However, two subjects (subject numbers PPD and PPD) enrolled at one site PPD were randomized in the SBIR before the subject's parent(s)/LAR(s) signed the ICF. No other study procedure was performed on these subjects before obtaining consent. This deviation did not result in elimination of the subjects from the According to Protocol (ATP) analyses.

Publication (reference): Not published as of 19 October 2015.

Study period: **Study initiation date:** 16-April-2014 **Study completion date:** 31-March-2015 (Visit 4) **Data lock point (Date of database freeze):** 19-June-2015	**Phase:** III

Indication: Active immunization against diphtheria, tetanus, pertussis, infection caused by all known subtypes of hepatitis B virus, poliomyelitis, and invasive disease caused by *Haemophilus influenzae* type B (Hib) in infants.

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Objectives: This abridged report provides all results available at the time of the database freeze (19 June 2015) which include safety data and immunogenicity data against Polyribosyl-Ribitol-Phosphate (PRP) antigen assessed till Visit 4.Objectives not relevant to this report (i.e. data not available at the time of the database freeze) are presented in square brackets.

Primary:

Epoch 001: Primary vaccination

- [To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens {pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)} one month after the third dose of the primary vaccination.
  - Criterion for non-inferiority*: Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) of the GMC ratio [Pedia divided by Hexa] is ≤ 1.5*.]

Secondary:

Epoch 001: Primary vaccination

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to [diphtheria (D), tetanus (T), hepatitis B surface antigen (HBs), pertussis, poliovirus types 1, 2 and 3] and PRP antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa,* of *Pentacel* co-administered with *Engerix-B,* and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events (AEs), new-onset chronic diseases (NOCDs) and serious adverse events (SAEs).

Epoch 002 : Booster vaccination

- [To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB,* in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.]
- [To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel,* in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.]
- [To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.]

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Methodology: This is a phase III, open-label, randomized, controlled, multi-center, single-country study with five parallel groups. The subjects were randomized in a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. The details of the study groups and vaccination schedules are given below:

Epoch 001:

- **Hexa Group:** Subjects in this group received three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - Hexa_1 Group: Subjects received lot A of *Infanrix* hexa,
  - Hexa_2 Group: Subjects received lot B of *Infanrix hexa,*
  - Hexa_3 Group: Subjects received lot C of *Infanrix hexa*.
- **Pedia Group:** Subjects in this group received three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
- **Penta Group**: Subjects in this group received three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

  *Subjects in the Penta Group who received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not have received *Engerix-B* at 4 months of age (Visit 2).

Epoch 002:

- **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
- **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
- **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The study is open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered.

Sampling schedule: One month after the third dose of primary vaccination (Visit 4), a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) was collected.

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

Vaccination schedule /site:

Three doses of *Infanrix hexa* vaccine (lyophilized Hib vaccine reconstituted with DTPA-HBV-IPV liquid vaccine) were administered at 2, 4 and 6 months of age as an intramuscular (IM) injection in the right thigh.

Vaccine composition /dose /lot number: One dose (0.5 mL) of *Infanrix hexa* contained DT≥30IU; TT≥40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+ and PRP=10µG; TT~=25µG Aluminum as salts=120 µg.
Lot numbers used were:
AHIBC950C (Hib) + AC21VB448C (Pediarix)
AHIBC907D (Hib) + AC21B514A (Pediarix)
AHIBC954A (Hib) + AC21B510B (Pediarix)

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Reference vaccine /Comparator, dose and mode of administration, lot no.:
Primary Vaccines

Pediarix:
Vaccination schedule /site: Three doses of *Pediarix* were administered at 2, 4 and 6 months of age as an IM injection in the right thigh.
Vaccine composition /dose /lot number: One dose (0.5 mL) of *Pediarix* contained DT≥30IU; TT≥40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+.
Lot number used for *Pediarix* was AC21VB448C.

ActHIB:
Vaccination schedule /site: Three doses of *ActHIB* were administered at 2, 4 and 6 months of age as an IM injection in the upper left thigh.
Vaccine composition /dose /lot number: One dose (0.5 mL) of *ActHIB* contained Hib=10µg, TT=24µg and NaCl=60mM.
Lot numbers used for *ActHIB* were UH971AA and UH954AB.

Pentacel:
Vaccination schedule /site: Three doses of *Pentacel* were administered at 2, 4 and 6 months of age as an IM injection in right thigh.
Vaccine composition /dose /lot number: One dose (0.5 mL) of *Pentacel* contained PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg, TT=24µg; $AlPO_4$=330µg Al3+.
Lot numbers used for *Pentacel* were C4574AA, C4517BA, C4507AA and C4557AA.

***Engerix-B*:**
Vaccination schedule /site: Two-three doses of *Engerix-B* were administered at 2, 4 (second dose was not given if subjects had received a dose prior to the study) and 6 months of age as an IM injection in the upper left thigh.
Vaccine composition /dose /lot number: One dose (0.5 mL) of *Engerix-B* contained HBsAg=10µg; $Al(OH)_3$=250µg Al3+.
Lot number used for *Engerix-B* was AHBVC253A.

Prevnar13:
Vaccination schedule /site: Three doses of *Prevnar13* were administered at 2, 4 and 6 months of age as an IM injection in the lower left thigh.
Vaccine composition /dose /lot number: One dose (0.5 mL) of *Prevnar13* contained PS1=2.2µg CRM197; PS3=2.2µg CRM197; PS4=2.2µg CRM197; PS5=2.2µg CRM197; PS6A=2.2µg CRM197; PS6B=4.4µg CRM197; PS7F=2.2µg CRM197; PS9V=2.2µg CRM197; PS14=2.2µg CRM197; PS18C=2.2µg CRM197; PS19A=2.2µg CRM197; PS19F=2.2µg CRM197; PS23F=2.2µg CRM197; $AlPO_4$=125µg Al3+.
Lot number used for *Prevnar13* was H39264.

***Rotarix*:**
Vaccination schedule /site: Two doses of *Rotarix* were given orally at 2 and 4 months of age.
Vaccine composition /dose /lot number: One dose (1.0 mL) of Rotarix contained HRV RIX4144=$10^{6.0}$ $CCID_{50}$ (median Cell Culture Infective Dose) and $CaCO_3$=60µg.
Lot numbers used for *Rotarix* were AROTA291D (HRV) and AD05VA833A (CaCO3).

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Study Population: Healthy males or females between, and including, 6 and 12 weeks of age at the time of the first vaccination were included in the study. The subjects were excluded from the study if they had any previous or intercurrent diphtheria, tetanus, pertussis, polio, hepatitis B, Hib, rotavirus and/or pneumococcal vaccination or disease, with the exception of hepatitis B vaccination at birth. Written informed consent was to be obtained from the parents/LAR(s) of the subject before entry into the study.

Duration of treatment: The intended duration of the study will be approximately 14-17 months for each subject.

Criteria for evaluations: For this abridged report, only the endpoints pertaining to the results for safety and immune response against PRP antigen up to one month after the third dose of primary vaccination were assessed descriptively. Endpoints not relevant to this report are presented within square brackets.

Primary endpoint: ***Epoch 001 (Primary vaccination)***

- [Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.]

Secondary endpoints: ***Epoch 001 (Primary vaccination)***

- [Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).]
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - [Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3] and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0-Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0-Day 3) after each vaccination.
- Unsolicited AEs.
  - Occurrence of unsolicited AEs within 31 days (Day 0-Day 30) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification.
- Specific AEs.
  - Occurrence of specific AEs, i.e., NOCDs (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.
- SAEs.
  - Occurrence of SAEs from Day 0 up to six months post primary vaccination.

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Epoch 002 (Booster vaccination)

- [Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti-PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).]
- [Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti-PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1.0 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1.0 IU/mL one month after the booster dose (Dose 4).]
- [Immunogenicity with respect to the study vaccine *Infanrix.*
  - Anti-D, anti-T, anti-PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1.0 IU/mL one month after the booster dose (Dose 4).]
- [Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix.*
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1.0 µg/mL one month after the booster dose (Dose 4).]
- [Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0-Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0-Day 3) after booster vaccination.]
- [Unsolicited AEs.
  - Occurrence of unsolicited AEs within 31 days (Day 0-Day 30) after booster vaccination, according to the MedDRA classification.]
- [Specific AEs.
  - Occurrence of specific AEs, i.e., NOCDs (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.]
- [SAEs.
  - Occurrence of SAEs from the booster dose up to one month after the booster vaccination.]

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Statistical methods: Analyses were performed as stated in the protocol and Statistical analysis plan (SAP).

For this abridged report, the analyses pertaining to immune response to *Infanrix hexa, ActHIB and Pentacel* in terms of antibody titers against PRP antigens (one month after the third dose of the primary vaccination), and safety and reactogenicity to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B* in terms of solicited local symptoms, solicited general symptoms, unsolicited AEs, NOCDs and SAEs are described below:

Analysis of demographics

Demographic characteristics (i.e. age {weeks}, gender, geographical ancestry, height in length {cm}, weight {kg} at first dose) and withdrawal status were summarized by group using descriptive statistics. Mean, median and standard error were provided for continuous data such as age.

Analysis of immunogenicity

The primary analysis of immunogenicity was performed on the Primary ATP cohort for immunogenicity. Within group assessment was performed for each group, one month post-dose 3 for each assay for which a serological result was available:

- Seropositivity and seroprotection rates with exact 95% CIs were calculated.
- GMCs/GMTs with 95% CIs were tabulated.

For each antigen, antibody concentration or titer distribution one month post-vaccination were tabulated and displayed using reverse cumulative curves (RCCs).

Analysis of safety

The primary analysis was based on the Primary Total Vaccinated cohort (TVC)

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period were tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period were tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses with local AEs (solicited and unsolicited) were calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered).
- The percentage of subjects/doses with each individual solicited local and general AE during the 4-day follow-up period were tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

The exact 95% CIs were calculated assuming independence between doses.

- All computations mentioned above were done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit.
- For fever, analyses were performed by 0.5°C increments.
- The verbatim reports of unsolicited AEs were reviewed by a clinical research development lead (CRDL) and the signs and symptoms were coded according to MedDRA. Every verbatim term was matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI was tabulated by Preferred Term. Similar tabulations were done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

- Subjects who experienced AEs of specific interest (i.e. NOCDs such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination were tabulated by Preferred Term.
- Subjects who experienced at least one SAE reported before the database lock for the Epoch 001 analysis with an onset date in the Epoch 001 were reported and the SAE was described in detail.

Data Quality assurance at study level: To ensure that the study procedures conformed across all investigator sites, the protocol, eCRF and safety reporting were reviewed with the investigators and his/her/their personnel responsible for the conduct of the study by the Company representatives prior to study start. A multi-investigator meeting 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 eCRF completion. All procedures were performed according to methodologies detailed in GlaxoSmithKline Biologicals Standard Operating Procedures (SOPs).
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.
We are communicating in this interim report to Center for Biologics Evaluation and Research (CBER) that, since the data were generated with a PRP serology assay not yet fully validated, there is a possibility, though unlikely, that the PRP immunogenicity results might change.

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

Study population (TVC):

Number of subjects	**Hexa group**	**Pedia group**	**Penta group**
Planned, N	195	195	195
Randomized, N (TVC)	195	194	196
Completed, n (%)	178 (91.3)	182 (93.8)	178 (90.8)
Demographics	**Hexa group**	**Pedia group**	**Penta group**
N (TVC)	195	194	196
Females: Males	101:94	80:114	95:101
Mean Age, weeks (SD)	8.5 (1.0)	8.6 (1.1)	8.6 (1.1)
Median Age, weeks (minimum, maximum)	8 (6, 12)	9 (6, 12)	8 (6, 12)
White-Caucasian / European Heritage, n (%)	118 (60.5)	128 (66.0)	115 (58.7)
Other, n (%)	29 (14.9)	27 (13.9)	32 (16.3)
American Indian or Alaskan Native, n (%)	15 (7.7)	15 (7.7)	17 (8.7)

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age; Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age; Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age; N = total number of subjects; n/% = number/percentage of subjects; SD = standard deviation

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

Summary:

Immunogenicity results:

Primary Objective: The primary objective was not evaluated at the time of this interim analysis.

Secondary Objective: Descriptive immunogenicity analysis pertaining to anti-PRP antibody concentrations was performed on the Primary ATP cohort for immunogenicity**.** Table 1 presents the results of the ATP analysis.

- One month after primary vaccination, 94.0% of the subjects in the Hexa group, 98.7% of the subjects in the Pedia group and 98.7% of the subjects in the Penta group had anti-PRP antibody concentrations
  ≥ 0.15 µg/ml.
- One month after primary vaccination, 55.7% of the subjects in the Hexa group, 94.1% of the subjects in the Pedia group and 82.4% of the subjects in the Penta group had anti-PRP antibody concentrations
  ≥ 1.0 µg/ml.

Table 1: Number and percentage of subjects with anti-PRP antibody concentration equal or above 0.15 µg/ml and 1.0 µg/ml and geometric mean concentration (GMC), one month after primary vaccination (Primary ATP cohort for immunogenicity)

				≥ 0.15 µg/ml				≥ 1 µg/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP antibody	Hexa group	PIII(M5)	149	140	94.0	88.8	97.2	83	55.7	47.3	63.8	1.4	1.1	1.7
	Pedia group	PIII(M5)	153	151	98.7	95.4	99.8	144	94.1	89.1	97.3	10.3	8.1	13.1
	Penta group	PIII(M5)	153	151	98.7	95.4	99.8	126	82.4	75.4	88.0	6.5	4.9	8.5

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age; Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age; Penta group = Subjects who received *Pentacel*, *Engerix* and; *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age; 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

Safety results: The safety analysis was performed on the Primary TVC.

Solicited local symptoms: During the 4-day (Days 0-3) post-vaccination period, injection site pain was the most frequently reported solicited local symptom, reported for 67.9%, 82.0% and 79.8% of the subjects in the Hexa, Pedia and Penta groups, respectively. Pain was also the most frequently reported Grade 3 solicited local symptom, reported for 4.3% of the subjects in the Hexa group, 18.0% of the subjects in the Pedia group and 11.7% of the subjects in the Penta group.

Solicited general symptoms: During the 4-day (Days 0-3) post-vaccination period, irritability/fussiness was the most frequently reported solicited general symptom, reported for 87.7%, 96.3% and 94.1% of the subjects in the Hexa, Pedia and Penta groups, respectively. It was also the most frequently reported Grade 3 solicited general symptom, reported for 9.6%, 18.5% and 16.0% of the subjects in the three groups. Grade 3 fever (> 40.0° C axillary temperature) was reported for 1.1% of the subjects in the Pedia group and for none of the subjects in the Hexa and Penta groups.

Unsolicited symptoms: During the 31-day (Days 0-30) post-vaccination period, at least one unsolicited symptom was reported for 56.9%, 55.7% and 49.0% of the subjects in the Hexa, Pedia and Penta groups, respectively. The most frequently reported unsolicited symptom was upper respiratory tract infection, which was reported for 14.9%, 11.9% and 13.3% of the subjects in the Hexa, Pedia and Penta groups, respectively.

Name of company: GlaxoSmithKline Biologicals, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa*	**Name of active substance:** Diphtheria toxoid (DT), tetanus toxoid (TT), pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), recombinant hepatitis B surface antigen (HBs), poliovirus types 1, 2, 3 and polyribosyl-ribitol-phosphate (PRP).

New onset of chronic diseases (NOCD): At least one NOCD was reported for four subjects (2.1%) in the Hexa group, two subjects (1.0%) in the Pedia group and three subjects (1.5%) in the Penta group up to the data lock point of 19 June 2015. The most frequently reported NOCD was atopic dermatitis, reported for two subjects (1.0%), each, in the Hexa and Penta groups. Bronchial hyperactivity was reported for two subjects (1.0%) in the Hexa group.

Serious adverse events (SAEs): SAEs were reported for seven subjects (3.6%) each in the Hexa and Penta groups and one subject (0.5%) in the Pedia group up to the data lock point of 19 June 2015. Three SAEs were reported in two subjects in the Hexa group that were considered by the investigator to be causally related to the vaccination. Lethargy was reported for one subject (Subject number PP). The subject was hospitalized and the event was resolved on the same day. The subject was withdrawn from the study due to this event. A moderate Grade 2 apparent life threatening event and mild Grade 1 leukocytosis was reported for another subject (Subject number PP) which led to the hospitalization. Both the events were resolved one day after primary vaccination. No fatal events were reported during the study.

Withdrawals due to AEs /SAEs: One subject in the Hexa group withdrew due to an SAE (lethargy) and one in the Penta group withdrew due to a non-serious AE (seizure). In the context of this interim analysis, withdrawal is defined as subjects not having attended Visit 4.

Conclusions:

- One month post primary vaccination, 94.0% of the subjects in the Hexa group and 98.7% of the subjects in the Pedia and Penta groups, had anti-PRP antibody concentrations ≥ 0.15 µg/ml.
- One month post primary vaccination, 55.7% of the subjects in the Hexa group, 94.1% of the subjects in the Pedia group and 82.4% of the subjects in the Penta group had anti-PRP antibody concentrations ≥ 1 µg/ml.
- During the 31-day period following primary vaccination, at least one unsolicited symptom was reported for 111 subjects (56.9%) in the Hexa group, 108 subjects (55.7%) in the Pedia group and 96 subjects (49.0%) in the Penta group.
- During the primary phase of the study (up to the data lock point of 19 June 2015), SAEs were reported for seven subjects each in the Hexa and Penta groups and one subject in the Pedia group. Three SAEs reported for two subjects in the Hexa group (lethargy in one subject and apparent life threatening event along with leukocytosis in the other subject) were considered by the investigator to be causally related to the vaccination. No fatal events were reported during the study.

Date of report: Final:19-October-2015

Statistical Analysis Plan

Study alias & e-track number(s): DTPA-HBV-IPV-135 (117119)

Detailed Title:	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age
SAP version	***Version 2 (Version 1: 10-Mar-2015)***
SAP date	***20-May-2015***
Scope:	All data pertaining to the above study.
Co-ordinating author:	PPD
Other author(s):	
Adhoc reviewers:	PPD (Regulatory representative) , PPD (Safety representative)
Approved by:	PPD (Clinical Research and Development Lead), PPD (Lead Statistician), PPD (Scientific Writer)

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LIST OF ABBREVIATIONS

AE	Adverse event
ANCOVA	Analysis of Co-variance
ANOVA	Analysis of Variance
ATP	According-To-Protocol
CI	Confidence Interval
CSR	Clinical Study Report
D	Diphtheria
EL.U/ml	ELISA unit per milliliter
ELISA	Enzyme-linked immunosorbent assay
Eli Type	Internal GSK database code for type of elimination code
ESFU	Extended Safety Follow-up
FHA	Filamentous hemagglutinin
GMC	Geometric mean antibody concentration
GMT	Geometric mean antibody titer
GSK	GlaxoSmithKline
HBs	Hepatitis B surface antigen
HHE	Hypotonic Hyporesponsive Episode
Hib	Haemophilus influenzae (H. influenzae) type b
IU/ml	International units per milliliter
LL	Lower Limit of the confidence interval
MedDRA	Medical Dictionary for Regulatory Activities
NOCD	New Onset of Chronic Disease
PRN	Pertactin
PRP	Polyribosyl-Ribitol-Phosphate: polysaccharide component of the Hib bacterium capsule
PT	Pertussis toxoid: a secreted exotoxin of the *Bordetella pertussis* bacterium
RCC	Reverse Cumulative Curve

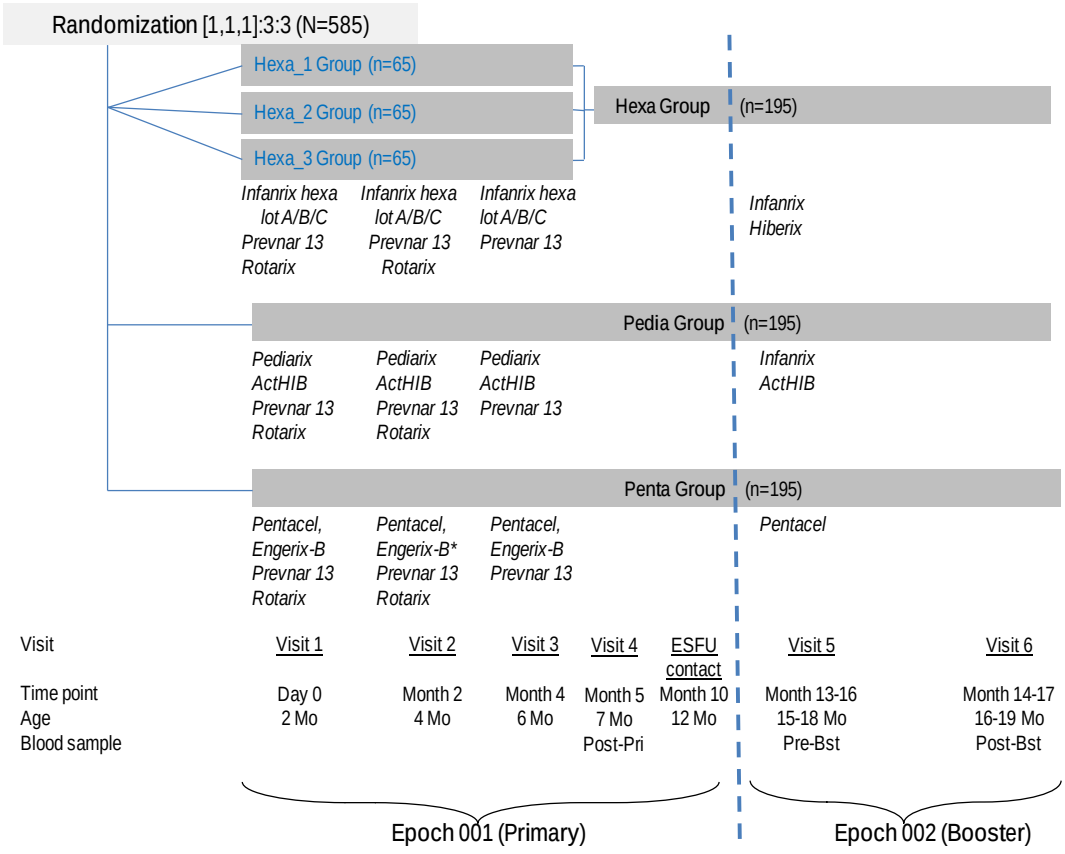
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SBIR	GSK Biological's Internet Randomization System
SD	Standard Deviation
SR	Study Report
T	Tetanus
TFL	Tables Figures and Listing template annexed to SAP
TVC	Total Vaccinated cohort
UL	Upper Limit of the confidence interval

1. DOCUMENT HISTORY

Date	Description	Protocol Version
10-Mar-2015	Version 1	Protocol Amendment 1 - 18-SEP-2014
06-May-2015	*Version 2. The SAP has been updated to incorporate the changes in the sequence of analysis as per the protocol amendment 2*	*Protocol Amendment 2 - 17-Apr-2015*

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, annex (-es) (called TFL) describing the flow and format of tables, figures and listings to be annexed to the SR. For this study, there is only one annex TFL.

2. STUDY DESIGN



N = number of subjects in the study; n = number of subjects in each group; Mo = months
Visit 3 should be conducted at least 8 weeks after Visit 2, with subjects at least 24 weeks of age, in order to comply with US recommendations on hepatitis B dosing
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002
* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group
ESFU = Extended safety follow-up

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups

- Duration of the study: The intended duration of the study per subject is approximately 14-17 months.

  - **Epoch 001:** Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10),

  - **Epoch 002:** Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).

- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel.*

- Vaccination schedules:

  Epoch 001

  - **Hexa Group:** Subjects in this group will receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
    - Hexa_1 Group: Subjects will receive lot A of *Infanrix hexa,*
    - Hexa_2 Group: Subjects will receive lot B of *Infanrix hexa*
    - Hexa_3 Group: Subjects will receive lot C of *Infanrix hexa*.
  - **Pedia Group:** Subjects in this group will receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - **Penta Group**: Subjects in this group will receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

*Subjects in the Penta Group who have received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not receive Engerix-B at 4 months of age (Visit 2).

Epoch 002

- **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
- **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
- **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls will be given in this study at 15-18 months of age, the fourth dose of *Prevnar13* will not be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) will be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

- As the analyses will be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups will be pooled together for the analysis and will be called the Hexa group.

- Treatment allocation: The subjects will be randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This will be done at study entry using GSK Biologicals' central randomization system on internet (SBIR).

- Blinding: The study is open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing will be blinded to the treatment, and codes will be used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

- Sampling schedule: Blood samples will be drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.

- Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) will be collected.

- Type of study: Self-contained.

The following group names will be used for the statistical analyses for Epoch 001:

Group order in tables	Group label in tables	Group definition for footnote	Pooled Groups label in tables	Pooled definition for footnote
1	Hexa_1 group	Subjects who received three doses of *Infanrix Hexa* from lot A and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age	Hexa group	Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
2	Hexa_2 group	Subjects who received three doses of *Infanrix Hexa* from lot B and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age	Hexa group	Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
3	Hexa_3 group	Subjects who received three doses of *Infanrix Hexa* from lot C and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age	Hexa group	Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
4	Pedia group	Subjects who received *Pediarix*, *ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age	Pedia group	Subjects who received *Pediarix*, *ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
5	Penta group	Subjects who received *Pentacel*, *Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age	Penta group	Subjects who received *Pentacel*, *Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

The following group names will be used for the statistical analyses for Epoch 002:

Group order in tables	Group label in tables	Group definition for footnote

1	Hexa group	Subjects who received a primary dose of *Infanrix Hexa* and booster dose of *Infanrix and Hiberix* vaccines at 15-18 months of age
2	Pedia group	Subjects who received a primary dose of *Pediarix* and booster dose of *Infanrix and ActHIB* vaccines at 15-18 months of age
3	Penta group	Subjects who received a primary dose of *Pentacel* and booster dose of *Pentacel* vaccine at 15-18 months of age

3. OBJECTIVES

3.1. Primary objective

3.1.1. Epoch 001 (Primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] is ≤ 1.5.

3.2. Secondary objectives

3.2.1. Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D, T, HBs, pertussis, poliovirus types 1, 2 and 3 and PRP antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa*, of *Pentacel* co-administered with *Engerix-B*, and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic diseases (NOCDs) and serious adverse events.

3.2.2. Epoch 002 (Booster vaccination)

- To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB*, in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.
- To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel*, in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.

- To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.

4. ENDPOINTS

4.1. Primary endpoint

4.1.1. Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

4.2. Secondary endpoints

4.2.1. Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa*, *Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B.*
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.

- Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the **Med**ical **D**ictionary for **R**egulatory **A**ctivities (MedDRA) classification.

- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.

- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

4.2.2. Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).

- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).

- Immunogenicity with respect to the study vaccine *Infanrix.*
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).

- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix.*

- Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
- Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4)

- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

5. STUDY POPULATION

Six cohorts are defined for the purpose of the analysis:

- Primary Total Vaccinated cohort
- Primary ATP cohort for analysis of safety
- Primary ATP cohort for analysis of immunogenicity
- Booster Total Vaccinated cohort
- Booster ATP cohort for analysis of safety
- Booster ATP cohort for analysis of immunogenicity

5.1.1. Primary Total vaccinated cohort

The Primary Total Vaccinated cohort (TVC) will include all vaccinated subjects for whom data are available.

- A safety analysis based on the Primary TVC will include all subjects with at least one vaccine administration documented.
- An immunogenicity analysis based on the Primary TVC will include all vaccinated subjects for whom data concerning at least one immunogenicity endpoint measure is available.

5.1.2. Primary ATP cohort for analysis of safety

The Primary ATP cohort for safety will consist of all subjects from the Primary TVC who complied with the protocol up to the end of Epoch 001, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received all planned study vaccines for each completed vaccination visit in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;
- who did not receive a product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2 of the protocol.

Note that for the purpose of ATP cohort definition, the Epoch 001 ends at Visit 4.

Adherence to the interval related to ESFU phone contact will not be taken into account for inclusion in ATP cohort for safety.

5.1.3. Primary ATP cohort for analysis of immunogenicity

The Primary ATP cohort for immunogenicity will consist of all subjects from the Primary ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 of the protocol for the definition of the intervals) up to the post-dose 3 blood sample and had immunogenicity results for the post-dose 3 blood sample. The analysis will be performed per treatment (first dose) actually administered.

More specifically, the analysis post-dose 3 based on the ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 3 as per the vaccination schedule;

- for whom administration site and route of study vaccines up to dose 3 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2 of the protocol
- who did not present with a medical condition before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.8 of the protocol.
- who comply with the post-dose 3 blood sample schedule, i.e. 21-48 days post-dose 3.
- who were not administered a vaccine not foreseen by the study protocol before the corresponding post-vaccination blood sample.
- who have immunogenicity results post-dose 3.

5.1.4. Booster Total vaccinated cohort

The Booster TVC will include all subjects from primary TVC that received the booster vaccine dose.

- For the Booster-TVC analysis of safety, this will include all subjects with booster vaccine administration documented.
- For the Booster-TVC analysis of immunogenicity, this will include vaccinated subjects for whom data concerning immunogenicity endpoint measures are available.

5.1.5. Booster ATP cohort for analysis of safety

The Booster ATP cohort for safety will consist of all subjects from the Booster TVC who complied with the protocol up to the end of Epoch 002, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received the planned booster dose at 15-18 months of age;
- who received 3 doses in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;
- who did not receive a product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis as listed in Section 6.7.2 of the protocol.

5.1.6. Booster ATP cohort for analysis of immunogenicity

The Booster ATP cohort for immunogenicity will consist of all subjects from the Booster ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 of the protocol for the definition of the intervals) up to the post-dose 4 blood sample and had immunogenicity results for the post-dose 4 blood sample.

More specifically, the analysis pre- and post-dose 4 based on the Booster ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 4 as per the vaccination schedule;
- for whom administration site and route of the study vaccines up to dose 4 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.7.2 of the protocol);
- who did not present with a medical condition before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.8 of the protocol);
- who comply with the booster vaccination schedule at 15-18 months of age and with the post-dose 4 blood sample schedule i.e. 21-48 days for post-dose 4;
- who have immunogenicity results post-dose 4.

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
Primary ATP cohort for analysis for safety	1030-2100	PR
Primary ATP cohort for analysis for immunogenicity	1030-2100	PR
Booster ATP cohort for analysis for safety	1030-2100	BO
Booster ATP cohort for analysis for immunogenicity	1030-2100	BO

6. STATISTICAL METHODS

6.1. Final analysis of the Epoch 001

6.1.1. Analysis of demographics

Demographic characteristics (age [weeks], gender, geographical ancestry, height in length [cm], weight [kg] at first dose, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status will be summarised by group using descriptive statistics:

Frequency tables will be generated for categorical variables such as center;

Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects enrolled among the study sites will be tabulated as a whole and per group.

6.1.2. Analysis of immunogenicity

The primary analysis will be based on the Primary ATP cohort for immunogenicity. An analysis on the Primary Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point, more than 5% of the vaccinated subjects with immunological data post-dose 3 are excluded from the Primary ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

6.1.2.1. Within group assessment

For each group, one month post-dose 3 and for each assay for which a serological result is available:

- Seropositivity and seroprotection rates with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.
- For each antigen, antibody concentration or titer distribution one month post-vaccination will be tabulated and displayed using reverse cumulative curves (RCCs).

All the above within group analysis for Epoch 001 except the reverse cumulative curves will also be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and by Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

6.1.2.2. Between group assessment

At one month post-dose 3,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seropositivity/ seroprotection rates will be computed for each antigen except for group difference (Penta group minus Hexa group) in the seroprotection/ seropositivity rates for pertussis antigens.
- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) will be computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers except for GMC ratio (Penta group divided by Hexa group) for pertussis antigens. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis b at birth vaccine dose status will also be used as regressor leading to an Analysis of Co-variance (ANCOVA) model. The model will include the data from the 2 groups compared. For analysis purpose, we will consider DTP vaccination of the mother during pregnancy as continuous variable.

6.1.2.3. Interpretation of analyses

Except for analyses addressing criteria specified in the primary objective, comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

6.1.3. Analysis of safety

The primary analysis will be based on the primary Total Vaccinated cohort. If, in any vaccine group and at any time point of the Epoch 001, the percentage of vaccinated subjects excluded from the primary ATP cohort for safety is more than 5%, a second analysis based on the primary ATP cohort for safety will be performed to complement the primary Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period will be tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period will be tabulated over the primary vaccination period, with exact 95% CI.

- The percentage of subjects/doses with local AEs (solicited and unsolicited) will be calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered) during the 4-day follow-up period will be tabulated over the primary vaccination period, with exact 95% CI..
- The percentage of subjects/doses reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

  The exact 95% CIs will be calculated assuming independence between doses.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects reporting each individual solicited local (any grade, grade 2, grade 3, medical advice) during the 4-day follow-up period will also be tabulated at each injection site for *Infanrix Hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines with exact 95% CI after each vaccine dose and overall where the same row on the table is used for all.vaccines given at the same site across the three study groups (e.g. *Infanrix Hexa*, *Pentacel* and *Pediarix* together are in one row and *ActHIB* and *Engerix-B* together are in one row).
- For fever, analyses will be performed by 0.5°C increments.
- The percentage of subjects/doses with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated after each dose and over the Epoch 001.
- The verbatim reports of unsolicited AEs will be reviewed by a Clinical Research and Development Lead and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.
- Subjects who experienced AEs of specific interest (i.e. convulsions, Hypotonic Hyporesponsive Episode) during 31 days with exact 95% CI will be tabulated by

Preferred Term. Similar tabulations will be done for AEs considered related to vaccination. Subjects who experienced AEs of specific interest will also be described in detail.

- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE reported before the database lock for the Epoch 001 analysis with an onset date in the Epoch 001 will be reported and the SAE will be described in detail.

All the above safety and reactogenicity analysis for Epoch 001 will also be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry) except the percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period.

6.2. Final analysis of the Epoch 002

6.2.1. Analysis of demographics/baseline characteristics

Demographic characteristics (age [months] at Visit 5, gender, geographical ancestry, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status will be summarized by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as race/ethnicity;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects vaccinated at Visit 5 among the study sites will be tabulated as a whole and per group.

For enrolled subjects that do not participate in the Epoch 002, the reason for not participating will be summarized.

6.2.2. Analysis of immunogenicity

The primary analysis will be based on the booster ATP cohort for immunogenicity. An analysis on the booster Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point of the Epoch 002, more than 5% of the vaccinated subjects with immunological data are excluded from the booster ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

6.2.2.1. Within group assessment

For each group, prior to the booster dose and one month post-booster dose and for each assay, for which a serological result is available:

- Seropositivity and seroprotection rates and booster response rates for pertussis with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.
- For each antigen, antibody concentration or titer distribution before and one month Post-booster (when available) will be tabulated and displayed using RCCs.

All the above within group analysis for Epoch 002 except the reverse cumulative curves will also be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

6.2.2.2. Between group assessment

At pre-booster and at one month post-booster,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection/ seropositivity rates will be computed for each antigen except for group difference (Penta group minus Hexa group) in the seroprotection/ seropositivity rates for pertussis antigens.
- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) will be computed using an ANOVA model on the logarithm-transformed concentrations/titers except for GMC ratio (Penta group divided by Hexa group) for pertussis antigens. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA). For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor leading to an ANCOVA model. The model will include the data from the 2 groups compared.

6.2.2.3. Interpretation of analyses

In Epoch 002, all comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These

descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

6.2.3. Analysis of safety

The primary analysis for the Epoch 002 will be based on the booster Total Vaccinated cohort and will only look at the booster dose. If, in any vaccine group, the percentage of vaccinated subjects excluded from the booster ATP cohort for safety is more than 5%, a second analysis based on the booster ATP cohort for safety will be performed to complement the booster Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose, will be tabulated with exact 95% CI for each group.
- The incidence of local AEs (solicited and unsolicited) will be calculated at each injection site as well as overall (all sites considered) for each group during the 4-day (Days 0-3) follow-up period after the booster dose.
- The percentage of subjects reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated with its exact 95% CI for each group.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects reporting each individual solicited local (any grade, grade 2, grade 3, medical advice) during the 4-day follow-up period will also be tabulated at each injection site for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines with exact 95% CI after each vaccine dose and overall where vaccine with same vaccine site is considered together (e.g. *Infanrix* and *Pentacel* together are on one row and *ActHIB* and *Hiberix* together are on one row).
- For fever, analyses will be performed by 0.5°C increments.
- The percentage of subjects with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated for each group.
- The verbatim reports of unsolicited AEs will be reviewed by a Clinical Research and Development Lead and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects with unsolicited AEs occurring within 31 days following the booster dose with its exact 95% CI will be tabulated by Preferred Term. Similar

tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Additionally,

- Any large injection site reaction (defined as a swelling with a diameter > 50 mm, noticeable diffuse swelling or increase in limb circumference of greater than 50 mm) reported within 4 days (Days 0-3) following the booster dose will be described in detail.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from booster dose up to one month after booster vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE from the booster dose to study end will be reported and the SAEs will be described in detail.

All the above safety and reactogenicity analysis for Epoch 002 will also be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestry, namely White Caucasian versus any other geographical ancestry) except percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose.

7. STATISTICAL CALCULATIONS

7.1. Derived and transformed data

7.1.1. Demography

For a given subject and a given demographic variable, missing measurement will not be replaced excepting for age.

Age will be calculated as the number of years between the date of birth and the date of vaccination.

To ensure that the collection of date of birth will not jeopardise the privacy of personally identifiable information, only a partial date of birth (MMYYYY) will be collected.

Therefore, the 15th of the month will be used to replace the missing date. In case the day and the months are missing, the date will be replaced by the June 30th of the year.

7.1.2. ImmunogenicityA seronegative subject is a subject whose antibody concentration/titer is below the assay cut-off.

- A seropositive subject is a subject whose antibody concentration/titer is greater than or equal to the assay cut-off defined in Table 7 of the protocol.

  Note: Due to ongoing re-validation of all assays, these cut-offs may be subject to change.

- A seroprotected subject is a subject whose antibody concentration/titer is greater than or equal to the level defining clinical protection. The following seroprotection thresholds are applicable:
  - Anti-diphtheria antibody concentrations ≥ 0.1 IU/mL.
  - Anti-tetanus antibody concentrations ≥ 0.1 IU/mL.
  - Anti-HBs antibody concentrations ≥ 10 mIU/mL.
  - Anti-poliovirus types 1, 2 and 3 antibody titers ≥ 8.
  - Anti-PRP antibody concentrations ≥ 0.15 µg/mL.
- Other cut-offs to be considered:
  - Anti-PRP antibody concentrations ≥ 1.0 µg/mL.
  - Anti-diphtheria and anti-tetanus antibody concentrations ≥ 1.0 IU/mL
- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies are defined as:
  - initially seronegative subjects (pre-booster antibody concentration below cut-off: < 5 ELISA EL.U/mL) with an increase of at least four times the cut-off one month after vaccination (post-booster antibody concentration ≥20 EL.U/mL), and
  - initially seropositive subjects with pre-booster antibody concentration ≥ 5 EL.U./mL and < 20 EL.U/mL with an increase of at least four times the pre-booster antibody concentration one month after vaccination, and,
  - For initially seropositive subjects with pre-booster antibody concentration ≥ 20 EL.U/mL with an increase of at least two times the pre-booster antibody concentration, one month after vaccination.

  Note: Due to ongoing re-validation of pertussis assays, the definition of booster response may be subject to change.
- The GMC/GMT calculations will be performed by taking the anti-log of the mean of the $\log_{10}$ titer/ concentration transformations. Antibody titers/concentrations below the cut-off of the assay will be given an arbitrary value of half the cut-off for the purpose of GMC/GMT calculation.

- Handling of missing data - For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements will not be replaced.

7.1.3. Safety/reactogenicity:

- For a given subject and the analysis of solicited symptom within 4 days post-vaccination, 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 vaccinated subjects and doses with documented safety data (i.e. symptom screen completed).
- For analysis of unsolicited adverse events, such as serious adverse events or adverse events by primary MedDRA term, and for the analysis of concomitant medications, all vaccinated subjects will be considered. Subjects who did not report the event or the concomitant medication will be considered as subjects without the event or the concomitant medication respectively.
- For analysis of convulsion, the adverse event will be identified by using narrow standard MedDRA query.
- For analysis of convulsion, the adverse event will be identified by using narrow standard MedDRA query.
- For analysis of Hypotonic Hyporesponsive Episode (HHE), the adverse event will be identified by using broad standard MedDRA query.
- For analysis of New Onset of Chronic Illness (NOCI), the adverse event will be identified by using narrow standard MedDRA query.
- For summaries reporting both solicited and unsolicited adverse events, all vaccinated subjects will be considered. Subjects for whom the event will not be reported will be considered as subjects without the event.
- Large injection site reactions are defined as either swelling with a diameter of >50 mm or a >50 mm increase in the circumference of any limb when compared to the baseline (pre-vaccination) measurement, or any diffuse swelling that interferes with or prevents everyday activities (for example, active playing, eating, sleeping).
- For the analysis, temperatures by any route will be coded as follows:

Grade	Temperature
0	< 38.0°C
1	≥ 38.0°C - ≤ 39.0°C
2	> 39.0°C - ≤ 40.0°C
3	> 40.0°C

- The way the percentage of subjects will be derived will depend on the event analysed (see table below for details). As a result, the N value will differ from one table to another.

Event	N used for deriving % per subject for Vaccination phase
Concomitant vaccination	All subjects with study vaccine administered
Solicited general symptom	All subjects with at least one solicited general symptom documented as either present or absent (i.e. symptom screen completed)
Solicited local symptom	All subjects with at least one solicited local symptom documented as either present or absent (i.e. symptom screen completed)
Unsolicited symptom	All subjects with study vaccine administered
Concomitant medication	All subjects with study vaccine administered

7.2. Data presentation description

The following decimal description from the decision rules will be used for the demography, immunogenicity and safety/ reactogenicity.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	SD (age)	1
anti-T	GMC	3
anti-D	GMC	3
anti-PT	GMC	1
anti-PHA	GMC	1
anti-PRN	GMC	1
anti-HBs	GMC	1
anti-PRP	GMC	3
anti-Polio 1	GMT	1
anti-Polio 2	GMT	1
anti-Polio 3	GMT	1
Immunogenicity	Ratio of GMT/C	2
Reactogenicity	Mean, Min, Q1, Median, Q3, Max for duration	1
All summaries	% of count, including LL & UL of CI	1

All summaries	% of difference, including LL & UL of CI	2

7.3. Methodology for computing confidence intervals

- All CI computed will be two-sided 95% CI.
- The exact 95% CIs for a proportion within a group will be based on the method by Clopper [Clopper, 1934*].
- The standardised asymptotic 95% CI for the group difference in proportions will be based on the method 6 described in paper by Newcombe [R Newcombe, 1998, method six**].
- The 95% CI for geometric mean titres/concentrations (GMTs/GMCs) will be obtained within each group separately. The 95% CI for the mean of log-transformed titre/concentration will be first obtained assuming that log-transformed values were normally distributed with unknown variance. The 95% CI for the GMTs/GMCs will be then obtained by exponential-transformation of the 95% CI for the mean of log-transformed titre/concentration.

  The GMC/GMT group ratio will be computed using an ANOVA model on the logarithm10 transformation of the concentrations/titres. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B vaccination at birth vaccine dose status will also be used as regressor leading to an Analysis of Co-variance (ANCOVA) model.

8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

The analyses will be performed stepwise:

1. ***A partial analysis of Epoch 001 up to one month after the third primary vaccine dose will be conducted. This analysis will include the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis will be displayed on GSK clinical trial registry as soon as possible.***
2. ***The final data analysis of the study covering both the epochs will be conducted at the end of the study. All these analyses will be presented in a final clinical study report.***

Following analysis folder will be created in SDD and CARS with given analysis ID to perform analysis and archival of statistical reports

Description	Analysis ID (SDD & CARS sub-folder)	Disclosure	TFL reference
Primary Epoch -Anti-PRP and safety	***E1_01***	***CTRS***	***From TFL Version 1 dated 10-Mar-2015, following tables will be generated for time point - one month post vaccination dose 3.*** • ***Post-Text table section – Table-29, 34, 35, 38, 39.*** • ***CTRS table sections – Table 1-5, 10, 12-15)*** • ***Annex table section – Table 3*** ***Please note that the tables from post text section will be generated with output destination 'ANNEX'.***
Final	***E1_02***	***CTRS, Clinical Study report, Publication***	***TFL***

8.2. Statistical considerations for interim analyses

All analyses will be conducted on final data and therefore no statistical adjustment for interim analyses is required.

9. MAJOR CHANGES FROM PLANNED ANALYSES

Following are the changed in the SAP from protocol:-

- The analysis of percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 31-day (Days 0-30) follow-up period will not be tabulated over the primary vaccination period and also over booster vaccination period, with exact 95% CI. Also the same analysis by gender and geographical ancestry will not be performed.

10. REFERENCE

* Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of binomial. *Biometrika*. 1934;26:404-413

** Robert G. Newcombe, interval estimation for the difference between independent proportions: comparison of eleven methods, *Statist Med.* 1998; 17, 873-890

1. TABLES AND FIGURES

1.1. Study Population

Table 1 Study population Primary Epoch (Primary TVC)

Number of subjects	**Hexa group**	**Pedia group**	**Penta group**
Planned, N	195	195	195
Randomized, N (TVC)	195	194	196
Completed, n (%)	178 (91.3)	182 (93.8)	178 (90.8)
Demographics	**Hexa group**	**Pedia group**	**Penta group**
N (TVC)	195	194	196
Females: Males	101:94	80:114	95:101
Mean Age, weeks (SD)	8.5 (1.0)	8.6 (1.1)	8.6 (1.1)
Median Age, weeks (minimum, maximum)	8 (6, 12)	9 (6, 12)	8 (6, 12)
White-Caucasian / European Heritage, n (%)	118 (60.5)	128 (66.0)	115 (58.7)
Other, n (%)	29 (14.9)	27 (13.9)	32 (16.3)
American Indian or Alaskan Native, n (%)	15 (7.7)	15 (7.7)	17 (8.7)

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
N = total number of subjects
n/% = number/percentage of subjects
SD = standard deviation

Table 2 Number of subjects vaccinated, completed and withdrawn with reasons of withdrawal up to Visit 4 (Primary TVC)

	Hexa group	Pedia group	Penta group	Total
Number of subjects vaccinated	195	194	196	585
Number of subjects completed	178	182	178	538
Number of subjects withdrawn	17	12	18	47
Reasons for withdrawal :				
Subject died	0	0	0	0
Serious Adverse Event	1	0	0	1
Non-Serious Adverse Event	0	0	1	1
Eligibility criteria not fulfilled (inclusion and exclusion criteria)	0	0	0	0
Protocol violation	1	0	4	5
Consent withdrawal (not due to an adverse event)	3	6	5	14
Migrated/moved from study area	2	3	0	5
Lost to follow-up (subjects with incomplete vaccination course)	2	0	2	4
Lost to follow-up (subjects with complete vaccination course)	4	0	0	4
Sponsor study termination	0	0	1	1
Other-loss of Kaiser insurance	0	0	1	1
Other-lost health plan	1	2	0	3
Other-lost health plan at Kaiser	0	1	0	1
Other-lost Kaiser insurance	1	0	0	1
Other-lost Kaiser permanente health insurance	0	0	1	1
Other-parent no show x3	1	0	0	1
Other-refuses blood draws	0	0	1	1
Other-subject was discontinued due to non-compliance	0	0	1	1
Other-terminated by pi due to non-compliance with appointment schedules	1	0	0	1
Other-travelling out of country and unable to meet visit window	0	0	1	1

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Vaccinated = number of subjects who were vaccinated in the study
Vaccinated = number of subjects who were vaccinated in the study up to Visit 4
Completed = number of subjects who completed Visit 4
Withdrawn = number of subjects who did not come back for Visit 4

Table 3 Number of enrolled subjects by country

	Hexa group N = 195	Pedia group N = 194	Penta group N = 196	Total N = 585
Country	**n**	**n**	**n**	**n**
United States	195	194	196	585

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
N = Number of enrolled subjects
n = number of enrolled subjects included in each group or in total for a given country or for all countries

Table 4 Number of enrolled subjects by age category

	Hexa group N = 195	Pedia group N = 194	Penta group N = 196	Total N = 585
Age category	**n**	**n**	**n**	**n**
Infants and toddlers (28 days-23 months)	195	194	196	585

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
N = Number of enrolled subjects
n = number of enrolled subjects included in each group or in total for a given age category or for all age categories

Table 5 Number of subjects enrolled into the study as well as the number excluded from ATP analyses for Primary Epoch with reasons for exclusion excluded from ATP analyses with reasons for exclusion

	Total			Hexa group		Pedia group		Penta group	
Title	**n**	**s**	**%**	**n**	**s**	**n**	**s**	**n**	**s**
Primary Total cohort	585			195		194		196	
Primary TVC	585		100	195		194		196	
Administration of vaccine(s) forbidden in the protocol (code 1040)	7	7		1	1	1	1	5	5
Study vaccine dose not administered according to protocol (code 1070)	0	2		0	0	0	0	0	2
ATP cohort for safety	578		98.8	194		193		191	
Underlying medical condition forbidden by the protocol (code 2050)	2	2		0	0	0	0	2	2
Concomitant infection related to the vaccine which may influence immune response (code 2060)	0	2		0	0	0	0	0	2
Non compliance with vaccination schedule (including wrong and unknown dates) (code 2080)	19	20		5	5	8	8	6	7
Non compliance with blood sampling schedule (including wrong and unknown dates (code 2090)	6	9		4	6	2	3	0	0
Essential serological data missing (code 2100)	85	93		31	34	27	27	27	32
Primary ATP cohort for immunogenicity	466		79.7	154		156		156	

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

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 TVC

1.2. Immunogenicity results

Table 6 Number and percentage of subjects with an anti-PRP antibody concentration equal to or above 0.15 and 1 µg/ml and GMCs by vaccine group (Primary ATP cohort for immunogenicity)

				≥ 0.15 µg/ml				≥ 1 µg/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP antibody	Hexa	PIII(M5)	149	140	94.0	88.8	97.2	83	55.7	47.3	63.8	1.4	1.1	1.7
	Pedia	PIII(M5)	153	151	98.7	95.4	99.8	144	94.1	89.1	97.3	10.3	8.1	13.1
	Penta	PIII(M5)	153	151	98.7	95.4	99.8	126	82.4	75.4	88.0	6.5	4.9	8.5

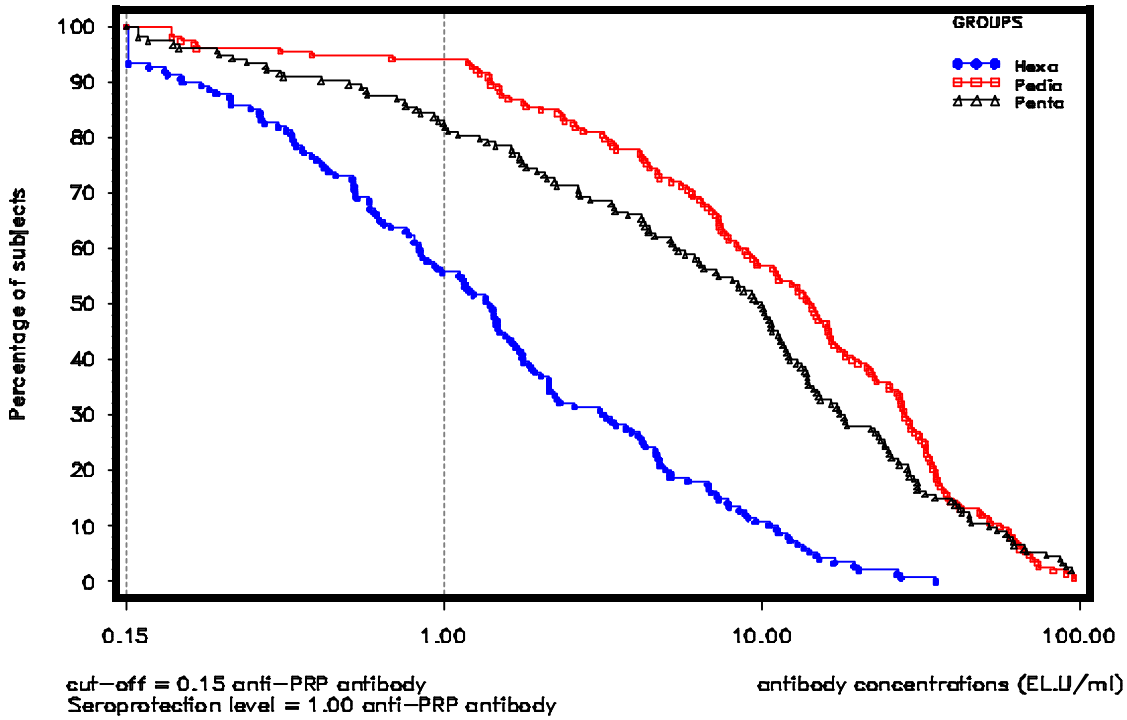
Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix, ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel, Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
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

Table 7 Number and percentage of subjects with an anti-PRP antibody concentration equal to or above 0.15 and 1 µg/ml and GMCs by vaccine and lot group (Primary ATP cohort for immunogenicity)

				≥ 0.15 µg/ml				≥ 1 µg/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP antibody	Hexa_A	PIII(M5)	53	50	94.3	84.3	98.8	34	64.2	49.8	76.9	1.5	1.0	2.1
	Hexa_C	PIII(M5)	48	45	93.8	82.8	98.7	25	52.1	37.2	66.7	1.5	0.9	2.3
	Hexa_B	PIII(M5)	48	45	93.8	82.8	98.7	24	50.0	35.2	64.8	1.2	0.8	1.9
	Pedia	PIII(M5)	153	151	98.7	95.4	99.8	144	94.1	89.1	97.3	10.3	8.1	13.1
	Penta	PIII(M5)	153	151	98.7	95.4	99.8	126	82.4	75.4	88.0	6.5	4.9	8.5

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix, ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel, Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
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

Figure 1 **Reverse cumulative distribution curve (Post dose 3) by vaccine group (Primary ATP cohort for immunogenicity)**

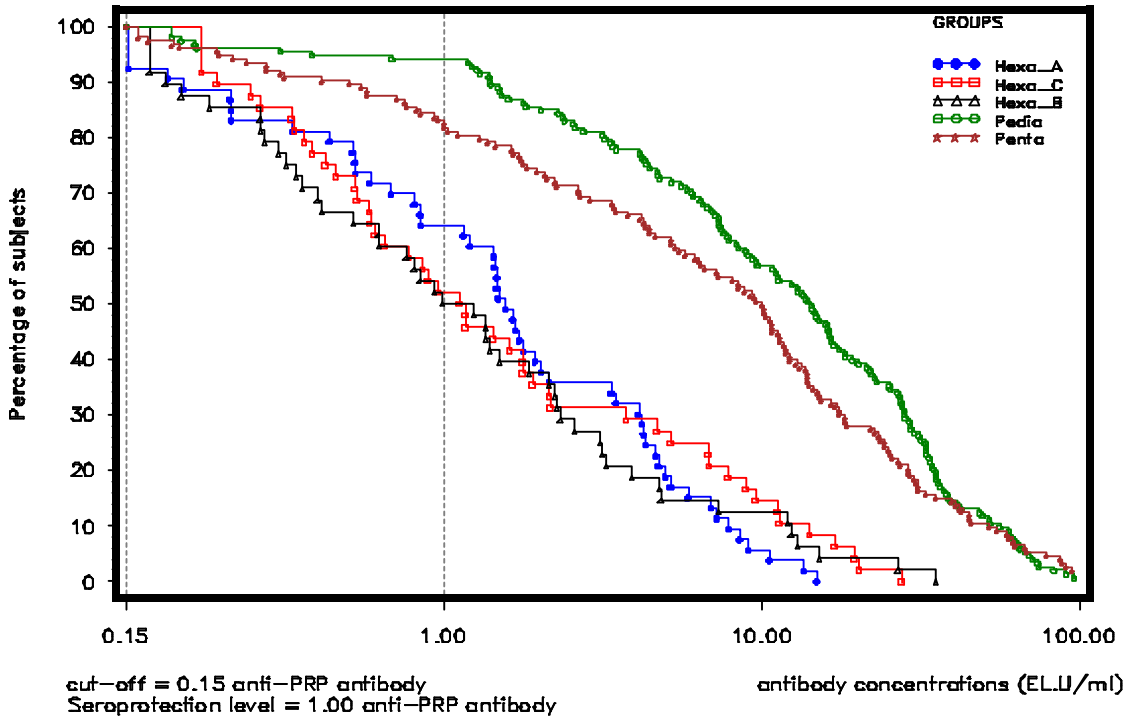


Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Pedia group = Subjects who received *Pediarix, ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Penta group = Subjects who received *Pentacel, Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Figure 2 **Reverse cumulative distribution curve (Post dose 3), by vaccine and lot group (Primary ATP cohort for immunogenicity)**



Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Pedia group = Subjects who received *Pediarix, ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Penta group = Subjects who received *Pentacel, Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

Table 8 Number and percentage of subjects with an anti-PRP antibody concentration equal to or above 0.15 and 1 µg/ml and GMCs by vaccine group (Primary TVC)

				≥ 0.15 µg/ml				≥ 1 µg/ml				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP antibody	Hexa	PIII(M5)	155	146	94.2	89.3	97.3	87	56.1	47.9	64.1	1.4	1.1	1.7
	Pedia	PIII(M5)	162	160	98.8	95.6	99.9	153	94.4	89.7	97.4	10.5	8.4	13.2
	Penta	PIII(M5)	161	159	98.8	95.6	99.8	134	83.2	76.5	88.6	6.6	5.1	8.6

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix, ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel, Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
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

1.3. Safety results

Table 9 Number (%) of subjects reporting solicited local symptoms during the 4-day (Days 0-3) post-vaccination period following each dose and overall (Primary TVC)

			Hexa group					Pedia group					Penta group				
						95% CI					95% CI					95% CI	
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																	
Pain	Total	All	185	94	50.8	43.4	58.2	189	128	67.7	60.6	74.3	188	119	63.3	56.0	70.2
		Grade 2 or 3	185	40	21.6	15.9	28.3	189	75	39.7	32.7	47.0	188	56	29.8	23.4	36.9
		Grade 3	185	8	4.3	1.9	8.3	189	24	12.7	8.3	18.3	188	12	6.4	3.3	10.9
		Medical advice	185	1	0.5	0.0	3.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	123	65.1	57.8	71.9	188	100	53.2	45.8	60.5
		Grade 2 or 3						189	66	34.9	28.1	42.2	188	45	23.9	18.0	30.7
		Grade 3						189	22	11.6	7.4	17.1	188	10	5.3	2.6	9.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	185	94	50.8	43.4	58.2	189	113	59.8	52.4	66.8	188	115	61.2	53.8	68.2
		Grade 2 or 3	185	40	21.6	15.9	28.3	189	65	34.4	27.6	41.6	188	51	27.1	20.9	34.1
		Grade 3	185	8	4.3	1.9	8.3	189	17	9.0	5.3	14.0	188	12	6.4	3.3	10.9
		Medical advice	185	1	0.5	0.0	3.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Redness (mm)	Total	All	185	47	25.4	19.3	32.3	189	73	38.6	31.6	46.0	188	67	35.6	28.8	42.9
		>5	185	15	8.1	4.6	13.0	189	27	14.3	9.6	20.1	188	27	14.4	9.7	20.2
		>20	185	3	1.6	0.3	4.7	189	10	5.3	2.6	9.5	188	4	2.1	0.6	5.4
		Medical advice	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	63	33.3	26.7	40.5	188	55	29.3	22.9	36.3
		>5						189	19	10.1	6.2	15.3	188	12	6.4	3.3	10.9
		>20						189	8	4.2	1.8	8.2	188	1	0.5	0.0	2.9
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	185	47	25.4	19.3	32.3	189	56	29.6	23.2	36.7	188	57	30.3	23.8	37.4
		>5	185	15	8.1	4.6	13.0	189	15	7.9	4.5	12.8	188	20	10.6	6.6	16.0
		>20	185	3	1.6	0.3	4.7	189	4	2.1	0.6	5.3	188	3	1.6	0.3	4.6
		Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Swelling (mm)	Total	All	185	31	16.8	11.7	22.9	189	46	24.3	18.4	31.1	188	53	28.2	21.9	35.2
		>5	185	10	5.4	2.6	9.7	189	18	9.5	5.7	14.6	188	24	12.8	8.4	18.4

			Hexa group					Pedia group					Penta group				
						95% CI					95% CI					95% CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>20	185	2	1.1	0.1	3.9	189	7	3.7	1.5	7.5	188	11	5.9	3.0	10.2
		Medical advice	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	41	21.7	16.0	28.3	188	39	20.7	15.2	27.2
		>5						189	14	7.4	4.1	12.1	188	14	7.4	4.1	12.2
		>20						189	6	3.2	1.2	6.8	188	3	1.6	0.3	4.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	185	31	16.8	11.7	22.9	189	35	18.5	13.3	24.8	188	45	23.9	18.0	30.7
		>5	185	10	5.4	2.6	9.7	189	14	7.4	4.1	12.1	188	24	12.8	8.4	18.4
		>20	185	2	1.1	0.1	3.9	189	3	1.6	0.3	4.6	188	11	5.9	3.0	10.2
		Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Dose 2																	
Pain	Total	All	182	84	46.2	38.8	53.7	184	112	60.9	53.4	68.0	179	93	52.0	44.4	59.5
		Grade 2 or 3	182	25	13.7	9.1	19.6	184	54	29.3	22.9	36.5	179	32	17.9	12.6	24.3
		Grade 3	182	1	0.5	0.0	3.0	184	10	5.4	2.6	9.8	179	6	3.4	1.2	7.2
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	ActHIB/Engerix B	All						184	104	56.5	49.0	63.8	13	6	46.2	19.2	74.9
		Grade 2 or 3						184	47	25.5	19.4	32.5	13	2	15.4	1.9	45.4
		Grade 3						184	9	4.9	2.3	9.1	13	0	0.0	0.0	24.7
		Medical advice						184	0	0.0	0.0	2.0	13	0	0.0	0.0	24.7
	Hexa/Pediarix/Pentacel	All	182	84	46.2	38.8	53.7	184	108	58.7	51.2	65.9	179	93	52.0	44.4	59.5
		Grade 2 or 3	182	25	13.7	9.1	19.6	184	44	23.9	17.9	30.7	179	31	17.3	12.1	23.7
		Grade 3	182	1	0.5	0.0	3.0	184	7	3.8	1.5	7.7	179	6	3.4	1.2	7.2
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
Redness (mm)	Total	All	182	57	31.3	24.7	38.6	184	77	41.8	34.6	49.3	179	64	35.8	28.7	43.2
		>5	182	15	8.2	4.7	13.2	184	22	12.0	7.6	17.5	179	16	8.9	5.2	14.1
		>20	182	3	1.6	0.3	4.7	184	3	1.6	0.3	4.7	179	2	1.1	0.1	4.0
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	ActHIB/Engerix B	All						184	66	35.9	28.9	43.3	13	5	38.5	13.9	68.4
		>5						184	17	9.2	5.5	14.4	13	1	7.7	0.2	36.0
		>20						184	1	0.5	0.0	3.0	13	0	0.0	0.0	24.7
		Medical advice						184	0	0.0	0.0	2.0	13	0	0.0	0.0	24.7
	Hexa/Pediarix/Pentacel	All	182	57	31.3	24.7	38.6	184	61	33.2	26.4	40.5	179	64	35.8	28.7	43.2
		>5	182	15	8.2	4.7	13.2	184	12	6.5	3.4	11.1	179	15	8.4	4.8	13.4

			Hexa group					Pedia group					Penta group				
						95% CI					95% CI					95% CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>20	182	3	1.6	0.3	4.7	184	3	1.6	0.3	4.7	179	2	1.1	0.1	4.0
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
Swelling (mm)	Total	All	182	40	22.0	16.2	28.7	184	51	27.7	21.4	34.8	179	44	24.6	18.5	31.6
		>5	182	10	5.5	2.7	9.9	184	16	8.7	5.1	13.7	179	7	3.9	1.6	7.9
		>20	182	2	1.1	0.1	3.9	184	2	1.1	0.1	3.9	179	3	1.7	0.3	4.8
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	ActHIB/Engerix B	All						184	40	21.7	16.0	28.4	13	3	23.1	5.0	53.8
		>5						184	11	6.0	3.0	10.4	13	0	0.0	0.0	24.7
		>20						184	1	0.5	0.0	3.0	13	0	0.0	0.0	24.7
		Medical advice						184	0	0.0	0.0	2.0	13	0	0.0	0.0	24.7
	Hexa/Pediarix/Pentacel	All	182	40	22.0	16.2	28.7	184	40	21.7	16.0	28.4	179	42	23.5	17.5	30.4
		>5	182	10	5.5	2.7	9.9	184	12	6.5	3.4	11.1	179	7	3.9	1.6	7.9
		>20	182	2	1.1	0.1	3.9	184	2	1.1	0.1	3.9	179	3	1.7	0.3	4.8
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
Dose 3																	
Pain	Total	All	172	67	39.0	31.6	46.7	175	98	56.0	48.3	63.5	171	83	48.5	40.8	56.3
		Grade 2 or 3	172	18	10.5	6.3	16.0	175	45	25.7	19.4	32.9	171	28	16.4	11.2	22.8
		Grade 3	172	0	0.0	0.0	2.1	175	8	4.6	2.0	8.8	171	7	4.1	1.7	8.3
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	171	0	0.0	0.0	2.1
	ActHIB/Engerix B	All						175	93	53.1	45.5	60.7	169	75	44.4	36.8	52.2
		Grade 2 or 3						175	41	23.4	17.4	30.4	169	25	14.8	9.8	21.1
		Grade 3						175	7	4.0	1.6	8.1	169	5	3.0	1.0	6.8
		Medical advice						175	1	0.6	0.0	3.1	169	0	0.0	0.0	2.2
	Hexa/Pediarix/Pentacel	All	172	67	39.0	31.6	46.7	175	90	51.4	43.8	59.0	170	76	44.7	37.1	52.5
		Grade 2 or 3	172	18	10.5	6.3	16.0	175	39	22.3	16.4	29.2	170	20	11.8	7.3	17.6
		Grade 3	172	0	0.0	0.0	2.1	175	7	4.0	1.6	8.1	170	7	4.1	1.7	8.3
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Redness (mm)	Total	All	172	63	36.6	29.4	44.3	175	81	46.3	38.7	54.0	171	65	38.0	30.7	45.7
		>5	172	7	4.1	1.7	8.2	175	14	8.0	4.4	13.1	171	16	9.4	5.4	14.7
		>20	172	2	1.2	0.1	4.1	175	4	2.3	0.6	5.7	171	2	1.2	0.1	4.2
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	171	0	0.0	0.0	2.1
	ActHIB/Engerix B	All						175	69	39.4	32.1	47.1	169	51	30.2	23.4	37.7
		>5						175	7	4.0	1.6	8.1	169	9	5.3	2.5	9.9

			Hexa group					Pedia group					Penta group				
						95% CI					95% CI					95% CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>20						175	1	0.6	0.0	3.1	169	2	1.2	0.1	4.2
		Medical advice						175	0	0.0	0.0	2.1	169	0	0.0	0.0	2.2
	Hexa/Pediarix/Pentacel	All	172	63	36.6	29.4	44.3	175	66	37.7	30.5	45.3	170	56	32.9	25.9	40.6
		>5	172	7	4.1	1.7	8.2	175	12	6.9	3.6	11.7	170	11	6.5	3.3	11.3
		>20	172	2	1.2	0.1	4.1	175	3	1.7	0.4	4.9	170	0	0.0	0.0	2.1
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Swelling (mm)	Total	All	172	43	25.0	18.7	32.2	175	53	30.3	23.6	37.7	171	44	25.7	19.4	33.0
		>5	172	7	4.1	1.7	8.2	175	12	6.9	3.6	11.7	171	8	4.7	2.0	9.0
		>20	172	1	0.6	0.0	3.2	175	3	1.7	0.4	4.9	171	0	0.0	0.0	2.1
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	171	0	0.0	0.0	2.1
	ActHIB/Engerix B	All						175	42	24.0	17.9	31.0	169	37	21.9	15.9	28.9
		>5						175	7	4.0	1.6	8.1	169	7	4.1	1.7	8.3
		>20						175	1	0.6	0.0	3.1	169	0	0.0	0.0	2.2
		Medical advice						175	0	0.0	0.0	2.1	169	0	0.0	0.0	2.2
	Hexa/Pediarix/Pentacel	All	172	43	25.0	18.7	32.2	175	44	25.1	18.9	32.2	170	35	20.6	14.8	27.5
		>5	172	7	4.1	1.7	8.2	175	10	5.7	2.8	10.3	170	4	2.4	0.6	5.9
		>20	172	1	0.6	0.0	3.2	175	3	1.7	0.4	4.9	170	0	0.0	0.0	2.1
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Overall/dose																	
Pain	Total	All	539	245	45.5	41.2	49.8	548	338	61.7	57.5	65.8	538	295	54.8	50.5	59.1
		Grade 2 or 3	539	83	15.4	12.5	18.7	548	174	31.8	27.9	35.8	538	116	21.6	18.2	25.3
		Grade 3	539	9	1.7	0.8	3.1	548	42	7.7	5.6	10.2	538	25	4.6	3.0	6.8
		Medical advice	539	1	0.2	0.0	1.0	548	2	0.4	0.0	1.3	538	0	0.0	0.0	0.7
	ActHIB/Engerix B	All						548	320	58.4	54.1	62.6	370	181	48.9	43.7	54.1
		Grade 2 or 3						548	154	28.1	24.4	32.1	370	72	19.5	15.5	23.9
		Grade 3						548	38	6.9	5.0	9.4	370	15	4.1	2.3	6.6
		Medical advice						548	2	0.4	0.0	1.3	370	0	0.0	0.0	1.0
	Hexa/Pediarix/Pentacel	All	539	245	45.5	41.2	49.8	548	311	56.8	52.5	60.9	537	284	52.9	48.6	57.2
		Grade 2 or 3	539	83	15.4	12.5	18.7	548	148	27.0	23.3	30.9	537	102	19.0	15.8	22.6
		Grade 3	539	9	1.7	0.8	3.1	548	31	5.7	3.9	7.9	537	25	4.7	3.0	6.8
		Medical advice	539	1	0.2	0.0	1.0	548	1	0.2	0.0	1.0	537	0	0.0	0.0	0.7
Redness (mm)	Total	All	539	167	31.0	27.1	35.1	548	231	42.2	38.0	46.4	538	196	36.4	32.4	40.7
		>5	539	37	6.9	4.9	9.3	548	63	11.5	8.9	14.5	538	59	11.0	8.5	13.9

			Hexa group					Pedia group					Penta group				
						95% CI					95% CI					95% CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>20	539	8	1.5	0.6	2.9	548	17	3.1	1.8	4.9	538	8	1.5	0.6	2.9
		Medical advice	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	538	0	0.0	0.0	0.7
	ActHIB/Engerix B	All						548	198	36.1	32.1	40.3	370	111	30.0	25.4	35.0
		>5						548	43	7.8	5.7	10.4	370	22	5.9	3.8	8.9
		>20						548	10	1.8	0.9	3.3	370	3	0.8	0.2	2.4
		Medical advice						548	1	0.2	0.0	1.0	370	0	0.0	0.0	1.0
	Hexa/Pediarix/Pentacel	All	539	167	31.0	27.1	35.1	548	183	33.4	29.5	37.5	537	177	33.0	29.0	37.1
		>5	539	37	6.9	4.9	9.3	548	39	7.1	5.1	9.6	537	46	8.6	6.3	11.3
		>20	539	8	1.5	0.6	2.9	548	10	1.8	0.9	3.3	537	5	0.9	0.3	2.2
		Medical advice	539	0	0.0	0.0	0.7	548	1	0.2	0.0	1.0	537	0	0.0	0.0	0.7
Swelling (mm)	Total	All	539	114	21.2	17.8	24.8	548	150	27.4	23.7	31.3	538	141	26.2	22.5	30.1
		>5	539	27	5.0	3.3	7.2	548	46	8.4	6.2	11.0	538	39	7.2	5.2	9.8
		>20	539	5	0.9	0.3	2.2	548	12	2.2	1.1	3.8	538	14	2.6	1.4	4.3
		Medical advice	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	538	0	0.0	0.0	0.7
	ActHIB/Engerix B	All						548	123	22.4	19.0	26.2	370	79	21.4	17.3	25.9
		>5						548	32	5.8	4.0	8.1	370	21	5.7	3.5	8.5
		>20						548	8	1.5	0.6	2.9	370	3	0.8	0.2	2.4
		Medical advice						548	1	0.2	0.0	1.0	370	0	0.0	0.0	1.0
	Hexa/Pediarix/Pentacel	All	539	114	21.2	17.8	24.8	548	119	21.7	18.3	25.4	537	122	22.7	19.2	26.5
		>5	539	27	5.0	3.3	7.2	548	36	6.6	4.6	9.0	537	35	6.5	4.6	8.9
		>20	539	5	0.9	0.3	2.2	548	8	1.5	0.6	2.9	537	14	2.6	1.4	4.3
		Medical advice	539	0	0.0	0.0	0.7	548	1	0.2	0.0	1.0	537	0	0.0	0.0	0.7
Overall/subject																	
Pain	Total	All	187	127	67.9	60.7	74.5	189	155	82.0	75.8	87.2	188	150	79.8	73.3	85.3
		Grade 2 or 3	187	58	31.0	24.5	38.2	189	104	55.0	47.6	62.3	188	88	46.8	39.5	54.2
		Grade 3	187	8	4.3	1.9	8.3	189	34	18.0	12.8	24.2	188	22	11.7	7.5	17.2
		Medical advice	187	1	0.5	0.0	2.9	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	148	78.3	71.7	84.0	188	127	67.6	60.4	74.2
		Grade 2 or 3						189	96	50.8	43.4	58.1	188	62	33.0	26.3	40.2
		Grade 3						189	30	15.9	11.0	21.9	188	14	7.4	4.1	12.2
		Medical advice						189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	187	127	67.9	60.7	74.5	189	151	79.9	73.5	85.4	188	147	78.2	71.6	83.9
		Grade 2 or 3	187	58	31.0	24.5	38.2	189	93	49.2	41.9	56.6	188	80	42.6	35.4	50.0

			Hexa group					Pedia group					Penta group				
						95% CI					95% CI					95% CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		Grade 3	187	8	4.3	1.9	8.3	189	27	14.3	9.6	20.1	188	22	11.7	7.5	17.2
		Medical advice	187	1	0.5	0.0	2.9	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
Redness (mm)	Total	All	187	93	49.7	42.4	57.1	189	120	63.5	56.2	70.4	188	106	56.4	49.0	63.6
		>5	187	27	14.4	9.7	20.3	189	49	25.9	19.8	32.8	188	45	23.9	18.0	30.7
		>20	187	7	3.7	1.5	7.6	189	15	7.9	4.5	12.8	188	8	4.3	1.9	8.2
		Medical advice	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	108	57.1	49.8	64.3	188	77	41.0	33.9	48.3
		>5						189	38	20.1	14.6	26.5	188	20	10.6	6.6	16.0
		>20						189	10	5.3	2.6	9.5	188	3	1.6	0.3	4.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	187	93	49.7	42.4	57.1	189	98	51.9	44.5	59.2	188	97	51.6	44.2	58.9
		>5	187	27	14.4	9.7	20.3	189	32	16.9	11.9	23.1	188	37	19.7	14.3	26.1
		>20	187	7	3.7	1.5	7.6	189	9	4.8	2.2	8.8	188	5	2.7	0.9	6.1
		Medical advice	187	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
Swelling (mm)	Total	All	187	72	38.5	31.5	45.9	189	88	46.6	39.3	53.9	188	81	43.1	35.9	50.5
		>5	187	20	10.7	6.7	16.0	189	34	18.0	12.8	24.2	188	29	15.4	10.6	21.4
		>20	187	4	2.1	0.6	5.4	189	11	5.8	2.9	10.2	188	12	6.4	3.3	10.9
		Medical advice	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	78	41.3	34.2	48.6	188	64	34.0	27.3	41.3
		>5						189	25	13.2	8.7	18.9	188	18	9.6	5.8	14.7
		>20						189	7	3.7	1.5	7.5	188	3	1.6	0.3	4.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	187	72	38.5	31.5	45.9	189	70	37.0	30.1	44.3	188	72	38.3	31.3	45.7
		>5	187	20	10.7	6.7	16.0	189	26	13.8	9.2	19.5	188	26	13.8	9.2	19.6
		>20	187	4	2.1	0.6	5.4	189	7	3.7	1.5	7.5	188	12	6.4	3.3	10.9
		Medical advice	187	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:

N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit
All = all reports of the specified symptom irrespective of intensity grade
Grade2*3=Grade 2 or Grade 3
Grade 2 For Pain: Moderate: Moderate: Cries/protests on touch
For Redness/Swelling: >5 mm but ≤ 20 mm
Grade 3 For Pain= Severe: Cries when limb is moved/spontaneously painful.
For Redness/Swelling: >20 mm

Table 10 Number (%) of subjects reporting solicited general symptoms during the 4-day (Days 0-3) post-vaccination period following each dose and overall (Primary TVC)

		Hexa group					Pedia group					Penta group				
					95% CI					95% CI					95% CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1																
Drowsiness	All	185	114	61.6	54.2	68.7	189	143	75.7	68.9	81.6	188	149	79.3	72.8	84.8
	Grade 2 or 3	185	36	19.5	14.0	25.9	189	56	29.6	23.2	36.7	188	53	28.2	21.9	35.2
	Grade 3	185	3	1.6	0.3	4.7	189	8	4.2	1.8	8.2	188	12	6.4	3.3	10.9
	Related	185	112	60.5	53.1	67.6	189	136	72.0	65.0	78.2	188	141	75.0	68.2	81.0
	Grade 3 Related	185	3	1.6	0.3	4.7	189	7	3.7	1.5	7.5	188	12	6.4	3.3	10.9
	Medical advice	185	1	0.5	0.0	3.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Irritability / Fussiness	All	185	115	62.2	54.8	69.2	189	165	87.3	81.7	91.7	188	153	81.4	75.1	86.7
	Grade 2 or 3	185	42	22.7	16.9	29.4	189	79	41.8	34.7	49.2	188	68	36.2	29.3	43.5
	Grade 3	185	9	4.9	2.2	9.0	189	17	9.0	5.3	14.0	188	15	8.0	4.5	12.8
	Related	185	113	61.1	53.7	68.1	189	163	86.2	80.5	90.8	188	147	78.2	71.6	83.9
	Grade 3 Related	185	9	4.9	2.2	9.0	189	17	9.0	5.3	14.0	188	15	8.0	4.5	12.8
	Medical advice	185	1	0.5	0.0	3.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Loss Of Appetite	All	185	53	28.6	22.3	35.7	189	76	40.2	33.2	47.6	188	80	42.6	35.4	50.0
	Grade 2 or 3	185	8	4.3	1.9	8.3	189	13	6.9	3.7	11.5	188	26	13.8	9.2	19.6
	Grade 3	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	4	2.1	0.6	5.4
	Related	185	48	25.9	19.8	32.9	189	73	38.6	31.6	46.0	188	77	41.0	33.9	48.3
	Grade 3 Related	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	4	2.1	0.6	5.4
	Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Temperature(°C)	All	185	22	11.9	7.6	17.4	189	34	18.0	12.8	24.2	188	29	15.4	10.6	21.4
	>39.0	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	2	1.1	0.1	3.8
	>40.0	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
	Related	185	15	8.1	4.6	13.0	189	31	16.4	11.4	22.5	188	27	14.4	9.7	20.2
	>40.0 Related	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
	Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Dose 2																
Drowsiness	All	182	97	53.3	45.8	60.7	184	132	71.7	64.6	78.1	179	109	60.9	53.3	68.1
	Grade 2 or 3	182	31	17.0	11.9	23.3	184	43	23.4	17.5	30.2	179	39	21.8	16.0	28.6
	Grade 3	182	8	4.4	1.9	8.5	184	7	3.8	1.5	7.7	179	4	2.2	0.6	5.6

		Hexa group					Pedia group					Penta group				
					95% CI					95% CI					95% CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Related	182	94	51.6	44.1	59.1	184	126	68.5	61.2	75.1	179	108	60.3	52.8	67.6
	Grade 3 Related	182	7	3.8	1.6	7.8	184	7	3.8	1.5	7.7	179	3	1.7	0.3	4.8
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
Irritability / Fussiness	All	182	128	70.3	63.1	76.9	184	147	79.9	73.4	85.4	179	136	76.0	69.0	82.0
	Grade 2 or 3	182	53	29.1	22.6	36.3	184	70	38.0	31.0	45.5	179	61	34.1	27.2	41.5
	Grade 3	182	6	3.3	1.2	7.0	184	14	7.6	4.2	12.4	179	11	6.1	3.1	10.7
	Related	182	125	68.7	61.4	75.3	184	143	77.7	71.0	83.5	179	133	74.3	67.2	80.5
	Grade 3 Related	182	6	3.3	1.2	7.0	184	13	7.1	3.8	11.8	179	11	6.1	3.1	10.7
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	2	1.1	0.1	4.0
Loss Of Appetite	All	182	56	30.8	24.2	38.0	184	55	29.9	23.4	37.1	179	56	31.3	24.6	38.6
	Grade 2 or 3	182	17	9.3	5.5	14.5	184	15	8.2	4.6	13.1	179	15	8.4	4.8	13.4
	Grade 3	182	1	0.5	0.0	3.0	184	1	0.5	0.0	3.0	179	2	1.1	0.1	4.0
	Related	182	52	28.6	22.1	35.7	184	51	27.7	21.4	34.8	179	55	30.7	24.1	38.0
	Grade 3 Related	182	1	0.5	0.0	3.0	184	1	0.5	0.0	3.0	179	2	1.1	0.1	4.0
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	1	0.6	0.0	3.1
Temperature(°C)	All	182	47	25.8	19.6	32.8	184	36	19.6	14.1	26.0	179	34	19.0	13.5	25.5
	>39.0	182	2	1.1	0.1	3.9	184	3	1.6	0.3	4.7	179	2	1.1	0.1	4.0
	>40.0	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	Related	182	37	20.3	14.7	26.9	184	32	17.4	12.2	23.7	179	32	17.9	12.6	24.3
	>40.0 Related	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
Dose 3																
Drowsiness	All	172	86	50.0	42.3	57.7	175	108	61.7	54.1	68.9	170	88	51.8	44.0	59.5
	Grade 2 or 3	172	24	14.0	9.1	20.0	175	37	21.1	15.3	27.9	170	25	14.7	9.7	20.9
	Grade 3	172	3	1.7	0.4	5.0	175	5	2.9	0.9	6.5	170	9	5.3	2.4	9.8
	Related	172	82	47.7	40.0	55.4	175	106	60.6	52.9	67.9	170	86	50.6	42.8	58.3
	Grade 3 Related	172	3	1.7	0.4	5.0	175	5	2.9	0.9	6.5	170	9	5.3	2.4	9.8
	Medical advice	172	0	0.0	0.0	2.1	175	2	1.1	0.1	4.1	170	1	0.6	0.0	3.2
Irritability / Fussiness	All	172	126	73.3	66.0	79.7	175	135	77.1	70.2	83.1	170	122	71.8	64.4	78.4
	Grade 2 or 3	172	46	26.7	20.3	34.0	175	58	33.1	26.2	40.6	170	58	34.1	27.0	41.8
	Grade 3	172	6	3.5	1.3	7.4	175	15	8.6	4.9	13.7	170	11	6.5	3.3	11.3
	Related	172	121	70.3	62.9	77.1	175	130	74.3	67.1	80.6	170	120	70.6	63.1	77.3

		Hexa group					Pedia group					Penta group				
					95% CI					95% CI					95% CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Grade 3 Related	172	6	3.5	1.3	7.4	175	13	7.4	4.0	12.4	170	11	6.5	3.3	11.3
	Medical advice	172	0	0.0	0.0	2.1	175	3	1.7	0.4	4.9	170	1	0.6	0.0	3.2
Loss Of Appetite	All	172	46	26.7	20.3	34.0	175	58	33.1	26.2	40.6	170	53	31.2	24.3	38.7
	Grade 2 or 3	172	11	6.4	3.2	11.2	175	13	7.4	4.0	12.4	170	15	8.8	5.0	14.1
	Grade 3	172	1	0.6	0.0	3.2	175	2	1.1	0.1	4.1	170	2	1.2	0.1	4.2
	Related	172	44	25.6	19.2	32.8	175	57	32.6	25.7	40.1	170	52	30.6	23.8	38.1
	Grade 3 Related	172	1	0.6	0.0	3.2	175	2	1.1	0.1	4.1	170	2	1.2	0.1	4.2
	Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Temperature/(Rectal) (°C	All	172	40	23.3	17.2	30.3	175	45	25.7	19.4	32.9	170	37	21.8	15.8	28.7
	>39.0	172	4	2.3	0.6	5.8	175	11	6.3	3.2	11.0	170	7	4.1	1.7	8.3
	>40.0	172	0	0.0	0.0	2.1	175	2	1.1	0.1	4.1	170	0	0.0	0.0	2.1
	Related	172	35	20.3	14.6	27.1	175	39	22.3	16.4	29.2	170	35	20.6	14.8	27.5
	>40.0 Related	172	0	0.0	0.0	2.1	175	2	1.1	0.1	4.1	170	0	0.0	0.0	2.1
	Medical advice	172	1	0.6	0.0	3.2	175	2	1.1	0.1	4.1	170	1	0.6	0.0	3.2
Overall/dose																
Drowsiness	All	539	297	55.1	50.8	59.4	548	383	69.9	65.9	73.7	537	346	64.4	60.2	68.5
	Grade 2 or 3	539	91	16.9	13.8	20.3	548	136	24.8	21.3	28.7	537	117	21.8	18.4	25.5
	Grade 3	539	14	2.6	1.4	4.3	548	20	3.6	2.2	5.6	537	25	4.7	3.0	6.8
	Related	539	288	53.4	49.1	57.7	548	368	67.2	63.0	71.1	537	335	62.4	58.1	66.5
	Grade 3 Related	539	13	2.4	1.3	4.1	548	19	3.5	2.1	5.4	537	24	4.5	2.9	6.6
	Medical advice	539	1	0.2	0.0	1.0	548	2	0.4	0.0	1.3	537	1	0.2	0.0	1.0
Irritability / Fussiness	All	539	369	68.5	64.4	72.4	548	447	81.6	78.1	84.7	537	411	76.5	72.7	80.1
	Grade 2 or 3	539	141	26.2	22.5	30.1	548	207	37.8	33.7	42.0	537	187	34.8	30.8	39.0
	Grade 3	539	21	3.9	2.4	5.9	548	46	8.4	6.2	11.0	537	37	6.9	4.9	9.4
	Related	539	359	66.6	62.4	70.6	548	436	79.6	75.9	82.9	537	400	74.5	70.6	78.1
	Grade 3 Related	539	21	3.9	2.4	5.9	548	43	7.8	5.7	10.4	537	37	6.9	4.9	9.4
	Medical advice	539	1	0.2	0.0	1.0	548	3	0.5	0.1	1.6	537	3	0.6	0.1	1.6
Loss Of Appetite	All	539	155	28.8	25.0	32.8	548	189	34.5	30.5	38.6	537	189	35.2	31.2	39.4
	Grade 2 or 3	539	36	6.7	4.7	9.1	548	41	7.5	5.4	10.0	537	56	10.4	8.0	13.3
	Grade 3	539	2	0.4	0.0	1.3	548	4	0.7	0.2	1.9	537	8	1.5	0.6	2.9
	Related	539	144	26.7	23.0	30.7	548	181	33.0	29.1	37.1	537	184	34.3	30.3	38.4
	Grade 3 Related	539	2	0.4	0.0	1.3	548	4	0.7	0.2	1.9	537	8	1.5	0.6	2.9

		Hexa group					Pedia group					Penta group				
					95% CI					95% CI					95% CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Medical advice	539	0	0.0	0.0	0.7	548	1	0.2	0.0	1.0	537	1	0.2	0.0	1.0
Temperature(°C)	All	539	109	20.2	16.9	23.9	548	115	21.0	17.6	24.6	537	100	18.6	15.4	22.2
	>39.0	539	6	1.1	0.4	2.4	548	14	2.6	1.4	4.2	537	11	2.0	1.0	3.6
	>40.0	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	537	0	0.0	0.0	0.7
	Related	539	87	16.1	13.1	19.5	548	102	18.6	15.4	22.1	537	94	17.5	14.4	21.0
	>40.0 Related	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	537	0	0.0	0.0	0.7
	Medical advice	539	1	0.2	0.0	1.0	548	2	0.4	0.0	1.3	537	1	0.2	0.0	1.0
Overall/subject																
Drowsiness	All	187	148	79.1	72.6	84.7	189	172	91.0	86.0	94.7	188	168	89.4	84.0	93.4
	Grade 2 or 3	187	67	35.8	29.0	43.2	189	88	46.6	39.3	53.9	188	81	43.1	35.9	50.5
	Grade 3	187	11	5.9	3.0	10.3	189	19	10.1	6.2	15.3	188	22	11.7	7.5	17.2
	Related	187	145	77.5	70.9	83.3	189	170	89.9	84.7	93.8	188	166	88.3	82.8	92.5
	Grade 3 Related	187	11	5.9	3.0	10.3	189	18	9.5	5.7	14.6	188	21	11.2	7.0	16.6
	Medical advice	187	1	0.5	0.0	2.9	189	2	1.1	0.1	3.8	188	1	0.5	0.0	2.9
Irritability / Fussiness	All	187	164	87.7	82.1	92.0	189	182	96.3	92.5	98.5	188	177	94.1	89.8	97.0
	Grade 2 or 3	187	96	51.3	43.9	58.7	189	128	67.7	60.6	74.3	188	120	63.8	56.5	70.7
	Grade 3	187	18	9.6	5.8	14.8	189	35	18.5	13.3	24.8	188	30	16.0	11.0	22.0
	Related	187	161	86.1	80.3	90.7	189	180	95.2	91.2	97.8	188	175	93.1	88.5	96.3
	Grade 3 Related	187	18	9.6	5.8	14.8	189	34	18.0	12.8	24.2	188	30	16.0	11.0	22.0
	Medical advice	187	1	0.5	0.0	2.9	189	3	1.6	0.3	4.6	188	3	1.6	0.3	4.6
Loss Of Appetite	All	187	95	50.8	43.4	58.2	189	111	58.7	51.4	65.8	188	117	62.2	54.9	69.2
	Grade 2 or 3	187	28	15.0	10.2	20.9	189	32	16.9	11.9	23.1	188	39	20.7	15.2	27.2
	Grade 3	187	2	1.1	0.1	3.8	189	3	1.6	0.3	4.6	188	6	3.2	1.2	6.8
	Related	187	91	48.7	41.3	56.1	189	109	57.7	50.3	64.8	188	116	61.7	54.3	68.7
	Grade 3 Related	187	2	1.1	0.1	3.8	189	3	1.6	0.3	4.6	188	6	3.2	1.2	6.8
	Medical advice	187	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	1	0.5	0.0	2.9
Temperature (°C)	All	187	72	38.5	31.5	45.9	189	78	41.3	34.2	48.6	188	71	37.8	30.8	45.1
	>39.0	187	6	3.2	1.2	6.9	189	14	7.4	4.1	12.1	188	10	5.3	2.6	9.6
	>40.0	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	Related	187	61	32.6	26.0	39.8	189	74	39.2	32.2	46.5	188	68	36.2	29.3	43.5
	>40.0 Related	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	Medical advice	187	1	0.5	0.0	2.9	189	2	1.1	0.1	3.8	188	1	0.5	0.0	2.9

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit
All = all reports of the specified symptom irrespective of intensity grade
Related = Symptoms which is assessed by the investigator as related to vaccination
Grade 3 For Drowsiness: Severe: Drowsiness that prevents normal activity
For Irritability: Severe: Crying that cannot be comforted/prevents normal activity
For Loss of appetite: Severe: Not eating at all
For Temperature: >40.0 °C

Table 11 Number (%) of subjects with adverse events reported during 31-day (Days 0-30) post-vaccination period (Primary TVC)

System Organ Class	Most frequent adverse events-On-Therapy (occurring within day 0-30 following vaccination)	Hexa group N = 195	Pedia group N = 194	Penta group N = 196
	Subjects with any AE(s), n (%)	111 (56.9)	108 (55.7)	96 (49.0)
Infections and infestations	Upper respiratory tract infection	29 (14.9)	23 (11.9)	26 (13.3)
General disorders and administration site conditions	Pyrexia	11 (5.6)	5 (2.6)	15 (7.7)
Respiratory, thoracic and mediastinal disorders	Cough	15 (7.7)	7 (3.6)	7 (3.6)
Gastrointestinal disorders	Vomiting	9 (4.6)	8 (4.1)	10 (5.1)
Infections and infestations	Otitis media	9 (4.6)	7 (3.6)	9 (4.6)
Gastrointestinal disorders	Diarrhoea	6 (3.1)	5 (2.6)	10 (5.1)
Gastrointestinal disorders	Teething	5 (2.6)	8 (4.1)	8 (4.1)
Infections and infestations	Conjunctivitis	10 (5.1)	8 (4.1)	-
General disorders and administration site conditions	Injection site pain	4 (2.1)	6 (3.1)	7 (3.6)
Skin and subcutaneous tissue disorders	Dermatitis diaper	-	-	9 (4.6)
Skin and subcutaneous tissue disorders	Eczema	4 (2.1)	5 (2.6)	-
Gastrointestinal disorders	Gastrooesophageal reflux disease	-	8 (4.1)	-
Gastrointestinal disorders	Constipation	-	-	6 (3.1)
Respiratory, thoracic and mediastinal disorders	Nasal congestion	-	6 (3.1)	-
Skin and subcutaneous tissue disorders	Rash	-	-	6 (3.1)
General disorders and administration site conditions	Injection site erythema	4 (2.1)	-	-
General disorders and administration site conditions	Injection site swelling	4 (2.1)	-	-
Psychiatric disorders	Irritability	4 (2.1)	-	-

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix, ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel, Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
-: Adverse event absent or not meeting the selected rule(s)
Detail of rule:
Display 10 most frequent primary preferred terms

Table 12 Number (%) of subjects with new onset of chronic illness (NOCD) events reported till DBF date (19Jun2015) for Primary Epoch analysis (Primary TVC)

System Organ Class	Most frequent adverse events-On-Therapy (occurring within day 0-9999 following vaccination)	Hexa group N = 195	Pedia group N = 194	Penta group N = 196
	Subjects with any AE(s), n (%)	4 (2.1)	2 (1.0)	3 (1.5)
Skin and subcutaneous tissue disorders	Dermatitis atopic	2 (1.0)	-	2 (1.0)
Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	2 (1.0)	-	-
Respiratory, thoracic and mediastinal disorders	Asthma	-	-	1 (0.5)
Immune system disorders	Drug hypersensitivity	-	1 (0.5)	-
Immune system disorders	Food allergy	-	-	1 (0.5)
Immune system disorders	Hypersensitivity	-	1 (0.5)	-

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
-: Adverse event absent or not meeting the selected rule(s)
Detail of rule:
Display 10 most frequent primary preferred terms

Table 13 Number (%) of subjects with serious adverse events reported till DBF date (19Jun2015) for Primary Epoch analysis (Primary TVC)

System Organ Class	All SAEs	Hexa group N = 195	Pedia group N = 194	Penta group N = 196
.	Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	7 (3.6) [2]	1 (0.5) [0]	7 (3.6) [0]
Infections and infestations	Gastroenteritis viral	1 (0.5) [0]	1 (0.5) [0]	0 (0.0) [0]
Infections and infestations	Parainfluenzae virus infection	0 (0.0) [0]	0 (0.0) [0]	2 (1.0) [0]
Respiratory, thoracic and mediastinal disorders	Respiratory distress	2 (1.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Infections and infestations	Respiratory syncytial virus bronchiolitis	1 (0.5) [0]	0 (0.0) [0]	1 (0.5) [0]
Respiratory, thoracic and mediastinal disorders	Apparent life threatening event	1 (0.5) [1]	0 (0.0) [0]	0 (0.0) [0]
Respiratory, thoracic and mediastinal disorders	Choking	1 (0.5) [0]	0 (0.0) [0]	0 (0.0) [0]
Metabolism and nutrition disorders	Dehydration	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [0]
Nervous system disorders	Febrile convulsion	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [0]
Gastrointestinal disorders	Gastrooesophageal reflux disease	1 (0.5) [0]	0 (0.0) [0]	0 (0.0) [0]
Respiratory, thoracic and mediastinal disorders	Hypoxia	1 (0.5) [0]	0 (0.0) [0]	0 (0.0) [0]
Nervous system disorders	Lethargy	1 (0.5) [1]	0 (0.0) [0]	0 (0.0) [0]
Blood and lymphatic system disorders	Leukocytosis	1 (0.5) [1]	0 (0.0) [0]	0 (0.0) [0]
Infections and infestations	Meningitis viral	1 (0.5) [0]	0 (0.0) [0]	0 (0.0) [0]
Psychiatric disorders	Mental status changes	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [0]
Infections and infestations	Pneumonia	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [0]
Infections and infestations	Respiratory syncytial virus infection	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [0]
Injury, poisoning and procedural complications	Road traffic accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.5) [0]
Nervous system disorders	Seizure	1 (0.5) [0]	0 (0.0) [0]	0 (0.0) [0]
.	Fatal SAEs	Hexa group	Pedia group	Penta group
.	Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Pedia group = Subjects who received *Pediarix*, *ActHIB* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Penta group = Subjects who received *Pentacel*, *Engerix* and *Prevnar* 13 at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age
Hexa group = Subjects who received three doses of *Infanrix Hexa* and *Prevnar 13* at 2, 4 and 6 month of age and *Rotarix* at 2 and 4 months of age

2. STUDY REPORT AUTHORS /CONTRIBUTING AUTHORS

Scientific Writer: PPD

Lead Statistician: PPD

Project Statistician: PPD

Study Delivery Lead: PPD

Study Delivery Manager: PPD *Synteract HCR, Inc*., contractor for GSK Biologicals.

Central Safety Contact: PPD

Clinical Research and Development Lead (CRDL): PPD

Regulatory Affairs representative: PPD

Project CRDL: PPD

3. SERIOUS ADVERSE EVENTS

3.1. SAE Listings

SAE listings were not generated for this interim timepoint.

GlaxoSmithKline Biologicals
Vaccine Value and Health Science
Sponsor Signatory Approval Page

Please note that by signing this page, you take responsibility for the content of the Abridged Interim Study Report.

STUDY TITLE: A Phase III, randomized, open-label, controlled, multi-center study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Study: 117119 (DTPA-HBV-IPV-135) Development Phase: III

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:	Narcisa Elena Mesaros, MD.
Title of Sponsor Signatory:	Project level Clinical Research and Development Lead, DTP/Polio Vaccines, Late Clinical Development, Vaccine Discovery and Development, GlaxoSmithKline Biologicals, SA.
Signature:	_____
Date:	_____

For internal use only

- ----------Checksum----------!Ver.!Created On - -
c2fcc169f3911cd6c9ecfe54cb699e25288cddb7 1.0 11/3/2015 12:53:26 PM - -
dafda7af3e6c4ed536d0d70018480a46455eaaa5 1.0 11/3/2015 12:53:28 PM - -
---------- -

GlaxoSmithKline Biologicals
Vaccine Value and Health Science
Sponsor Signatory Approval Page

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Study: 117119 (DTPA-HBV-IPV-135) Development Phase: III

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:	Narcisa Elena Mesaros, MD.
Title of Sponsor Signatory:	Project level Clinical Research and Development Lead, DTP/Polio Vaccines, Late Clinical Development, Vaccine Discovery and Development, GlaxoSmithKline Biologicals, SA.
Signature:	PPD
Date:	5 Nov 2015

For internal use only

- ----------Checksum----------!Ver.!Created On - -
c2fcc169f3911cd6c9ecfe54cb699e25288cddb7 1.0 11/3/2015 12:53:26 PM - -
dafda7af3e6c4ed536d0d70018480a46455eaaa5 1.0 11/3/2015 12:53:28 PM - -
---------- -

Annotated Study Book for Study Design: DTPA-HBV-IPV-135 (117119)

Study Design Version: 1.0

Sponsor: GlaxoSmithKline Vaccines

Protocol: DTPA-HBV-IPV-135 (117119)

Generic Drug Name: DTPA-HBV-IPV Vaccine

Trade Drug Name: Infanrix Hexa

A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Generated by Central Designer TM

January 2, 2017 10:31

DTPA-HBV-IPV-135 (117119): SCREENING (Screening) [frmSCREENING]

SCREENING [sctSCR]

1.	Initials: *[hidden]* [Initials]	[*txtScrSINIT* : Not submitted - for internal use] A3
2.* ✔	Please tick box to confirm CRF creation:	[*itmCRF_FLG* : Not submitted - for internal use] ☐

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DTPA-HBV-IPV-135 (117119): ENROLLMENT (Enrollment) [frmENROLLMENT]

ENROLLMENT [sctENROLLMENT]

1.* ✔	Subject Number: [Subj Nr]	[*itmPID* : Not submitted - for internal use] *N9*

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): SUBJECT IDENTIFICATION (Subj ID) [frmPATIENTIDENTIFICATION]

SUBJECT IDENTIFICATION [sctPATIENTIDENTIFICATION]

1.* ✔	Subject Number: [Subj Nr]	[*itmPID* : **PID_SCHD.ITMPID**] N9

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DTPA-HBV-IPV-135 (117119): DEMOGRAPHICS (Demog) [frmDEMOGRAPHY]

DEMOGRAPHICS [sctDEMOGRAPHY]

1.* ✔	Date of birth: [DOB]	[*itmDOB_RAW* : **DEMOG.DOB_RAW**] Req/Unk / Req/Unk / Req (2013-2018)
2.	Date of Birth for OCEANS (DO NOT delete) *[hidden]*	[*itmBIRTHDT_HID* : Not submitted - for internal use] NReq / NReq / NReq (2013-2018)
3.* ✔	Gender: [Gender]	[*itmSEX* : **DEMOG.SEX**] Male Female
4.* ✔	Ethnicity: [Ethnicity]	[*itmETHNIC* : **DEMOG.ETHNIC**] American Hispanic or Latino Not American Hispanic or Latino
5.* ✔	Geographic Ancestry: [Geographic Ancestry]	[*itmRACE* : **DEMOG.RACE**] African Heritage / African American American Indian or Alaskan Native Asian - Central/South Asian Heritage Asian - East Asian Heritage Asian - Japanese Heritage Asian - South East Asian Heritage Native Hawaiian or Other Pacific Islander White - Arabic / North African Heritage White - Caucasian / European Heritage [*itmRACE_OTH* : **DEMOG.RACE_OTH**] Other, Specify: *A40*
6.	Weight for OCEANS (Do not delete) *[hidden]*	[*itmWEIGHT_HID* : Not submitted - for internal use] *xxxx.*
7.* ✔	Please specify subject group: [Please specify subject group:]	[*itmSUBSET* : **CRIT_VAL.VALUE**] HEXA GROUP PEDIA GROUP PENTA GROUP

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DTPA-HBV-IPV-135 (117119): INFORMED CONSENT (IC) [frmINFORMEDCONSENT]

DATE OF VISIT [sctDATEOFVISIT]

1.* ✔	Date of visit: [DOV]	[*itmACTRDATE* : **ACTDATES.ACTRDATE**] Req / Req / Req (2013-2018)

INFORMED CONSENT [sctINFORMEDCONSENT]

I certify that Informed Consent has been obtained prior to any study procedure.

2.* ✔	Informed Consent Date: [IC date]	[*itmCONS_DAT* : **CONSENT.CONS_DAT**] Req / Req / Req (2013-2018)
3.* ✔	Did the subjects' parent(s)/Legally Acceptable Representative(s) agree that subjects' biological sample(s) may be used by GSK Biologicals for future research? (Type 4 tests) [Did the subject's parent(s)/Legally Acceptable Representative(s) agree that subject's biological sample(s) may be used by GSK Biologicals for future research? (Type 4 tests)]	[*itmCONS_LAB_Q4* : **CONS_LAB.CONSLABA**] Yes No Not applicable
4.	Informed consent section number *[hidden]* [Section number]	[*itmINF_NB1_HID* : Not submitted - for internal use] *N10*

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): GENERAL MEDICAL HISTORY / EXAMINATION (Gen med hist) [frmGENERALMEDICALHISTORYEXAMINATION]

GENERAL MEDICAL HISTORY / EXAMINATION [sctGENERALMEDICALHISTORY]

1.* ✔	Are you aware of any pre-existing conditions, signs or symptoms having started before first study vaccination? [Are you aware of any pre-existing conditions, signs or symptoms having started before first study vaccination?]	[itmMED_COND : GENHIST.MED_COND] ☐ No ☐ Yes -> Please give diagnosis and tick appropriate Past/Current box in the table below
2.	General medical history section number *[hidden]* [General medical history section number]	[itmGENMED_NB1_HID : Not submitted - for internal use] N10

	MedDRA SYSTEM ORGAN CLASS	Diagnosis	Past / Current?
3. ✔			

DIAGNOSIS Entry [sctDIAGNOSIS]

Please report medication(s) as specified in the protocol and fill in the medication section.

3.1* ✔	MedDRA SYSTEM ORGAN CLASS: [MedDRA SYSTEM ORGAN CLASS]	[itmDIAGTERM : DIAGNOS.DIAGTERM] ☐ [clMEDHIST] ☐
3.2* ✔	Diagnosis: [Diagnosis]	[itmDIAGNOSI : DIAGNOS.DIAGNOSI] A80
3.3* ✔	Past / Current? [Past / Current?]	[itmDIAGSTAT : DIAGNOS.DIAGSTAT] ☐ Past ☐ Current
3.4	Diagnosis: *[hidden]* [Diagnosis]	[itmDIAGNOSI_HID : Not submitted - for internal use] A128

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): DISEASE HISTORY (Dis Hist) [frmDISEASEHISTORY]

DISEASE HISTORY [sctDISEASEHISTORY]

Please note that If disease history is answered Yes, then exclusion criteria 12 needs to be ticked.

1.* ✔	Has the subject had history of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and/or hepatitis B diseases? [DTP-Hib-Pn-Rot-Pol-HB disease history?]	[*itmDIS_HIST_FLG_X* : **HIST_DIS.HIST_FLG**] ☐ Yes -> Please complete table below with appropriate information ☐ No ☐ Unknown, no information available

	Disease	Date(s) of diagnosis
2. ✔		

DISEASE DETAILS Entry [sctDISEASEDETAILS]

2.1* ✔	Disease: [Disease]	[*itmDIS_HIST_TYP* : **HIST_DIS.HIST_TYP**] ☐ DIPHTHERIA ☐ PERTUSSIS ☐ TETANUS ☐ PNEUMOCOCCAL ☐ ROTAVIRUS ☐ POLIOVIRUS ☐ HEPATITIS-B ☐ HIB
2.2* ✔	Date(s) of diagnosis [Date(s) of diagnosis]	[*itmHIST_DAT* : **HIST_DIS.HIST_DAT**] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): MOTHERS INFORMED CONSENT (Mot Inf Cons) [frmMOTHER_INF_CON]

MOTHERS INFORMED CONSENT [sctMOTH_INF_CON]

1.* ✔	Did the Mother give her consent to collect the Tdap Vaccination History Information ? [Did the Mother give her consent to collect the Tdap Vaccination History Information ?]	[*itmMOTH_INF_CONS_Q* : **MOT_CONS.MOTH_CON**] ☐ No ☐ Yes
2. ✔	Mother's Informed Consent date : [Mother's Informed Consent date :]	[*itmMOTH_CONS_DAT* : **MOT_CONS.MCON_DAT**] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): MOTHER'S TDAP VACCINATION HISTORY (Mot Tdap hist) [frmVACC_HISTORY_MOT]

MOTHERS VACCINATION HISTORY FLAG [sctVACC_HIST_FLG_MOT]

1.* ✔	Has the mother of the subject received Tdap vaccination during pregnancy before enrolment? [Has the mother of the subject received Tdap vaccination during pregnancy before enrolment?]	[*itmVACC_HIST_FLG_MOT* : **HIST_SHT.HIST_FLG**] ☐ Yes ☐ No ☐ Unknown, no information available

	Vaccine name	Route	Dose number	Date of administration
2. ✔				

VACCINATION HISTORY DETAILS Entry [sctVACC_HIST_DET_MOT]

2.1* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	[*itmCVACC_TRADNAME* : **HIST_VAC.TRADNAME**] *A60*
2.2	Vaccine name: (Trade name is preferred) *[hidden]* [Vaccine name]	[*itmCVACC_TRADNAME_HID* : Not submitted - for internal use] *A60*
2.3* ✔	Route: [Route]	[*itmCVACC_ROUTE* : **HIST_VAC.MED_ROUT**] ☐ *[clMEDROUT_CVACC]* ☐
2.4* ✔	Dose number: [Dose number]	[*itmNB_DOSE* : **HIST_VAC.NB_DOSE**] *N10*
2.5* ✔	Date of administration: [Date of administration]	[*itmCVACC_RDAT_MOT* : **HIST_VAC.HIST_DAT**] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018)
2.6	For GSK - MON: *[hidden]* [For GSK - MON]	[*itmMON_TRANS* : **HIST_VAC.MD_TRANS**] *A60*
2.7	For GSK - DM: *[hidden]* [For GSK - DM]	[*itmGSK_MOD_HID* : **HIST_VAC.GSK_MOD**] *A60*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): HEPATITIS B VACCINATION HISTORY (HepB Hist) [frmVACC_HISTORY_HEPB]

VACCINATION HISTORY FLAG [sctVACC_HIST_FLG_HEPB]

1.* ✔	Has the subject received any vaccination against Hepatitis B before enrolment? [Has the subject received any vaccination against Hepatitis B before enrolment?]	[*itmVACC_HIST_FLG_HEPB* : **HIST_SHT.HIST_FLG**] ☐ Yes -> Please complete the following table ☐ No ☐ Unknown

	Vaccine name	Route	Dose number	Date of administration
2. ✔				

VACCINATION HISTORY DETAILS Entry [sctVACC_HIST_DET]

2.1* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	[*itmCVACC_TRADNAME* : **HIST_VAC.TRADNAME**] *A60*
2.2	Vaccine name: (Trade name is preferred) *[hidden]* [Vaccine name]	[*itmCVACC_TRADNAME_HID* : Not submitted - for internal use] *A60*
2.3* ✔	Route: [Route]	[*itmCVACC_ROUTE* : **HIST_VAC.MED_ROUT**] ☐ *[clMEDROUT_CVACC]* ☐
2.4* ✔	Dose number: [Dose number]	[*itmNB_DOSE* : **HIST_VAC.NB_DOSE**] *N10*
2.5* ✔	Date of administration: [Date of administration]	[*itmCVACC_RDAT* : **HIST_VAC.HIST_DAT**] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018)
2.6	For GSK - MON: *[hidden]* [For GSK - MON]	[*itmMON_TRANS* : **HIST_VAC.MD_TRANS**] *A60*
2.7	For GSK - DM: *[hidden]* [For GSK - DM]	[*itmGSK_MOD_HID* : **HIST_VAC.GSK_MOD**] *A60*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): OTHER VACCINATION HISTORY (Oth Hist) [frmVACC_HISTORY_OTH]

VACCINATION HISTORY FLAG [sctVACC_HIST_FLG_OTH]

1.* ✔	Has the subject received any other vaccination before enrolment? [Has the subject received any other vaccination before enrolment?]	[itmVACC_HIST_FLG_OTH : HIST_SHT.HIST_FLG] ☐ Yes ☐ No ☐ Unknown, no information available

	Vaccine name	Route	Dose number	Date of administration
2. ✔				

VACCINATION HISTORY DETAILS Entry [sctVACC_HIST_DET]

2.1* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	[itmCVACC_TRADNAME : HIST_VAC.TRADNAME] A60
2.2	Vaccine name: (Trade name is preferred) *[hidden]* [Vaccine name]	[itmCVACC_TRADNAME_HID : Not submitted - for internal use] A60
2.3* ✔	Route: [Route]	[itmCVACC_ROUTE : HIST_VAC.MED_ROUT] ☐ [clMEDROUT_CVACC] ☐
2.4* ✔	Dose number: [Dose number]	[itmNB_DOSE : HIST_VAC.NB_DOSE] N10
2.5* ✔	Date of administration: [Date of administration]	[itmCVACC_RDAT : HIST_VAC.HIST_DAT] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018)
2.6	For GSK - MON: *[hidden]* [For GSK - MON]	[itmMON_TRANS : HIST_VAC.MD_TRANS] A60
2.7	For GSK - DM: *[hidden]* [For GSK - DM]	[itmGSK_MOD_HID : HIST_VAC.GSK_MOD] A60

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): PHYSICAL EXAMINATION / VITAL SIGNS (VS) [frmVITALSIGNS_US]

HEIGHT / WEIGHT [sctHEIGHTWEIGHT_US]

1.* ✔	Height: [Height]	[itmFEET : VS.VSORRES] [itmINCHES : VS.VSORRES] N2 feet xxx. inches
2.	Feet unit: *[hidden]*	[itmFEET_UNI_HID : VS.VSORRESU] [clVSORRESU]
3.	Inches unit: *[hidden]*	[itmINCHES_UNI_HID : VS.VSORRESU] [clVSORRESU]
4.* ✔	Weight: [Weight]	[itmPOUNDS : VS.VSORRES] [itmOUNCES : VS.VSORRES] N3 pounds N2 ounces
5.	Pounds unit: *[hidden]*	[itmPOUNDS_UNI_HID : VS.VSORRESU] [clVSORRESU]
6.	Ounces unit: *[hidden]*	[itmOUNCES_UNI_HID : VS.VSORRESU] [clVSORRESU]
7.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]
8.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): ELIGIBILITY CHECK (Eligibility) [frmELIGIBILITYCHECK]

ELIGIBILITY CHECK [sctELIGIBILITYCHECK]

1.* ✔	Did the subject meet all the entry criteria? [Eligible]	[*itmELIGIBIL* : **ELISHEET.ELIGIBIL**] ☐ Yes ☐ No -> 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. [*itmINCL_CRITERIA* : **ELIGIBIL.CRIT_NR**] **INCLUSION CRITERIA** Tick the boxes corresponding to any of the inclusion criteria the subject failed. ☐ 1.Subjects' parent(s)/Legally Acceptable Representative(s) [LAR(s)] who, in the opinion of the investigator, can and will comply with the requirements of the protocol (e.g. completion of the diary cards, return for follow-up visits). ☐ 2. A male or female between, and including, 6 and 12 weeks of age at the time of first vaccination. ☐ 3. Born full-term (i.e. after a gestation period of 37 weeks to less than 42 completed weeks [259 to 293 days]). ☐ 4. Written informed consent obtained from the parent(s)/LAR(s) of the subject ☐ 5. Healthy subjects as established by medical history and clinical examination before entering into the study. ☐ 6. Infants who have not received a previous dose of hepatitis B vaccine or those who have received only 1 dose of hepatitis B vaccine administered at least 30 days prior to enrolment. [*itmEXCL_CRITERIA* : **ELIGIBIL.CRIT_NR**] **EXCLUSION CRITERIA** Tick the boxes corresponding to any of the exclusion criteria that disqualified the subject from entry. ☐ 7. Child in care ☐ 8. Use of any investigational or non-registered product (drug or vaccine) other than the study vaccines within 30 days preceding the first dose of study vaccines, or planned use during the study period ☐ 9. Chronic administration (defined as more than 14 days in total) of immunosupp. or other immune-modifying drugs since birth. (For corticosteroids, this will mean prednisone > or = 0.5 mg/kg/day, or equivalent). Inhaled and topical steroids are allowed. ☐ 10. Planed adm/adm of vac not forseen by prot 30d before dose1 till 30d after dose3 & 30d before/after booster. Inactiv. flu & HepA vac allowed. Rout.admin. of MMR, varicella, pneumo vac allowed 30d after last pri vacc till 30d before Bst&post-bst samplng ☐ 11. Concurrently participating in another clinical study, at any time during the study period, in which the subject has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device). ☐ 12. History of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and hepatitis B diseases. ☐ 13. Previous vaccination against Hib, diphtheria, tetanus, pertussis, pneumococcus, rotavirus and/or poliovirus; more than one previous dose of hepatitis B vaccine. ☐ 14. Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required). ☐ 15. Family history of congenital or hereditary immunodeficiency. ☐ 16. History of any reaction or hypersensitivity likely to be exacerbated by any component of the vaccines (including yeast). ☐ 17. Hypersensitivity to latex. ☐ 18. Major congenital defects or serious chronic illness. ☐ 19. History of any neurological disorders including seizures. ☐ 20. Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period. ☐ 21. History of intussusception or of any uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception. ☐ 22. History of Severe Combined Immunodeficiency Disease (SCID). ☐ 23. Acute disease and/or fever at time of enrol.– Fever: temp>or=38.0°C /100.4°F by any rout. Pref route: rectal for pri & axilary for bst. Sub. with minor illnes (eg: mild diar, mild uper resp.infection) with no fever may be enrol. at discretion of INV
2.	Eligibility section number *[hidden]* [Section number]	[*itmELI_NB1_HID* : Not submitted - for internal use] *N10*

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 1 (HEXA GROUP) (vac adm hexa-dose1) [frmVACC_ADMIN_D1_HEXA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_HEXA]

Infanrix Hexa Vaccine

5.* ✔	Has Infanrix Hexa Vaccine been administered? [Vaccinated]	[itmV_ADM_HEXA_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_HEXA : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_HEXA : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_HEXA : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_HEXA : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_HEXA : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_HEXA : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_HEXA_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_HEXA_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_HEXA_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_HEXA_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_PREVNAR13]

Prevnar13 Vaccine

10.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[itmV_ADM_PREVNAR13 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PREVNAR13 : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PREVNAR13 : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Lower Left - IM)

		☐ Not according to protocol -> [*itmP_APSITE_PREVNAR13* : **VACCPROD.P_APSITE**] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
11.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
12.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
14.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_ROTARIX]		
Rotarix Vaccine		
15.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	[*itmV_ADM_ROTARIX* : **VACCPROD.V_ADM**] ☐ Yes -> [*itmV_TRT_ROTARIX* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_ROTARIX* : **VACCPROD.P_AP**] ☐ According to protocol (Oral) ☐ Not according to protocol [*itmVADM_COM_ROTARIX* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
16.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ROTARIX_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_CVACC]*
17.	P_CODE *[hidden]*	[*itmP_CODE_ROTARIX_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
VACCINATION DETAILS [sctVACCDETAILS_2VACC_D1]		
18. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
19. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* ☐ [*itmAE_NB* : **VAC_INFO.AE_NB**] Non-Serious Adverse Event -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**]

		Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) *A100* [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives
20.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)

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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 1 (PENTA GROUP) (vac adm penta-dose1) [frmVACC_ADMIN_D1_PENTA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_PENTACEL]

Pentacel Vaccine

5.* ✔	Has Pentacel Vaccine been administered? [Vaccinated]	[itmV_ADM_PENTACEL_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PENTACEL : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PENTACEL : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_PENTACEL : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PENTACEL : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PENTACEL : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PENTACEL : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_PENTACEL_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_PENTACEL_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_PENTACEL_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_PENTACEL_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_ENGERIX_B]

Engerix-B Vaccine

10.* ✔	Has Engerix-B Vaccine been administered? [Vaccinated]	[itmV_ADM_ENGERIX_B_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_ENGERIX_B : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ENGERIX_B : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Upper Left - IM) Not according to protocol -> [itmP_APSITE_ENGERIX_B : VACCPROD.P_APSITE]

		Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_ENGERIX_B* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_ENGERIX_B* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_ENGERIX_B* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
11.	P_SITE *[hidden]*	[*itmP_SITE_ENGERIX_B_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
12.	P_SIDE *[hidden]*	[*itmP_SIDE_ENGERIX_B_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ENGERIX_B_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
14.	P_CODE *[hidden]*	[*itmP_CODE_ENGERIX_B_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_PREVNAR13]		
Prevnar13 Vaccine		
15.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[*itmV_ADM_PREVNAR13* : **VACCPROD.V_ADM**] ☐ Yes -> [*itmV_TRT_PREVNAR13* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_PREVNAR13* : **VACCPROD.P_AP**] Injection Site/Side/Route: ☐ According to protocol (Thigh – Lower Left - IM) ☐ Not according to protocol -> [*itmP_APSITE_PREVNAR13* : **VACCPROD.P_APSITE**] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
16.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
17.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
18.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
19.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_ROTARIX]		
Rotarix Vaccine		
20.*	Has Rotarix Vaccine been administered?	[*itmV_ADM_ROTARIX* : **VACCPROD.V_ADM**]

✔	[Vaccinated]	☐ Yes -> [*itmV_TRT_ROTARIX* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_ROTARIX* : **VACCPROD.P_AP**] ☐ According to protocol (Oral) ☐ Not according to protocol [*itmVADM_COM_ROTARIX* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
21.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ROTARIX_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_CVACC]* ☐
22.	P_CODE *[hidden]*	[*itmP_CODE_ROTARIX_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
VACCINATION DETAILS [sctVACCDETAILS_2VACC_D1]		
23. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
24. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* ☐ [*itmAE_NB* : **VAC_INFO.AE_NB**] Non-Serious Adverse Event -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) *A100* [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives
25.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 1 (PEDIA GROUP) (vac adm pedia-dose1) [frmVACC_ADMIN_D1_PEDIA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] *[clVSORRESU]*
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] *[clVSTEST]*
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] *[clVSTESTCD]*

[sctVACC_ADMIN_PEDIARIX]

Pediarix Vaccine

5.* ✔	Has Pediarix Vaccine been administered? [Vaccinated]	[itmV_ADM_PEDIARIX_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PEDIARIX : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PEDIARIX : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_PEDIARIX : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PEDIARIX : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PEDIARIX : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PEDIARIX : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_PEDIARIX_HID : VACCPROD.P_SITE] *[clVACCSITE]*
7.	P_SIDE *[hidden]*	[itmP_SIDE_PEDIARIX_HID : VACCPROD.P_SIDE] *[clVACCSIDE]*
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_PEDIARIX_HID : VACCPROD.P_ROUTE] *[clMEDROUT_VACC]*
9.	P_CODE *[hidden]*	[itmP_CODE_PEDIARIX_HID : VACCPROD.P_CODE] *[clPRODNAMES]*

[sctVACC_ADMIN_ACTHIB]

ActHib Vaccine

10.* ✔	Has ActHib Vaccine been administered? [Vaccinated]	[itmV_ADM_ACTHIB_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_ACTHIB : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ACTHIB : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Upper Left - IM) Not according to protocol -> [itmP_APSITE_ACTHIB : VACCPROD.P_APSITE]

		Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_ACTHIB* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_ACTHIB* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_ACTHIB* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
11.	P_SITE *[hidden]*	[*itmP_SITE_ACTHIB_HID* : **VACCPROD.P_SITE**] ☐ *[clVACCSITE]* ☐
12.	P_SIDE *[hidden]*	[*itmP_SIDE_ACTHIB_HID* : **VACCPROD.P_SIDE**] ☐ *[clVACCSIDE]* ☐
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ACTHIB_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_VACC]* ☐
14.	P_CODE *[hidden]*	[*itmP_CODE_ACTHIB_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
[sctVACC_ADMIN_PREVNAR13]		
Prevnar13 Vaccine		
15.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[*itmV_ADM_PREVNAR13* : **VACCPROD.V_ADM**] ☐ Yes -> [*itmV_TRT_PREVNAR13* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_PREVNAR13* : **VACCPROD.P_AP**] Injection Site/Side/Route: ☐ According to protocol (Thigh – Lower Left - IM) ☐ Not according to protocol -> [*itmP_APSITE_PREVNAR13* : **VACCPROD.P_APSITE**] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
16.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] ☐ *[clVACCSITE]* ☐
17.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] ☐ *[clVACCSIDE]* ☐
18.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_VACC]* ☐
19.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
[sctVACC_ADMIN_ROTARIX]		
Rotarix Vaccine		
20.*	Has Rotarix Vaccine been administered?	[*itmV_ADM_ROTARIX* : **VACCPROD.V_ADM**]

✔	[Vaccinated]	☐ Yes -> [*itmV_TRT_ROTARIX* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_ROTARIX* : **VACCPROD.P_AP**] ☐ According to protocol (Oral) ☐ Not according to protocol [*itmVADM_COM_ROTARIX* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
21.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ROTARIX_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_CVACC]* ☐
22.	P_CODE *[hidden]*	[*itmP_CODE_ROTARIX_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
VACCINATION DETAILS [sctVACCDETAILS_2VACC_D1]		
23. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
24. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* ☐ [*itmAE_NB* : **VAC_INFO.AE_NB**] Non-Serious Adverse Event -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) *A100* [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives
25.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - HEXA (Loc symp flg Hexa) [frmLOCSYMPTOMS_FLAG_HEXA]

LOCAL SIGNS/SYMPTOMS FLAG - HEXA [sctLOCSYMPTOMS_FLG_HEXA]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Infanrix Hexa]	[*itmLOCSOL_YN_HEXA* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (INFANRIX HEXA) (Loc symp-Hexa)
[frmLOCSYMPTOMS_HEXA]

Infanrix Hexa vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: ☐ [clINTENSITYSOL] ☐

		[*itmPA_ONG* : **SOLAE.SYMP_ONG**] **After Day 3:** Ongoing? No Yes -> [*itmSYMP_MAX_INTEN* : **SOLAE.SYMP_MAX**] Maximum intensity: *[clINTENSITYSOL_MAX]* [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] *[clSYMPCODE]*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - PEDIARIX (Loc symp flg Pediarix) [frmLOCSYMPTOMS_FLAG_PEDIARIX]

LOCAL SIGNS/SYMPTOMS FLAG - PEDIARIX [sctLOCSYMPTOMS_FLG_PEDIARIX]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Pediarix]	[*itmLOCSOL_YN_PEDIARIX* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PEDIARIX) (Loc symp-Pediarix)
[frmLOCSYMPTOMS_PEDIARIX]

Pediarix vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: ☐ [clINTENSITYSOL] ☐

		[*itmPA_ONG* : **SOLAE.SYMP_ONG**] **After Day 3:** Ongoing? No Yes -> [*itmSYMP_MAX_INTEN* : **SOLAE.SYMP_MAX**] Maximum intensity: *[clINTENSITYSOL_MAX]* [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] *[clSYMPCODE]*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib) [frmLOCSYMPTOMS_FLAG_ACTHIB_D1]

LOCSYMPTOMS_FLG_ACTHIB [sctLOCSYMPTOMS_FLG_ACTHIB_D1]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	[*itmLOCSOL_YN_ACTHIB_D1* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ACTHIB) (Loc symp-ActHib) [frmLOCSYMPTOMS_ACTHIB]

ActHib vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: ☐ [clINTENSITYSOL] ☐ [itmPA_ONG : SOLAE.SYMP_ONG]

		After Day 3: Ongoing? No Yes -> [*itmSYMP_MAX_INTEN* : **SOLAE.SYMP_MAX**] Maximum intensity: *[clINTENSITYSOL_MAX]* [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] *[clSYMPCODE]*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - PENTACEL (Loc symp flg Pentacel) [frmLOCSYMPTOMS_FLAG_PENTACEL]

LOCAL SIGNS/SYMPTOMS FLAG - PENTACEL [sctLOCSYMPTOMS_FLG_PENTACEL]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Pentacel]	[*itmLOCSOL_YN_PENTACEL* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PENTACEL) (Loc symp-Pentacel)
[frmLOCSYMPTOMS_PENTACEL]

Pentacel vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: ☐ [clINTENSITYSOL] ☐

		[*itmPA_ONG* : **SOLAE.SYMP_ONG**] **After Day 3:** Ongoing? No Yes -> [*itmSYMP_MAX_INTEN* : **SOLAE.SYMP_MAX**] Maximum intensity: *[clINTENSITYSOL_MAX]* [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] *[clSYMPCODE]*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ENGERIX B (Loc symp flg Engerix-B) [frmLOCSYMPTOMS_FLAG_ENGERIX_B]

LOCAL SIGNS/SYMPTOMS FLAG - ENGERIX B [sctLOCSYMPTOMS_FLG_ENGERIX_B]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Engerix-B]	[*itmLOCSOL_YN_ENGERIX_B* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ENGERIX-B) (Loc symp-Engerix-B)
[frmLOCSYMPTOMS_ENGERIX_B]

Engerix-B vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: ☐ [clINTENSITYSOL] ☐ [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: ☐ [clINTENSITYSOL] ☐

		[*itmPA_ONG* : **SOLAE.SYMP_ONG**] **After Day 3:** Ongoing? No Yes -> [*itmSYMP_MAX_INTEN* : **SOLAE.SYMP_MAX**] Maximum intensity: *[clINTENSITYSOL_MAX]* [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] *[clSYMPCODE]*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): GENERAL SIGNS/SYMPTOMS FLAG (Gen symp flg) [frmGENSYMPTOMS_FLAG]

GENERAL SIGNS/SYMPTOMS FLAG [sctGENSYMPTOMS_FLG]

1.* ✔	Has the subject experienced any of the General Solicited signs/symptoms between Day 0 and Day 3?	[*itmGENSOL_YN* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS (Gen symp) [frmGENSYMPTOMS]

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

TEMPERATURE (°F) [sctTEMPERATURE_SOL]

Record temperatures if during the solicited period at least one axillary/oral/tympanic/rectal measure is above or equal to 100.4 °F

1.* ✔	Occurred?	[itmFE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Not taken ☐ Yes -> Day 0: [itmFE_VAL_D0 : SOLVAL.SYMP_VAL] Not taken xxx.x [itmFE_NT_D0 : SOLVAL.T_N_TAK] ☐ Day 1: [itmFE_VAL_D1 : SOLVAL.SYMP_VAL] xxx.x [itmFE_NT_D1 : SOLVAL.T_N_TAK] ☐ Day 2: [itmFE_VAL_D2 : SOLVAL.SYMP_VAL] xxx.x [itmFE_NT_D2 : SOLVAL.T_N_TAK] ☐ Day 3: [itmFE_VAL_D3 : SOLVAL.SYMP_VAL] xxx.x [itmFE_NT_D3 : SOLVAL.T_N_TAK] ☐ [itmTEMP_ROUTE : SOLAE.SYMP_T_S] Route: ☐ Axillary ☐ Oral ☐ Rectal (Preferred) ☐ Tympanic [itmFE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_TEMP : SOLAE.SYMP_MAX] Max temperature: xxx.x [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? ☐ No ☐ Yes [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	Unit: *[hidden]* [Unit]	[itmTEMP_UNIT : Not submitted - for internal use] ☐ Fahrenheit
3.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
4.	Threshold for fever based on route and unit *[hidden]*	[itmFEV_VAL_HID : Not submitted - for internal use] xxxxxxxxxxxx.xx
5.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

DROWSINESS [sctDROWSINESS]

6.* ✔	Occurred?	[itmDR_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: Day 0: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ Day 1: [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ Day 2: [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ Day 3: [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ [itmDR_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: ☐ [clINTENSITYSOL_MAX] ☐ [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? ☐ No ☐ Yes

		[itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
7.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]
IRRITABILITY/FUSSINESS [sctIRRITABILITY]		
8.* ✔	Occurred?	[itmIF_YN : SOLAE.SYMP_EXP] No Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: [clINTENSITYSOL] [itmIF_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? No Yes [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
9.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]
LOSS OF APPETITE [sctLOSSOFAPPETITE]		
10.* ✔	Occurred?	[itmLO_YN : SOLAE.SYMP_EXP] No Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: [clINTENSITYSOL] [itmLO_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? No Yes [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
11.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): CHECK FOR STUDY CONTINUATION (Study Cont.) [frmSTUDYCONTINUATION_DISC]

CHECK FOR STUDY CONTINUATION [sctSTUDYCONTINUATION]

1.* ✔	Did the subject return for this visit?	[itmVIS_FLG : VIS_INFO.VIS_FLG] [itmACTRDATE : ACTDATES.ACTRDATE] Yes -> Date of visit: Req / Req / Req (2013-2018) No [itmVIS_REAS : VIS_INFO.V_REAS] **-> Please select the major reason:** Serious Adverse Event [itmSAE_CASE : VIS_INFO.SAE_CASE] -> Please complete a **SAE** Report and specify SAE Report No. N2 [itmFATAL : VIS_INFO.FATAL] -> Tick box if SAE is fatal: [itmAE_NB : VIS_INFO.AE_NB] -> Please complete Non-Serious Adverse Event section and specify AE No. N2 [itmSYMP_COD : VIS_INFO.SYMP_COD] or Solicited AE code: [clSYMPCODE] Non-Serious Adverse Event [itmPTV_SP : VIS_INFO.REAS_COM] Protocol violation, please specify: A50 Consent Withdrawal not due to an adverse event ->Please specify the reason (only if the Subject's parents / Legally Acceptable Representative has / have spontaneously explained it): [itmCWS_SP : VIS_INFO.REAS_COM] A50 [itmCWS_NA : Not submitted - for internal use] Or tick box if reason not provided Migrated / moved from the study area Lost to follow-up Sponsor study termination [itmV_OTH : VIS_INFO.REAS_COM] Other, please specify A100 [itmDECISION : VIS_INFO.DECISION] **-> For serious (except death), non-serious adverse events and Other reasons only:** **Please select who made the decision:** Investigator Subject's parents / Legally Acceptable Representatives

PERMANENT DISCONTINUATION [sctPERM_DISCONTINUATION]

2. ✔	Study discontinuation:	-> [itmDISCNT : VIS_INFO.DISCNT] Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study In this case, terminate the CRF: Complete Medication, Concomitant Vaccination, (S)AE sections and Study Conclusion.

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 2 (HEXA GROUP) (vac adm hexa-dose2) [frmVACC_ADMIN_D2_HEXA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_HEXA]

Infanrix Hexa Vaccine

5.* ✔	Has Infanrix Hexa Vaccine been administered? [Vaccinated]	[itmV_ADM_HEXA_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_HEXA : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_HEXA : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_HEXA : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_HEXA : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_HEXA : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_HEXA : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_HEXA_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_HEXA_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_HEXA_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_HEXA_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_PREVNAR13]

Prevnar13 Vaccine

10.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[itmV_ADM_PREVNAR13 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PREVNAR13 : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PREVNAR13 : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Lower Left - IM) Not according to protocol -> [itmP_APSITE_PREVNAR13 : VACCPROD.P_APSITE]

		Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
11.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] ☐ *[clVACCSITE]* ☐
12.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] ☐ *[clVACCSIDE]* ☐
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_VACC]* ☐
14.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
[sctVACC_ADMIN_ROTARIX]		
Rotarix Vaccine		
15.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	[*itmV_ADM_ROTARIX* : **VACCPROD.V_ADM**] ☐ Yes -> [*itmV_TRT_ROTARIX* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_ROTARIX* : **VACCPROD.P_AP**] ☐ According to protocol (Oral) ☐ Not according to protocol [*itmVADM_COM_ROTARIX* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
16.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ROTARIX_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_CVACC]* ☐
17.	P_CODE *[hidden]*	[*itmP_CODE_ROTARIX_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
18. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
19.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
20. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2*

Non-Serious Adverse Event [*itmAE_NB* : **VAC_INFO.AE_NB**]
-> Please complete Non-Serious Adverse Event section and specify AE No. N2

[*itmSYMP_COD* : **VAC_INFO.SYMP_COD**]
or Solicited AE code: *[clSYMPCODE]*

[*itmV_OTH* : **VAC_INFO.V_OTH**]
Other, please specify (e.g.: consent withdrawal, Protocol violation, ...)
A100

[*itmDECISION* : **VAC_INFO.DECISION**]
Please select who made the decision: Investigator
Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 2 (PEDIA GROUP) (vac adm pedia-dose2) [frmVACC_ADMIN_D2_PEDIA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_PEDIARIX]

Pediarix Vaccine

5.* ✔	Has Pediarix Vaccine been administered? [Vaccinated]	[itmV_ADM_PEDIARIX_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PEDIARIX : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PEDIARIX : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_PEDIARIX : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PEDIARIX : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PEDIARIX : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PEDIARIX : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_PEDIARIX_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_PEDIARIX_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_PEDIARIX_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_PEDIARIX_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_ACTHIB]

ActHib Vaccine

10.* ✔	Has ActHib Vaccine been administered? [Vaccinated]	[itmV_ADM_ACTHIB_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_ACTHIB : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ACTHIB : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Upper Left - IM) Not according to protocol -> [itmP_APSITE_ACTHIB : VACCPROD.P_APSITE]

		Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_ACTHIB* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_ACTHIB* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_ACTHIB* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
11.	P_SITE *[hidden]*	[*itmP_SITE_ACTHIB_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
12.	P_SIDE *[hidden]*	[*itmP_SIDE_ACTHIB_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ACTHIB_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
14.	P_CODE *[hidden]*	[*itmP_CODE_ACTHIB_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_PREVNAR13]		
Prevnar13 Vaccine		
15.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[*itmV_ADM_PREVNAR13* : **VACCPROD.V_ADM**] ☐ Yes -> [*itmV_TRT_PREVNAR13* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_PREVNAR13* : **VACCPROD.P_AP**] Injection Site/Side/Route: ☐ According to protocol (Thigh – Lower Left - IM) ☐ Not according to protocol -> [*itmP_APSITE_PREVNAR13* : **VACCPROD.P_APSITE**] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
16.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
17.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
18.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
19.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_ROTARIX]		
Rotarix Vaccine		
20.*	Has Rotarix Vaccine been administered?	[*itmV_ADM_ROTARIX* : **VACCPROD.V_ADM**]

✔	[Vaccinated]	☐ Yes -> [*itmV_TRT_ROTARIX* : **VACC_TRT.V_TRT**] Administered treatment number: N10 [*itmP_AP_ROTARIX* : **VACCPROD.P_AP**] ☐ According to protocol (Oral) ☐ Not according to protocol [*itmVADM_COM_ROTARIX* : **VACCPROD.VADM_COM**] If relevant, comment on administration: A200 ☐ No
21.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ROTARIX_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_CVACC]* ☐
22.	P_CODE *[hidden]*	[*itmP_CODE_ROTARIX_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
23. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
24.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
25. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 ☐ Non-Serious Adverse Event [*itmAE_NB* : **VAC_INFO.AE_NB**] -> Please complete Non-Serious Adverse Event section and specify AE No. N2 [*itmSYMP_COD* : **VAC_INFO.SYMP_COD**] Or Solicited AE code: ☐ *[clSYMPCODE]* ☐ ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify A100 [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 2 (PENTA GROUP) (vac adm penta-dose2) [frmVACC_ADMIN_D2_PENTA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_PENTACEL]

Pentacel Vaccine

5.* ✔	Has Pentacel Vaccine been administered? [Vaccinated]	[itmV_ADM_PENTACEL_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PENTACEL : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PENTACEL : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_PENTACEL : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PENTACEL : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PENTACEL : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PENTACEL : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_PENTACEL_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_PENTACEL_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_PENTACEL_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_PENTACEL_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_ENGERIX_B]

Engerix-B Vaccine (should not be given at Month 2 (4 months of age) if a dose of Hepatitis B vaccine was given at birth up to 30 days prior to study dose 1)

10.* ✔	Has Engerix-B Vaccine been administered? [Vaccinated]	[itmV_ADM_ENGERIX_B_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_ENGERIX_B : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ENGERIX_B : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Upper Left - IM) Not according to protocol -> [itmP_APSITE_ENGERIX_B : VACCPROD.P_APSITE]

		Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_ENGERIX_B* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_ENGERIX_B* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_ENGERIX_B* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
11.	P_SITE *[hidden]*	[*itmP_SITE_ENGERIX_B_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
12.	P_SIDE *[hidden]*	[*itmP_SIDE_ENGERIX_B_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ENGERIX_B_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
14.	P_CODE *[hidden]*	[*itmP_CODE_ENGERIX_B_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_PREVNAR13]		
Prevnar13 Vaccine		
15.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[*itmV_ADM_PREVNAR13* : **VACCPROD.V_ADM**] ☐ Yes -> [*itmV_TRT_PREVNAR13* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_PREVNAR13* : **VACCPROD.P_AP**] Injection Site/Side/Route: ☐ According to protocol (Thigh – Lower Left - IM) ☐ Not according to protocol -> [*itmP_APSITE_PREVNAR13* : **VACCPROD.P_APSITE**] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* ☐ No
16.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
17.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
18.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
19.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_ROTARIX]		
Rotarix Vaccine		
20.*	Has Rotarix Vaccine been administered?	[*itmV_ADM_ROTARIX* : **VACCPROD.V_ADM**]

✔	[Vaccinated]	☐ Yes -> [*itmV_TRT_ROTARIX* : **VACC_TRT.V_TRT**] Administered treatment number: N10 [*itmP_AP_ROTARIX* : **VACCPROD.P_AP**] ☐ According to protocol (Oral) ☐ Not according to protocol [*itmVADM_COM_ROTARIX* : **VACCPROD.VADM_COM**] If relevant, comment on administration: A200 ☐ No
21.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ROTARIX_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_CVACC]* ☐
22.	P_CODE *[hidden]*	[*itmP_CODE_ROTARIX_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
23. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
24.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
25. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 ☐ Non-Serious Adverse Event [*itmAE_NB* : **VAC_INFO.AE_NB**] > Please complete Non-Serious Adverse Event section and specify AE No. N2 [*itmSYMP_COD* : **VAC_INFO.SYMP_COD**] Or Solicited AE code: ☐ *[clSYMPCODE]* ☐ ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify A100 [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

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DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib) [frmLOCSYMPTOMS_FLAG_ACTHIB_D2]

LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB [sctLOCSYMPTOMS_FLG_ACTHIB_D2]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	[*itmLOCSOL_YN_ACTHIB_D2* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 3 (HEXA GROUP) (vac adm hexa-dose3) [frmVACC_ADMIN_D3_HEXA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_HEXA]

Infanrix Hexa

5.* ✔	Has Infanrix Hexa Vaccine been administered? [Vaccinated]	[itmV_ADM_HEXA_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_HEXA : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_HEXA : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_HEXA : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_HEXA : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_HEXA : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_HEXA : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_HEXA_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_HEXA_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_HEXA_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_HEXA_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_PREVNAR13]

Prevnar13 Vaccine

10.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[itmV_ADM_PREVNAR13 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PREVNAR13 : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PREVNAR13 : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Lower Left - IM) Not according to protocol -> [itmP_APSITE_PREVNAR13 : VACCPROD.P_APSITE]

		Site: Deltoid Thigh Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: Left Right Upper Left Lower Left Upper Right Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: Intramuscular Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* No
11.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
12.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
14.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
15. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] Req / Req / Req (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date
16.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] NReq / NReq / NReq (2013-2018)
17. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* Non-Serious Adverse Event [*itmAE_NB* : **VAC_INFO.AE_NB**] -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* [*itmSYMP_COD* : **VAC_INFO.SYMP_COD**] or Solicited AE code: *[clSYMPCODE]* [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) *A100* [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: Investigator Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 3 (PEDIA GROUP) (vac adm pedia-dose3) [frmVACC_ADMIN_D3_PEDIA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: ☐ Axillary ☐ Oral ☐ Rectal (Preferred) ☐ Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] ☐ [clVSORRESU] ☐
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] ☐ [clVSTEST] ☐
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] ☐ [clVSTESTCD] ☐

VACCINE ADMINISTRATION - PEDIARIX [sctVACC_ADMIN_PEDIARIX]

5.* ✔	Has Pediarix Vaccine been administered? [Vaccinated]	[itmV_ADM_PEDIARIX_D1 : VACCPROD.V_ADM] ☐ Yes -> [itmV_TRT_PEDIARIX : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PEDIARIX : VACCPROD.P_AP] Injection Site/Side/Route: ☐ According to protocol (Thigh - Right - IM) ☐ Not according to protocol -> [itmP_APSITE_PEDIARIX : VACCPROD.P_APSITE] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [itmP_APSIDE_PEDIARIX : VACCPROD.P_APSIDE] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [itmP_APROUTE_PEDIARIX : VACCPROD.P_APROUT] Route: ☐ Intramuscular ☐ Subcutaneous [itmVADM_COM_PEDIARIX : VACCPROD.VADM_COM] If relevant, comment on administration: A200 ☐ No
6.	P_SITE *[hidden]*	[itmP_SITE_PEDIARIX_HID : VACCPROD.P_SITE] ☐ [clVACCSITE] ☐
7.	P_SIDE *[hidden]*	[itmP_SIDE_PEDIARIX_HID : VACCPROD.P_SIDE] ☐ [clVACCSIDE] ☐
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_PEDIARIX_HID : VACCPROD.P_ROUTE] ☐ [clMEDROUT_VACC] ☐
9.	P_CODE *[hidden]*	[itmP_CODE_PEDIARIX_HID : VACCPROD.P_CODE] ☐ [clPRODNAMES] ☐

[sctVACC_ADMIN_ACTHIB]

ActHib Vaccine

10.* ✔	Has ActHib Vaccine been administered? [Vaccinated]	[itmV_ADM_ACTHIB_D1 : VACCPROD.V_ADM] ☐ Yes -> [itmV_TRT_ACTHIB : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ACTHIB : VACCPROD.P_AP] Injection Site/Side/Route: ☐ According to protocol (Thigh – Upper Left - IM) ☐ Not according to protocol -> [itmP_APSITE_ACTHIB : VACCPROD.P_APSITE] Site: ☐ Deltoid ☐ Thigh ☐ Buttock

		[itmP_APSIDE_ACTHIB : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_ACTHIB : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_ACTHIB : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
11.	P_SITE *[hidden]*	[itmP_SITE_ACTHIB_HID : VACCPROD.P_SITE] [clVACCSITE]
12.	P_SIDE *[hidden]*	[itmP_SIDE_ACTHIB_HID : VACCPROD.P_SIDE] [clVACCSIDE]
13.	P_ROUTE *[hidden]*	[itmP_ROUTE_ACTHIB_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
14.	P_CODE *[hidden]*	[itmP_CODE_ACTHIB_HID : VACCPROD.P_CODE] [clPRODNAMES]
[sctVACC_ADMIN_PREVNAR13]		
Prevnar13 Vaccine		
15.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[itmV_ADM_PREVNAR13 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PREVNAR13 : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PREVNAR13 : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Lower Left - IM) Not according to protocol -> [itmP_APSITE_PREVNAR13 : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PREVNAR13 : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PREVNAR13 : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PREVNAR13 : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
16.	P_SITE *[hidden]*	[itmP_SITE_PREVNAR13_HID : VACCPROD.P_SITE] [clVACCSITE]
17.	P_SIDE *[hidden]*	[itmP_SIDE_PREVNAR13_HID : VACCPROD.P_SIDE] [clVACCSIDE]
18.	P_ROUTE *[hidden]*	[itmP_ROUTE_PREVNAR13_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
19.	P_CODE *[hidden]*	[itmP_CODE_PREVNAR13_HID : VACCPROD.P_CODE] [clPRODNAMES]
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
20. ✔	Date of administration:	[itmVACCRDAT : VAC_INFO.VACCRDAT] If at least one vaccine administered Req / Req / Req (2013-2018) [itmSAME_DATE : Not submitted - for internal use]

		Or tick box if date is the same as visit date ☐
21.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
22. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* ☐ Non-Serious Adverse Event [*itmAE_NB* : **VAC_INFO.AE_NB**] -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* [*itmSYMP_COD* : **VAC_INFO.SYMP_COD**] Solicited AE code: ☐ *[clSYMPCODE]* ☐ ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify *A100* [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 3 (PENTA GROUP) (vac adm penta-dose3) [frmVACC_ADMIN_D3_PENTA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary Oral Rectal (Preferred) Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_PENTACEL]

Pentacel Vaccine

5.* ✔	Has Pentacel Vaccine been administered? [Vaccinated]	[itmV_ADM_PENTACEL_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_PENTACEL : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PENTACEL : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh - Right - IM) Not according to protocol -> [itmP_APSITE_PENTACEL : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PENTACEL : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PENTACEL : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PENTACEL : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
6.	P_SITE *[hidden]*	[itmP_SITE_PENTACEL_HID : VACCPROD.P_SITE] [clVACCSITE]
7.	P_SIDE *[hidden]*	[itmP_SIDE_PENTACEL_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_PENTACEL_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_PENTACEL_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_ENGERIX_B]

Engerix-B Vaccine

10.* ✔	Has Engerix-B Vaccine been administered? [Vaccinated]	[itmV_ADM_ENGERIX_B_D1 : VACCPROD.V_ADM] Yes -> [itmV_TRT_ENGERIX_B : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ENGERIX_B : VACCPROD.P_AP] Injection Site/Side/Route: According to protocol (Thigh – Upper Left - IM) Not according to protocol -> [itmP_APSITE_ENGERIX_B : VACCPROD.P_APSITE]

		Site: Deltoid Thigh Buttock [*itmP_APSIDE_ENGERIX_B* : **VACCPROD.P_APSIDE**] Side: Left Right Upper Left Lower Left Upper Right Lower Right [*itmP_APROUTE_ENGERIX_B* : **VACCPROD.P_APROUT**] Route: Intramuscular Subcutaneous [*itmVADM_COM_ENGERIX_B* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* No
11.	P_SITE *[hidden]*	[*itmP_SITE_ENGERIX_B_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
12.	P_SIDE *[hidden]*	[*itmP_SIDE_ENGERIX_B_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_ENGERIX_B_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
14.	P_CODE *[hidden]*	[*itmP_CODE_ENGERIX_B_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
[sctVACC_ADMIN_PREVNAR13]		
Prevnar13 Vaccine been administered?		
15.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	[*itmV_ADM_PREVNAR13* : **VACCPROD.V_ADM**] Yes -> [*itmV_TRT_PREVNAR13* : **VACC_TRT.V_TRT**] Administered treatment number: *N10* [*itmP_AP_PREVNAR13* : **VACCPROD.P_AP**] Injection Site/Side/Route: According to protocol (Thigh – Lower Left - IM) Not according to protocol -> [*itmP_APSITE_PREVNAR13* : **VACCPROD.P_APSITE**] Site: Deltoid Thigh Buttock [*itmP_APSIDE_PREVNAR13* : **VACCPROD.P_APSIDE**] Side: Left Right Upper Left Lower Left Upper Right Lower Right [*itmP_APROUTE_PREVNAR13* : **VACCPROD.P_APROUT**] Route: Intramuscular Subcutaneous [*itmVADM_COM_PREVNAR13* : **VACCPROD.VADM_COM**] If relevant, comment on administration: *A200* No
16.	P_SITE *[hidden]*	[*itmP_SITE_PREVNAR13_HID* : **VACCPROD.P_SITE**] *[clVACCSITE]*
17.	P_SIDE *[hidden]*	[*itmP_SIDE_PREVNAR13_HID* : **VACCPROD.P_SIDE**] *[clVACCSIDE]*
18.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PREVNAR13_HID* : **VACCPROD.P_ROUTE**] *[clMEDROUT_VACC]*
19.	P_CODE *[hidden]*	[*itmP_CODE_PREVNAR13_HID* : **VACCPROD.P_CODE**] *[clPRODNAMES]*
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
20. ✔	Date of administration:	[*itmVACCRDAT* : **VAC_INFO.VACCRDAT**] If at least one vaccine administered Req / Req / Req (2013-2018)

		[*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
21.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
22. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : **VAC_INFO.V_REAS**] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : **VAC_INFO.SAE_CASE**] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* ☐ Non-Serious Adverse Event [*itmAE_NB* : **VAC_INFO.AE_NB**] -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* [*itmSYMP_COD* : **VAC_INFO.SYMP_COD**] Solicited AE code: ☐ *[clSYMPCODE]* ☐ ☐ [*itmV_OTH* : **VAC_INFO.V_OTH**] Other, please specify *A100* [*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib) [frmLOCSYMPTOMS_FLAG_ACTHIB_D3]

LOCSYMPTOMS_FLG_ACTHIB [sctLOCSYMPTOMS_FLG_ACTHIB_D3]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	[*itmLOCSOL_YN_ACTHIB_D3* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LABORATORY TESTS (Labo tests) [frmLABORATORYTESTS]

BLOOD SAMPLE [sctSERUMSAMPLE]

1.* ✔	Has a blood sample been taken? [SER sample taken]	[*itmSAMPTAKE_SER* : **LABSHEET.SAMPTAKE**] ☐ Yes -> [*itmSAMPRDAT_D* : **LABSHEET.SAMPRDAT**] Date of collection: ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐ [*itmNB_TUBES* : **LABSHEET.NB_TUBES**] Number of tube(s) taken: *N2* [*itmREQ_NUM* : **LABSHEET.REQ_NUM**] Requisition number: *A9* ☐ No
2.	For GSK: *[hidden]* [Reconciled]	[*itmRECONCIL_HID* : **LABSHEET.RECONCIL**] Reconciled (CDR only): ☐ 0 - Lost in transit ☐ 1 - Lost in site ☐ 2 - Lost in GSK ☐ 3 - Scrapped
3.	EVENTTYP *[hidden]*	[*itmEVENTTYP_HID* : **LABO_CRF.EVENTTYP**] ☐ *[clSYSTEMCD]* ☐

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): INVESTIGATOR SIGNATURE (Inv sign) [INVSIGN_CR]

INVESTIGATOR SIGNATURE [sctINVSIGN]

1.* ✔	Is this casebook ready to sign? If not, click on the **RETURN** button below	[*INVSIGN*: Not submitted - for internal use] ☐ Ready to sign
2.	For Data Managers only: Tick or untick this box to require the investigator to re-sign the case book *By ticking or unticking this box you are evoking a change to this form back to an unsigned state. This should be done when significant changes (e.g. those that require medical opinion or other significants situation) occur after the original signature. If the box is already ticked upon arrival on this form, unticking and submitting it accomplishes the same task as ticking and submitting it; that is, the signature will be validated in both [hidden]*	[*INVSIG2*: Not submitted - for internal use] ☐ 1

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): ESFU CONTACT (M10) (ESFU contact) [frmPHONECONTACT_DISC]

ESFU CONTACT (M10) [sctPHONECONTACT]

Please contact the subject's parent(s) / guardian(s) by phone to follow up on the administration of medication or vaccination and to check on the occurrence of intercurrent medical conditions or NOCDs or SAEs .

1.* ✔	Has safety information been obtained?	[itmPHCT_FLG : VIS_INFO.VIS_FLG] ☐ [itmACTRDATE : ACTDATES.ACTRDATE] Yes -> Date of contact Req ☐☐ / Req ☐☐ / Req ☐☐☐☐ (2013-2018) ☐ No [itmVIS_REAS : VIS_INFO.V_REAS] **-> Please tick the major reason:** ☐ Serious Adverse Event [itmSAE_CASE : VIS_INFO.SAE_CASE] -> Please complete a **SAE** Report and specify SAE Report No. N2 [itmFATAL : VIS_INFO.FATAL] -> Tick box if SAE is fatal: ☐ ☐ Non-Serious Adverse Event [itmAE_NB : VIS_INFO.AE_NB] -> Please complete **Non-Serious Adverse Event** section and specify AE No. N2 [itmSYMP_COD : VIS_INFO.SYMP_COD] or Solicited AE code: [clSYMPCODE] ☐ ☐ [itmPTV_SP : VIS_INFO.REAS_COM] Protocol violation, please specify: A50 ☐ Consent Withdrawal not due to an adverse event ->Please specify the reason (only if the Subject's parents / Legally Acceptable Representative has / have spontaneously explained it): [itmCWS_SP : VIS_INFO.REAS_COM] A50 [itmCWS_NA : Not submitted - for internal use] Or tick box if reason not provided ☐ ☐ Migrated / moved from the study area ☐ Lost to follow-up ☐ Sponsor study termination ☐ [itmV_OTH : VIS_INFO.REAS_COM] Other, please specify A100 [itmDECISION : VIS_INFO.DECISION] **-> For serious (except death), non-serious adverse events and Other reasons only:** **Please select who made the decision:** ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

PERMANENT DISCONTINUATION [sctPERM_DISCONTINUATION]

2. ✔	Study discontinuation:	-> [itmDISCNT : VIS_INFO.DISCNT] ☐ Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study In this case, terminate the CRF: Complete Medication, Concomitant Vaccination, (S)AE sections and Study Conclusion.

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): CHECK FOR STUDY CONTINUATION (BOOSTER EPOCH) (Study Cont) [frmSTUDYCONTINUATIONEPOCH_DISC]

CHECK FOR STUDY CONTINUATION (BOOSTER EPOCH) [sctSTUDYCONTINUATION_EPOCH]

1.* ✔	Did the subject return for the booster epoch?	[itmVIS_FLG_EPOCH : VIS_INFO.VIS_FLG] [itmACTRDATE : ACTDATES.ACTRDATE] Yes -> Date of visit: Req / Req / Req (2013-2018) No [itmVIS_REAS_EPOCH : VIS_INFO.V_REAS] **-> Please select the major reason:** Serious Adverse Event onset in the course or after primary epoch leading to withdrawal from the study, please specify: [itmSAE_CASE : VIS_INFO.SAE_CASE] -> Please complete a **SAE** Report and specify SAE Report No. N2 [itmFATAL : VIS_INFO.FATAL] -> Tick box if SAE is fatal: Non-Serious Adverse Event in the course or after previous study epoch leading to withdrawal from the study, please specify: [itmAE_NB : VIS_INFO.AE_NB] [itmSYMP_COD : VIS_INFO.SYMP_COD] AE No. N2 Solicited AE code: [clSYMPCODE] [itmPTV_SP : VIS_INFO.REAS_COM] Protocol violation, please specify: A50 Consent Withdrawal / not willing to participate, not due to a (S)AE ->Please specify the reason (only if the Subject's parents / Legally Acceptable Representatives has / have spontaneously explained it): [itmCWS_SP : VIS_INFO.REAS_COM] A50 [itmCWS_NA : Not submitted - for internal use] Or tick box if reason not provided Migrated / moved from the study area Lost to follow-up [itmDEATHDAT : VIS_INFO.DEATHDAT] Subject died --> Date of death: NReq / NReq / NReq (2013-2018) Sponsor study termination [itmV_OTH : VIS_INFO.REAS_COM] Other, please specify: A100 [itmDECISION : VIS_INFO.DECISION] Please select who made the decision: Investigator Subject's parents / Legally Acceptable Representatives

PERMANENT DISCONTINUATION [sctPERM_DISCONTINUATION]

2. ✔	Study discontinuation:	[itmDISCNT : VIS_INFO.DISCNT] Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study If Yes, please sign off booster epoch

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 4 (HEXA GROUP) (vac adm hexa-dose4) [frmVACC_ADMIN_D4_HEXA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary (Preferred) Oral Rectal Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_INFANRIX]

Infanrix Vaccine

5.* ✔	Pre vaccination Limb Circumference measurement (Infanrix):	[itmNT_LIMB : VACCPROD.C_N_TAK] Not taken [itmCIRC_LIMB : VACCPROD.CIRC_LMB] Circumference of Injected Limb (in mm) N10
6.* ✔	Has Infanrix Vaccine been administered? [Vaccinated]	[itmV_ADM_INFANRIX : VACCPROD.V_ADM] Yes -> [itmV_TRT_INFANRIX : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_INFANRIX : VACCPROD.P_AP] Injection Site/Side/Route: [itmP_SITE_INFANRIX_HID : VACCPROD.P_SITE] According to protocol: (Deltoid/Thigh - Right - IM) Deltoid Thigh Not according to protocol -> [itmP_APSITE_INFANRIX : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_INFANRIX : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_INFANRIX : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_INFANRIX : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
7.	P_SIDE *[hidden]*	[itmP_SIDE_INFANRIX_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_INFANRIX_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_INFANRIX_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_HIBERIX]

Hiberix Vaccine

10.* ✔	Pre vaccination Limb Circumference measurement (Hiberix):	[itmNT_LIMB : VACCPROD.C_N_TAK] Not taken [itmCIRC_LIMB : VACCPROD.CIRC_LMB] Circumference of Injected Limb (in mm) N10

11.* ✔	Has Hiberix Vaccine been administered? [Vaccinated]	[*itmV_ADM_HIBERIX* : VACCPROD.V_ADM] ☐ Yes -> [*itmV_TRT_HIBERIX* : VACC_TRT.V_TRT] Administered treatment number: *N10* [*itmP_AP_HIBERIX* : VACCPROD.P_AP] Injection Site/Side/Route: ☐ [*itmP_SITE_HIBERIX_HID* : VACCPROD.P_SITE] According to protocol: (Deltoid/Thigh - Left - IM) ☐ *[clVACCSITE_AP]* ☐ ☐ Not according to protocol -> [*itmP_APSITE_HIBERIX* : VACCPROD.P_APSITE] Site: ☐ Deltoid ☐ Thigh ☐ Buttock [*itmP_APSIDE_HIBERIX* : VACCPROD.P_APSIDE] Side: ☐ Left ☐ Right ☐ Upper Left ☐ Lower Left ☐ Upper Right ☐ Lower Right [*itmP_APROUTE_HIBERIX* : VACCPROD.P_APROUT] Route: ☐ Intramuscular ☐ Subcutaneous [*itmVADM_COM_HIBERIX* : VACCPROD.VADM_COM] If relevant, comment on administration: *A200* ☐ No
12.	P_SIDE *[hidden]*	[*itmP_SIDE_HIBERIX_HID* : VACCPROD.P_SIDE] ☐ *[clVACCSIDE]* ☐
13.	P_ROUTE *[hidden]*	[*itmP_ROUTE_HIBERIX_HID* : VACCPROD.P_ROUTE] ☐ *[clMEDROUT_VACC]* ☐
14.	P_CODE *[hidden]*	[*itmP_CODE_HIBERIX_HID* : VACCPROD.P_CODE] ☐ *[clPRODNAMES]* ☐
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
15. ✔	Date of administration:	If at least one vaccine administered [*itmVACCRDAT* : VAC_INFO.VACCRDAT] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) [*itmSAME_DATE* : Not submitted - for internal use] Or tick box if date is the same as visit date ☐
16.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
17. ✔	If at least one vaccination not done: [Reason for non-admin]	[*itmVACC_REAS* : VAC_INFO.V_REAS] Please select the major reason for non administration: ☐ [*itmSAE_CASE* : VAC_INFO.SAE_CASE] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. *N2* ☐ Non-Serious Adverse Event [*itmAE_NB* : VAC_INFO.AE_NB] -> Please complete Non-Serious Adverse Event section and specify AE No. *N2* [*itmSYMP_COD* : VAC_INFO.SYMP_COD] or Solicited AE code: ☐ *[clSYMPCODE]* ☐ ☐ [*itmV_OTH* : VAC_INFO.V_OTH] Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) *A100* [*itmDECISION* : VAC_INFO.DECISION] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 4 (PEDIA GROUP) (vac adm pedia-dose4) [frmVACC_ADMIN_D4_PEDIA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary (Preferred) Oral Rectal Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_INFANRIX]

Infanrix Vaccine

5.* ✔	Pre vaccination Limb Circumference measurement (Infanrix):	[itmNT_LIMB : VACCPROD.C_N_TAK] Not taken [itmCIRC_LIMB : VACCPROD.CIRC_LMB] Circumference of Injected Limb (in mm) N10
6.* ✔	Has Infanrix Vaccine been administered? [Vaccinated]	[itmV_ADM_INFANRIX : VACCPROD.V_ADM] Yes -> [itmV_TRT_INFANRIX : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_INFANRIX : VACCPROD.P_AP] Injection Site/Side/Route: [itmP_SITE_INFANRIX_HID : VACCPROD.P_SITE] According to protocol: (Deltoid/Thigh - Right - IM) Deltoid Thigh Not according to protocol -> [itmP_APSITE_INFANRIX : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_INFANRIX : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_INFANRIX : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_INFANRIX : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
7.	P_SIDE *[hidden]*	[itmP_SIDE_INFANRIX_HID : VACCPROD.P_SIDE] [clVACCSIDE]
8.	P_ROUTE *[hidden]*	[itmP_ROUTE_INFANRIX_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
9.	P_CODE *[hidden]*	[itmP_CODE_INFANRIX_HID : VACCPROD.P_CODE] [clPRODNAMES]

[sctVACC_ADMIN_ACTHIB_BST]

ActHib Vaccine

10.* ✔	Pre vaccination Limb Circumference measurement (ActHib):	[itmNT_LIMB : VACCPROD.C_N_TAK] Not taken [itmCIRC_LIMB : VACCPROD.CIRC_LMB] Circumference of Injected Limb (in mm) N10

11.* ✔	Has ActHib Vaccine been administered? [Vaccinated]	[itmV_ADM_ACTHIB_BST : VACCPROD.V_ADM] Yes -> [itmV_TRT_ACTHIB : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_ACTHIB : VACCPROD.P_AP] Injection Site/Side/Route: [itmP_SITE_ACTHIB_BST : VACCPROD.P_SITE] According to protocol: (Deltoid/Thigh - Left - IM) Deltoid Thigh Not according to protocol -> [itmP_APSITE_ACTHIB : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_ACTHIB_BST : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_ACTHIB : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_ACTHIB : VACCPROD.VADM_COM] If relevant, comment on administration: A200 No
12.	P_SIDE *[hidden]*	[itmP_SIDE_ACTHIB_HID : VACCPROD.P_SIDE] [clVACCSIDE]
13.	P_ROUTE *[hidden]*	[itmP_ROUTE_ACTHIB_HID : VACCPROD.P_ROUTE] [clMEDROUT_VACC]
14.	P_CODE *[hidden]*	[itmP_CODE_ACTHIB_HID : VACCPROD.P_CODE] [clPRODNAMES]
VACCINATION DETAILS [sctVACCDETAILS_2VACC]		
15. ✔	Date of administration:	If at least one vaccine administered [itmVACCRDAT : VAC_INFO.VACCRDAT] Req / Req / Req (2013-2018) [itmSAME_DATE : Not submitted - for internal use] Or tick box if date is the same as visit date
16.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[itmP_RDAT : Not submitted - for internal use] NReq / NReq / NReq (2013-2018)
17. ✔	If at least one vaccination not done: [Reason for non-admin]	[itmVACC_REAS : VAC_INFO.V_REAS] Please select the major reason for non administration: [itmSAE_CASE : VAC_INFO.SAE_CASE] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 Non-Serious Adverse Event [itmAE_NB : VAC_INFO.AE_NB] -> Please complete Non-Serious Adverse Event section and specify AE No. N2 [itmSYMP_COD : VAC_INFO.SYMP_COD] or Solicited AE code: [clSYMPCODE] [itmV_OTH : VAC_INFO.V_OTH] Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 [itmDECISION : VAC_INFO.DECISION] Please select who made the decision: Investigator Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 4 (PENTA GROUP) (vac adm penta-dose4) [frmVACC_ADMIN_D4_PENTA]

PRE-VACC TEMPERATURE [sctPREVACCTEMPERATURE]

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	[itmPRE_TEMP : VS.VSORRES] Temperature (°F) xxx.x [itmTEMP_ROUTE : VS.VSLOC] Route: Axillary (Preferred) Oral Rectal Tympanic
2.	Unit: *[hidden]*	[itmTEMP_UNIT_HID : Not submitted - for internal use] [clVSORRESU]
3.	VSTEST *[hidden]*	[itmVSTEST_HID : VS.VSTEST] [clVSTEST]
4.	VSTESTCD *[hidden]*	[itmVSTESTCD_HID : VS.VSTESTCD] [clVSTESTCD]

[sctVACC_ADMIN_PENTACEL_BST]

Pentacel Vaccine

5.* ✔	Pre vaccination Limb Circumference measurement (Pentacel):	[itmNT_LIMB : VACCPROD.C_N_TAK] Not Taken [itmCIRC_LIMB : VACCPROD.CIRC_LMB] Circumference of Injected Limb (in mm) N10
6.* ✔	Has Pentacel Vaccine been administered? [Vaccinated]	[itmV_ADM_PENTACEL_BST : VACCPROD.V_ADM] [itmVACCRDAT : VAC_INFO.VACCRDAT] Yes -> Req / Req / Req (2013-2018) [itmSAME_DATE : Not submitted - for internal use] Or tick box if date is the same as visit date [itmV_TRT_PENTACEL : VACC_TRT.V_TRT] Administered treatment number: N10 [itmP_AP_PENTACEL : VACCPROD.P_AP] Injection Site/Side/Route: [itmP_SITE_PENTACEL_BST : VACCPROD.P_SITE] According to protocol: (Deltoid/Thigh - Right - IM) Deltoid Thigh Not according to protocol -> [itmP_APSITE_PENTACEL : VACCPROD.P_APSITE] Site: Deltoid Thigh Buttock [itmP_APSIDE_PENTACEL : VACCPROD.P_APSIDE] Side: Left Right Upper Left Lower Left Upper Right Lower Right [itmP_APROUTE_PENTACEL : VACCPROD.P_APROUT] Route: Intramuscular Subcutaneous [itmVADM_COM_PENTACEL : VACCPROD.VADM_COM] If relevant, comment on administration: A200 [itmVACC_REAS : VAC_INFO.V_REAS] No -> Please select the major reason for non administration: [itmSAE_CASE : VAC_INFO.SAE_CASE] Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 Non-Serious Adverse Event [itmAE_NB : VAC_INFO.AE_NB] -> Please complete Non-Serious Adverse Event section and specify AE No. N2 [itmSYMP_COD : VAC_INFO.SYMP_COD] or Solicited AE code: [clSYMPCODE] [itmV_OTH : VAC_INFO.V_OTH] Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100

		[*itmDECISION* : **VAC_INFO.DECISION**] Please select who made the decision: ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives
7.	P_SIDE *[hidden]*	[*itmP_SIDE_PENTACEL_HID* : **VACCPROD.P_SIDE**] ☐ *[clVACCSIDE]* ☐
8.	P_ROUTE *[hidden]*	[*itmP_ROUTE_PENTACEL_HID* : **VACCPROD.P_ROUTE**] ☐ *[clMEDROUT_VACC]* ☐
9.	P_CODE *[hidden]*	[*itmP_CODE_PENTACEL_HID* : **VACCPROD.P_CODE**] ☐ *[clPRODNAMES]* ☐
10.	Vaccination date (or visit date when same as visit date) *[hidden]* [Vaccination date (or visit date when same as visit date)]	[*itmP_RDAT* : Not submitted - for internal use] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - INFANRIX (Loc symp flg Infanrix) [frmLOCSYMPTOMS_FLAG_INFANRIX]

LOCAL SIGNS/SYMPTOMS FLAG - INFANRIX [sctLOCSYMPTOMS_FLG_INFANRIX]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Infanrix]	[*itmLOCSOL_YN_INFANRIX* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (INFANRIX) (Loc symp-Infanrix)
[frmLOCSYMPTOMS_INFANRIX]

Infanrix vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3:

		[clINTENSITYSOL] [clINTENSITYSOL] [clINTENSITYSOL] [clINTENSITYSOL] [itmPA_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - HIBERIX (Loc symp flg Hiberix) [frmLOCSYMPTOMS_FLAG_HIBERIX]

LOCAL SIGNS/SYMPTOMS FLAG - HIBERIX [sctLOCSYMPTOMS_FLG_HIBERIX]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Hiberix]	[*itmLOCSOL_YN_HIBERIX* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (HIBERIX) (Loc symp-Hiberix) [frmLOCSYMPTOMS_HIBERIX]

Hiberix vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[*itmRE_YN* : **SOLAE.SYMP_EXP**] ☐ No ☐ Yes -> Size (mm): [*itmSYMP_VAL_MM_D0* : **SOLVAL.SYMP_VAL**] Day 0: N5 [*itmSYMP_VAL_MM_D1* : **SOLVAL.SYMP_VAL**] Day 1: N5 [*itmSYMP_VAL_MM_D2* : **SOLVAL.SYMP_VAL**] Day 2: N5 [*itmSYMP_VAL_MM_D3* : **SOLVAL.SYMP_VAL**] Day 3: N5 [*itmRE_ONG* : **SOLAE.SYMP_ONG**] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [*itmSYMP_MAX_SIZE* : **SOLAE.SYMP_MAX**] Maximum size: N5 [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? ☐ [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] ☐ *[clSYMPCODE]* ☐
3.	Unit: *[hidden]*	[*itmSYMP_UNI_HID* : **SOLAE.SYMP_UNI**] ☐ *[clSYMPUNITS]* ☐

SWELLING [sctSWELLING]

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

4.* ✔	Occurred?	[*itmSW_YN* : **SOLAE.SYMP_EXP**] ☐ No ☐ Yes -> Size (mm): [*itmSYMP_VAL_MM_D0* : **SOLVAL.SYMP_VAL**] Day 0: N5 [*itmSYMP_VAL_MM_D1* : **SOLVAL.SYMP_VAL**] Day 1: N5 [*itmSYMP_VAL_MM_D2* : **SOLVAL.SYMP_VAL**] Day 2: N5 [*itmSYMP_VAL_MM_D3* : **SOLVAL.SYMP_VAL**] Day 3: N5 [*itmSW_ONG* : **SOLAE.SYMP_ONG**] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [*itmSYMP_MAX_SIZE* : **SOLAE.SYMP_MAX**] Maximum size: N5 [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? ☐ [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] ☐ *[clSYMPCODE]* ☐
6.	Unit: *[hidden]*	[*itmSYMP_UNI_HID* : **SOLAE.SYMP_UNI**] ☐ *[clSYMPUNITS]* ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[*itmPA_YN* : **SOLAE.SYMP_EXP**] ☐ No ☐ Yes -> Intensity: [*itmSYMP_VAL_INTEN_D0* : **SOLVAL.SYMP_VAL**] Day 0: ☐ *[clINTENSITYSOL]* ☐ [*itmSYMP_VAL_INTEN_D1* : **SOLVAL.SYMP_VAL**] Day 1: ☐ *[clINTENSITYSOL]* ☐ [*itmSYMP_VAL_INTEN_D2* : **SOLVAL.SYMP_VAL**] Day 2: ☐ *[clINTENSITYSOL]* ☐ [*itmSYMP_VAL_INTEN_D3* : **SOLVAL.SYMP_VAL**] Day 3: ☐ *[clINTENSITYSOL]* ☐

		[*itmPA_ONG* : **SOLAE.SYMP_ONG**] **After Day 3:** Ongoing? No Yes -> [*itmSYMP_MAX_INTEN* : **SOLAE.SYMP_MAX**] Maximum intensity: *[clINTENSITYSOL_MAX]* [*itmERDAT* : **SOLAE.SYMP_LST**] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [*itmCONT_END* : **SOLAE.SYMPCONT**] Continuing at the end of the study? [*itmMED_TYPE* : **SOLAE.MED_TYPE**] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[*itmSYMP_COD_HID* : **SOLAE.SYMP_COD**] *[clSYMPCODE]*

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib) [frmLOCSYMPTOMS_FLAG_ACTHIB_BST]

LOCSYMPTOMS_FLG_ACTHIB [sctLOCSYMPTOMS_FLG_ACTHIB_BST]

1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	[*itmLOCSOL_YN_ACTHIB_BST* : **SOLSHEET.SOL_YN**] ☐ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary ☐ No ☐ Unknown, no information available
2.	Solicited symptoms type *[hidden]* [Solicited symptoms type]	[*itmSOL_TYP_HID* : Not submitted - for internal use] ☐ Generalised ☐ Localised

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ACTHIB) (Loc symp-ActHib)
[frmLOCSYMPTOMS_ACTHIB_BST]

ActHib vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3:

		[clINTENSITYSOL] [clINTENSITYSOL] [clINTENSITYSOL] [clINTENSITYSOL] [itmPA_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PENTACEL) (Loc symp-Pentacel)
[frmLOCSYMPTOMS_PENTACEL_BST]

Pentacel vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS [sctREDNESS]

1.* ✔	Occurred?	[itmRE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmRE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
3.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

SWELLING [sctSWELLING]

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

4.* ✔	Occurred?	[itmSW_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Size (mm): [itmSYMP_VAL_MM_D0 : SOLVAL.SYMP_VAL] Day 0: N5 [itmSYMP_VAL_MM_D1 : SOLVAL.SYMP_VAL] Day 1: N5 [itmSYMP_VAL_MM_D2 : SOLVAL.SYMP_VAL] Day 2: N5 [itmSYMP_VAL_MM_D3 : SOLVAL.SYMP_VAL] Day 3: N5 [itmSW_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_SIZE : SOLAE.SYMP_MAX] Maximum size: N5 [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
5.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
6.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

PAIN [sctPAIN]

7.* ✔	Occurred?	[itmPA_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3:

		[clINTENSITYSOL] [clINTENSITYSOL] [clINTENSITYSOL] [clINTENSITYSOL] [itmPA_ONG : SOLAE.SYMP_ONG] **After Day 3:** Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
8.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED SYMPTOMS (Large swell flg) [frmLARGESWELLING_FLAG]

LARGE SWELLING REACTION_FLG [sctLARGSWELLING_FLG]

Definition of a Large swelling reaction:
- any local swelling with diameter >50 mm
- and/or any noticeable diffuse injection site swelling (diameter not measurable)
- and/or any noticeable increased circumference of the injected limb

1.* ✔	Is a large swelling reaction as defined above present? [Large swelling reaction]	[*itmLARGSWEL_FLAG* : **SWELLSHT.SWELL_YN**] ☐ Yes ☐ No

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LARGE SWELLING REACTION (Large swelling) - Repeating Form [frmLARGESWELLINGREACTION_CHILD]

#	Vaccine	Date of physical examination	Start date of swelling	Size of swelling	Type of swelling	Circumference	Temperature	Redness	Induration	Pruritis	Pain	Functional impairment	Case description	Last date when the swelling was still considered to be a large swelling reaction:	Outcome of the large swelling reaction	Is there an alternative explanation for the swelling?
1																

If hospitalisation is required, please also complete a Serious Adverse Event Report.

VACCINE [sctVACCINE]

1.* ✔	Vaccine: [Vaccine]	[*itmP_CODE_LSW* : **SWELLRPT.P_CODE**] [*clPRODNAMES_LSW*]

REPORT OF PHYSICAL EXAMINATION [sctPHYSICALEXAMINATION]

2.* ✔	Date of physical examination: [Date of physical examination]	[*itmPHYSDAT* : **SWELLRPT.PHYSDAT**] NReq / NReq / NReq (2013-2018) [*itmPHYEXAM* : **SWELLRPT.PHYSEXAM**] Was the examination performed by a member of study personnel during the large swelling reaction period? No Yes
3.* ✔	Date when the swelling was first considered to be a large swelling reaction: [Start date of swelling]	[*itmSWFDAT* : **SWELLRPT.SWFDAT**] NReq / NReq / NReq (2013-2018)
4.* ✔	Size of swelling: [Size of swelling]	[*itmSWSIZE* : **SWELLRPT.SWSIZE**] Measurement of the greatest diameter: mm *N10*
5.	Size of swelling unit: *[hidden]* [Size of swelling unit]	[*itmSWSIZE_UNI_HID* : **SWELLRPT.SWFUNIT**] [*clSYMPUNITS*]
6.* ✔	Type of swelling: *Please specify in the case description section* [Type of swelling]	[*itmSWTYPE* : **SWELLRPT.SWTYPE**] Local swelling around injection site, not involving adjacent joint Diffuse swelling, not involving adjacent joint Swelling, involving adjacent joint
7.* ✔	Circumference: [Circumference]	[*itmCIRC_SWOLLEN* : **SWELLRPT.VAC_L_C**] Circumference of swollen limb (at the site of maximum swelling): mm *N10*
8.	Circumference swollen limb unit: *[hidden]* [Circumference swollen limb unit]	[*itmCIRC_SW_UNI_HID* : Not submitted - for internal use] [*clSYMPUNITS*]
9.	Circumference of the opposite limb (at the same level): *[hidden]* [Circumference of the opposite limb]	[*itmCIRC_OPPOSITE* : **SWELLRPT.OPP_L_C**] Circumference of the opposite limb (at the same level): mm *N10*
10.	Circumference of the opposite limb unit: *[hidden]* [Circumference of the opposite limb unit]	[*itmCIRC_OPP_UNI_HID* : Not submitted - for internal use] [*clSYMPUNITS*]
11.	If occurring within 24 hours after vaccination, please specify how long after vaccination: *[hidden]* [If occurring within 24 hours after vaccination, please specify how long after vaccination]	[*itmSWFHH* : **SWELLRPT.SWFHH**] If occurring within 24 hours after vaccination, please specify how long after vaccination: NReq *24-hour clock*

ASSOCIATED SIGNS [sctASSOCIATEDSIGN_CHILD]

For Redness, Induration, Pruritis, Pain and Functional impairment, please select the Yes/No box for each symptom occurring during the large swelling reaction period. If other symptoms are associated with the large swelling, please specify in the case description section.

12.* ✔	Temperature: *Please record the temperature. If temperature has been taken more than once a day please report the highest value.* *[Temperature]*	[*itmTEMP_VAL* : **SWELLRPT.SWFEV**] Temperature (°F) *xxx.x* [*itmTEMP_ROUTE* : **SWELLRPT.SWT_SITE**] Route: Axillary (Preferred) Oral Rectal Tympanic
13.*	Redness	[*itmREDNESS* : **SWELLRPT.SWRED_YN**]

✔	[Redness]	☐ No ☐ [*itmDIAMETER_RED* : **SWELLRPT.SWRED**] Yes -> Largest diameter: mm *N10*
14.* ✔	Induration [Induration]	[*itmINDURATION* : **SWELLRPT.SWIND_YN**] ☐ No ☐ [*itmDIAMETER_IND* : **SWELLRPT.SWIND**] Yes -> Largest diameter: mm *N10*
15.* ✔	Pruritis [Pruritis]	[*itmPRURITIS* : **SWELLRPT.SWPRU_YN**] ☐ No ☐ [*itmINTENS_PRURI* : **SWELLRPT.SWPRU**] Yes -> Intensity ☐ Grade 1(An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
16.* ✔	Pain (at administration site): [Pain]	[*itmPAIN_CHILD* : **SWELLRPT.SWPAI_YN**] ☐ No ☐ [*itmINSTENS_PAIN* : **SWELLRPT.SWPAI**] Yes -> Intensity ☐ Grade 1 (Minor reaction to touch) ☐ Grade 2 (Cries / protests on touch) ☐ Grade 3 (Cries when limb is moved / spontaneously painful)
17.* ✔	Functional impairment: [Functional impairment]	[*itmIMPAIR* : **SWELLRPT.SWFUN_YN**] ☐ No ☐ [*itmINSTENS_IMPAIR* : **SWELLRPT.SWFUN**] Yes -> Intensity ☐ Grade 1(An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
CLINICAL CASE DESCRIPTION [sctCLINICALCASEDESCRIPTION]		
18.* ✔	Case description [Case description]	[*itmCASE_DESC* : **SWELLRPT.CAS_DESC**] Please give a clinical description of the observed swelling reaction, including a description of the joint involved and specific associated symptoms. Please mention also eventual diagnostic(s) procedures and therapeutic interventions. *A500*
19. ✔	Last date when the swelling was still considered to be a large swelling reaction: [Last date when the swelling was still considered to be a large swelling reaction:]	[*itmSWLDAT* : **SWELLRPT.SWLDAT**] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)
20.* ✔	Outcome of the large swelling reaction: [Outcome of the large swelling reaction]	[*itmOUTCOME_SW* : **SWELLRPT.OUTCOME**] ☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not recovered / Not resolved -> Please provide further follow-up data ☐ Recovered / Resolved with sequelae -> Please specify in the case description section
21.* ✔	Is there an alternative explanation for the swelling? (e.g.: allergy, infection, trauma, underlying conditions) [Is there an alternative explanation for the swelling?]	[*itmSW_ALT* : **SWELLRPT.SWALT_YN**] ☐ No ☐ [*itmSW_EXPLAIN* : **SWELLRPT.SWEXPLN**] Yes -> Please specify: *A500*

22.	If lasting for less than 24 hours, please specify duration: *[hidden]* [If lasting for less than 24 hours, please specify duration]	[*itmSWLHH* : **SWELLRPT.SWLHH**] NReq *24-hour clock*

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS (Gen symp) [frmGENSYMPTOMS_BST]

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

TEMPERATURE (°F) [sctTEMPERATURE_SOL]

Record temperatures if during the solicited period at least one axillary/oral/tympanic/rectal measure is above or equal to 100.4 °F

1.* ✔	Occurred?	[itmFE_YN : SOLAE.SYMP_EXP] ☐ No ☐ Not taken ☐ Yes -> Day 0: [itmFE_VAL_D0 : SOLVAL.SYMP_VAL] Not taken xxx.x [itmFE_NT_D0 : SOLVAL.T_N_TAK] ☐ Day 1: [itmFE_VAL_D1 : SOLVAL.SYMP_VAL] xxx.x [itmFE_NT_D1 : SOLVAL.T_N_TAK] ☐ Day 2: [itmFE_VAL_D2 : SOLVAL.SYMP_VAL] xxx.x [itmFE_NT_D2 : SOLVAL.T_N_TAK] ☐ Day 3: [itmFE_VAL_D3 : SOLVAL.SYMP_VAL] xxx.x [itmFE_NT_D3 : SOLVAL.T_N_TAK] ☐ [itmTEMP_ROUTE : SOLAE.SYMP_T_S] Route: ☐ Axillary (Preferred) ☐ Oral ☐ Rectal ☐ Tympanic [itmFE_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_TEMP : SOLAE.SYMP_MAX] Max temperature: xxx.x [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? ☐ No ☐ Yes [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
2.	Unit: *[hidden]* [Unit]	[itmTEMP_UNIT : Not submitted - for internal use] ☐ Fahrenheit
3.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] ☐ [clSYMPCODE] ☐
4.	Threshold for fever based on route and unit *[hidden]*	[itmFEV_VAL_HID : Not submitted - for internal use] xxxxxxxxxxxx.xx
5.	Unit: *[hidden]*	[itmSYMP_UNI_HID : SOLAE.SYMP_UNI] ☐ [clSYMPUNITS] ☐

DROWSINESS [sctDROWSINESS]

6.* ✔	Occurred?	[itmDR_YN : SOLAE.SYMP_EXP] ☐ No ☐ Yes -> Intensity: Day 0: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ Day 1: [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ Day 2: [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ Day 3: [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] ☐ [clINTENSITYSOL] ☐ [itmDR_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? ☐ No ☐ Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: ☐ [clINTENSITYSOL_MAX] ☐ [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? ☐ [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? ☐ No ☐ Yes

		[itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
7.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]
IRRITABILITY/FUSSINESS [sctIRRITABILITY]		
8.* ✔	Occurred?	[itmIF_YN : SOLAE.SYMP_EXP] No Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: [clINTENSITYSOL] [itmIF_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? No Yes [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
9.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]
LOSS OF APPETITE [sctLOSSOFAPPETITE]		
10.* ✔	Occurred?	[itmLO_YN : SOLAE.SYMP_EXP] No Yes -> Intensity: [itmSYMP_VAL_INTEN_D0 : SOLVAL.SYMP_VAL] Day 0: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D1 : SOLVAL.SYMP_VAL] Day 1: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D2 : SOLVAL.SYMP_VAL] Day 2: [clINTENSITYSOL] [itmSYMP_VAL_INTEN_D3 : SOLVAL.SYMP_VAL] Day 3: [clINTENSITYSOL] [itmLO_ONG : SOLAE.SYMP_ONG] **After Day 3**: Ongoing? No Yes -> [itmSYMP_MAX_INTEN : SOLAE.SYMP_MAX] Maximum intensity: [clINTENSITYSOL_MAX] [itmERDAT : SOLAE.SYMP_LST] Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) [itmCONT_END : SOLAE.SYMPCONT] Continuing at the end of the study? [itmCAUSAL : SOLAE.CAUSAL] Is there a reasonable possibility that the AE may have been caused by the investigational product? No Yes [itmMED_TYPE : SOLAE.MED_TYPE] Medically attended visit: Emergency Room Hospitalisation Medical Personnel None
11.	SYMP_COD *[hidden]*	[itmSYMP_COD_HID : SOLAE.SYMP_COD] [clSYMPCODE]

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): CHECK FOR STUDY CONTINUATION (Study cont.) [frmSTUDYCONTINUATION]

CHECK FOR STUDY CONTINUATION [sctSTUDYCONTINUATION]

1.* ✔	Did the subject return for this visit?	[itmVIS_FLG : VIS_INFO.VIS_FLG] ☐ [itmACTRDATE : ACTDATES.ACTRDATE] Yes -> Date of visit: ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) ☐ No [itmVIS_REAS : VIS_INFO.V_REAS] **-> Please select the major reason:** ☐ Serious Adverse Event [itmSAE_CASE : VIS_INFO.SAE_CASE] -> Please complete a **SAE** Report and specify SAE Report No. N2 [itmFATAL : VIS_INFO.FATAL] -> Tick box if SAE is fatal: ☐ ☐ Non-Serious Adverse Event [itmAE_NB : VIS_INFO.AE_NB] -> Please complete **Non-Serious Adverse Event** section and specify AE No. N2 [itmSYMP_COD : VIS_INFO.SYMP_COD] or Solicited AE code: ☐ [clSYMPCODE] ☐ ☐ [itmPTV_SP : VIS_INFO.REAS_COM] Protocol violation, please specify: A50 ☐ Consent Withdrawal not due to an adverse event ->Please specify the reason (only if the Subject's parents / Legally Acceptable Representative has / have spontaneously explained it): [itmCWS_SP : VIS_INFO.REAS_COM] A50 [itmCWS_NA : Not submitted - for internal use] Or tick box if reason not provided ☐ ☐ Migrated / moved from the study area ☐ Lost to follow-up ☐ Sponsor study termination ☐ [itmV_OTH : VIS_INFO.REAS_COM] Other, please specify A100 [itmDECISION : VIS_INFO.DECISION] **-> For serious (except death), non-serious adverse events and Other reasons only:** **Please select who made the decision:** ☐ Investigator ☐ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): LOG STATUS (Log status) [frmLOG_STATUS]

CONCOMITANT VACCINATION [sctCONC_VACCINATION_FLG]

1.* ✔	Have any vaccines required to be reported as per protocol other than the study vaccine(s) been administered?	[*itmCV_FLAG* : **CVSHEET.CV_FLAG**] ☐ Yes -> Please complete the following page ☐ No

MEDICATION [sctMEDICATION_FLG]

2.* ✔	Have any medications that are required to be reported per protocol been administered?	[*itmMD_FLAG* : **MDSHEET.MD_FLAG**] ☐ Yes -> Please complete the following page ☐ No

NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS [sctNONSERIOUS_AES_FLG]

Please report serious adverse events only in the Serious Adverse Events Report, not here.

3.* ✔	Have any non-serious adverse events that are required to be reported per protocol occurred?	[*itmAE_FLAG* : **AESHEET.AE_FLAG**] ☐ Yes -> Please complete the following page ☐ No

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): CONCOMITANT VACCINATION (Conc vacc) - Repeating Form [frmCONC_VACCINATION]

#	Vaccine name	Route	Date of administration
1			

CONCOMITANT VACCINATION [sctCONC_VACCINATION_DET]

Please record any concomitant vaccination according to the protocol reporting requirements. **Vaccination admistered prior to the first dose of study vaccine are to be recorded in vaccination history section**

1.* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	[*itmCVACC_TRADNAME* : **VACC_CON.TRADNAME**] *A60*
2.* ✔	Route: [Route]	[*itmCVACC_ROUTE* : **VACC_CON.MED_ROUT**] *[clMEDROUT_CVACC]*
3.* ✔	Date of administration: [Date of administration]	[*itmCVACC_RDAT* : **VACC_CON.MEDSRDAT**] Req/Unk / Req/Unk / Req/Unk (2013-2018)
4.	For GSK - MON: *[hidden]* [For GSK - MON]	[*itmMON_TRANS* : **VACC_CON.MD_TRANS**] *A60*
5.	For GSK - DM: *[hidden]* [For GSK - DM]	[*itmGSK_MOD_HID* : **VACC_CON.GSK_MOD**] *A60*

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): MEDICATION (Medic) - Repeating Form [CONMEDS_CR]

#	Drug Name	Medical indication:	Total daily dose	Route	Start date	End date
1						

MEDICATION [sctCM]

Please record any concomitant medication according to the protocol reporting requirements.

1.* ✔	Drug name: [Drug Name]	[CMTERM : MEDIC.TRADNAME] A100
2.	Modified reported term *[hidden]*	[CMMODIFY : MEDIC.GSK_MOD] A100
3.	GSK Drug synonym *[hidden]*	[CMDRGSYN : Not submitted - for internal use] A100
4.	GSK Drug Collection code *[hidden]*	[CMDRGCOL : MEDIC.GSK_COD] A10
5.	Failed coding *[hidden]*	[calCM_FAILED : Not submitted - for internal use] A10
6.* ✔	Medical indication:	[itmMEDINDIC : MEDIC.MEDINDIC] A80 [itmPROPH_CK : MEDIC.PROPH_CK] In anticipation of study vaccine reaction ☐ [itmCHRON_CK : MEDIC.CHRON_CK] Chronic use ☐
7.* ✔	Total daily dose: [Total daily dose]	[itmMED_DOSE : MEDIC.MED_DOSE] Dose: A20 [itmMED_UNIT : MEDIC.MED_UNIT] Unit: A20
8.* ✔	Route: [Route]	[itmMED_ROUT : MEDIC.MED_ROUT] ☐ [clMEDROUT_MED] ☐
9.* ✔	Start date: [Start date]	[itmSRDAT : MEDIC.MEDSRDAT] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018)
10.* ✔	End date: or tick box if continuing at the end of the study [End date]	[itmERDAT : MEDIC.MEDERDAT] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [itmCONT_END : MEDIC.CONT_END] Continuing at the end of the study ☐
11.	For GSK - MON: *[hidden]* [For GSK - MON]	[itmMD_TRANS : MEDIC.MD_TRANS] A60
12.	Drug name: Generic name is preferred but trade name is preferred in case of multi-component drugs *[hidden]* [Drug name]	[CMCOMPARE : Not submitted - for internal use] A100
13.	Drug name: Generic name is preferred but trade name is preferred in case of multi-component drugs	[CMMODCOMPARE : Not submitted - for internal use] A100

	[hidden] [Drug name]	

Key: [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS (Non-Ser AE) - Repeating Form

[AE_CR]

#	AE No.	Event	Site:	Start date:	Outcome	End date	Maximum intensity	Is there a reasonable possibility that the AE may have been caused by the investigational product?	Medically attended visit
1									

NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS [sctAE]

Please record any non-serious AEs to the protocol reporting requirements.

1.	AE No. *[read-only]*	[*itmAE_NO* : **AE.AE_NB**] *N3*
2.* ✔	Event: Diagnosis only (if known), otherwise sign/symptom [Event]	[*AETERM* : **AE.AE_DESC**] *A100*
3.	Modified term ***Do not query this item. it is not displayed for sites.*** *[hidden]* [Modified term]	[*AEMODIFY* : Not submitted - for internal use] *A100*
4.	MedDRA synonym *[hidden]*	[*AEMEDSYN* : Not submitted - for internal use] *A100*
5.	MedDRA lower level term code *[hidden]*	[*AELLTCD* : **AE.MD_CODE**] *A10*
6.	Failed coding *[hidden]*	[*calAE_FAILED* : Not submitted - for internal use] *A10*
7.	New Onset of Chronic Disease (NOCD)?(for DM only) *[hidden]* [NOCD?]	[*itmNOCD* : **AE.GSK_NOCD**] ☐ NOCD
8.* ✔	Site:	[*itmAE_LG* : **AE.AE_LG**] ☐ [*itmP_CODE* : **AE.P_CODE**] Administration site: ☐ *[clPRODNAMES]* ☐ ☐ Non-administration site
9.* ✔	Start date:	[*itmSRDAT* : **AE.AE_SRDAT**] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018) [*itmAEPOSTVC* : **AE.AEPOSTVC**] 30 minutes immediate post-vaccination ☐
10.	For incomplete start date: *[hidden]* [For incomplete start date]	[*itmAE_VACC* : **AE.AE_VACC**] ☐ *[clAFTERBEFORE]* ☐
11.* ✔	Outcome: [Outcome]	[*itmOUTCOME_NSAE* : **AE.OUTCOME**] ☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Recovered/resolved with sequelae
12. ✔	End date: [End date]	[*itmERDAT* : **AE.AE_ERDAT**] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req/Unk ☐ (2013-2018)
13.* ✔	Maximum intensity: [Maximum intensity]	[*itmAE_INTEN* : **AE.AE_INTEN**] ☐ Mild ☐ Moderate ☐ Severe
14.* ✔	Is there a reasonable possibility that the AE may have been caused by the investigational product?	[*itmCAUSAL* : **AE.CAUSAL**] ☐ No ☐ Yes

15.* ✔	Medicially attended visit: [Medically attended visit]	[*itmMED_TYPE* : **AE.MED_TYPE**] ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
16.	For MON: *[hidden]* [For MON]	[*itmAE_TRANS* : **AE.AE_TRANS**] *A80*
17.	AE description: Diagnosis only (if known), otherwise sign/symptom *[hidden]* [AE description]	[*AECOMPARE* : Not submitted - for internal use] *A100*
18.	AE description: Diagnosis only (if known), otherwise sign/symptom *[hidden]* [AE description]	[*AEMODCOMPARE* : Not submitted - for internal use] *A100*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): OCCURRENCE OF SERIOUS ADVERSE EVENTS (SAE Flg) [frmSAE_FLG]

OCCURRENCE OF SERIOUS ADVERSE EVENTS [sctSAE_FLG]

1.* ✔	Did the subject experience any Serious Adverse Events that are required to be reported per protocol?	[*itmSAE_FLG* : **AESHEET.AE_FLAG**] ☐ Yes -> Please remember to complete a SAE Report ☐ No

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SERIOUS ADVERSE EVENTS (SAE) - Repeating Form [AE_SER_CR]

#	SAE Report No.	Did SAE occur after initiation of study medication?	SERIOUS ADVERSE EVENT	Seriousness	RELEVANT CONCOMITANT/TREATMENT MEDICATIONS/VACCINATIONS	RELEVANT MEDICAL CONDITIONS/RISK FACTORS	RELEVANT DIAGNOSTIC RESULTS	Relevant diagnostic results not noted on the left columns	General narrative comments
1									

If you wish to record a new SAE please determine if the new SAE is clinically or temporally related to an SAE previously entered on this form.
If yes, record the details below using the 'Add Entry' button in this form.
If not clinically or temporally related, create a new SAE form for this subject by clicking on the 'New' button at the top of the page.
Do not record pre and post randomization events on the same form.

SAE REPORT NO. [sctSAE_REPORT_NO]

1. ✔	SAE Report No. *[read-only]* [SAE Report No.]	[*itmSAE_NB* : SAE.SAE_NB] N2
2.	Start date of SAE (minimum date from sctSAE) *[hidden]* [Start date if SAE (minimum date from sctSAE)]	[*itmSAE_STRT* : Not submitted - for internal use] NReq / NReq / NReq (2013-2018)
3.	Stop date of SAE (maximum date from sctSAE) *[hidden]* [Stop date of SAE (maximum date from sctSAE)]	[*itmSAE_STOP* : Not submitted - for internal use] NReq / NReq / NReq (2013-2018)

TYPE OF REPORT [sctSAE_TOR]

4.	Initial Report *[hidden]* [Initial Report]	[*chkSAE* : Not submitted - for internal use] Initial
5.	Follow-Up Report *[hidden]* [Follow-Up Report]	[*chkFU* : Not submitted - for internal use] Follow-Up

RANDOMIZATION [sctSAE_RAND]

6.*	Did the event occur after initiation of investigational product(s)? [Did SAE occur after initiation of study medication?]	[*rdcSAERAND* : SAE.SAE_RAND] No Yes

	No.	Event	Start date and time	Outcome / End date and time	Maximum Intensity	Action taken with investigational product(s) as a result of the event	Did the subject withdraw from study due to this event?	Is there a reasonable possibility that the event may have been caused by the investigational product(s)?	Was the AE caused by activities related to study participation other than investigational product?	Medically attended visit
7. ✔										

SERIOUS ADVERSE EVENT Entry [sctSAE]

Use the 'Add Entry' button to enter details of the SAE. For additional SAEs that are clinically or temporally related (e.g., SAEs that occur during the same hospitalization) use the 'Add Entry' button to create a new row for entry of the additional SAE. Enter ONE event per row.

7.1	No. *[read-only]* [No.]	[*AESEQ* : AE.AESEQ] N5
7.2* ✔	Event: Diagnosis only (if known), otherwise sign/symptom [Event]	[*AETERM* : AE.AE_DESC] A100
7.3	Serious? *[hidden]* [Serious?]	[*itmAESER* : AE.AE_SER] Serious Non-Serious
7.4	Potential immune mediated disease (pIMD)? *[hidden]*	[*itmPIMD* : AE.P_IMD] pIMD Non pIMD
7.5	MedDRA synonym *[hidden]*	[*AEMEDSYN* : Not submitted - for internal use] A100

7.6	MedDRA lower level term code *[hidden]*	[*AELLTCD* : **AE.MD_CODE**] *A10*
7.7	Failed coding *[hidden]*	[*calAE_FAILED* : Not submitted - for internal use] *A10*
7.8	New Onset of Chronic Disease (NOCD)?(for DM only) *[hidden]* [NOCD?]	[*itmNOCD* : **AE.GSK_NOCD**] NOCD
7.9*	Start date and time Hr:Min (00:00-23:59) [Start date and time]	[*AESTDTTM* : **AE.AE_SRDAT**] Req/Unk / Req/Unk / Req (2013-2018) NReq : NReq *24-hour clock*
7.10*	Outcome / End date and time Hr:Min (00:23-59) [Outcome / End date and time]	[*AEOUTCD1* : **AE.OUTCOME**] [*AEENDTTM1* : **AE.AE_ERDAT**] Recovered/resolved, provide End date and time Req/Unk / Req/Unk / Req/Unk (2013-2018) NReq : NReq *24-hour clock* Recovering/resolving Not recovered/not resolved [*AEENDTTM2* : **AE.AE_ERDAT**] Recovered/resolved with sequelae, provide End date and time Req/Unk / Req/Unk / Req/Unk (2013-2018) NReq : NReq *24-hour clock* [*AEENDTTM3* : **AE.AE_ERDAT**] Fatal, record Date and time of Death Req/Unk / Req/Unk / Req/Unk (2013-2018) NReq : NReq *24-hour clock*
7.11*	Maximum Intensity **Record maximum intensity throughout duration of event** [Maximum Intensity]	[*AESEVCD* : **AE.AE_INTEN**] Mild Moderate Severe Not applicable
7.12	Intensity at onset of event **Record intensity at the onset of the event** *[hidden]* [Intensity at onset of event]	[*ADSEVCD* : Not submitted - for internal use] Mild Moderate Severe Not applicable
7.13	Maximum Grade **Record maximum grade throughout duration of event** *[hidden]* [Maximum Grade]	[*AETOXCD* : Not submitted - for internal use] Grade 1 Grade 2 Grade 3 Grade 4 Grade 5
7.14	Grade at onset of event **Record grade at the onset of the event** *[hidden]* [Grade at onset of event]	[*ADTOXCD* : Not submitted - for internal use] Grade 1 Grade 2 Grade 3 Grade 4 Grade 5
7.15	Maximum Grade or Intensity **Record maximum grade or intensity throughout duration of event** *[hidden]* [Maximum Grade or Intensity]	[*AETXHVCD* : Not submitted - for internal use] Mild or Grade 1 Moderate or Grade 2 Severe or Grade 3 Grade 4 Not applicable
7.16	Grade or Intensity at onset of event **Record grade or intensity at the onset of the event** *[hidden]*	[*ADTXHVCD* : Not submitted - for internal use] Mild or Grade 1 Moderate or Grade 2

	[Grade or Intensity at onset of event]	☐ Severe or Grade 3 ☐ Grade 4 ☐ Not applicable
7.17*	Action taken with investigational product(s) as a result of the event: [Action taken with investigational product(s) as a result of the event]	[*AEACTRCD* : **OC_SAE.SAE_ACT**] ☐ Investigational product(s) withdrawn ☐ Dose not changed ☐ Dose delayed ☐ Not applicable
7.18	Modified term ***Do not query this item. it is not displayed for sites.*** *[hidden]* [Modified term]	[*AEMODIFY* : **AE.MD_MOD**] *A100*
7.19*	Did the subject withdraw from study due to this event? [Did the subject withdraw from study due to this event?]	[*AEWD* : **OC_SAE.WITHDRAW**] ☐ Yes ☐ No
7.20*	Is there a reasonable possibility that the event may have been caused by the investigational product(s)? ***Use best judgment at initial entry. May be amended when additional information becomes available.*** [Is there a reasonable possibility that the event may have been caused by the investigational product(s)?]	[*AEREL* : **AE.CAUSAL**] ☐ No ☐ Yes
7.21	Duration of AE if < 24 hours *[hidden]* [Duration of AE if < 24 hours]	[*AEDURHR* : Not submitted - for internal use] [*AEDURMIN* : Not submitted - for internal use] *0 <= N2 <= 23* Hr(s) *0 <= N2 <= 59* Min(s)
7.22	Time to Onset Since Last Dose *[hidden]* [Time to Onset]	[*AEONLDSH* : Not submitted - for internal use] [*AEONLDSM* : Not submitted - for internal use] Hr(s) *0 <= N2 <= 23* Min(s) *0 <= N2 <= 59*
7.23*	Was the AE caused by activities related to study participation other than investigational product? [Was the AE caused by activities related to study participation other than investigational product?]	[*rdcAESREL* : **OC_SAE.REL_PART**] ☐ Yes ☐ No
7.24	Was the event serious? *[hidden]* [Was the event serious?]	[*AESER* : Not submitted - for internal use] ☐ Yes ☐ No
7.25	Related Investigational Product *[hidden]* [Related Investigational Product]	[*txtAERDG* : Not submitted - for internal use] *A80*
7.26	AE description: Diagnosis only (if known), otherwise sign/symptom *[hidden]* [AE description]	[*AECOMPARE* : Not submitted - for internal use] *A100*
7.27	AE description: Diagnosis only (if known), otherwise sign/symptom *[hidden]* [AE description]	[*AEMODCOMPARE* : Not submitted - for internal use] *A100*
7.28	Yes, select appropriate investigational product(s) *[hidden]* [Investigational product(s)]	[*AERDGCD* : Not submitted - for internal use] ☐ [enter protocol specific IP definition 1] ☐ [enter protocol specific IP definition 2] ☐ [enter protocol specific IP definition 3]
7.29	SAEEmailFlag *[hidden]* [SAEEmailFlag]	[*txtSAEEmailFlag* : Not submitted - for internal use] *A6*

7.30* ✔	Medically attended visit: [Medically attended visit]	[*itmMED_TYPE* : **AE.MED_TYPE**] ☐ Emergency Room ☐ Hospitalisation ☐ Medical Personnel ☐ None
7.31	Narrative include clinical *[hidden]*	[*itmNARRATIVEINCLUDECLINICAL* : Not submitted - for internal use] *A255*
[sctEMERGENT]		
8.	Sequence Number *[hidden]* [Sequence Number]	[*AESEQ2* : Not submitted - for internal use] *N5*
9.	AE description: Diagnosis only (if known), otherwise sign/symptom *[hidden]*	[*AETERM_1* : Not submitted - for internal use] *A100*
10.	Start Date and Time of event segment Hr:Min (00:00-23:59) *[hidden]* [Start Date of event segment]	[*ADSTDTTM* : Not submitted - for internal use] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2013-2018) ☐ NReq ☐ : ☐ NReq ☐ *24-hour clock*
11.	Intensity of event segment *[hidden]* [Intensity of event segment]	[*ADSEVCD1* : Not submitted - for internal use] ☐ Mild ☐ Moderate ☐ Severe
12.	Grade of event segment *[hidden]* [Grade of event segment]	[*ADTOXCD2* : Not submitted - for internal use] ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Grade 5
13.	Grade or Intensity of event segment *[hidden]* [Grade or Intensity of event segment]	[*ADTXHVCD2* : Not submitted - for internal use] ☐ Mild or Grade 1 ☐ Moderate or Grade 2 ☐ Severe or Grade 3 ☐ Grade 4 ☐ Grade 5
SERIOUSNESS [sctSAE_SER]		
14. ✔	Specify the reason for considering this event as SAE. (Tick all that apply) [Seriousness]	[*chkAESER* : **SAE.SER_CRIT**] ☐ Results in death ☐ Is life-threatening (subject was at risk of death at time of event) ☐ Requires hospitalisation or prolongation of hospitalisation (Provide admission and discharge date(s) in narrative) ☐ Results in disability/incapacity (substantial / permanent) ☐ Congenital anomaly/birth defect (in offspring of subject) ☐ Other, specify within general narrative comment

	Drug Name	Total daily dose	Route	Start Date	End date	Medical Indication	Drug type
15. ✔							

RELEVANT CONCOMITANT/TREATMENT MEDICATIONS/VACCINATIONS Entry [sctSAE_CM]

Use the 'Add Entry' button to enter details of any medication/vaccine that may help to explain the SAE, may have caused the SAE or was used to treat the SAE. Ensure each concomitant vaccination or medication recorded in this section is also recorded in the corresponding form located in the LOGS section of the eCRF.

15.1	CM Sequence Number *[hidden]* [CM Sequence Number]	[*txtSAECMSEQ* : Not submitted - for internal use] *A4*

15.2* ✔	Drug name: [Drug Name]	[*CMTERM* : **OC_CMVAC.TRADNAME**] (Trade name is preferred) *A100*
15.3	Modified reported term *[hidden]* [Modified reported term]	[*txtCMMODIFY* : **OC_CMVAC.GSK_MOD**] *A100*
15.4 ✔	Total daily dose: [Total daily dose]	[*txtSAECMDOS* : **SAE.CT_DOSE**] Dose: *xxxxxxxxx.* [*pdcCMUNIT* : **OC_CMMED.MED_UNIT**] Unit: *[clCMUNITSAE]*
15.5	Frequency *[hidden]* [Frequency]	[*pdcSAECMFRQ* : Not submitted - for internal use] *[clSAECMFRQ]*
15.6*	Route [Route]	[*pdcCMROUTCD* : **OC_CMVAC.MED_ROUT**] *[clMEDROUT_MEDSAE]*
15.7*	Start Date [Start Date]	[*dtmSAECMSTD* : **OC_CMVAC.MEDSRDAT**] NReq/Unk / NReq/Unk / NReq/Unk (2002-2018)
15.8 ✔	End date: or tick box if continuing at the end of the study [End date]	[*dtmSAECMEND* : **SAE.CT_END**] NReq/Unk / NReq/Unk / NReq/Unk (2002-2018) [*rdcSAECMONG* : **SAE.CT_CONT**] Continuing at the end of the study
15.9	Medical indication *Enter a medical diagnosis not description* [Medical Indication]	[*txtCMIND* : Not submitted - for internal use] *A50*
15.10	Modified reported term *[hidden]* [Modified reported term]	[*txtCMINDMODIFY* : Not submitted - for internal use] *A100*
15.11*	Drug type: [Drug type]	[*pdcCMDRGTYP* : **OC_CMVAC.DRUG_TYP**] *[clDRUGTYP]*
15.12	CM COMPARE (Hidden) *[hidden]* [CM COMPARE (Hidden)]	[*txtCMCOMPARE* : Not submitted - for internal use] *A100*
15.13	CMIN COMPARE (Hidden) *[hidden]* [CMIN COMPARE (Hidden)]	[*txtCMINCOMPARE* : Not submitted - for internal use] *A100*

	Condition	Start date	Continuing at time of SAE?
16. ✔			

RELEVANT MEDICAL CONDITIONS/RISK FACTORS Entry [sctSAE_MHX]

Use the 'Add Entry' button to enter each past or current medical disorder, allergy or surgery that may be RELEVANT to the SAE. Enter a diagnosis, not description. Relevant family or social history shoud be described in the 'General Narrative Comments' at the bottom of this form. Ensure each medical condition/risk factor recorded in this section is also recorded in the General Medical History form located at the beginning of the eCRF.

16.1	MHx Sequence Number *[hidden]* [MHx Sequence Number]	[*txtMHXSEQ* : Not submitted - for internal use] *A4*
16.2*	Condition ***Enter a medical diagnosis not description.*** [Condition]	[*txtSAEMHTRM* : **OC_MDCON.CON_DESC**] *A100*

16.3	Modified reported term *[hidden]* [Modified reported term]	[*txtSAEMHMODIFY* : **OC_MDCON.MD_MOD**] *A100*
16.4*	Start date: [Start date]	[*dtmMHSTDTM* : **OC_MDCON.MCSTR_DT**] Req/Unk / Req/Unk / Req/Unk (2002-2018)
16.5*	Continuing at time of SAE? [Continuing at time of SAE?]	[*rdcMHCONT* : **OC_MDCON.CONT_SAE**] Yes [*dtmMHLSTOC* : **OC_MDCON.MCEND_DT**] No, specify end date or date of last occurrence Req/Unk / Req/Unk / Req/Unk (2002-2018) Unknown, no information available
16.6	SAE MHX COmpare (Hidden) *[hidden]* [SAE MHX COmpare (Hidden)]	[*txtMHXCOMPARE* : Not submitted - for internal use] *A100*

	Test name	Test date	Test result	Test units	Normal low range	Normal high range
17. ✔						

RELEVANT DIAGNOSTIC RESULTS Entry [sctSAE_LAB]

Use the 'Add Entry' button to enter details of relevant tests or procedures carried out to diagnose or confirm the SAE or rule out other diagnoses

17.1	Lab Sequence Number *[hidden]* [Lab Sequence Number]	[*txtSAELBSEQ* : Not submitted - for internal use] *A4*
17.2*	Test name [Test name]	[*pdcLBTST* : **OC_LABRS.LAB_NAME**] *[clSAELBTST]*
17.3*	Test date [Test date]	[*dtmLABDTM* : **OC_LABRS.LAB_DT**] Req/Unk / Req/Unk / Req (2002-2018)
17.4*	Test result [Test result]	[*txtLABRES* : **OC_LABRS.LAB_RES**] *A12*
17.5*	Test units [Test units]	[*txtLABUNIT* : **OC_LABRS.LAB_U**] *A12*
17.6*	Normal low range [Normal low range]	[*txtLABNLR* : **OC_LABRS.LAB_L**] *xxxxxxxxx.xx*
17.7*	Normal high range [Normal high range]	[*txtLABNHR* : **OC_LABRS.LAB_H**] *xxxxxxxxx.xx*

[sctSAE_LABTXT]

18.	Enter here only the diagnostic results that could not be entered in the above grid, including procedure such as ECG, X rays, etc and tests on stool, CSF etc. Also provide dates. [Relevant diagnostic results not noted on the left columns]	[*txtLABTEXT* : **OC_LABRS.LAB_DET**] *A1000* [*txtLABTEXT1* : **OC_LABRS.LABTEXT1**] *A1000*

[sctSAE_IP]

19.	If investigational product(s) were stopped	[*rdcSAEIP* : Not submitted - for internal use]

	temporarily, did the reported event(s) recur after investigational products were restarted? *[hidden]* [If investigational product(s) were stopped temporarily, did the reported event(s) recur after investigation products were restarted?]	☐ No ☐ Yes ☐ Unknown at this time ☐ Not applicable

GENERAL NARRATIVE COMMENTS [sctSAE_COM]

Provide a clear (this narrative will be provided to regulatory authorities) and brief chronological description (with dates) of the clinical course of the event including:
- Associated signs and symptoms
- Clinical evolution (hospitalisation, outcome, description of sequelae if any, autopsy results, etc.)
- Non-drug treatment such as surgery
- Other information useful for the medical assessment of the case (e.g. reason for diagnosis if not obvious or if diagnosis changed)
- Relevant additional risk factors including family or social history (negative sentence can also be helpful)
- Possible cause(s) of the event
- Rationale for relationship when SAE is possibly related to study product, concomitant product or study procedure, etc.

Complete a new box only when the previous one is full.

20.*	General narrative comments	[*txtSAECOMM* : **OC_SAEDT.SAECOMM**] *A1000* [*txtSAECOMM1* : **OC_SAEDT.SAECOMM1**] *A1000* [*txtSAECOMM2* : **OC_SAEDT.SAECOMM2**] *A1000*

		[txtSAECOMM3 : OC_SAEDT.SAECOMM3] A1000
NON CLINICAL [sctSAE_NC]		
21.	Send incomplete SAE data to GSK Safety *[hidden]* [Send incomplete SAE data to GSK Safety]	[chkSENDI : OC_SAFAD.REQDLOAD] Incomplete SAE
22.	Receipt by GSK date *[hidden]* [Receipt by GSK date]	[dtmSAEDTM : AE.DTMSAEDTM] Req / Req / Req (2013-2018) Req : Req *24-hour clock*
23.	Was the event serious? *[hidden]* [Was the event serious?]	[AESER : Not submitted - for internal use] Yes No
24.	Sequence Number *[hidden]* [Sequence Number]	[AESEQ1 : Not submitted - for internal use] N5
25.	Version Number *[hidden]* [Version Number]	[txtSAEVERSION : Not submitted - for internal use] A4
26.	Case ID *[hidden]* [Case ID]	[txtSAEID : OC_SAFAD.OCEAN_ID] A20
27.	Randomisation Number *[hidden]* [Randomisation Number]	[txtSAERNDNO : Not submitted - for internal use] A255
28.	OCEANS Code *[hidden]* [OCEANS Code]	[txtOCEANSCD : SAE.CASE_ID] A13
29.	eMail flag *[hidden]*	[calSAEEmailFlag : Not submitted - for internal use] A6
30.	Message sender identifier *[hidden]* [mssgsendid]	[itmMESSAGESENDERIDENTIFIER : Not submitted - for internal use] A128

31.	Study Type *[hidden]* [Study Type]	[*itmSAESTUDYTPE* : Not submitted - for internal use] *A128*
32.	Modification datetime *[hidden]*	[*itmMOD_DATE* : **SAE_MNGT.MODIFIED_DT**] NReq / NReq / NReq (2013-2018) NReq : NReq : NReq *24-hour clock*

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): STUDY CONCLUSION (Conclusion) [frmSTUDYCONCLUSION]

STUDY CONCLUSION [sctSTUDYCONCLUSION]

1.* ✔	Date of subject completion or withdrawal (or date of death if applicable):	[*itmLC_RDAT*: **CONCLUS.LC_RDAT**] Req / Req / Req (2013-2018)
2.	For Data Managers only: Tick or untick this box to require the investigator to re-sign the case book *By ticking or unticking this box you are evoking a change to this form back to an unsigned state. This should be done when significant changes (e.g. those that require medical opinion or other significants situation) occur after the original signature. If the box is already ticked upon arrival on this form, unticking and submitting it accomplishes the same task as ticking and submitting it; that is, the signature will be validated in both [hidden]*	[*INVSIG2*: Not submitted - for internal use] 1

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): USE OF HUMAN SAMPLES (UHS) - Repeating Form [frmUHS]

#	Text 3A	Text 3B	Text 4	Please check GSK Biologicals sample storage period specified in the ICF in use at your centre.	If new version of UHS: Date at which the new ICF version was first signed by a Subject :
1					

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.

1.	UHS form version *[hidden]* [UHS form version]	[*itmUHS_NB_HID* : Not submitted - for internal use] *N10*
TYPE 3A TESTS [sctUHS_3A]		
2.* ✔	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. [Text 3A]	[*itmCONS_YN_3A* : **UHS.CONS_YN**] ☐ Yes ☐ No
TYPE 3B TESTS [sctUHS_3B]		
3.* ✔	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. [Text 3B]	[*itmCONS_YN_3B* : **UHS.CONS_YN**] ☐ Yes ☐ No
TYPE 4 TESTS [sctUHS_4]		
4.* ✔	With the prior permission of the Subject's parents / Legally Acceptable Representatives: 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. [Text 4]	[*itmCONS_YN_4* : **UHS.CONS_YN**] ☐ Yes ☐ No
SAMPLE STORAGE PERIOD [sctUHS_PERIOD]		
5.* ✔	Please check GSK Biologicals sample storage period specified in the ICF in use at your centre. [Please check GSK Biologicals sample storage period specified in the ICF in use at your centre.]	[*itmPERIOD* : **UHS.PERIOD**] ☐ For a maximum of 20 years ☐ [*itmPERIODSP* : **UHS.PERIODSP**] Other, please specify: *A200*
IF NEW VERSION OF UHS FORM [sctUHS_DATE]		
Complete and submit a new Use of Human Samples by GSK form for each change in the ICF that affects the use of samples.		
6. ✔	Date at which the new ICF version was first signed by a Subject : [If new version of UHS: Date at which the new ICF version was first signed by a Subject :]	[*itmUHS_DATE* : **UHS.UHS_DATE**] ☐ NReq ☐ / ☐ NReq ☐ / ☐ NReq ☐ (2013-2018)

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Clinical Study Protocol

Sponsor:
GlaxoSmithKline Biologicals
Rue de l'Institut 89
1330 Rixensart, Belgium

Primary Study vaccine and number	GlaxoSmithKline (GSK) Biologicals' Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine (DTPa-HBV-IPV/Hib) (SB217744, *Infanrix hexa*™).
Other Study vaccines	• Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine (*Pediarix*®, GSK Biologicals) • *Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate) (*ActHIB*®, Sanofi Pasteur SA) • Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus* b Conjugate (Tetanus Toxoid Conjugate) vaccine (*Pentacel*®, Sanofi Pasteur SA) • Hepatitis B Vaccine (Recombinant) (*Engerix-B*®, GSK Biologicals) • Pneumoccocal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) (*Prevnar13*®, Manufactured by Wyeth Pharmaceuticals Inc. Marketed by Pfizer Inc.) • Rotavirus Vaccine, Live, Oral (*Rotarix*®, GSK Biologicals) • Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (*Infanrix*®, GSK Biologicals) • *Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate) (*Hiberix*™, GSK Biologicals)
eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
Investigational New Drug (IND) number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol	Final Version 01: 18 October 2013
Date of protocol amendment	Amendment 1 Final: 18 September 2014 Amendment 2 Final Version 02: 17 April 2015
Title	Immunogenicity and safety study of GSK Biologicals' Infanrix hexa™ at 2, 4 and 6 months of age in healthy infants.

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
Investigational New Drug (IND) number	BB-IND 006687
EudraCT number:	2013-004304-19
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Co-ordinating author	Prapti Bose, Scientific Writer
Contributing authors	• PPD, Clinical Research and Development Lead (CRDL) • PPD, Senior Director and Head, Portfolio Head CRDL • PPD, Project Statistician • PPD, Director, Biostatistics • PPD, PPD, Study Delivery Manager • PPD, PPD, Study Delivery Lead • PPD, GVCL Project Manager • PPD, Clinical Safety representative • PPD, Study Data Manager • PPD, Global Regulatory Lead • PPD, Global Patents representative • PPD, Global Regulatory Affairs, GSK Vaccines • PPD, Director, Clinical Medical Affairs, Pediatric Vaccines, US, GSK Vaccines • PPD, Director, Clinical Medical Affairs, US, GSK Vaccines • PPD, Local Delivery Lead • PPD, US Medical Affairs Lead

GSK Biologicals' Protocol DS v 14.0

Protocol Amendment 2 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 2 Final Version 02: 17 April 2015
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Sponsor signatory	Narcisa Elena Mesaros Project level CRDL, DTP/Polio Vaccines Late Clinical Development, Vaccine Discovery and Development, GlaxoSmithKline Biologicals.
Signature	_____
Date	_____

For internal use only

- ----------Checksum----------!Ver.!Created On - -
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Protocol Amendment 2 Rationale

Amendment number: Amendment 2
Rationale/background for changes: The amendment 2 has been implemented to amend the following sections of the protocol: • The assay for testing antibodies against polyribosyl ribitol phosphate (anti-PRP) has been re-developed but is not yet qualified or validated for testing the one month post dose-3 samples. This has been clarified in the protocol in Table 7 Humoral immunity (antibody determination) and Section 5.7.3 Laboratory assays. • Investigator sign-off on the patient identification (PIDS) will be done after Visit 4 instead of extended safety follow-up (ESFU). In Table 4 List of study procedures, the bullets pertaining to investigator sign-off and analysis of Epoch 001 has been removed from the ESFU visit and retained at Visit 4 to reflect this change. • The collection of baseline measurement of limb length has been removed since it will not be used in analysis; only limb circumference will be used in analysis. Accordingly, text related to this has been amended in Table 4 List of study procedures, Sections 5.6.2.11, Baseline measurement of limb circumference after booster vaccination at visit 5 and 5.6.2.13 Recording of AEs, SAEs and NOCDs. • Errors in the vaccines dictionary of Study Master Repository (SMR) have been rectified for *Infanrix hexa*, *Pediarix* and *Pentacel* vaccines. The corresponding correction has been made in Table 9 Study vaccines. • The sequence of analysis in Section 10.9.1 Sequence of analyses, has been amended to reflect that there will first be an analysis of immunogencity for anti-PRP and safety for Epoch 001, followed by a final analysis covering both Epochs at the end of the study.

Protocol Amendment 2 Investigator Agreement

I agree:

- To conduct the study in compliance with this protocol, any future protocol amendments or protocol administrative changes, with the terms of the clinical trial agreement and with any other study conduct procedures and/or study conduct documents provided by GlaxoSmithKline (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 vaccine 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 subject and/or the subject's legally acceptable representative.
- To perform no other biological assays on the clinical samples except those described in the protocol or its amendment(s).
- To co-operate 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 vaccine, 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.

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 2 Final Version 02: 17 April 2015
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Investigator name	_____
Signature	_____
Date	_____

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Sponsor Information

1. Sponsor

GlaxoSmithKline Biologicals, Rue de l'Institut 89, 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 8.4.2.

SYNOPSIS

Detailed Title

A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Indication

Active immunization against diphtheria, tetanus, pertussis infection caused by all known subtypes of hepatitis B virus, poliomyelitis, and invasive disease caused by *Haemophilus influenzae* type B (Hib) in infants.

Rationale for the study and study design

- **Rationale for the study**

Infanrix hexa was first licensed in the European Union in 2000. More than 100 million doses have been distributed to date and the benefit/risk profile remains favorable. Licensure of *Infanrix hexa* combination vaccine in the United States (US) will provide an additional option for vaccination within the routine US pediatric schedule with the fewest number of injections, which would create opportunities to add further injections in case other novel vaccines against important pediatric diseases become available. Furthermore, *Infanrix hexa* will provide an additional source of DTaP, hepatitis B, poliovirus, and Hib-containing vaccine to the US market, which will help ensure a more stable supply.

The present study 117119 (DTPA-HBV-IPV-135) is intended to generate pivotal immunogenicity data demonstrating non-inferiority of the immune responses against pertussis antigens of *Infanrix hexa* compared to *Pediarix,* which is currently one of the DTaP combination vaccines widely used as a standard of care in the US. Additionally, this study will also provide descriptive data with regard to the immunogenicity of the other vaccine antigens and the safety profile in US subjects. These pivotal immunogenicity non-inferiority data for pertussis and descriptive safety data are intended to support the registration of GSK Biologicals' combined DTPa-HBV-IPV/Hib (*Infanrix hexa*) vaccine in the US. A subsequent Phase III study is planned to provide pivotal data regarding lot-to-lot consistency, safety and the immunogenicity of the other vaccine antigens.

Comparison of immunogenicity data from separate clinical studies for *Infanrix hexa* and *Pentacel*, given on a 2-4-6 month schedule, suggests that the immune response to the Hib

component of these vaccines is similar. This study will provide descriptive information regarding the immune response to the Hib components of *Infanrix hexa* and *Pentacel* following a 3 dose primary series, prior to further evaluation in Phase III studies.

- **Rationale for the study design**

Design of Epoch 001 (primary vaccination):

The study is designed as a randomized, controlled, open-label study with five parallel groups:

- The first three groups (Hexa_1, Hexa_2 and Hexa_3 group) will receive three doses of the *Infanrix hexa* vaccine (either lot A, lot B or lot C, respectively). These three groups will be pooled together for the analyses and the pooled group will be called the Hexa group.
- The Pedia Group (Control 1) will receive three doses of the US-licensed control vaccines, *Pediarix* and *ActHIB*.
- The Penta Group (Control 2) will receive three doses of the US-licensed control vaccines, *Pentacel* (only two doses of *Engerix-B* will be administered if a subject has received a birth dose of hepatitis B vaccine).

Three distinct vaccine lots manufactured according to the same procedures will be used in the Hexa group in order to obtain more representative data for the vaccine.

The study will be open-label due to the differences in the number of injections and the appearance of the vaccines administered.

Vaccines (i.e., *Prevnar13* and *Rotarix*) that are recommended for children in the US during the first year of life will be administered concomitantly with the other study vaccines as part of the study.

Design of Epoch 002 (booster vaccination):

In Epoch 002, the subjects will be assessed for antibody persistence to the vaccine antigens of *Infanrix hexa*. This epoch will also assess the adequacy of priming subjects with *Infanrix hexa* by evaluating the boostability of D, T, Pa and Hib antigens with the US-licensed vaccines. The pooled Hexa Group will receive booster doses of *Infanrix* and *Hiberix* vaccines at 15 through 18 months of age, the subjects in the Penta Group will receive *Pentacel* vaccine as a booster, and

the subjects in the Pedia Group will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15 through 18 months of age.

The study will continue to be open-label in Epoch 002.

Objectives

Primary

Epoch 001 (primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] is ≤ 1.5.

Secondary

Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D, T, HBs, pertussis, poliovirus types 1, 2 and 3 and PRP antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa,* of *Pentacel* co-administered with *Engerix-B,* and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic diseases (NOCDs) and serious adverse events.

Epoch 002 (Booster vaccination)

- To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB,* in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.

- To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel,* in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.

Study design

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups.
- Duration of the study: The intended duration of the study per subject is approximately 14-17 months.
  - **Epoch 001**: Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10),
  - **Epoch 002**: Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).
- Study groups: The study groups are presented in Synopsis Table 1.

Synopsis Table 1 Study groups and epochs foreseen in the study

Study groups	Number of subjects	Age (Min/Max) at Visit 1	Epochs	
			Epoch 001	Epoch 002
Hexa_1	65	6 WEEK -12weeks	x	x
Hexa_2	65	6 WEEK -12weeks	x	x
Hexa_3	65	6 WEEK -12weeks	x	x
Pedia	195	6 WEEK -12weeks	x	x
Penta	195	6 WEEK -12weeks	x	x

The study groups and treatment foreseen in the study is presented in Synopsis Table 2.

Synopsis Table 2 Study groups and treatment foreseen in the study

Treatment name	Vaccine/Product name	Study Groups				
		Hexa_1	Hexa_2	Hexa_3	Pedia	Penta
Epoch 001						
Infanrix hexa		x	x	x		
	Hib					
Pediarix					x	
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					
Engerix-B*	HBV					x
Prevnar13	Prevenar 13	x	x	x	x	x
Rotarix	HRV	x	x	x	x	x
	$CaCO_3$					
Epoch 002						
Infanrix	DTPa	x	x	x	x	
Hiberix	Hib	x	x	x		
	NaCl					
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					

* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group.

- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*
- Vaccination schedules:

  <u>*Epoch 001*</u>
  - **Hexa Group:** Subjects in this group will receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
    - Hexa_1 Group: Subjects will receive lot A of *Infanrix hexa,*
    - Hexa_2 Group: Subjects will receive lot B of *Infanrix hexa*
    - Hexa_3 Group: Subjects will receive lot C of *Infanrix hexa*.

- **Pedia Group:** Subjects in this group will receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
- **Penta Group**: Subjects in this group will receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

*Subjects in the Penta Group who have received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not receive *Engerix-B* at 4 months of age (Visit 2).

Epoch 002

- **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
- **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
- **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls will be given in this study at 15-18 months of age, the fourth dose of *Prevnar13* will not be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) will be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

As the analyses will be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups will be pooled together for the analysis and will be called the Hexa group.

- Treatment allocation: The subjects will be randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This will be done at study entry using GSK Biologicals' central randomization system on internet (SBIR).
- Blinding: The study is open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the

laboratory in charge of the serology testing will be blinded to the treatment, and codes will be used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

The blinding of study epochs is presented in Synopsis Table 3.

Synopsis Table 3 Blinding of study epochs

Study Epochs	Blinding
Epoch 001	open
Epoch 002	open

- Sampling schedule: Blood samples will be drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) will be collected.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

Number of subjects The total number of subjects planned to be enrolled is 585 subjects (65 each in Hexa_1, Hexa_2, Hexa_3 groups and 195 each in Pedia and Penta groups).

Endpoints

Primary

Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix*.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

Secondary

Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the **Med**ical **D**ictionary for **R**egulatory **A**ctivities (MedDRA) classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.

- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).

- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

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LIST OF ABBREVIATIONS

ACIP:	Advisory Committee on Immunization Practices
AE:	Adverse Event
ANCOVA:	Analysis of Co-variance
ANOVA:	Analysis of Variance
ATP:	According-To-Protocol
CDC:	Centers for Disease Control and Prevention, United States of America
CI:	Confidence Interval
CSR:	Clinical Study Report
D:	Diphtheria
DTPa-HBV-IPV/Hib:	Combined diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus and *Haemophilus influenzae* type b vaccine (*Infanrix hexa*).
eCRF:	electronic Case Report Form
EL.U:	ELISA unit(s)
ELISA:	Enzyme-linked immunosorbent assay
ESFU:	Extended safety follow-up
eTDF:	electronic Temperature excursion Decision Form
FHA:	Filamentous hemagglutinin
GCP:	Good Clinical Practice
GMC:	Geometric Mean Concentration
GMT:	Geometric Mean Titer
GSK:	GlaxoSmithKline
HBs:	Hepatitis B surface antigen
Hib:	*Haemophilus influenzae* (*H. influenzae*) type b
HRV:	Human Rotavirus

IB:	Investigator Brochure
ICF:	Informed Consent Form
ICH:	International Conference on Harmonisation
IEC:	Independent Ethics Committee
IM:	Intramuscular
IMP:	Investigational Medicinal Product
IND:	Investigational New Drug
IRB:	Institutional Review Board
IU:	International unit(s)
LAR:	Legally Acceptable Representative
Lf:	Limits of flocculation unit(s)
LSLV:	Last Subject Last Visit
MedDRA:	Medical Dictionary for Regulatory Activities
NI:	Non-inferiority
NOCD:	New Onset of Chronic Disease
Pa:	Acellular *Bordetella pertussis* component
PI:	Product Information
PRN:	Pertactin
PRP:	Polyribosyl-Ribitol-Phosphate: polysaccharide component of the Hib bacterium capsule
PT:	Pertussis toxoid: a secreted exotoxin of the *Bordetella pertussis* bacterium
RCC:	Reverse Cumulative Curve
RDE:	Remote Data Entry
SAE:	Serious Adverse Event
SBIR:	Randomization System on Internet

SCID:	Severe Combined Immunodeficiency Disease
SDV:	Source Document Verification
SPC:	Summary of Product Characteristics
SPM:	Study Procedures Manual
T:	Tetanus
TVC:	Total Vaccinated cohort
US:	United States

GLOSSARY OF TERMS

Adverse event:	Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An adverse event (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 open-label study, no blind is used. Both the investigator and the subject know the identity of the treatment assigned.
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 legal guardian.
Eligible:	Qualified for enrolment into the study based upon strict adherence to inclusion/exclusion criteria.
Epoch:	An epoch is a self-contained set of consecutive timepoints or a single timepoint from a single protocol. Self-contained means that data collected for all subjects at all timepoints within that epoch allows to draw a complete conclusion to define or precise the targeted label of the product. Typical examples of epochs are primary vaccinations, boosters, yearly immunogenicity follow-ups, and surveillance periods for efficacy or safety.

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 (see Sections 6.7.2 and 10.4 for details on criteria for evaluability).
Immunological correlate of protection:	The defined humoral antibody response above which there is a high likelihood of protection in the absence of any host factors that might increase susceptibility to the infectious agent.
Intercurrent medical condition:	A condition that has the capability of altering a subject's immune response or are confirmed to have an immunodeficiency condition during the study.
Investigational vaccine/product: **(Synonym of Investigational Medicinal Product)**	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Primary completion date:	The date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.
Randomization:	Process of random attribution of treatment to subjects in order to reduce bias of selection.
Self-contained study:	Study with objectives not linked to the data of another study.
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:	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 contacted in order to participate or participates in the clinical study, either as a recipient of the vaccines or as a control.
Subject number:	A unique number identifying a subject, assigned to each subject consenting to participate in the study.
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.
Treatment number:	A number identifying a treatment to a subject, according to the study randomization or treatment allocation.
Unsolicited adverse event:	Any 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 protocol.

In the body of the protocol (including the synopsis), the names of the vaccines will be written without the superscript symbol ™ or ® and in *italics*.

Trademarks of the GlaxoSmithKline group of companies	Generic description
Engerix-B®	Hepatitis B vaccine (recombinant)
Hiberix™	*Haemophilus* b conjugate vaccine (tetanus toxoid conjugate)
Infanrix®	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed
Infanrix hexa™	Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine
Pediarix®	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine
Rotarix®	Rotavirus Vaccine, Live, Oral

Trademarks not owned by the GlaxoSmithKline group of companies	**Generic description**
ActHIB® **(Sanofi Pasteur SA)**	*Haemophilus* type b conjugate vaccine (tetanus toxoid conjugate)
Pentacel® **(Sanofi Pasteur SA)**	Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus* b conjugate (tetanus toxoid conjugate)
Prevnar® **(Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)**	Pneumoccocal 7-valent conjugate vaccine (diphtheria CRM_{197} protein)
Prevnar13® **(Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)**	Pneumoccocal 13-valent conjugate vaccine (diphtheria CRM_{197} protein)

1. INTRODUCTION

1.1. Background

Combination vaccines have been developed to provide multiple immunizations in a single injection. They can simplify vaccine administration and have the potential to promote compliance and cost-effectiveness by decreasing the number of injections needed to immunize a child [Zinke, 2010; Kalies, 2006]. Use of combination vaccines can alleviate concerns associated with the number of injections to be given at one time [ACIP, 2011].

GlaxoSmithKline (GSK) Biologicals' *Infanrix hexa* vaccine helps prevent six diseases in a single injection. *Infanrix hexa* is licensed for primary and booster vaccination in more than 98 countries around the globe, including the entire European Union. The vaccine complies with the WHO requirements for manufacture of biological substances for all of its antigenic components. The *Infanrix hexa* vaccine consists of a combination of GSK's *Pediarix* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined); STN 103907, approved in the United States (US) on December 13, 2002 and a Hib vaccine consisting of purified polyribosyl-ribitol-phosphate (PRP) capsular polysaccharide of *Haemophilus influenzae* type b covalently bound to tetanus toxoid (TT). The conjugated Hib-TT is the same as that used for the formulation of *Hiberix* [*Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate)] (licensed in the US as a booster dose in August 2009), with the only difference that in *Infanrix hexa*, the Hib-conjugate is adsorbed onto aluminum phosphate.

The *Infanrix hexa* combination vaccine would provide an additional source of DTaP, hepatitis B, poliovirus, and Hib containing vaccines for the US market and would potentially reduce the number of injections required to provide infants with recommended vaccinations.

GSK has an extensive clinical safety database for *Infanrix hexa*. The safety and immunogenicity data of the vaccine have been evaluated in numerous controlled studies [Dhillon, 2010; Zepp, 2009], of which 4 were conducted in the US with approximately 3000 US subjects exposed to a primary vaccination with *Infanrix hexa*.

Please refer to the current Investigator Brochure for information regarding the pre-clinical and clinical studies and the potential risks and benefits of *Infanrix hexa*.

1.2. Rationale for the study and study design

1.2.1. Rationale for the study

Infanrix hexa was first licensed in the European Union in 2000. More than 100 million doses have been distributed to date and the benefit/risk profile remains favorable. Licensure of *Infanrix hexa* combination vaccine in the US will provide an additional option for vaccination within the routine US pediatric schedule with the fewest number of injections, which would create opportunities to add further injections in case other novel vaccines against important pediatric diseases become available. Furthermore, *Infanrix hexa* will provide an additional source of DTaP, hepatitis B, poliovirus, and Hib-containing vaccine to the US market, which will help ensure a more stable supply.

The present study 117119 (DTPA-HBV-IPV-135) is intended to generate pivotal immunogenicity data demonstrating non-inferiority of the immune responses against pertussis antigens of *Infanrix hexa* compared to *Pediarix,* which is currently one of the DTaP combination vaccines widely used as a standard of care in the US. Additionally, this study will also provide descriptive data with regard to the immunogenicity of the other vaccine antigens and the safety profile in US subjects. These pivotal immunogenicity non-inferiority data for pertussis and descriptive safety data are intended to support the registration of GSK Biologicals' combined DTPa-HBV-IPV/Hib (*Infanrix hexa*) vaccine in the US. A subsequent Phase III study is planned to provide pivotal data regarding lot-to-lot consistency, safety and the immunogenicity of the other vaccine antigens.

Comparison of immunogenicity data from separate clinical studies for *Infanrix hexa* and *Pentacel*, given on a 2-4-6 month schedule, suggests that the immune response to the Hib component of these vaccines is similar. This study will provide descriptive information regarding the immune response to the Hib components of *Infanrix hexa* and *Pentacel* following a 3-dose primary series, prior to further evaluation in Phase III studies.

1.2.2. Rationale for the study design

1.2.2.1. Design of Epoch 001 (primary vaccination):

The study is designed as a randomized, controlled, open-label study with five parallel groups:

- The first three groups (Hexa_1, Hexa_2 and Hexa_3 group) will receive three doses of the *Infanrix hexa* vaccine (either lot A, lot B or lot C, respectively). These three groups will be pooled together for the analyses and the pooled group will be called the Hexa group.
- The Pedia Group (Control 1) will receive three doses of the US-licensed control vaccines, *Pediarix* and *ActHIB*.
- The Penta Group (Control 2) will receive three doses of the US-licensed control vaccines, *Pentacel* (only two doses of *Engerix-B* will be administered if a subject has received a birth dose of hepatitis B vaccine).

Three distinct vaccine lots manufactured according to the same procedures will be used in the Hexa group in order to obtain more representative data for the vaccine.

The study will be open-label due to the differences in the number of injections and the appearance of the vaccines administered.

Vaccines (i.e., *Prevnar13* and *Rotarix*) that are recommended for children in the US during the first year of life will be administered concomitantly with the other study vaccines as part of the study.

1.2.2.2. Design of Epoch 002 (booster vaccination):

In Epoch 002, the subjects will be assessed for antibody persistence to the vaccine antigens of *Infanrix hexa*. This epoch will also assess the adequacy of priming subjects with *Infanrix hexa* by evaluating the boostability of D, T, Pa and Hib antigens with the US-licensed vaccines. The pooled Hexa Group will receive booster doses of *Infanrix* and *Hiberix* vaccines at 15 through 18 months of age, the subjects in the Penta Group will receive *Pentacel* vaccine as a booster, and the subjects in the Pedia Group will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15 through 18 months of age.

The study will continue to be open-label in Epoch 002.

2. OBJECTIVES

2.1. Primary objective

2.1.1. Epoch 001 (Primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] is ≤ 1.5.

Refer to Section 10.1 for the definition of the primary endpoint.

2.2. Secondary objectives

2.2.1. Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D, T, HBs, pertussis, poliovirus types 1, 2 and 3 and PRP antigens, one month after the third dose of the primary vaccination.

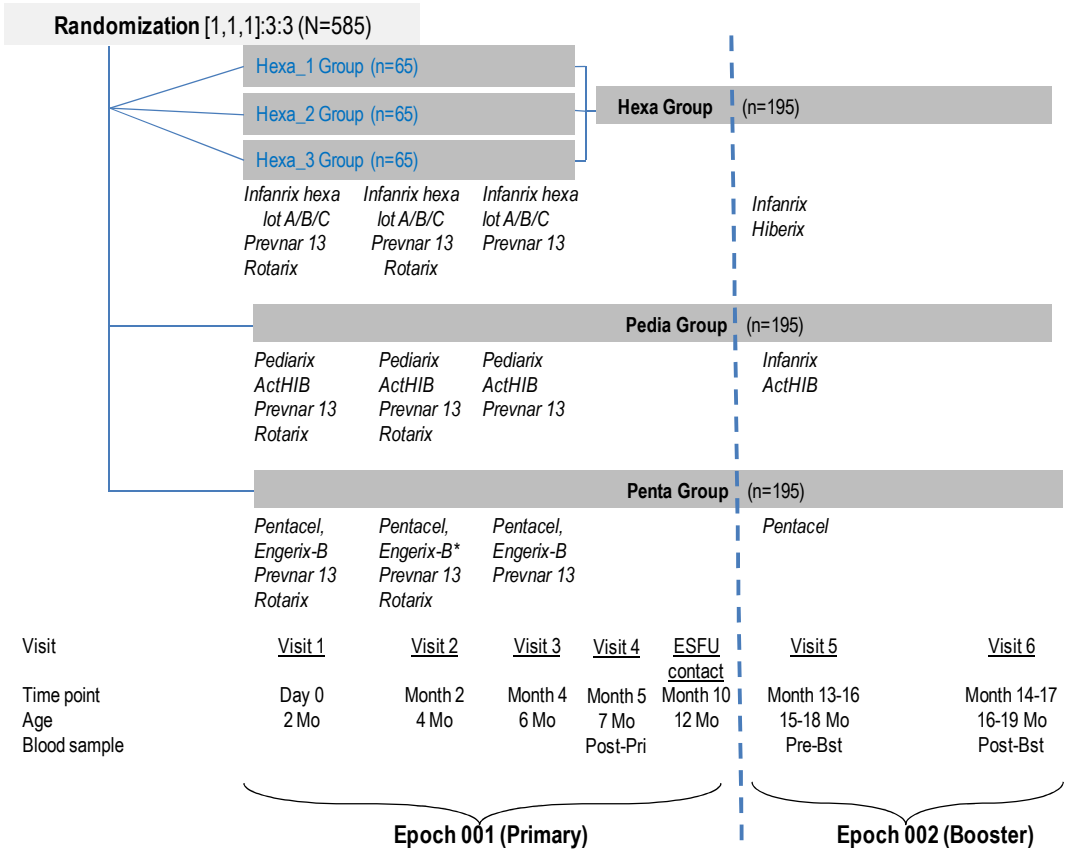
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa,* of *Pentacel* co-administered with *Engerix-B,* and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic diseases (NOCDs) and serious adverse events.

2.2.2. Epoch 002 (Booster vaccination)

- To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB,* in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.
- To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel,* in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.

Refer to Section 10.2 for the definition of the secondary endpoints.

3. STUDY DESIGN OVERVIEW



N = number of subjects in the study; n = number of subjects in each group; Mo = months
Visit 3 should be conducted at least 8 weeks after Visit 2, with subjects at least 24 weeks of age, in order to comply with US recommendations on hepatitis B dosing
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002
* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group
ESFU = Extended safety follow-up

Protocol waivers or exemptions are not allowed with the exception of immediate safety concerns. Therefore, adherence to the study design requirements, including those specified in the outline of study procedures (Section 5.5), are essential and required for study conduct.

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups.
- Duration of the study: The intended duration of the study per subject is approximately 14-17 months.
  - **Epoch 001:** Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10),

– **Epoch 002:** Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).

- Study groups: The study groups and epochs foreseen in the study are presented in Table 1.

Table 1 Study groups and epochs foreseen in the study

Study groups	Number of subjects	Age (Min/Max) at Visit 1	Epochs	
			Epoch 001	Epoch 002
Hexa_1	65	6 WEEK -12weeks	x	x
Hexa_2	65	6 WEEK -12weeks	x	x
Hexa_3	65	6 WEEK -12weeks	x	x
Pedia	195	6 WEEK -12weeks	x	x
Penta	195	6 WEEK -12weeks	x	x

The study groups and treatment foreseen in the study are presented in Table 2.

Table 2 Study groups and treatment foreseen in the study

Treatment name	Vaccine/Product name	Study Groups				
		Hexa_1	Hexa_2	Hexa_3	Pedia	Penta
Epoch 001						
Infanrix hexa		x	x	x		
	Hib					
Pediarix					x	
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					
Engerix-B*	HBV					x
Prevnar13	Prevenar 13	x	x	x	x	x
Rotarix	HRV	x	x	x	x	x
	$CaCO_3$					
Epoch 002						
Infanrix	DTPa	x	x	x	x	
Hiberix	Hib	x	x	x		
	NaCl					
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					

* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group.

- Control: active controls.
  – Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*
  – Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*.

Vaccination schedules:

Epoch 001

- **Hexa Group:** Subjects in this group will receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - Hexa_1 Group: Subjects will receive lot A of *Infanrix hexa,*
  - Hexa_2 Group: Subjects will receive lot B of *Infanrix hexa*
  - Hexa_3 Group: Subjects will receive lot C of *Infanrix hexa*.
- **Pedia Group:** Subjects in this group will receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
- **Penta Group**: Subjects in this group will receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

*Subjects in the Penta Group who have received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not receive *Engerix-B* at 4 months of age (Visit 2).

Epoch 002

- **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
- **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
- **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls will be given in this study at 15-18 months of age, the fourth dose of *Prevnar13* will not be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) will be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

- As the analyses will be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups will be pooled together for the analysis and will be called the Hexa group.

- Treatment allocation: The subjects will be randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This will be done at study entry using GSK Biologicals' central randomization system on internet (SBIR).

- Blinding: The study is open-label for both epochs (Table 3) due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing will be blinded to the treatment, and

codes will be used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

The blinding of study epochs is presented in Table 3.

Table 3 Blinding of study epochs

Study Epochs	Blinding
Epoch 001	open
Epoch 002	open

- Sampling schedule: Blood samples will be drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) will be collected.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

4. STUDY COHORT

4.1. Number of subjects/centers

Target enrolment will be 585 subjects (65 each in Hexa_1, Hexa_2, Hexa_3 groups and 195 each in Pedia and Penta groups). Enrolment will be terminated when the target number of subjects has been enrolled. Refer to Section 10.3 for a detailed description of the criteria used in the estimation of sample size.

This study will be conducted at multiple centers in the US.

Actual numbers of subjects enrolled versus target will be monitored by the site monitor using SBIR.

4.2. Inclusion criteria for enrolment

Deviations from inclusion criteria are not allowed because they can potentially jeopardize the scientific integrity of the study, regulatory acceptability or subject safety. Therefore, adherence to the criteria as specified in the protocol is essential.

All subjects must satisfy ALL the following criteria at study entry:

- Subjects' parent(s)/ LAR(s) who, in the opinion of the investigator, can and will comply, with the requirements of the protocol (e.g. completion of the diary cards, return for follow-up visits).
- A male or female between, and including, 6 and 12 weeks of age at the time of the first vaccination.
- Born full-term (i.e. after a gestation period of 37 weeks to less than 42 completed weeks [259 to 293 days]).
- Written informed consent obtained from parent(s)/LAR(s) of the subject.
- Healthy subjects as established by medical history and clinical examination before entering into the study.
- Infants who have not received a previous dose of hepatitis B vaccine or those who have received only 1 dose of hepatitis B vaccine administered at least 30 days prior to enrolment.

4.3. Exclusion criteria for enrolment

Deviations from exclusion criteria are not allowed because they can potentially jeopardize the scientific integrity of the study, regulatory acceptability or subject safety. Therefore, adherence to the criteria as specified in the protocol is essential.

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

  Please 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 vaccines within 30 days preceding the first dose of study vaccines, or planned use during the study period.
- Chronic administration (defined as more than 14 days in total) of immunosuppressants or other immune-modifying drugs since birth. 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 within the period starting from 30 days before the first vaccination until 30 days after Dose 3 (Epoch 001, primary vaccination) and from 30 days before the booster Dose 4 until 30 days after booster Dose 4 (Epoch 002, booster vaccination), i.e. the end of the study:
  - Inactivated influenza and hepatitis A vaccines are allowed throughout the study.
  - Routine administration(s) of vaccines are allowed from 30 days after the last dose of primary vaccination until 30 days before the booster dose and after post-booster blood sampling. Routine administration of measles-mumps-rubella

vaccine, varicella, pneumococcal vaccines are allowed from 30 days after last dose of primary vaccine until 30 days before booster dose and from post-booster blood sampling, as well as according to the recommended immunization schedule in US.

- Concurrently participating in another clinical study, at any time during the study period, in which the subject has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device).
- History of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and hepatitis B diseases.
- Previous vaccination against Hib, diphtheria, tetanus, pertussis, pneumococcus, rotavirus and/or poliovirus; more than one previous dose of hepatitis B vaccine.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
- Family history of congenital or hereditary immunodeficiency.
- History of any reaction or hypersensitivity likely to be exacerbated by any component of the vaccines (including yeast).
- Hypersensitivity to latex.
- Major congenital defects or serious chronic illness.
- History of any neurological disorders including seizures.
- Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period.
- History of intussusception or of any uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception.
- History of Severe Combined Immunodeficiency Disease (SCID).
- Acute disease and/or fever at the time of enrolment.
  - Fever is defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.
  - Subjects with a minor illness (such as mild diarrhea, mild upper respiratory infection) without fever may, be enrolled at the discretion of the investigator.

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 ICH Guideline for Good Clinical Practice (GCP), all applicable subject 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 Harmonised Tripartite Guideline for clinical investigation of medicinal products in the paediatric 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.
- Subject'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 subject's parent(s)/LAR(s) 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 judgement, 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

5.2.1. Subject identification

After checking the inclusion/exclusion criteria, subject numbers will be assigned sequentially to subjects whose parent(s)/LAR(s) give consent for their child to participate in the study, according to the range of subject numbers allocated to each study center. Subject numbers will also be used to identify blood samples collected during the study.

5.2.2. Randomization of treatment

5.2.2.1. Randomization of supplies

The numbering of supplies will be performed at GSK Biologicals, using MATerial EXcellence (MATEX), a program developed for use in Statistical Analysis System (SAS®) (Cary, NC, USA) by GSK Biologicals.

To allow GSK Biologicals to take advantage of greater rates of recruitment than anticipated at individual centers in this multi-center study and to thus reduce the overall study recruitment period, an over-randomization of supplies will be prepared.

5.2.2.1.1. Epoch 001

A first list based on a randomization blocking scheme using a [1:1:1]:3:3 randomization ratio will be used to number the following vaccines for Doses 1, 2 and 3.

- DTPa-HBV-IPV/Hib lot A
- DTPa-HBV-IPV/Hib lot B
- DTPa-HBV-IPV/Hib lot C
- *Pediarix*
- *Pentacel*

The vaccines from this list will be distributed to the study center while respecting the randomization block size.

ActHIB, Engerix-B, Prevnar13 and *Rotarix* will be numbered independently using a sequential numbering.

5.2.2.1.2. Epoch 002

Four sequential lists (one for *Infanrix*, one for *Hiberix*, one for *ActHIB* and one for *Pentacel*) will be used to number the vaccine doses for the Epoch 002.

The study staff in charge of the vaccine administration will access SBIR, provide the subject identification number and the dose number. The system will provide a new treatment number for all the vaccines to be administered to a subject (*Pentacel, Infanrix + ActHIB* or *Infanrix + Hiberix*). This will be consistent with the allocated study group.

5.2.2.2. Treatment allocation to the subject

The treatment numbers will be allocated by dose.

5.2.2.2.1. Study group and treatment number allocation

The target is to enroll 585 subjects to be randomly assigned to five study groups in a [1:1:1]:3:3 ratio (195 subjects in the pooled lots group).

Allocation of the subject to a study group at the investigator site will be performed using SBIR. The randomization algorithm will use a minimization procedure accounting for the study as a whole and each of the centers.

After obtaining the signed and dated ICF from the subject's parent(s)/LAR(s) and having checked the eligibility of the subject, the site staff in charge of the vaccine administration will access SBIR. Upon providing the subject identification number, the randomization system will ask whether the subject had a previous hepatitis B vaccination and will use the minimization algorithm to determine the group allocation and the appropriate treatment number for *Pentacel*, *Pediarix* or for *Infanrix hexa* (lot A, lot B or lot C) to be used for the subject.

SBIR will also provide treatment numbers for co-administered vaccines *Engerix B, ActHib, Prevnar13* vaccine and a *Rotarix* vaccine, each one labelled with a different treatment number. Therefore a subject will have three or four different treatment numbers allocated at dose 1.

The number of each administered treatment must be recorded in the eCRF on the Vaccine Administration screen.

When SBIR is not available, please refer to the SBIR user guide or the Study Procedures Manual (SPM) for specific instructions.

5.2.2.2.2. Treatment number allocation for subsequent doses

For each dose subsequent to the first dose, the study staff in charge of the vaccine administration will access SBIR, provide the subject identification number, the dose number and the system will provide new treatment numbers consistent with the allocated study group.

Each vaccine will be labeled with a different treatment number.

The number of each administered treatment must be recorded in the eCRF on the Vaccine Administration screen.

Note that in the Penta Group, the investigator will be reminded that *Engerix-B* is not allowed at dose 2 for subjects with previous hepatitis B vaccination. So for these subjects, the treatment identified by SBIR for dose 2 should not be used.

5.3. Method of blinding

The study will be open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing will be blinded to the treatment, and codes will be used to link the subject and study (without any link to the treatment attributed to the subject) 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 subjects.

5.5. Outline of study procedures

The outline of study procedures is presented in Table 4.

Table 4 List of study procedures

(Amendment 2: 17 April 2015)

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Informed consent	●						
Check inclusion/exclusion criteria	●						
Medical history	●						
Collect demography data	●						
Vaccination history including HepB vaccination history	●						
Informed consent for Tdap vaccination history of mother[α]	●						
Last Tdap vaccination history of mother[β]	●						
History directed physical examination including length and weight	●					●	
Study group and treatment number allocation (Randomization)	O						
Treatment number allocation for subsequent doses		O	O			O	
Recording of administered treatment number	●	●	●			●	
Pre-vaccination body temperature	●	●	●			●	
Blood sampling				●		●	●
Check warnings and precautions	O	O	O			O	
Check contraindications to subsequent vaccination		●	●			●	
Pre-vaccination measurement of circumference of limb(s) at site of injection by investigator[δ]						●	
Vaccination	●	● **	●			●	
Distribution of thermometer	O						
Distribution of measuring device	O					O	
Distribution of diary cards	O	O	O			O	

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Daily post-vaccination recording of solicited adverse events during the 4-day (Day 0–3) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of non-serious (unsolicited) adverse events during the 31-day (Day 0–30) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of any large injection site reactions in the eCRF by the investigator*						●	
Return of diary cards and transcription by the investigator		●	●	●			●
Record any concomitant medication and vaccination §	●	●	●	●	●	●	●
Record any intercurrent medical conditions‖		●	●	●	●	●	●
Recording of serious adverse events including related to study participation or to a concurrent GSK medication/vaccine	●	●	●	●	●	●	●
Recording of NOCDs‡	●	●	●	●	●	●	●
Investigator sign-off				●			●
Analysis of the Epoch 001 #				O			
Analysis of the Epoch 002 #							O
Study Conclusion							●

Note: The double-line border indicates the analyses which will be performed on all data obtained up to that visit or contact.

● is used to indicate a study procedure that requires documentation in the individual eCRF

○ is used to indicate a study procedure that does not require documentation in the individual eCRF

Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001

Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002

Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

† Visit 3 should be conducted at least 8 weeks after Visit 2 and when the subject is at least 24 weeks of age

$^{\alpha}$ The child can still continue in the study even if the mother does not wish to provide consent to record her Tdap vaccination history.

$^{\beta}$ Only the Tdap vaccination history (during the pregnancy of the enrolled child) from mothers who have given consent to provide this information will be obtained and recorded in the eCRF.

[δ] For the Penta group, which receives only one vaccine at Visit 5, baseline measurement of only the limb receiving the vaccine is required
** If subject in the Penta Group received a birth dose of Hep B vaccine, no administration of *Engerix-B* is foreseen at Visit 2 (4-months of age)
* Refer to Section 8.1.3.1 and 5.6.2.11 for detailed explanation on the reporting of large injection site reactions
§ Refer to Section 6.7 for details
‖ Refer to Section 6.8 for details
‡ New onset of chronic disease (NOCD) includes events such as autoimmune disorders, asthma, type I diabetes and allergies
# Refer to Section 10.9.1 for details

.

It is the investigator's responsibility to ensure that intervals between visits are strictly followed. The intervals between study visits are presented in Table 5.

Table 5 Intervals between study visits

Interval	Optimal length of interval[1]
Birth→Visit 1	6-12 weeks (42-90 days) of age[2]
Visit 1 →Visit 2	49-83 days[2]
Visit 2 →Visit 3 *	56-90 days[2]
Visit 3 → Visit 4	30-48 days[2] †
Visit 3 → Phone call (ESFU contact)	180-210 days**
Birth→ Visit 5^	15-18 months of age[2]
Visit 5 → Visit 6	30-48 days[2] †

[1] Whenever possible the investigator should arrange within this interval;
[2] Subjects may not be eligible for inclusion in one or more cohorts for analysis if they make the study visit outside this interval. For Visit 3-Visit 4 and Visit 5-Visit 6, an interval of 21-48 days will be considered for the According-to-protocol (ATP) cohort of immunogenicity. Refer to Section 10.4 for the definition of the cohorts for analysis;
* Advisory Committee on Immunization Practices (ACIP) recommendation states that minimum age of last Hep B dose is 24 weeks and this last dose should be administered at least 8 weeks after the previous dose. So, Visit 3 should be conducted at least 8 weeks after Visit 2 and when the subject is at least 24 weeks of age
† It is preferred that subjects come in for Visit 4 and Visit 6, at least 30 days after Visits 3 and 5, respectively. If subjects return for the visit prior to 30 days, they should take home the diary card and continue to record unsolicited safety information until 30 days post-vaccination and mail/send it upon completion. Investigators will make an attempt to retrieve diary cards from subjects who have not mailed/sent them in.
^ Visit 5 should occur after the ESFU. ESFU must occur prior to vaccination if Visit 5 coincides with the 6 months post-Visit 3 time-point
** Adherence to the interval pertaining to phone contact is only indicative and will not determine a subject's eligibility for inclusion for ATP analysis. However, the interval should be respected in order to obtain safety information over the complete 6 months extended safety follow up period.

5.6. Detailed description of study procedures

5.6.1. Procedures prior to study participation

5.6.1.1. Informed consent

The signed informed consent of the subject's parent(s)/LAR(s) must be obtained before study participation.

5.6.2. Procedures during the study

5.6.2.1. Check inclusion and exclusion criteria

Check all inclusion and exclusion criteria as described in Sections 4.2 and 4.3 before enrolment.

5.6.2.2. Collect demographic data

Record demographic data such as date of birth, gender, geographic ancestry and ethnicity in the subject's eCRF.

5.6.2.3. Medical history

Obtain the subject's medical history by interview and/or review of the subject's medical records and record any pre-existing conditions or signs and/or symptoms present in a subject prior to the first study vaccination in the eCRF.

5.6.2.4. Vaccination history

Obtain the subject's vaccination history by interview and/or review of the subject's medical records and record any vaccinations given to the subject, including hepatitis B vaccines, prior to the first study vaccination in the eCRF. The Tdap vaccination history of the mother during pregnancy will also be collected and recorded in the eCRF (provided that the mother has consented to provide this information).

Note: Maternal vaccination is requested in order to be able to summarize the responses of the subjects to pertussis antigens according to whether or not the mothers received a pertussis vaccine during their pregnancy. This information will aid in understanding the effect of transplacentally transferred antibodies on the childs' immune response to vaccination.

5.6.2.5. History directed physical examination

Perform a history directed physical examination at Visit 1 (Epoch 001) and Visit 5 (Epoch 002). If the investigator determines that the subject's health on the day of vaccination temporarily precludes vaccination, the visit will be rescheduled. Collected information, including length and weight, needs to be recorded in the eCRF.

Treatment of any abnormality observed during this examination has to be performed according to local medical practice outside this study or by referral to an appropriate health care provider.

5.6.2.6. Study group and treatment number allocation

Study group and treatment number allocation will be performed as described in Section 5.2.2. The number of each administered treatment must be recorded in the eCRF.

5.6.2.7. Treatment number allocation for subsequent doses

The treatment number allocation for subsequent doses will be performed at Visits 2, 3 and 5 as described in Section 5.2.2. The number of each administered treatment must be recorded in the eCRF.

5.6.2.8. Assess pre-vaccination body temperature

The axillary, rectal, oral or tympanic body temperature of all subjects needs to be measured prior to the study vaccine administration at Visits 1, 2, 3 and 5. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002. If the subject has fever [fever is defined as temperature ≥38.0°C /100.4°F by any route] on the day of vaccination, the vaccination visit will be rescheduled within the allowed interval for this visit (see Table 5).

5.6.2.9. Sampling

Refer to the Module on Biospecimen Management in the SPM for detailed instructions for the collection, handling and processing of the samples.

5.6.2.9.1. Blood sampling for immune response assessments

Blood samples will be taken during certain study visits as specified in Section 5.5 List of Study Procedures.

- A volume of approximately 5.0 mL of whole blood to provide approximately 1.7 mL of serum should be drawn from all subjects for the analysis of humoral immune response at Visits 4 and 5. At least 3.5 mL of whole blood to provide approximately 1.2 mL of serum should be drawn from all subjects for the analysis of humoral immune response at Visit 6. After centrifugation, serum samples should be kept at –20°C/ –4°F or below until shipment. Refer to the SPM for more details on sample storage conditions.

5.6.2.10. Check contraindications, warnings and precautions to vaccination

Contraindications, warnings and precautions to vaccination must be checked at the beginning of each vaccination visit. Refer to Sections 6.5 and 6.6 for more details.

5.6.2.11. Baseline measurement of limb circumference after booster vaccination at visit 5

(Amendment 2: 17 April 2015)

During Epoch 002, baseline measurement of limb circumference (arms or legs according to where the vaccine was administered) at the level of the injection site should be obtained. For the Penta group, baseline measurement is only required for the limb that will be vaccinated. Clothing should be removed so as not to interfere with the measurement of the limb circumference. For measuring upper arm circumference, the measurement will be performed while the arm is held parallel to the trunk and the elbow is flexed in front at 90° (as if the subject is carrying a tray) [Kohl, 2007]. For measuring leg circumference the child should be standing or lying flat, as appropriate, as long as the leg is straight.

5.6.2.12. Study Vaccines administration

- After completing all prerequisite procedures prior to vaccination, one dose of study vaccine/control vaccines will be administered intramuscularly (IM) (refer to Section 6.3 for detailed description of the vaccines administration procedure). If the investigator or delegate determines that the subject's health on the day of administration temporarily precludes vaccine administration, the visit will be rescheduled within the allowed interval for this visit (refer to Table 5).

- The subjects will be observed closely for at least 30 minutes following the administration of the vaccines, with appropriate medical treatment readily available in case of anaphylaxis.

5.6.2.13. Recording of AEs, SAEs and NOCDs

(Amendment 2: 17 April 2015)

- Refer to Section 8.3 for procedures for the investigator to record AEs, SAEs and NOCDs. NOCDs include events such as autoimmune disorders, asthma, type I diabetes and allergies. Refer to Section 8.4 for guidelines on how to submit SAE reports to GSK Biologicals.

The subjects' parent(s)/LAR(s) will be instructed to contact the investigator immediately should the subjects manifest any signs or symptoms they perceive as serious.

- At each vaccination visit, diary cards will be provided to the subject's parent(s)/LAR(s). The subject's parent(s)/LAR(s) will record body (rectal for subjects in Epoch 001 and axillary for subjects in Epoch 002) temperature and any solicited local/general AEs (i.e. on the day of vaccination and during the next 3 days) or any unsolicited AEs (i.e. on the day of vaccination and during the next 30 days occurring after vaccination). The subject's parent(s)/LAR(s) will be instructed to return the completed diary card to the investigator at the next study visit.
- Collect and verify completed diary cards during discussion with the subject's parent(s)/LAR(s) on Visits 2, 3, 4 and 6.
- During Epoch 002, following the fourth dose vaccination, the parents/LAR(s) should be provided with a measurement device for recording circumference of injected limbs (arms or legs according to where vaccine was administered) at the level of the injection site on the day of vaccination and during the next three days on a diary card. The parents/LAR(s) should be instructed on how and where to perform the measurement of the circumference of the vaccinated limb. Daily measurements should be performed in the same manner preferably by the same person and at the same time of day during the 4-day follow-up (Day 0-Day 3) period.
- If the parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of limb circumference) during the 4-day follow-up (Day 0-Day 3) period they are to contact study personnel and to visit the investigator's office for evaluation as soon as possible and to bring the diary card with them.

- In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms, the parent(s)/LAR(s) will record the following additional symptoms/characteristics that may be associated with large injection site swelling reactions on the diary card:
  - Type of swelling (local swelling only around the injection site, diffuse swelling not involving the elbow or knee joint, swelling involving the elbow or knee joint)
  - Induration at injection site (largest diameter)
  - Pruritis at the injection site (intensity – scale provided)
  - Functional impairment (intensity – scale and description provided)
- The study personnel's evaluation will be recorded in the medical chart. In case the diary card score is not in line with the medical chart score, the medical chart will indicate what is the most intense score. The largest or most intense score for a given day will be recorded in the eCRF at the level of the solicited symptoms and at the level of the large swelling report form.
- Any unreturned diary cards will be sought from the subject's parent(s)/LAR(s) through telephone call(s) or any other convenient procedure. The investigator will transcribe the collected information into the eCRF in English.

5.6.2.14. Check and record concomitant medication/vaccination and intercurrent medical conditions

Concomitant medication/vaccination must be checked and recorded in the eCRF as described in Section 6.7.

Intercurrent medical conditions must be checked and recorded in the eCRF as described in Section 6.8.

5.6.2.15. Study conclusion

The investigator will:

- review data collected to ensure accuracy and completeness at ESFU contact and Visit 6
- complete the Study Conclusion screen in the eCRF.

At study completion, post-trial commercial vaccines will not be provided to the subjects.

5.7. Biological sample handling and analysis

Please refer to the SPM for details on biospecimen management (handling, storage and shipment).

Samples will not be labelled with information that directly identifies the subject but will be coded with the identification number for the subject (subject number).

Under the following circumstances, additional testing on the samples may be performed by GSK Biologicals outside the scope of this protocol:

- Collected samples may be used in other assays, for test improvement or development of analytical methods related to the study vaccines and its constituents or the disease under study.
- Collected samples may be used for purposes related to the quality assurance of data generated linked to the study vaccines or the disease under study, such as for maintenance of assays described in this protocol and comparison between analytical methods and/or laboratories.

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 subject's parent(s)/LAR(s).

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 a maximum of 20 years (counting from when the last subject 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 subject 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 subject from the ATP analysis (See Section 10.4 for the definition of study cohorts/ data sets to be analysed). 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

Table 6 Biological samples

Sample type	Quantity*	Unit	Timepoint
Blood	5	mL	Month 5 (Post-Pri)
Blood	5	mL	Month 13-16 (Pre-Bst)
Blood	3.5	mL	Month 14-17 (Post-Bst)

* Approximate quantity
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

5.7.3. Laboratory assays

(Amendment 2: 17 April 2015)

Please refer to APPENDIX A for the address of the clinical laboratories used for sample analysis.

At Visits 4, 5 and 6, blood will be collected for measurement of immune response. Total blood volume to be taken from each subject over the study period is approximately 13.5 mL (approximately 5.0 mL of whole blood to provide approximately 1.7 mL of serum at Visits 4 and 5 and at least 3.5 mL of whole blood to provide approximately 1.2 mL of serum at Visit 6). All serology will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized procedures with adequate controls. ***All serology for primary endpoints will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized, validated procedures with adequate controls.***

The laboratory assays for humoral immunity are presented in Table 7.

Table 7 Humoral Immunity (Antibody determination)

(Amendment 2: 17 April 2015)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off†	Laboratory**
Serum	Bordetella pertussis.Pertussis Toxin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Filamentous Hemaglutinin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Pertactin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Corynebacterium diphtheriae.Diphtheria Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Clostridium tetani.Tetanus Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Hepatitis B Virus.Surface Ab	CLIA	Centaur (Siemens Healthcare)	mIU/mL	6.2	GSK Biologicals§
Serum	Poliovirus Sabin Types 1, 2 and 3	NEUTRA	In-house*	ED_{50}	8	GSK Biologicals§
Serum	Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab ‡	ELISA	In-house*	µg/mL	0.15	GSK Biologicals§

*In-house refers to assays developed internally by GSK which can be performed at GSK Biologicals' laboratories or external laboratory designated by GSK
**Refer to APPENDIX A for the laboratory addresses.
§GSK Biologicals laboratory refers to the Global Vaccines Clinical Laboratories (GVCL) in Rixensart, Belgium; Wavre, †
†Due to ongoing re-validation of all assays, the cut-offs may be subject to change.
‡For anti-PRP post-dose 3, the assay is not yet qualified or validated.
Belgium and Laval, Canada.
ELISA = Enzyme-Linked Immunosorbent Assay
NEUTRA = Neutralization Assay
CLIA = ChemiLuminescence ImmunoAssay

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.

5.7.4. Biological samples evaluation

5.7.4.1. Immunological read-outs

The immunological read-outs are presented in Table 8.

Table 8 Immunological read-outs

Blood sampling time point		No. of subjects	Components and priority rank
Type of contact and time point	Sampling time point		
Visit 4 (Month 5)	Post-Pri	585 (All)	PRN, FHA, PT PRP, D, T, HBs, Poliovirus type 1, Poliovirus type 2, Poliovirus type 3
Visit 5 (Month 13-16)	Pre-Bst	585 (All)	PRN, FHA, PT PRP, D, T, HBs, Poliovirus type 1, Poliovirus type 2, Poliovirus type 3
Visit 6 (Month 14-17)	Post-Bst	585 (All)	PRN, FHA, PT, PRP, D, T

Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

In case of insufficient blood sample volume to perform assays for all antibodies, the samples will be analysed according to priority ranking provided in Table 8.

5.7.5. Immunological correlates of protection

The following cut-offs are accepted as immunological correlates of protection:

- Specific antibodies against diphtheria toxoid (anti-diphtheria) and tetanus toxoid (anti-tetanus) will be measured by enzyme-linked immunosorbent assay (ELISA). The assay cut-off of ELISA is set at 0.1 International Units per ml (IU/ml), which provides a conservative estimate of the percentage of subjects deemed to be protected [Camargo, 1984; Melville-Smith, 1983].
- Antibodies to the hepatitis B surface antigen (anti-HBs) will be measured using CLIA. The cut-off of the test is set at 6.2 mIU/ml. An antibody concentration ≥10 mIU/ml defines seroprotection [CDC, 1991; WHO, 1988].
- Antibodies against poliovirus types 1, 2 and 3 will be determined by a virus micro-neutralization test adapted from the World Health Organization Guidelines for WHO/EPI Collaborative Studies on Poliomyelitis [WHO, 1993]. The lowest dilution at which serum samples will be tested is 1:8, from which a test will be considered positive. Titers will be expressed in terms of the reciprocal of the dilution resulting in 50% inhibition. Antibody titers greater than or equal to this value are considered as protective.
- Data from subjects given unconjugated Hib vaccine suggest that, in the absence of induction of immunological memory, a concentration of 0.15 µg/mL is indicative of short-term protection, with 1 µg/mL considered indicative of long-term protection [Käyhty, 1983; Anderson, 1984].
- No serological correlate of protection against pertussis has been established [Granström, 1987; Karpinsky, 1987]. Antibodies against the pertussis components

s PT, FHA and PRN will be measured by ELISA. The seropositivity cut-off for all three pertussis antibodies in ELISA is 5 EL.U/ml. Subjects with antibody concentration below the cut-off will be considered seronegative.

For the purpose of identification of sub-optimal responders and communication to the investigators, anti-HBs and anti-poliovirus types 1, 2 and 3 assessment of the protection level will be done for each subject on samples taken approximately 4 weeks after the 3rd dose of the primary vaccination. For PRP, D and T antigens, the assessment of the protection level will be done for each subject on samples taken approximately 4 weeks after the administration of the booster dose. In addition a listing of subjects who did not seroconvert to anti-PT, anti-FHA and anti-PRN will be provided.

The immunological assay results will be communicated to the investigator within one year following the last subject visit for the relevant time point (Visit 4 for HBV and poliovirus; Visit 6 for PRP, D, T and pertussis antigens).

The investigator is encouraged to share the immunological assay results for non-responders with the study subjects' parent(s)/LAR(s).

For the study subjects identified as non-responders, it remains the responsibility of the study investigator in charge of the subject's clinical management to determine the medical need for re-vaccination and to re-vaccinate the subjects as per local/regional practices.

6. STUDY VACCINES AND ADMINISTRATION

6.1. Description of study vaccines

All candidate vaccines to be used have been developed and manufactured by GSK Biologicals.

The Quality Control Standards and Requirements for each candidate vaccine are described in separate Quality Assurance documents (e.g. release protocols, certificate of analysis) 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.

Table 9 Study vaccines

(Amendment 2: 17 April 2015)

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix hexa	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	full volume^	3
	Hib	PRP=10µG; TT~=25µG Aluminum as salts = 0.12 mg	The lyophilized Hib component is presented as a white pellet in a glass vial; it must be reconstituted before use with the DTPa-HBV-IPV component.		
Pediarix	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	0.5 mL	3
ActHIB	ActHIB	Hib=10µg TT, TT=24µg	White lyophilized pellet in a single dose vial, it must be reconstituted before use with sterile 0.4% saline solution	0.5 mL*	4
	NaCl	NaCl=60mM	Sterile 0.4% saline solution		
Pentacel	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial. ***The lyophilized Hib component is presented as a white pellet in a separate glass vial. It must be reconstituted with the liquid DTaP-IPV component before use.***	0.5 mL*	4
Engerix-B	HBV	HBsAg=10µg; $Al(OH)_3$=250µg Al3+	Suspension pre-filled syringe	0.5 mL	2 or 3**

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix	DTPa	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; $AlPO_4$=500µg Al3+	Homogeneous, turbid, white suspension in a pre-filled syringe	0.5 mL	1
Hiberix	Hib	PRP=10µG; TT~=25µG	The lyophilized Hib component is presented as a white pellet in a glass vial; it must be reconstituted before use with sterile 0.9% saline solution.	0.5 mL*	1
	NaCl	NaCl=150mM	Sterile 0.9% saline solution		
Prevnar13	Prevenar 13	PS1=2.2µg CRM197; PS3=2.2µg CRM197; PS4=2.2µg CRM197; PS5=2.2µg CRM197; PS6A=2.2µg CRM197; PS6B=4.4µg CRM197; PS7F=2.2µg CRM197; PS9V=2.2µg CRM197; PS14=2.2µg CRM197; PS18C=2.2µg CRM197; PS19A=2.2µg CRM197; PS19F=2.2µg CRM197; PS23F=2.2µg CRM197; $AlPO_4$=125µg Al3+	Suspension for injection in a pre-filled syringe.	0.5 mL	3
Rotarix	HRV	HRV RIX4144=$10^{6.0}$ $CCID_{50}$	Lyophilized vaccine in a monodose glass vial to be reconstituted with the calcium carbonate buffer diluent)	1.0 mL*	2
	$CaCO_3$	$CaCO_3$=60µg	Diluent (calcium carbonate liquid buffer) supplied separately in prefilled syringe		

$CCID_{50}$ = median Cell Culture Infective Dose; DMEM = Dulbecco's Modified Eagle Medium
* After reconstitution
** Subjects in the Penta Group who receive a birth dose of hepatitis B vaccine should not receive *Engerix-B* at the Month 4 visit (Visit 2)
^ Full volume after reconstitution (approximately 0.5 mL) to be administered

6.2. Storage and handling of study vaccines

The study vaccines must be stored at the respective label storage temperature conditions in a safe and locked place. Access to the storage space should be limited to authorized study personnel. The storage conditions will be assessed during pre-study activities under the responsibility of the sponsor study contact. The storage temperature should be continuously monitored with calibrated (if not validated) temperature monitoring device(s) and recorded. Refer to the Module on Clinical Trial Supplies in the SPM for more details on storage of the study vaccines.

Temperature excursions must be reported in degree Celsius.

Any temperature excursion outside the range of 0.0 to +8.0°C (for +2 to +8°C/+36 to +46°F label storage condition) impacting investigational medicinal products (IMPs) must

be reported in the appropriate (electronic) temperature excursion decision form ([e]TDF). The impacted IMPs must not be used and must be stored in quarantine at label temperature conditions until usage approval has been obtained from the sponsor.

In case of temperature excursion below +2.0°C down to 0.0°C impacting IMP(s) there is no need to report in (e)TDF, but adequate actions must be taken to restore the +2 to +8°C/+36 to +46°F label storage temperature conditions. The impacted IMP(s) may still be administered, but the site should avoid re-occurrence of such temperature excursion. Refer to the Module on Clinical Trial Supplies in the SPM for more details on actions to take.

Refer to the Module on Clinical Trial Supplies in the SPM for details and instructions on the temperature excursion reporting and usage decision process, packaging and accountability of the study vaccines.

6.3. Dosage and administration of study vaccines

The injectable vaccines must be administered intramuscularly, at a 90-degree angle into the anterolateral side of the thigh [CDC, 2002] on the side stated in Table 10. The buttock should not be used.

In order to ensure proper intramuscular injection of the vaccines, a needle of at least 1 inch (2.54 cm) length, 25 gauge will be used [Diggle, 2006; Zuckerman, 2000].

For reconstitution of *Infanrix hexa* vaccine, an appropriate needle should be attached to the prefilled syringe containing the DTPa-HBV-IPV liquid vaccine and inserted into the vial containing the lyophilized Hib vaccine. The entire contents of the syringe should be transferred to the vial. With needle still inserted, the vial should be vigorously shaken. After reconstitution, the full volume of the vial (approximately 0.5 mL) is then withdrawn using the same syringe. A new needle should then be affixed to the syringe for administration of the vaccine.

NOTE: After reconstitution, *Infanrix hexa* should be injected immediately. However the vaccine may be kept for up to 8 hours at room temperature (21°C).

The vaccinees 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.

Rotarix must be exclusively administered orally. DO NOT INJECT.

Table 10 Dosage and administration

Visit	Study Group	Treatment name	Route [1]	Site [2]	Side [3]
Epoch 001					
1, 2, 3	Hexa Group	*Infanrix hexa* (lot A, lot B or lot C)	IM	T	R
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
1, 2, 3	Pedia Group	*Pediarix*	IM	T	R
1, 2, 3		*ActHIB*	IM	T	UpL
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
1, 2, 3	Penta Group	*Pentacel*	IM	T	R
1, 2, 3		*Engerix-B*†	IM	T	UpL
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
Epoch 002*					
5	Hexa Group	*Infanrix*	IM	T	R
		Hiberix	IM	T	L
5	Pedia Group	*Infanrix*	IM	T	R
		ActHIB	IM	T	L
5	Penta Group	*Pentacel*	IM	T	R

[1]Oral (O), Intramuscular (IM); [2]Thigh (T), [3]Left (L), Right (R), Upper Left (UpL), Lower Left (LoL)
Note: Vaccination can be performed in the opposite side in case of medical indication preventing vaccination in the side stated in the table, as judged by the investigator
†Subjects in the Penta Group who receive a birth dose of hepatitis B vaccine should not receive *Engerix-B* at the Month 4 visit (Visit 2).
***** Toddlers (12 Months through 2 Years): For toddlers, the vastus lateralis muscle in the anterolateral thigh is preferred. The needle should be at least 1-inch long. The deltoid muscle can be used if the muscle mass is adequate.

6.4. Replacement of unusable vaccine doses

In addition to the vaccine doses provided for the planned number of subjects (including over-randomization when applicable), at least 60% additional vaccine doses will be supplied to replace those that are unusable.

6.5. Contraindications to subsequent vaccination

6.5.1. Absolute contraindications:

The following events constitute absolute contraindications to further administration of the study and co-administration vaccines. If any of these events occur during the study, the subject must not receive additional doses of vaccine but may continue other study procedures at the discretion of the investigator.

- Anaphylaxis following the administration of vaccine(s).
- Other hypersensitivity reaction to any component of the vaccine(s) and any excipients in the formulation, including yeast.
- Hypersensitivity to latex.

- Contraindication for pertussis-containing vaccines:
  - Encephalopathy of unknown etiology, defined as an acute, severe central nervous system disorder, occurring within 7 days following previous vaccination with pertussis-containing vaccine and generally consisting of major alterations in consciousness, unresponsiveness, generalised or focal seizures that persist more than a few hours, with failure to recover within 24 hours.
  - Individuals with progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy should not receive a pertussis-containing vaccine until a treatment regimen has been established and the condition has stabilized.
- Contraindications to *Rotarix*:
  - Subjects with uncorrected congenital malformation (such as Meckel's diverticulum) of the gastrointestinal tract that would predispose for intussusceptions.
  - History of intussusception or history of SCID.

6.5.2. Temporary contraindications:

The following events constitute contraindications to administration of the study and co-administration vaccines at that point in time; if any of these events occur at the time scheduled for vaccination, the subject may be vaccinated at a later date, within the time window specified in the protocol, or withdrawn at the discretion of the investigator.

- Acute disease and/or fever at the time of vaccination.
  - Fever is defined as temperature ≥ 38.0°C/100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.
  - Subjects with a minor illness (such as mild upper respiratory infection) without fever can be administered all vaccines.
- Acute diarrhea or vomiting is a contra-indication to the administration of *Rotarix* at that point in time.

6.6. Warnings and precautions

The information below presents, in addition to the contraindications in Section 6.5, warnings and precautions to administration of *Infanrix hexa.*

- As with other vaccines, administration of *Infanrix hexa* should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contra-indication.
- Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

- If any of the following events are known to have occurred in temporal relation to receipt of pertussis-containing vaccine, the decision to give further doses of pertussis-containing vaccines should be carefully considered:
  - Temperature of ≥ 40.0°C within 48 hours, not due to another identifiable cause.
  - Collapse or shock-like state (hypotonic-hyporesponsiveness episode) within 48 hours of vaccination.
  - Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours of vaccination.
  - Convulsions with or without fever, occurring within 3 days of vaccination.
- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
- *Infanrix hexa* should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.
- *Infanrix hexa* should under no circumstances be administered intravascularly or intradermally.
- A protective immune response may not be elicited in all vaccinees.
- A history of febrile convulsions, a family history of convulsions or Sudden Infant Death Syndrome (SIDS) do not constitute contraindications for the use of *Infanrix hexa*. Vaccinees with a history of febrile convulsions should be closely followed up as such adverse events may occur within 2 to 3 days post vaccination.
- Since the Hib capsular polysaccharide antigen is excreted in the urine a positive urine test can be observed within 1-2 weeks following vaccination. Other tests should be performed in order to confirm Hib infection during this period.
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Refer to the approved product label/package insert for warnings and precautions for the use of *Pediarix, ActHIB, Pentacel, Engerix-B, Prevnar13, Rotarix, Hiberix* and *Infanrix* vaccines.

6.7. Concomitant medication/product and concomitant vaccination

At each study visit/contact, the investigator should question the subject's parent(s)/LAR(s) about any medication/product taken and vaccination received by the subject.

6.7.1. Recording of concomitant medications/products and concomitant vaccination

The following concomitant medications/products/vaccines must be recorded in the eCRF if administered during the indicated recording period:

- All concomitant medications/products, except vitamins and dietary supplements, administered within 30 days following each dose of study vaccine.
- Any concomitant vaccination administered since birth and ending 30 days after the booster dose (Visit 6). Vaccinations listed prior to the first dose of study vaccine are to be recorded as vaccination history. The fourth dose of *Prevnar 13* will be recorded as concomitant vaccination.
- Prophylactic medication (i.e. 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 by any route].
- Any concomitant medications/products/vaccines listed in Section 6.7.2.
- Any concomitant medication/product/vaccine relevant to a SAE* or administered at any time during the study period for the treatment of a SAE*.

  * Refer to those SAEs that are required to be reported per protocol.

6.7.2. Concomitant medications/products/vaccines that may lead to the elimination of a subject from ATP analyses

The use of the following concomitant medications/products/vaccines will not require withdrawal of the subject from the study but may determine a subject's evaluability in the ATP analysis. See Section 10.4 for study cohorts/ data sets to be analysed.

- Any investigational or non-registered product (drug or vaccine) other than the study vaccines used during the study period (starting from Visit 1 and ending at Visit 6).
- Immunosuppressants or other immune-modifying drugs administered chronically (i.e. more than 14 days) during the study period until the final blood sample (Visit 6). For corticosteroids, this will mean prednisone ≥ 0.5 mg/kg/day, or equivalent. Inhaled and topical steroids are allowed.
- A vaccine not foreseen by the study protocol administered during the period starting from 30 days before the first vaccination until Post-Pri blood sampling i.e. approximately 30 days after Dose 3 (Epoch 001) and from 30 days before Pre-Bst until Post-Bst blood sampling i.e. approximately 30 days after Dose 4 (Epoch 002). Thus, routine administration(s) of measles-mumps-rubella, varicella and pneumococcal vaccines are allowed from 30 days after the last dose of primary vaccination (after Post-Pri blood sampling) until 30 days before the booster dose and from 30 days after the booster dose (after Post-Bst blood sampling), as well as according to the recommended immunization schedule in the US.

- Exceptions:
  - Inactivated influenza vaccine and hepatitis A vaccines are allowed throughout the study.

  In case an emergency mass vaccination for an unforeseen public health threat (e.g.: a pandemic) is organized by the public health authorities, outside the routine immunization program, the time period described above can be reduced if necessary for that vaccine provided it is licensed and used according to its SPC or PI and according to the local governmental recommendations and provided a written approval of the Sponsor is obtained.
- Immunoglobulins and/or any blood products administered during the study period until the final blood sample (Visit 6).

6.8. Intercurrent medical conditions that may lead to elimination of a subject from ATP analyses

At each study visit subsequent to the first vaccination visit, it must be verified if the subject has experienced or is experiencing any intercurrent medical condition. If it is the case, the condition(s) must be recorded in the eCRF.

- Subjects may be eliminated from the ATP cohort for immunogenicity if they incur a condition that has the capability of altering their immune response or are confirmed to have an immunodeficiency condition.
- Subjects will be eliminated from the ATP cohort for immunogenicity if they experience intercurrent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and/or Hib prior to the post-dose 3 blood draw and diphtheria, tetanus, pertussis and/or Hib post-dose 4 blood draw.

7. HEALTH ECONOMICS

Not applicable.

8. SAFETY

The investigator or site staff is/are responsible for the detection, documentation and reporting of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE) as provided in this protocol.

Each subject's parent(s)/LAR(s) will be instructed to contact the investigator immediately should the subject 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.
- New conditions detected or diagnosed after investigational vaccines 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 vaccines 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.
- Pre- or post-treatment events that occur as a result of protocol-mandated procedures (i.e. invasive procedures, modification of subject's previous therapeutic regimen).

AEs to be recorded as endpoints (solicited AEs) are described in Section 8.1.3. All other AEs will be recorded as UNSOLICITED AEs.

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/SAE.
- Situations where an untoward medical occurrence did not occur (e.g. social and/or 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.
- Pre-existing conditions or signs and/or symptoms present in a subject prior to the first study vaccination. These events will be recorded in the medical history section of the eCRF**.**

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,

   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, had it been more severe.

c. Requires hospitalisation or prolongation of existing hospitalisation,

   Note: In general, hospitalisation signifies that the subject 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 hospitalisation are also considered AEs. If a complication prolongs hospitalisation or fulfils any other serious criteria, the event will also be considered serious. When in doubt as to whether 'hospitalisation' occurred or was necessary, the AE should be considered serious.

   Hospitalisation 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,

   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, 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 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 hospitalisation but may jeopardise 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 hospitalisation.

8.1.3. Solicited adverse events

A 4-day follow-up (Day 0-Day 3) of solicited local (at each injection site) and general AEs will be performed after administration of the vaccine. Data concerning the following AEs will be solicited using diary cards provided by the sponsor.

8.1.3.1. Solicited local (injection-site) adverse events

The following local (injection-site) AEs will be solicited (Table 11):

Table 11 Solicited local adverse events

Pain at injection site
Redness at injection site
Swelling at injection site
Post-dose 4 measurements of circumference of limbs (arm or leg according to where vaccine was administered)

N.B. If parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of limb circumference) after the booster dose at Visit 5, they are to contact study personnel and to visit the investigator's office for evaluation as soon as possible and bring the diary card with them. The investigator will record detailed information describing the AE on a specific large injection site reaction form in the eCRF. In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms the parent(s)/LAR(s) will need to record additional symptoms/characteristics as mentioned in Section 5.6.2.13.

Note: local AEs will not be solicited for co-administered vaccines like *Prevnar 13*.

8.1.3.2. Solicited general adverse events

The following general AEs will be solicited (Table 12):

Table 12 Solicited general adverse events

Drowsiness
Fever
Irritability/Fussiness
Loss of appetite

Note: Temperature will be recorded in the evening. Should additional temperature measurements be performed at other times of day, the highest temperature will be recorded. Fever is defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.

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

In absence of diagnosis, abnormal laboratory findings (e.g. clinical chemistry, haematology, urinalysis) or other abnormal assessments (e.g. vital signs etc.) that are judged by the investigator to be clinically significant will be recorded as AE or SAE if they meet the definition of an AE or SAE (refer to Sections 8.1.1 and 8.1.2). Clinically significant abnormal laboratory findings or other abnormal assessments that are present at

baseline and significantly worsen following the start of the study will also be reported as AEs or SAEs. However, clinically significant abnormal laboratory findings or other abnormal assessments that are associated with the disease being studied, unless judged by the investigator as more severe than expected for the subject's condition, or that are present or detected at the start of the study and do not worsen, will not be reported as AEs or SAEs.

The investigator will exercise his or her medical and scientific judgement in deciding whether an abnormal laboratory finding or other abnormal assessment is clinically significant.

8.1.5. Adverse events of specific interest

Adverse events of specific interest (i.e. NOCDs such as autoimmune disorders, asthma, type I diabetes and allergies) will be recorded from Day 0 up to 6 months after the last primary vaccination (Epoch 001) and from booster dose up to one month after booster vaccination (Epoch 002). NOCDs will be reported as either AEs or SAEs, as appropriate in the eCRF.

8.2. Events or outcomes not qualifying as adverse events or serious adverse events

Not applicable.

8.3. Detecting and recording adverse events and serious adverse events

8.3.1. Time period for detecting and recording adverse events and serious adverse events

All AEs starting within 30 days following administration of each dose of study vaccine/comparator must be recorded into the appropriate section of the eCRF, irrespective of intensity or whether or not they are considered vaccination-related.

The time period for collecting and recording SAEs and AEs of specific interest will begin at the first receipt of study vaccine/comparator and will end 180 days following administration of the last dose of study vaccine/comparator of the primary vaccination course for each subject and 30 days following administration of the booster dose. See Section 8.4 for instructions on reporting of SAEs.

All AEs/SAEs leading to withdrawal from the study will be collected and recorded from the time of the first receipt of study vaccine/comparator.

In addition to the above-mentioned reporting requirements and in order to fulfil 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 will be collected and recorded from the time the subject consents to participate in the study until she/he is discharged from the study.

Note: With the exception of AEs/SAEs leading to withdrawal, study participation and concurrent GSK medications or vaccines, there is no reporting of SAEs from the time of the Epoch 1 ESFU phone contact and administration of dose 4 (approximately three months).

An overview of the protocol-required reporting periods for AEs and SAEs is given in Table 13.

Table 13 Reporting periods for adverse events and serious adverse events

Study activity	C.O	V1	4-days post vac	31-days post-vac	V2	4-days post vac	31-days post-vac	V3	4-days post- vac	31-days post-vac	Phone call 6 months post-V3	V5	4-days post- vac	31-days post-vac
Age of subject		2 months			4 months			6 months		7 months	12 months	15-18 months		16-19 months
Solicited local and general AEs														
Large injection site reactions														
Unsolicited AEs														
AEs/SAEs leading to withdrawal from the study														
NOCDs														
SAEs														
SAEs related to study participation or concurrent GSK medication/vaccine														

NOCD: New Onset of Chronic Diseases; C.O: consent obtained; V: Visit; Post-V: Post-Visit; vac: vaccination

8.3.2. Post-Study adverse events and serious adverse events

A post-study AE/SAE is defined as any event that occurs outside of the AE/SAE reporting period defined in Table 13. 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 subject has been discharged from the study, and he/she considers the event reasonably related to the investigational vaccine/product, the investigator will promptly notify the Study Contact for Reporting SAEs.

8.3.3. Evaluation of adverse events and serious adverse events

8.3.3.1. Active questioning to detect adverse events and serious adverse events

As a consistent method of collecting AEs, the subject'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 in the eCRF. The investigator is not allowed to send photocopies of the subject's medical records to GSK Biologicals instead of appropriately completing the eCRF. However, there may be instances when copies of medical records for certain cases are requested by GSK Biologicals. In this instance, all subject 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.

8.3.3.2. Assessment of adverse events

8.3.3.2.1. Assessment of intensity

The intensity of the following solicited AEs will be assessed as described:

Table 14 Intensity scales for solicited symptoms in infants/toddlers

Infant/Toddler (15–24 months)		
Adverse Event	**Intensity grade**	**Parameter**
Pain at injection site	0	None
	1	Mild: Minor reaction to touch
	2	Moderate: Cries/protests on touch
	3	Severe: Cries when limb is moved/spontaneously painful
Redness at injection site		Record greatest surface diameter in mm
Swelling at injection site		Record greatest surface diameter in mm
Increase in limb circumference post-dose 4 (arm or leg according to where vaccine was administered)		Record the limb circumference at the level of the injection site
Fever*		Record temperature in °C/°F
Irritability/Fussiness	0	Behaviour as usual
	1	Mild: Crying more than usual/no effect on normal activity
	2	Moderate: Crying more than usual/interferes with normal activity
	3	Severe: Crying that cannot be comforted/prevents normal activity
Drowsiness	0	Behaviour as usual
	1	Mild: Drowsiness easily tolerated
	2	Moderate: Drowsiness that interferes with normal activity
	3	Severe: Drowsiness that prevents normal activity
Loss of appetite	0	Appetite as usual
	1	Mild: Eating less than usual/no effect on normal activity
	2	Moderate: Eating less than usual/interferes with normal activity
	3	Severe: Not eating at all

* Fever is defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.

The maximum intensity of local injection site redness/swelling/fever will be scored at GSK Biologicals as follows:

0 : Absent
1 : ≤ 5 mm
2 : > 5 mm and ≤ 20 mm
3 : > 20 mm

The maximum intensity of fever will be scored at GSK Biologicals as follows:

0	=	<100.4°F	<38.0°C
1	=	≥100.4°F to ≤102.2°F	≥38.0°C to ≤39.0°C
2	=	>102.2°F to ≤104.0°F	>39.0°C to ≤40.0°C
3	=	> 104.0°F	> 40.0°C

Following each vaccination (3 doses during the primary vaccination course and one booster dose) during the 4 days after the vaccine dose has been administered (day of vaccination and subsequent 3 days), the child's temperature will be screened each evening, at bedtime, for signs of fever by means of the rectal/axillary thermometer. Children < 15 months will have their temperature taken rectally and children ≥ 15 months will have their temperature taken by the axillary route. Rectal/axillary temperatures will be recorded on the diary card. Temperature measured by any route will be presented in 0.5°C increments starting at 38°C/100.4°F.

Prior to analysis, the increase in limb circumference of each limb as compared to the baseline pre-vaccination measurement will be scored for each subject at GSK Biologicals' as follows:

Grade 0 = Increase in limb circumference ≤5 mm

1 = Increase in limb circumference >5 mm but ≤20 mm

2 = Increase in limb circumference >20 mm but ≤40 mm

3 = Increase in limb circumference >40 mm

The investigator will assess the maximum intensity that occurred over the duration of the event for all unsolicited AEs (including SAEs) recorded during the study. The assessment will be based on the investigator's clinical judgement.

For unsolicited symptoms and adverse events associated with large injection site reactions (e.g. pruritus, induration and functional impairment, the intensity should be assigned to one of the following categories:

1 (mild)	=	An AE which is easily tolerated by the subject, 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/kindergarten/a day-care center 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 used 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.

8.3.3.2.2. Assessment of causality

The investigator is obligated to assess the relationship between investigational vaccines and the occurrence of each AE/SAE. The investigator will use clinical judgement to determine the relationship. Alternative plausible causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors, and the temporal relationship of the event to the investigational vaccines will be considered and investigated. The investigator will also consult the IB and/or PI for marketed products to determine his/her assessment. Investigational vaccines include vaccines such as *Infanrix hexa*, *Pediarix*, *Pentacel*, *ActHIB*, *Engerix-B*, *Rotarix*, *Prevnar 13*, *Infanrix* and *Hiberix*.

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 report to GSK Biologicals. The investigator may change his/her opinion of causality in light of follow-up information and update 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.

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 vaccines?

YES	:	There is a reasonable possibility that the vaccines contributed to the AE.
NO	:	There is no reasonable possibility that the AE is causally related to the 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.

If an event meets the criteria to be determined as 'serious' (see Section 8.1.2), additional examinations/tests will be performed by the investigator in order to determine ALL possible contributing factors for 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 vaccines, if applicable.
- Erroneous administration.
- Other cause (specify).

8.3.3.3. Assessment of outcomes

The investigator will assess the outcome of all unsolicited AEs (including SAEs) recorded during the study as:

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

8.3.3.4. Medically attended visits

For each solicited and unsolicited symptom the subject experiences, the subject's parent(s)/LAR(s) will be asked if the subject received medical attention defined as hospitalisation, or an otherwise unscheduled visit to or from medical personnel for any reason, including emergency room visits. This information will be recorded in the eCRF.

8.4. Reporting of serious adverse events and other events

8.4.1. Prompt reporting of serious adverse events and other events to GSK Biologicals

SAEs that occur in the time period defined in Section 8.3 will be reported promptly to GSK within the timeframes described in Table 15, once the investigator determines that the event meets the protocol definition of a SAE.

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

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

* Timeframe allowed after receipt or awareness of the information.

8.4.2. Contact information for reporting serious adverse events and other events to GSK Biologicals

Back-up Study Contact for Reporting SAEs
24/24 hour and 7/7 day availability: GSK Biologicals Clinical Safety & Pharmacovigilance Fax: +PPD or +PPD Please refer to the Study Procedure Manual for the dedicated US Fax Machine number.

8.4.3. Completion and transmission of SAE reports to GSK Biologicals

Once an investigator becomes aware that a SAE has occurred in a study subject, the investigator (or designate) must complete the information in the electronic SAE report WITHIN 24 HOURS. The SAE report 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 report should still be completed within 24 hours. Once additional relevant information is received, the report should be updated WITHIN 24 HOURS.

The investigator will always provide an assessment of causality at the time of the initial report.

8.4.3.1. 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 paper SAE report and fax it to the GSK Biologicals Clinical Safety and Pharmacovigilance department within 24 hours. Please refer to the Study Procedure Manual for the dedicated US Fax Machine number.

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 electronic SAE report within 24 hours. The final valid information for regulatory reporting will be the information reported through the electronic SAE reporting system.

8.4.4. Updating of SAE information after freezing of the subject's eCRF

When additional SAE information is received after freezing of the subject's eCRF, new or updated information should be recorded on a paper report, with all changes signed and dated by the investigator. The updated report 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 the designated reporting time frames specified in Table 15.

8.4.5. 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 subjects 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 vaccine/product and unexpected. The purpose of the report is to fulfil specific regulatory and GCP requirements, regarding the product under investigation.

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

8.5.1. Follow-up during the study

After the initial AE/SAE report, the investigator is required to proactively follow each subject and provide additional relevant information on the subject's condition to GSK Biologicals (within 24 hours for SAEs; refer to Table 15).

All SAEs documented at a previous visit/contact 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/contact and designated as not recovered/not resolved or recovering/resolving will be reviewed at subsequent visits/contacts until 30 days after the last vaccination.

New onset of chronic diseases (such as autoimmune disorders, asthma, type I diabetes and allergies) documented at a previous visit/contact and designated as not recovered/not

resolved or recovering/resolving will be reviewed at subsequent visits/contacts until end of the study.

8.5.2. Follow-up after the subject is discharged from the study

The investigator will follow subjects:

- with SAEs, or subjects 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 subject is lost to follow-up.
- with other non-serious AEs of specific interest, i.e. NOCDs, such as autoimmune disorders, asthma, type I diabetes and allergies, until the end of the study period or they are lost to follow-up.

If the investigator receives additional relevant information on a previously reported SAE, he/she will provide this information to GSK Biologicals using a paper SAE form.

GSK Biologicals may request that the investigator performs or arranges the conduct of additional clinical examinations/tests and/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 subject dies during participation in the study or during a recognized follow-up period, GSK Biologicals will be provided with any available post-mortem findings, including histopathology.

8.6. 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 subject's eCRF (refer to Section 6.7).

8.7. Subject card

Study subjects' 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 subject's parent(s)/LAR(s). In an emergency situation this card serves to inform the responsible attending physician that the subject is in a clinical study and that relevant information may be obtained by contacting the investigator.

Subjects' parent(s)/LAR(s) must be instructed to keep subject cards in their possession at all times.

9. SUBJECT COMPLETION AND WITHDRAWAL

9.1. Subject completion

A subject who returns for the concluding visit/is available for the concluding contact foreseen in the protocol is considered to have completed the study.

9.2. Subject withdrawal

Withdrawals will not be replaced.

9.2.1. Subject withdrawal from the study

From an analysis perspective, a 'withdrawal' from the study refers to any subject who did not come back for the concluding visit/was not available for the concluding contact foreseen in the protocol.

All data collected until the date of withdrawal/last contact of the subject will be used for the analysis.

A subject 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 subject from the date of withdrawal/last contact.

Investigators will make an attempt to contact those subjects 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 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).

*In case a subject is withdrawn from the study because the subject's parent(s) has withdrawn consent, the investigator will document the reason for withdrawal of consent, if specified by the subject, in the eCRF.

Subjects who are withdrawn from the study because of SAEs/AEs must be clearly distinguished from subjects who are withdrawn for other reasons. Investigators will follow subjects who are withdrawn from the study as result of a SAE/AE until resolution of the event (see Section 8.5.2).

9.2.2. Subject withdrawal from investigational vaccine

A 'withdrawal' from the investigational vaccine refers to any subject who does not receive the complete treatment, i.e. when no further planned dose is administered from

the date of withdrawal. A subject withdrawn from the investigational vaccine may not necessarily be withdrawn from the study as further study procedures or follow-up may be performed (safety or immunogenicity) if planned in the study protocol.

Information relative to premature discontinuation of the investigational vaccine will be documented on the Vaccine Administration screen of the eCRF. The investigator will document whether the decision to discontinue further vaccination/treatment 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.
- Other (specify).

10. STATISTICAL METHODS

10.1. Primary endpoint

10.1.1. Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

10.2. Secondary endpoints

10.2.1. Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.

- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the **Med**ical **D**ictionary for **R**egulatory **A**ctivities (MedDRA) classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

10.2.2. Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix.*
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).

  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).

- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4)
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

10.3. Determination of sample size

Target enrolment will be 585 subjects. Assuming 65% of the subjects will be evaluable post-dose 3, this will provide approximately 378 subjects (126 subjects in each group) evaluable for immunogenicity in the Epoch 001.

The sample size has been estimated in order to obtain at least 94% power to demonstrate the primary inferential objective (i.e. non-inferiority of the response to the pertussis antigens). The power associated to the target sample size for the conclusion on the inferential primary objective of this study is detailed in the next section.

10.3.1. Control on type I error

A 2.5% nominal type I error will be used for each pertussis non-inferiority (NI) evaluation. Since NI has to be met simultaneously for the 3 pertussis antigens, the global type I error will be below 2.5%.

10.3.2. References for sample size

References were chosen based on observed standard deviations observed in studies Hib-MenCY-TT-005 (101858) and Hib-MenCY-TT-009 (103813) one month post-dose 3 from the subjects that receive *ActHIB* co-administered with *Pediarix* and *Prevnar*, and from study DTPa-HBV-IPV-027 (217744/027) one month post-dose 3 from the DTPa-HBV-IPV/Hib pooled groups. All these studies enrolled subjects in the US.

The standard deviation for $\log_{10}$ transformed concentrations post vaccination for pertussis antigens is presented in Table 16.

Table 16 Standard deviation for $\log_{10}$ transformed concentration post vaccination

Study	Antigen					
	PT		FHA		PRN	
	N	SD	N	SD	N	SD
Hib-MenCY-TT-005-US	215	0.274	213	0.312	217	0.392
Hib-MenCY-TT-009 – US cohort	100	0.258	97	0.252	101	0.482
DTPa-HBV-IPV-027-US	865	0.274	802	0.254	869	0.376
Reference taken		0.274		0.307		0.392

N: Number of subjects; SD: standard deviation

10.3.3. Power computation

Out of the 585 subjects enrolled, 65% (126 in each pooled group) are expected to be evaluable post-Dose 3.

The individual type II error for each pertussis antigen was obtained using PASS 2005, one-sided non-inferiority test for 2 means from normal data with common variance between groups, under the alternative of equal means and alpha=2.5% (Table 17).

To account for the multiplicity of comparisons, the global type II error was conservatively estimated as the sum of individual type II errors, ensuring a global power for the study of 94.02% as presented in Table 17.

Table 17 Power for pertussis NI post-Dose 3

Antigen	Margin	SD on $\log_{10}$ transformed titer	Type I error	N evaluable per pooled group	Type II error
PT	1.5	0.274	2.5%	126	0.08%
FHA	1.5	0.307	2.5%	126	0.48%
PRN	1.5	0.392	2.5%	126	5.42%
Global Power = 100-(0.08+0.48+5.42) % = 94.02%					

10.4. Study cohorts/ data sets to be analysed

Six cohorts are defined for the purpose of the analysis:

- Primary Total Vaccinated cohort
- Primary ATP cohort for analysis of safety
- Primary ATP cohort for analysis of immunogenicity
- Booster Total Vaccinated cohort
- Booster ATP cohort for analysis of safety
- Booster ATP cohort for analysis of immunogenicity

10.4.1. Primary Total vaccinated cohort

The Primary Total Vaccinated cohort (TVC) will include all vaccinated subjects for whom data are available.

- A safety analysis based on the Primary TVC will include all subjects with at least one vaccine administration documented.
- An immunogenicity analysis based on the Primary TVC will include all vaccinated subjects for whom data concerning at least one immunogenicity endpoint measure is available.

10.4.2. Primary ATP cohort for analysis of safety

The Primary ATP cohort for safety will consist of all subjects from the Primary TVC who complied with the protocol up to the end of Epoch 001, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received all planned study vaccines for each completed vaccination visit in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;
- who did not receive a product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2.

Note that for the purpose of ATP cohort definition, the Epoch 001 ends at Visit 4.

Adherence to the interval related to ESFU phone contact will not be taken into account for inclusion in ATP cohort for safety.

10.4.3. Primary ATP cohort for analysis of immunogenicity

The Primary ATP cohort for immunogenicity will consist of all subjects from the Primary ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 for the definition of the intervals) up to the post-dose 3 blood sample and had immunogenicity results for the post-dose 3 blood sample. The analysis will be performed per treatment (first dose) actually administered.

More specifically, the analysis post-dose 3 based on the ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 3 as per the vaccination schedule;
- for whom administration site and route of study vaccines up to dose 3 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2
- who did not present with a medical condition before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.8.
- who comply with the post-dose 3 blood sample schedule, i.e. 21-48 days post-dose 3.
- who were not administered a vaccine not foreseen by the study protocol before the corresponding post-vaccination blood sample.
- who have immunogenicity results post-dose 3.

10.4.4. Booster Total vaccinated cohort

The Booster TVC will include all subjects from primary TVC that received the booster vaccine dose.

- For the Booster-TVC analysis of safety, this will include all subjects with booster vaccine administration documented.
- For the Booster-TVC analysis of immunogenicity, this will include vaccinated subjects for whom data concerning immunogenicity endpoint measures are available.

10.4.5. Booster ATP cohort for analysis of safety

The Booster ATP cohort for safety will consist of all subjects from the Booster TVC who complied with the protocol up to the end of Epoch 002, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received the planned booster dose at 15-18 months of age;
- who received 3 doses in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;

- who did not receive a product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis as listed in Section 6.7.2.

10.4.6. Booster ATP cohort for analysis of immunogenicity

The Booster ATP cohort for immunogenicity will consist of all subjects from the Booster ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 for the definition of the intervals) up to the post-dose 4 blood sample and had immunogenicity results for the post-dose 4 blood sample.

More specifically, the analysis pre- and post-dose 4 based on the Booster ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 4 as per the vaccination schedule;
- for whom administration site and route of the study vaccines up to dose 4 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.7.2);
- who did not present with a medical condition before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.8);
- who comply with the booster vaccination schedule at 15-18 months of age and with the post-dose 4 blood sample schedule i.e. 21-48 days for post-dose 4;
- who have immunogenicity results post-dose 4.

10.5. Derived and transformed data

- A seronegative subject is a subject whose antibody concentration/titer is below the assay cut-off.
- A seropositive subject is a subject whose antibody concentration/titer is greater than or equal to the assay cut-off defined in Table 7.

  Note: Due to ongoing re-validation of all assays, these cut-offs may be subject to change.
- A seroprotected subject is a subject whose antibody concentration/titer is greater than or equal to the level defining clinical protection. The following seroprotection thresholds are applicable:
  - Anti-diphtheria antibody concentrations ≥ 0.1 IU/mL.
  - Anti-tetanus antibody concentrations ≥ 0.1 IU/mL.
  - Anti-HBs antibody concentrations ≥ 10 mIU/mL.
  - Anti-poliovirus types 1, 2 and 3 antibody titers ≥ 8.
  - Anti-PRP antibody concentrations ≥ 0.15 µg/mL.
- Other cut-offs to be considered:
  - Anti-PRP antibody concentrations ≥ 1.0 µg/mL.

  - Anti-diphtheria and anti-tetanus antibody concentrations ≥ 1.0 IU/mL

- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies are defined as:
  - initially seronegative subjects (pre-booster antibody concentration below cut-off: < 5 ELISA EL.U/mL) with an increase of at least four times the cut-off one month after vaccination (post-booster antibody concentration ≥20 EL.U/mL), and
  - initially seropositive subjects with pre-booster antibody concentration ≥ 5 EL.U./mL and < 20 EL.U/mL with an increase of at least four times the pre-booster antibody concentration one month after vaccination, and,
  - For initially seropositive subjects with pre-booster antibody concentration ≥ 20 EL.U/mL with an increase of at least two times the pre-booster antibody concentration, one month after vaccination.

  Note: Due to ongoing re-validation of pertussis assays, the definition of booster responses may be subject to change.

- The GMC/GMT calculations will be performed by taking the anti-log of the mean of the $\log_{10}$ titer/ concentration transformations. Antibody titers/concentrations below the cut-off of the assay will be given an arbitrary value of half the cut-off for the purpose of GMC/GMT calculation.

Handling of missing data:

Immunogenicity:

- For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements will not be replaced.

Safety/reactogenicity:

- For a given subject and the analysis of solicited symptom within 4 days post-vaccination, 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 vaccinated subjects and doses with documented safety data (i.e. symptom screen completed).
- For analysis of unsolicited adverse events, such as serious adverse events or adverse events by primary MedDRA term, and for the analysis of concomitant medications, all vaccinated subjects will be considered. Subjects who did not report the event or the concomitant medication will be considered as subjects without the event or the concomitant medication respectively.
- For summaries reporting both solicited and unsolicited adverse events, all vaccinated subjects will be considered. Subjects for whom the event will not be reported will be considered as subjects without the event.

10.6. Final analysis of the Epoch 001

10.6.1. Analysis of demographics

Demographic characteristics (age [weeks], gender, geographical ancestry, height in length [cm], weight [kg] at first dose, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status will be summarised by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as center;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects enrolled among the study sites will be tabulated as a whole and per group.

10.6.2. Analysis of immunogenicity

The primary analysis will be based on the primary ATP cohort for immunogenicity. An analysis on the primary Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point, more than 5% of the vaccinated subjects with immunological data post-dose 3 are excluded from the primary ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

10.6.2.1. Within group assessment

For each group, one month post-dose 3 and for each assay for which a serological result is available:

- Seropositivity and seroprotection rates with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.
- For D,T and pertussis antigens, additional summaries will be provided according to the Tdap vaccination history of mother during pregnancy.

For each antigen, antibody concentration or titer distribution one month post-vaccination will be tabulated and displayed using reverse cumulative curves (RCCs).

10.6.2.2. Between group assessment

At one month post-dose 3,

- The asymptotic standardized 95% CI for the group difference in the seropositivity/ seroprotection rates will be computed for each antigen.
- The 95% CI for each group GMC/GMT ratio will be computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of

Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis b at birth vaccine dose status will also be used as regressor.

10.6.2.3. Interpretation of analyses

Except for analyses addressing criteria specified in the primary objective, comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

10.6.3. Analysis of safety

The primary analysis will be based on the primary Total Vaccinated cohort. If, in any vaccine group and at any time point of the Epoch 001, the percentage of vaccinated subjects excluded from the primary ATP cohort for safety is more than 5%, a second analysis based on the primary ATP cohort for safety will be performed to complement the primary Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period will be tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period will be tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses with local AEs (solicited and unsolicited) will be calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered).
- The percentage of subjects/doses reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

  The exact 95% CIs will be calculated assuming independence between doses.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit.

- For fever, analyses will be performed by 0.5°C increments.
- The percentage of subjects/doses with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated after each dose and over the Epoch 001.
- The verbatim reports of unsolicited AEs will be reviewed by a clinical development manager and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE reported before the database lock for the Epoch 001 analysis with an onset date in the Epoch 001 will be reported and the SAE will be described in detail.

10.7. Final analysis of the Epoch 002

10.7.1. Analysis of demographics/baseline characteristics

Demographic characteristics (age in months at Visit 5) and withdrawal status will be summarized by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as race/ethnicity;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects vaccinated at Visit 5 among the study sites will be tabulated as a whole and per group.

For enrolled subjects that do not participate in the Epoch 002, the reason for not participating will be summarized.

10.7.2. Analysis of immunogenicity

The primary analysis will be based on the booster ATP cohort for immunogenicity. An analysis on the booster Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point of the Epoch 002, more than 5% of the vaccinated subjects with immunological data are excluded from the booster ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

10.7.2.1. Within group assessment

For each group, prior to the booster dose and one month post-booster dose and for each assay for which a serological result is available:

- Seropositivity and seroprotection rates and booster response rates for pertussis with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.

For D,T and pertussis antigens, additional summaries will be provided according to the Tdap vaccination history of mother during pregnancy.

For each antigen, antibody concentration or titer distribution before and one month Post-booster (when available) will be tabulated and displayed using RCCs.

10.7.2.2. Between group assessment

At pre-booster and at one month post-booster,

- The asymptotic standardized 95% CI for the group difference in the seroprotection/ seropositivity rates will be computed for each antigen.
- The 95% CI for each group GMC/GMT ratio will be computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor.

10.7.2.3. Interpretation of analyses

In Epoch 002, all comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

10.7.3. Analysis of safety

The primary analysis for the Epoch 002 will be based on the booster Total Vaccinated cohort and will only look at the booster dose. If, in any vaccine group, the percentage of vaccinated subjects excluded from the booster ATP cohort for safety is more than 5%, a second analysis based on the booster ATP cohort for safety will be performed to complement the booster Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose, will be tabulated with exact 95% CI for each group.

- The incidence of local AEs (solicited and unsolicited) will be calculated at each injection site as well as overall (all sites considered) for each group.
- The percentage of subjects reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated with its exact 95% CI for each group.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit.
- For fever, analyses will be performed by 0.5°C increments.
- The percentage of subjects with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated for each group.
- The verbatim reports of unsolicited AEs will be reviewed by a clinical development manager and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects with unsolicited AEs occurring within 31 days following the booster dose with its exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Additionally,

- Any large injection site reaction (defined as a swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase in limb circumference) reported within 4 days (Days 0-3) following the booster dose will be described in detail.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from booster dose up to one month after booster vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE from the booster dose to study end will be reported and the SAEs will be described in detail.

10.8. Statistical methods

- The exact CIs for a proportion within a group will be calculated from Proc StatXact [Clopper, 1934].
- The standardized asymptotic CI for the group difference in proportion is the method implemented in Proc StatXact 7.0. It corresponds to method 6 in the Newcombe paper [Newcombe, 1998].
- The CI for GMTs/GMCs will be obtained within each group separately. The 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 CI for

the GMTs/GMCs will then be obtained by exponential-transformation of the CI for the mean of log-transformed titer/concentration.

- The GMT/GMC group ratio will be obtained using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B status at birth vaccine dose will also be used as regressor. The GMC/GMT group ratio and its CI will be derived as exponential-transformation of the corresponding group contrast in the model.

10.9. 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.

10.9.1. Sequence of analyses

(Amendment 2: 17 April 2015)

The analyses will be performed ***stepwise***:

1. ***A partial analysis of Epoch 001 up to one month after the third primary vaccine dose will be conducted. This analysis will include the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis will be displayed on GSK clinical trial registry as soon as possible.***
2. ***The final data analysis of the study covering both the epochs will be conducted at the end of the study. All these analyses will be presented in a final clinical study report.***

10.9.2. Statistical considerations for interim analyses

All analyses will be conducted on final data and therefore no statistical adjustment for interim analyses is required.

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. Remote Data Entry instructions

RDE, a validated computer application, will be used as the method for data collection.

In all cases, subject initials will not be collected nor transmitted to GSK. Subject 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 GSK Biologicals' 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.

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.

11.2. Study Monitoring by GSK Biologicals

GSK will monitor the study to verify that, amongst others, the:

- Data are authentic, accurate, and complete.
- Safety and rights of subjects are being protected.
- Study is conducted in accordance with the currently approved protocol, 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.

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 a RDE review and a Source Document Verification (SDV). By SDV we understand verifying RDE 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 RDE. 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 RDE will serve as the source must be identified, agreed and documented in the source documentation agreement form.

For RDE, the monitor will mark completed and approved screens at each visit.

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.

11.3. Record retention

Following closure of the study, the investigator must maintain all site study records (except for those required by local regulations to be maintained elsewhere) in a safe and secure location. The records must be easily accessible, when needed (e.g. audit or inspection), and must be available for review 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); however, caution needs to be exercised before such action is taken. The investigator must ensure 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 that an acceptable back-up of the reproductions exists and that there is an acceptable quality control procedure in place 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 a particular site, as dictated by ICH GCP, any institutional requirements, 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 archival at an off-site facility, transfer of ownership of the records in the event the investigator leaves the site.

11.4. Quality assurance

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 publicly available clinical trial registers and publication policy

Study information from this protocol will be posted on publicly available clinical trial registers before enrolment of subjects begins.

Summaries of the results of GSK interventional studies (phase I-IV) are posted on publicly available results registers within 12 months of the primary completion date for studies of authorized vaccines and 18 months for studies of non-authorized vaccines.

GSK also aims to publish the results of these studies in the searchable, peer reviewed scientific literature. Manuscripts are submitted for publication within 24 months of the last subject’s last visit.

11.6. Provision of study results to investigators

Where required by applicable regulatory requirements, an investigator signatory will be identified for the approval of the 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 Biologicals 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 subjects, as appropriate.

12. COUNTRY SPECIFIC REQUIREMENTS

Not applicable.

13. REFERENCES

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Zuckerman JN. The importance of injecting vaccines into muscles. *BMJ* 2000;321:1.

APPENDIX A CLINICAL LABORATORIES

Table 18 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

Table 19 Outsourced laboratories

Laboratory	Address
Quest Diagnostics Clinical Trials (US)	27027 Tourney Road, Suite 2E Valencia, CA 91355 USA
Quest Diagnostics Clinical Trials (Biomarkers)	27027 Tourney Road, Suite 2E Valencia, CA 91355 USA
Quest Diagnostics Nichols Institute	33608 Ortega Highway San Juan Capistrano, CA 92675-2042 USA
Quest Diagnostics, Inc.	1 Malcolm Way Teterboro, NJ 07608 USA
Quest Diagnostics Nichols Institute	14225 Newbrook Drive Chantilly, VA 20153 USA

APPENDIX B AMENDMENTS AND ADMINISTRATIVE CHANGES TO THE PROTOCOL

GlaxoSmithKline Biologicals Clinical Research & Development **Protocol Amendment 1**	
eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number	2013-004304-19
Amendment number:	Amendment 1
Amendment date:	Final: 18 September 2014
Co-ordinating author:	PPD, Scientific Writer

Rationale/background for changes:

- Clarification has been provided that large injection site reactions and measurement of the injected limb should be collected as a solicited symptom. Specific instructions regarding measurement of limb circumference and clinical details of large injection site reactions have been added.
- Additional minor clarifications of study procedures and data analyses have been made throughout the document.
- Instructions regarding interval between preparation and administration of vaccine has been aligned with the stability data described in the current Investigator Brochure.
- Due to ongoing re-validation of serological assays for antibodies to diphtheria and tetanus toxoids, pertussis antigens, poliovirus, hepatitis B surface antigen and polyribosyl ribitol phosphate, the cut-offs for these assays could potentially change and hence a note has been added in the protocol regarding this. The definition of booster response to pertussis antigens could also potentially be revised.
- Sequence of reporting the results has been clarified.
- The contributing authors and sponsor signatory were updated to reflect changes in the study team.

Amended text has been included in *bold italics* and deleted text in ~~strikethrough~~ in the following sections:

Primary study vaccine and number	GlaxoSmithKline (GSK) Biologicals' Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine (DTPa-HBV-IPV/Hib) (~~GSK~~ ***SB***217744, *Infanrix hexa*™).

Section 1.2.1 Rationale for the study

More than ~~73~~ ***100*** million doses have been distributed to date and the benefit/risk profile remains favorable.

Section 5.5 Outline of study procedures

Table 4 List of study procedures

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Informed consent	●						
Check inclusion/exclusion criteria	●						
Medical history	●						
Collect demography data	●						
Vaccination history including HepB vaccination history	●						
Informed consent for Tdap vaccination history of mother[α]	●						
Last Tdap vaccination history of mother[β]	●						
History directed physical examination including length and weight	●					●	
Study group and treatment number allocation (Randomization)	O						
Treatment number allocation for subsequent doses		O	O			O	
Recording of administered treatment number	●	●	●			●	
Pre-vaccination body temperature	●	●	●			●	
Blood sampling				●		●	●
Check warnings and precautions	O	O	O			O	
Check contraindications to subsequent vaccination		●	●			●	
Pre-vaccination measurement of limb length and circumference of limb(s) at site of injection by investigator[δ]						●	
Vaccination	●	● **	●			●	
Distribution of thermometer	O						
Distribution of measuring device	O					O	
Distribution of diary cards	O	O	O			O	

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Daily post-vaccination recording of solicited adverse events during the 4-day (Day 0–3) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of non-serious (unsolicited) adverse events during the 31-day (Day 0–30) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of any large injection site reactions in the eCRF by the investigator*						●	
Return of diary cards and transcription by the investigator		●	●	●			●
Record any concomitant medication and vaccination §	●	●	●	●	●	●	●
Record any intercurrent medical conditions‖		●	●	●	●	●	●
Recording of serious adverse events including related to study participation	●	●					
Investigator sign-off					●		O
Analysis of the Epoch 001 #				O	O		
Analysis of the Epoch 002 #							O
Study Conclusion							●

α Child can still continue in the study if the mother does not wish to provide consent to record her Tdap vaccination history.

β Only the Tdap vaccination history (during the pregnancy of the enrolled child) from mothers who have given consent to provide this information will be obtained and recorded in the eCRF..

δ For the Penta group, which receives only one vaccine at Visit 5, baseline measurement of only the limb receiving the vaccine is required

* Refer to Section 8.1.3.1 ***and 5.6.2.9*** for detailed explanation on the reporting of large injection site reaction

Section 5.6.2.4 Vaccination history

The Tdap vaccination history of the mother during pregnancy will also be collected and recorded in the eCRF ***(provided that the mother has consented to provide this information).***

Note: Maternal vaccination is requested in order to be able to summarize the responses of the subjects to pertussis antigens according to whether or not the mothers received a pertussis vaccine during their pregnancy. This information will aid in understanding the effect of transplacentally transferred antibodies on the childs' immune response to vaccination.

Section 5.6.2.9.1 Blood sampling for immune response assessments

- A volume of approximately 5.0 mL of whole blood ~~(~~to provide approximately 1.7 mL of serum~~)~~ should be drawn from all subjects for the analysis of humoral immune response at Visits 4 and 5. At least 3.5 mL of whole blood ~~(~~to provide ~~atleast~~ ***approximately*** 1.2 mL of serum~~)~~ should be drawn from all subjects for the analysis of humoral immune response at Visit 6. After centrifugation, serum samples should be kept at –20°C/ –4°F or below until shipment. Refer to the SPM for more details on sample storage conditions.

Section 5.6.2.11 Baseline measurement of limb length and circumference after booster vaccination at visit 5

During Epoch 002, baseline measurement of length of limb(s) and circumference (arms or legs according to where the vaccine was administered) at the level of the injection site should be obtained. For the Penta group, baseline measurement is only required for the limb that will be vaccinated. Clothing should be removed so as not to interfere with the measurement of the length of the limb and the circumference. Upper arm length will be determined from the acromion process of the scapula to the tip of the elbow and thigh length will be determined from the midpoint of the abdomen thigh flexure crease and the proximal end of the patella. For measuring upper arm circumference, the measurement will be performed while the arm is held parallel to the trunk and the elbow is flexed in front at 90° (as if the subject is carrying a tray) [Kohl, 2007]. For measuring leg circumference the child should be standing or lying flat, as appropriate, as long as the leg is straight.

Section 5.6.2.13 Recording of AEs, SAEs and NOCDs

- ***During Epoch 002, following the fourth dose vaccination, the parents/LAR(s) should be provided with a measurement device for recording circumference of injected limbs (arms or legs according to where vaccine was administered) at the level of the injection site on the day of vaccination and during the next three days on a diary card. The parents/LAR(s) should be instructed on how and where to perform the measurement of the circumference of the vaccinated limb. Daily measurements should be performed in the same manner preferably by the same person and at the same time of day during the 4-day follow-up (Day 0-Day3) period.***
- ~~During Epoch 002,~~ ~~i~~***If*** the parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of ~~arm~~ ***limb*** circumference) during the 4-day follow-up (Day 0-Day 3) period, they ~~will be asked~~ ***are*** to contact study personnel and to visit the investigator's office for evaluation as soon as possible ***and to bring the diary card with them.*** ~~. The investigator will record detailed information describing the AE on a specific large injection site reaction in the eCRF.~~
- ***In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms, the parents(s)/LAR(s) will record the following additional symptoms/characteristics that may be associated with large injection site swelling reactions on the diary card:***
  - ***Type of swelling (local swelling only around the injection site, diffuse swelling not involving the elbow or knee joint, swelling involving the elbow or knee joint)***
  - ***Whether or not the diameter of the swelling involves more than 50% of the limb (baseline measurement of the length of the limb taken by study personnel at the vaccination visit will be provided on the diary cards)***
  - ***Induration at injection site (largest diameter)***
  - ***Pruritis at the injection site (intensity – scale provided)***
  - ***Functional impairment (intensity – scale and description provided)***
- ***The study personnel's evaluation will be recorded in the medical chart. In case the diary card score is not in line with the medical chart score, the medical chart will indicate what is the most intense score. The largest or most intense score for a given day will be recorded in the eCRF at the level of the solicited symptoms and at the level of the large swelling report form.***

Section 5.7.3 Laboratory assays

At Visits 4, 5 and 6, blood will be collected for measurement of immune response. Total blood volume to be taken from each subject over the study period is approximately 13.5 mL (approximately 5.0 mL of whole blood ***to provide approximately 1.7 mL of serum*** at Visits 4 and 5 and at least 3.5 mL of whole blood ***to provide approximately 1.2 mL of serum*** at Visit 6).

Table 7 Humoral Immunity (Antibody determination)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off†	Laboratory**
Serum	Bordetella pertussis.Pertussis Toxin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Filamentous Hemaglutinin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Pertactin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Corynebacterium diphtheriae.Diphtheria Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Clostridium tetani.Tetanus Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Hepatitis B Virus.Surface Ab	CLIA	Centaur (Siemens Healthcare)	mIU/mL	6.2	GSK Biologicals§
Serum	Poliovirus Sabin Types 1, 2 and 3	NEUTRA	In-house*	ED50	8	GSK Biologicals§
Serum	Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab	ELISA	In-house*	µg/mL	0.15	GSK Biologicals§

*In-house refers to ***assays developed internally by GSK which can be performed at*** GSK Biologicals' laboratories or ***external*** laboratory designated by GSK
**Refer to APPENDIX A for the laboratory addresses.
§GSK Biologicals laboratory refers to the Global Vaccines Clinical Laboratories (GVCL) in Rixensart, Belgium; Wavre,
†***Due to ongoing re-validation of all assays, the cut-offs may be subject to change.***
Belgium ***and*** Laval, Canada.

Section 6.1 Description of study vaccines

Table 9 Study vaccines

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Pentacel	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial	0.5 mL*	4
	~~ActHIB~~ ***Hib***	~~Hib=10µg TT, TT=24µg~~ ***PRP=10µG; TT~=25µG***	~~White lyophilized pellet in a single dose vial, it must be reconstituted before use with the liquid DTaP- IPV component.~~ ***The lyophilized Hib component is presented as a white pellet in a glass vial; it must be reconstituted with the liquid DTaP-IPV component before use***		

Section 6.3 Dosage and administration of study vaccines

NOTE: After reconstitution, *Infanrix hexa* should be ~~administered promptly or stored refrigerated between 2° and 8°C and administered within 24 hours. If the vaccine is not administered promptly, shake the solution vigorously again before injection~~ ***injected immediately. However the vaccine may be kept for up to 8 hours at room temperature (21°C).***

Section 6.7.1 Recording of concomitant medications/products and concomitant vaccination

- Any concomitant vaccination administered ***since birth*** ~~in the period starting 30 days before the first dose of the study vaccine~~ and ending 30 days after the booster dose (Visit 6). ~~Notes: 1).~~ Vaccinations listed prior to the first dose of study vaccine are to be recorded as vaccination history. ~~2)~~ The fourth dose of *Prevnar 13* will be recorded as concomitant vaccination.

  * ***Refer to those*** SAEs that are required to be reported per protocol.

Section 8.1.3.1 Solicited local (injection-site) adverse events

Table 11 Solicited local adverse events

Pain at injection site
Redness at injection site
Swelling at injection site
Post-dose 4 measurements of circumference of limbs (arm or leg according to where vaccine was administered)

N.B. If parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of ~~arm~~ ***limb*** circumference) after the booster dose at Visit 5, they ~~will be asked~~ ***are*** to contact study personnel and to visit the investigator's office for evaluation as soon as possible ***and bring the diary card with them***. The investigator will record detailed information describing the AE on a specific large injection site reaction ***form*** in the eCRF. ***In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms the parent(s)/LAR(s) will need to record additional symptoms/characteristics as mentioned in Section 5.6.2.13.***

Note: local AEs will not be ~~collected~~ ***solicited*** for co-administered vaccines like *Prevnar 13* ~~and *Rotarix*.~~

Section 8.3.1 Time period for detecting and recording adverse events and serious adverse events

Note: With the exception of AEs/SAEs leading to withdrawal, study participation and concurrent GSK medications or vaccines, there is no reporting of SAEs from the time of the Epoch 1 ESFU phone contact and administration of dose 4 (approximately three months).

Section 8.3.3.2.1 Assessment of intensity

Table 14 Intensity scales for solicited symptoms in infants/toddlers

Infant/Toddler (15–24 months)		
Adverse Event	**Intensity grade**	**Parameter**
Pain at injection site	0	None
	1	Mild: Minor reaction to touch
	2	Moderate: Cries/protests on touch
	3	Severe: Cries when limb is moved/spontaneously painful
Redness at injection site		Record greatest surface diameter in mm
Swelling at injection site		Record greatest surface diameter in mm
Increase in limb circumference post-dose 4 (arm or leg according to where vaccine was administered)		***Record the limb circumference at the level of the injection site***

The maximum intensity of fever ~~was~~ ***will be*** scored at GSK Biologicals as follows:

0	=	***<100.4°F***	***<38.0°C***
1	=	***≥100.4°F to ≤102.2°F***	***≥38.0°C to ≤39.0°C***
2	=	***>102.2°F to ≤104.0°F***	***>39.0°C to ≤40.0°C***
3	=	***> 104.0°F***	***> 40.0°C***

Prior to analysis, the increase in limb circumference of each limb as compared to the baseline pre-vaccination measurement will be scored for each subject at GSK Biologicals' as follows:

Grade 0 = Increase in limb circumference ≤5 mm
1 = Increase in limb circumference >5 mm but ≤20 mm
2 = Increase in limb circumference >20 mm but ≤40 mm
3 = Increase in limb circumference >40 mm

For unsolicited symptoms and adverse events associated with large injection site reactions (e.g. pruritus, induration and functional impairment, t~~T~~he intensity should be assigned to one of the following categories:

Section 10.4.2 Primary ATP cohort for analysis of safety

- who have received all ***planned*** study vaccines ~~as planned~~ ***for each completed vaccination visit in*** ~~up to the end of~~ Epoch 001;

Section 10.4.5 Booster ATP cohort for analysis of safety

- who have received the ***planned*** booster dose at 15-18 months of age;

Section 10.5 Derived and transformed data

- A seropositive subject is a subject whose antibody concentration/titer is greater than or equal to the assay cut-off defined in Table 7.
  Note: Due to ongoing re-validation of all assays, these cut-offs may be subject to change.
- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies are defined as:
  – For initially seropositive subjects with pre-booster antibody concentration ≥ 20 EL.U/mL with an increase of at least two times the pre-booster antibody concentration, one month after vaccination.

  Note: Due to ongoing re-validation of pertussis assays, the definition of booster responses may be subject to change.

Section 10.6.2.2 Between group assessment

- The 95% CI for each group GMC/GMT ratio will be computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect ***and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model***.. For hepatitis B antigen, the hepatitis b at birth vaccine dose status will also be used as regressor ~~leading to an Analysis of Co-variance (ANCOVA) model~~.

Section 10.7.2.2 Between group assessments

- The 95% CI for each group GMC/GMT ratio will be computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect ***and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model***. For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor ~~leading to an ANCOVA model.~~

Section 10.8 Statistical methods

- The GMT/GMC group ratio will be obtained using an ANOVA model on the logarithm-transformed concentrations/titers. ***The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model.*** For hepatitis B antigen, the hepatitis B status at birth vaccine dose will also be used as regressor ~~leading to an Analysis of Co-variance (ANCOVA) model~~.

Section 10.9.1 Sequence of analyses

1. The final data analysis of Epoch 001 including all as clean as possible data, up to one month after the third primary vaccine dose, and some partial data from the ESFU contact will be conducted as soon as possible. This analysis will include the final analysis of immunogenicity and the final analysis of solicited symptoms for the primary vaccination course. ~~All analyses will be presented in Clinical Study Report (CSR). The CSR will be shared with the investigators.~~
2. All these analyses will be presented in a~~n Epoch 002 specific~~ ***final*** CSR. ~~The final CSR will be shared with the investigators.~~

Section 13 References

Kohl KS, Walop W, Gidudu J, et al. Swelling at or near injection site: case definition and guidelines for collection, analysis and presentation of immunization safety data. Vaccine. 2007; 25(31):5858-74.

Appendix A Clinical laboratories

Table 19 Outsourced laboratories

Laboratory	Address
~~BARC USA Inc~~	~~5, Delaware Drive~~ ~~Lake Success~~ ~~NY 11042-1114~~ ~~USA~~

GlaxoSmithKline Biologicals

Clinical Research & Development

Protocol Amendment 2

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number	2013-004304-19
Amendment number:	Amendment 2
Amendment date:	Final Version 02: 17 April 2015
Co-ordinating author:	PPD , Scientific Writer

Rationale/background for changes:
The amendment 2 has been implemented to amend the following sections of the protocol:

- The assay for testing antibodies against polyribosyl ribitol phosphate (anti-PRP) has been re-developed but is not yet qualified or validated for testing the one month post dose-3 samples. This has been clarified in the protocol in Table 7 Humoral immunity (antibody determination) and Section 5.7.3 Laboratory assays.
- Investigator sign-off on the patient identification (PIDS) will be done after Visit 4 instead of extended safety follow-up (ESFU). In Table 4 List of study procedures, the bullets pertaining to investigator sign-off and analysis of Epoch 001 has been removed from the ESFU visit and retained at Visit 4 to reflect this change.
- The collection of baseline measurement of limb length has been removed since it will not be used in analysis; only limb circumference will be used in analysis. Accordingly, text related to this has been amended in Table 4 List of study procedures, Sections 5.6.2.11, Baseline measurement of limb circumference after booster vaccination at visit 5 and 5.6.2.13 Recording of AEs, SAEs and NOCDs.
- Errors in the vaccines dictionary of Study Master Repository (SMR) have been rectified for *Infanrix hexa*, *Pediarix* and *Pentacel* vaccines. The corresponding correction has been made in Table 9 Study vaccines.
- The sequence of analysis in Section 10.9.1 Sequence of analyses, has been amended to reflect that there will first be an analysis of immunogencity for anti-PRP and safety for Epoch 001, followed by a final analysis covering both Epochs at the end of the study.

Amended text has been included in *bold italics* and deleted text in ~~strikethrough~~ in the following sections:

Section 5.5 Outline of study procedures:
Table 4 List of study procedures

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Pre-vaccination measurement of ~~limb length and~~ circumference of limb(s) at site of injection by investigator[δ]						●	
Investigator sign-off				●	~~●~~		●
Analysis of the Epoch 001 #				O	~~O~~		

In Section 5.6.2.11 Baseline measurement of limb circumference after booster vaccination at visit 5

In Section 5.6.2.11 Baseline measurement of limb ~~length and~~ circumference after booster vaccination at visit 5

During Epoch 002, baseline measurement of ~~length of~~ limb~~(s) and~~ circumference (arms or legs according to where the vaccine was administered) at the level of the injection site should be obtained. For the Penta group, baseline measurement is only required for the limb that will be vaccinated. Clothing should be removed so as not to interfere with the measurement of the ~~length of the~~ limb ~~and the~~ circumference. ~~Upper arm length will be determined from the acromion process of the scapula to the tip of the elbow and thigh length will be determined from the midpoint of the abdomen thigh flexure crease and the proximal end of the patella.~~

In Section 5.6.2.13 Recording of AEs, SAEs and NOCDs:

- ~~Whether or not the diameter of the swelling involves more than 50% of the limb (baseline measurement of the length of the limb taken by study personnel at the vaccination visit will be provided on the diary cards).~~

In Section 5.7.3 Laboratory assays

All serology will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized ~~validated~~ procedures with adequate controls. ***All serology for primary endpoints will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized, validated procedures with adequate controls.***

Table 7 Humoral immunity (antibody determination)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off†	Laboratory**
Serum	Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab ‡	**ELISA**	**In-house***	**µg/mL**	**0.15**	**GSK Biologicals§**

‡For anti-PRP post-dose 3, the assay is not yet qualified or validated.

Section 6.1 Description of study vaccines

Table 9 Study vaccines

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix hexa	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=***32DU***; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	full volume^	3
Pediarix	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=***32DU***; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	0.5 mL	3
Pentacel	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial***. The lyophilized Hib component is presented as a white pellet in a separate glass vial. It must be reconstituted with the liquid DTaP-IPV component before use.***	0.5 mL*	4
	~~Hib~~	~~PRP=10µG; TT~=25µG~~			

Section 10.9.1 Sequence of analyses

The analyses will be performed ***stepwise*** ~~in 2 steps~~:

~~**1.** The final data analysis of Epoch 001 including all as clean as possible data, up to one month after the third primary vaccine dose, and some partial data from the ESFU contact will be conducted as soon as possible. This analysis will include the final analysis of immunogenicity and the final analysis of solicited symptoms for the primary vaccination course.~~ ***A partial analysis of Epoch 001 up to one month after the third primary vaccine dose will be conducted. This analysis will include the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis will be displayed on GSK clinical trial registry as soon as possible.***

2. ~~The final data analysis of Epoch 002 will be conducted subsequently. This analysis will include final analysis of the ESFU from Epoch 001 and the final analysis of immunogenicity and safety from Epoch 002. All these analyses will be presented in a final CSR~~. ***The final data analysis of the study covering both the epochs will be conducted at the end of the study. All these analyses will be presented in a final clinical study report.***

Protocol Amendment 2 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 2 Final Version 02: 17 April 2015
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Sponsor signatory	Narcisa Elena Mesaros Project level CRDL, DTP/Polio Vaccines Late Clinical Development, Vaccine Discovery and [redacted]icals.
Signature	[redacted]
Date	6.04.2015

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GlaxoSmithKline Biologicals, SA

Study detailed title

A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' *Infanrix hexa* vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with *Prevnar* and *Rotarix* with a booster dose of GSK Biologicals' *Infanrix* and *Hiberix* vaccines at 15-18 months of age.

Clinical Study Report for Study 117119 (DTPA-HBV-IPV-135)

Development Phase III

IND Number: BB-IND 006687

EUDRACT Number: 2013-004304-19

Name of Investigational Product: GlaxoSmithKline (GSK) Biologicals' Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine (DTPa-HBV-IPV/Hib) (SB217744, *Infanrix hexa*).

Indication Studied: Active immunization against diphtheria, tetanus, pertussis infection caused by all known subtypes, of hepatitis B virus, poliomyelitis, and invasive disease caused by *Haemophilus influenzae* type B (Hib) in infants.

Study initiation date:	16-April-2014
Study completion date:	13-November-2015
Data lock point (Date of database freeze):	15-March-2018
Date of report:	Final: 06-July-2018
Earlier Study Reports Abridged Interim Report	19-October-2015

Sponsor Signatory: Narcisa Mesaros, MD,
Clinical and Epidemiology R&D Project Leader,
DTP, Polio and Hib containing vaccines –
R&D Centre Belgium, GlaxoSmithKline Biologicals.

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

SYNOPSIS

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Study No.: 117119 (DTPA-HBV-IPV-135)

Title of the study:
A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' *Infanrix hexa* vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co administered with *Prevnar* and *Rotarix* with a booster dose of GSK Biologicals' *Infanrix* and *Hiberix* vaccines at 15-18 months of age.

Investigator(s) and study centre(s):
Multicenter study conducted in 43 centers in the United States of America (USA).
Principal investigator: Dr Nicola Klein, M.D. at the Kaiser Permanente Oakland, One Kaiser Plaza, Oakland, CA, USA.

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

Study period: **Study initiation date:** 16-April-2014 **Study completion date:** 13-November-2015 **Data lock point (Date of database freeze):** 15-March-2018	**Phase:** Phase III

Indication: Active immunization against diphtheria, tetanus, pertussis infection caused by all known subtypes, of hepatitis B virus, poliomyelitis, and invasive disease caused by *Haemophilus influenzae* type B (Hib) in infants.

Objectives:

Primary: **Epoch 001 (Primary vaccination):**

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens was to be demonstrated if, for each of the three antigens, the upper limit (UL) of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] was ≤ 1.5.

Secondary: **Epoch 001 (Primary vaccination)**

- To assess the immune response to *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D (Diphtheria), T (Tetanus), HBs (Hepatitis B surface antigen), pertussis, poliovirus types 1, 2 and 3 and PRP (Polyribosyl-Ribitol-Phosphate) antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa*, of *Pentacel* co-administered with *Engerix-B*, and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic illnesses (NOCIs; referred to as new-onset chronic diseases (NOCDs) in the protocol) and serious adverse events.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Secondary: **Epoch 002 (Booster vaccination)**

- To assess the immunogenicity of *Infanrix hexa*, *Pentacel*, *Engerix-B*, *Pediarix* and *ActHIB*, in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.
- To assess the immune response to *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*, in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix* and *Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix, Hiberix, ActHIB* and *Pentacel*.

Methodology:

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups.
  - **Epoch 001**: Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10);
  - **Epoch 002**: Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).
- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*;
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*.

Vaccination schedules:

<u>*Epoch 001*</u>

- **Hexa Group**: Subjects in this group were to receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - Hexa_1 Group: Subjects were to receive lot A of *Infanrix hexa*;
  - Hexa_2 Group: Subjects were to receive lot B of *Infanrix hexa;*
  - Hexa_3 Group: Subjects were to receive lot C of *Infanrix hexa*.
- **Pedia Group:** Subjects in this group were to receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
- **Penta Group:** Subjects in this group were to receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
- *Subjects in the Penta Group who received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination were not to receive *Engerix-B* at 4 months of age (Visit 2).

<u>*Epoch 002*</u>

- **Hexa Group:** Subjects were to receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
- **Pedia Group:** Subjects were to receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
- **Penta Group:** Subjects were to receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls were given in this study at 15-18 months of age, the fourth dose of *Prevnar13* was not to be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) were to be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

- As the analyses were to be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups were pooled together for the analysis and were called the Hexa group.
- Treatment allocation: The subjects were randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This was done at study entry using GSK Biologicals' central randomization system on internet (SBIR).
- Blinding: The study was open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology 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 subject) to each sample.
- Sampling schedule: Blood samples were drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) was collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) was collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) was collected.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

Study vaccine, dose, mode of administration, lot no.:
Vaccination schedule /site: See Vaccination schedules for the Hexa group in Epoch 001 and Epoch 002 in Methodology section above. Injections of *Infanrix hexa, Infanrix, Hiberix* and *Prevnar13* were via intramuscular injection in the thigh, with *Rotarix* given orally.

Vaccine composition /dose /lot number: AC21VB448C and AHIBC950C (Infanrix hexa Lot A);
AC21B514A and AHIBC907D (Infanrix hexa Lot B);
AC21B510B and AHIBC954A (Infanrix hexa Lot C); AC14B195A (*Infanrix*);
AHIBC875A and DEXTA517AZ (*Hiberix*); AROTVA291D and AD05VA833A (*Rotarix*); DLOCA107A (Alternative Lot no. H39264; *Prevnar13*).

Reference vaccine /Comparator, dose and mode of administration, lot no.:
Vaccination schedule /site: See Vaccination schedules for the Pedia and Penta groups in Epoch 001 and Epoch 002 in Methodology section above. Injections of *Pediarix, ActHIB, Pentacel, Engerix-B* and *Prevnar13* were via intramuscular injection in the thigh, with *Rotarix* given orally.

Vaccine composition /dose /lot number: AC21VB448C (*Pediarix*); AHBVC253A (*Engerix-B*); AROTVA291D and AD05VA833A (*Rotarix*);
First Pentacel Lot: Lot no. DLOCA102AY (Alternative Lot no. C4507AA), Lot no. DLOCA102AZ (Alternative Lot no. C4557AA); Second Pentacel Lot: Lot no. DLOCA108AY (Alternative Lot no. C4517BA), Lot no. DLOCA108AZ (Alternative Lot no. C4574AA);

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Third Pentacel Lot: Lot no. DLOCA144AY (Alternative Lot no. C4724AA), Lot no. DLOCA144AZ (Alternative Lot no. C4642AA);
Lot no.: DLOCA106AZ (Alternative Lot no. UH971AA), DLOCA150AZ (Alternative Lot no. UI117AA; only for Epoch 2; *ActHIB*); Lot no.: DLOCA106AY (Alternative Lot no. UH954AB), DLOCA150AY (Alternative Lot no. UI128AA; only for Epoch 2; *ActHIB*);
DLOCA107A (Alternative Lot no. H39264; *Prevnar13*)

Study Population: Healthy male and female infants, between and including, 6 and 12 weeks of age at the time of the first dose who were free of obvious health problems, born full-term after a gestation period of 37 weeks to less than 42 completed weeks and who had not received vaccination against diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, rotavirus, pneumococcus, and/or poliovirus; or more than one previous dose of hepatitis B vaccine administered at least 30 days prior to enrolment. Written informed consent was obtained from the parent/guardian of the subject prior to any study-related activity.

Duration of treatment: The intended duration of the study per subject is approximately 14-17 months.

Criteria for evaluations:

Primary endpoint: Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

Secondary endpoints: Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited adverse events (AEs) within 31 days (Day 0 – Day 30) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic illnesses (NOCI; e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.
- Serious adverse events (SAEs).
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

Secondary endpoints: Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1.0 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1.0 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1.0 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1.0 µg/mL one month after the booster dose (Dose 4)
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Serious adverse events (SAEs).
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Statistical methods: Final analysis of the Epoch 001

Analysis of demographics

Demographic characteristics (age [weeks], gender, geographical ancestry, height in length [cm], weight [kg] at first dose, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status were summarised by group using descriptive statistics:

- Frequency tables were generated for categorical variables such as center;
- Mean, median and standard error were provided for continuous data such as age.

The distribution of subjects enrolled among the study sites was tabulated as a whole and per group.

Analysis of immunogenicity

The primary analysis was based on the Primary according-to-protocol (ATP) cohort for immunogenicity. An analysis on the Primary Total Vaccinated cohort (TVC) was performed only if, in any vaccine group and at any time point, more than 5% of the vaccinated subjects with immunological data post-dose 3 were excluded from the Primary ATP cohort for immunogenicity.
The following sections describe the analyses that were performed.

Within group assessment

For each group, one month post-dose 3 and for each assay for which a serological result was available:

- Seropositivity and seroprotection rates with exact 95% CIs were calculated.
- GMCs/geometric mean titers (GMTs) with 95% CIs were tabulated.
- For each antigen, antibody concentration or titer distribution one month post-vaccination was tabulated and displayed using reverse cumulative curves (RCCs).
- For anti-PRP post primary vaccinate at Visit 4, seropositivity and seroprotection rates and GMCs were calculated per *Infanrix hexa* lot.

All the above within group analysis for Epoch 001, except the reverse cumulative curves (RCCs) and the presentation per *Infanrix hexa* lot, were also to be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and by Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

Between group assessment

At one month post-dose 3,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection rates was computed for each antigen.

Antigen	Threshold considered for protection
• Anti-D	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-T	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-polio	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (short term protection) • 1.0 µg/mL (long term protection)
• Anti-HBs	• 10 mIU/mL

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) was computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers. The ANOVA model was to include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as continuous regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B vaccine birth dose status was also to be used as regressor leading to an ANCOVA model. The model was to include the data from the 3 groups compared. For analysis purpose, DTP vaccination of the mother during pregnancy and Hepatitis B vaccination at birth were considered as continuous variables. More specifically 2 continuous indicator variables were to be used for Tdap vaccination of mother during pregnancy (an indicator for no Tdap vaccination at birth and an indicator for unknown vaccination at birth) while one indicator of hepatitis B vaccination at birth was used.

Interpretation of analyses

Except for analyses addressing criteria specified in the primary objective, comparative analyses were descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses were not to be interpreted for formal conclusions since there was no adjustment for multiplicity of endpoints.

Analysis of safety

The primary analysis was based on the primary Total Vaccinated cohort. If, in any vaccine group and at any time point of the Epoch 001, the percentage of vaccinated subjects excluded from the primary ATP cohort for safety was more than 5%, a second analysis based on the primary ATP cohort for safety was to be performed to complement the primary Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period was tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period was tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses with local AEs (solicited and unsolicited) were calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered) during the 4-day follow-up period was tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses reporting each individual solicited local and general AE during the 4-day follow-up period were tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

  The exact 95% CIs were calculated assuming independence between doses.

- All computations mentioned above were done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects/doses reporting each individual solicited local symptom (any grade, grade 2, grade 3, medical advice) during the 4-day follow-up period were also to be tabulated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines with exact 95% CI after each vaccine dose and overall where the same row on the table was used for all vaccines given at the same site across the three study groups (e.g. *Infanrix hexa*, *Pentacel* and *Pediarix* together were in one row and *ActHIB* and *Engerix-B* together were in one row). The percentage of subjects/doses reporting each individual general solicited symptom (any grade, Grade ≥2, Grade 3,

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

causally related, Grade 3 causally related, medical advice) during the 4-day follow-up period were also to be tabulated with exact 95% CI. For fever, the analyses were also to be performed by 0.5°C increments.

- The percentage of subjects/doses with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination was tabulated after each dose and over the Epoch 001.
- The verbatim reports of unsolicited AEs were reviewed by a Clinical Research and Development Lead (CRDL) and the signs and symptoms were coded according to MedDRA. Every verbatim term was matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI was tabulated by Preferred Term. Similar tabulations were done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.
- Subjects who experienced AEs of specific interest (i.e. convulsions, Hypotonic Hyporesponsive Episode) during 31 days with exact 95% CI were tabulated by Preferred Term. Similar tabulations were done for AEs considered related to vaccination. Subjects who experienced AEs of specific interest were also to be described in detail.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination were tabulated by Preferred Term.
- Subjects who experienced at least one SAE with onset from Dose 1 up to six months post primary vaccination were tabulated with MedDRA primary preferred term.
  - All analyses of reactogenicity and for unsolicited symptoms were also to be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry).

Statistical methods: Final analysis of the Epoch 002

Analysis of demographics/baseline characteristics

Demographic characteristics (age [months] at Visit 5, gender, geographical ancestry, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status were summarized by group using descriptive statistics:

- Frequency tables were generated for categorical variables such as race/ethnicity;
- Mean, median and standard error were provided for continuous data such as age.

Analysis of immunogenicity

The primary analysis was based on the booster ATP cohort for immunogenicity. An analysis on the booster Total Vaccinated cohort was to be performed only if, in any vaccine group and at any time point of the Epoch 002, more than 5% of the vaccinated subjects with immunological data were excluded from the booster ATP cohort for immunogenicity.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

The following section describes the analyses that were performed.

Within group assessment

For each group, prior to the booster dose and one month post-booster dose and for each assay, for which a serological result was available:

- Seropositivity and seroprotection rates and, for pertussis, booster response rates were calculated with exact 95% CIs.
- GMCs/GMTs with 95% CIs were tabulated.
- For each antigen, antibody concentration or titer distribution before and one month Post-booster (when available) were tabulated and displayed using RCCs.

All the above within group analysis for Epoch 002 except the reverse cumulative curves were also to be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

Between group assessment

At pre-booster and at one month post-booster,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection rates were computed for each antigen.

Antigen	Threshold considered for protection
• Anti-D	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-T	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-polio (Pre-Booster)	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (short term protection) • 1.0 µg/mL (long term protection)
• Anti-HBs (Pre-Booster)	• 10 mIU/mL

- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) were computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model was to include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as regressor leading to an ANCOVA. For hepatitis B antigen, the hepatitis B vaccine birth dose status was also to be used as regressor leading to an ANCOVA model. The model was also to include the data from the 3 groups compared. For analysis purpose, DTP vaccination of the mother during pregnancy and Hepatitis B vaccination at birth were considered as continuous variables. More specifically 2 continuous indicator variables were used for Tdap vaccination of mother during pregnancy (an indicator for no Tdap vaccination at birth and an indicator for unknown vaccination at birth) while one indicator of hepatitis B vaccination at birth was used.

Interpretation of analyses

In Epoch 002, all comparative analyses were descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses were not to be interpreted for formal conclusions since there was no adjustment for multiplicity of endpoints.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Analysis of safety

The primary analysis for the Epoch 002 was based on the booster Total Vaccinated cohort and was only to look at the booster dose. If, in any vaccine group, the percentage of vaccinated subjects excluded from the booster ATP cohort for safety was more than 5%, a second analysis based on the booster ATP cohort for safety was to be performed to complement the booster Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose, were tabulated with exact 95% CI for each group.
- The incidence of local AEs (solicited and unsolicited) was calculated at each injection site as well as overall (all sites considered) for each group during the 4-day (Days 0-3) follow-up period after the booster dose.
- The percentage of subjects reporting each individual solicited local and general AE during the 4-day follow-up period was tabulated with its exact 95% CI for each group.
- All computations mentioned above were to be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects reporting each individual solicited local symptoms (any grade, Grade ≥2, Grade 3, medical advice) during the 4-day follow-up period were also to be tabulated at each injection site for *Infanrix, Hiberix, ActHIB* and *Pentacel* vaccines with exact 95% CI after each vaccine dose and overall where vaccination with same vaccine site was considered together (e.g. *Infanrix* and *Pentacel* together were on one row and *ActHIB* and *Hiberix* together were on one row). The percentage of subjects reporting each individual general solicited symptom (any grade, Grade ≥2, Grade 3, causally related, Grade 3 causally related, medical advice) during the 4-day follow-up period was also to be tabulated with exact 95% CI. For fever, analyses were also to be performed by 0.5°C increments.
- The percentage of subjects with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination were tabulated for each group.
- The verbatim reports of unsolicited AEs were reviewed by a Clinical Research and Development Lead and the signs and symptoms were coded according to MedDRA. Every verbatim term was matched with the appropriate Preferred Term. The percentage of subjects with unsolicited AEs occurring within 31 days following the booster dose with its exact 95% CI was tabulated by Preferred Term. Similar tabulations were done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Additionally,

- Any large injection site reaction (defined as a swelling with a diameter > 50 mm, noticeable diffuse swelling or increase in limb circumference of greater than 50 mm) reported within 4 days (Days 0-3) following the booster dose was to be tabulated.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from booster dose up to one month after booster vaccination were tabulated by Preferred Term.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

- Subjects who experienced at least one SAE from the booster dose up to one month after were tabulated with MedDRA primary preferred term. The same summary was provided for all SAEs reported after dose 1 up to study end.

All analyses of reactogenicity and for unsolicited symptoms were also to be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestry, namely White Caucasian versus any other geographical ancestry).

Synopsis Table 1 - Study population (Primary Total vaccinated cohort)

Number of subjects	**Hexa group**	**Pedia group**	**Penta group**
Planned, N	195	195	195
Randomised, N (Total Vaccinated Cohort)	195	194	196
Completed to visit 6 M 14-17, n (%)	161 (82.6)	158 (81.4)	157 (80.1)
Demographics	**Hexa group**	**Pedia group**	**Penta group**
N (Total Vaccinated Cohort)	195	194	196
Females:Males	101:94	80:114	95:101
Mean Age, weeks (SD)	8.5 (1.0)	8.6 (1.1)	8.6 (1.1)
Median Age, weeks (minimum, maximum)	8 (6, 12)	9 (6, 12)	8 (6, 12)
White - Caucasian / European Heritage, n (%)	118 (60.5)	128 (66.0)	115 (58.7)

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = total number of subjects
n/% = number/percentage of subjects
SD = standard deviation

Synopsis Table 2 - Ratio of GMCs for anti-PT, anti-FHA and ant-PRN between groups (Pedia group divided by Hexa group), one month post primary vaccination (Primary ATP cohort for immunogenicity)

					Adjusted GMC ratio (Pedia group / Hexa group)		
	Pedia group		**Hexa group**			**95% CI**	
Antibody	**N**	**Adjusted GMC**	**N**	**Adjusted GMC**	**Value**	**LL**	**UL**
anti-PT antibody (IU/mL)	149	47.9	146	43.6	1.10	0.92	1.31
anti-FHA antibody (IU/mL)	149	122.6	146	107.3	1.14	0.97	1.35
anti-PRN antibody (IU/mL)	149	46.1	146	58.2	0.79	0.63	0.99

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
Adjusted GMC = geometric mean antibody concentration adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 3 - Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ assay cut-off				GMC		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PT antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	43.2	38.1	48.9
	Pedia group	PIII(M5)	149	148	99.3	96.3	100	48.3	42.7	54.5
	Penta group	PIII(M5)	149	148	99.3	96.3	100	24.2	21.1	27.7
anti-FHA antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	106.3	95.0	119.0
	Pedia group	PIII(M5)	149	149	100	97.6	100	122.7	109.9	137.0
	Penta group	PIII(M5)	149	149	100	97.6	100	59.9	51.7	69.3
anti-PRN antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	57.4	49.5	66.6
	Pedia group	PIII(M5)	149	148	99.3	96.3	100	46.9	39.9	55.3
	Penta group	PIII(M5)	149	148	99.3	96.3	100	33.0	27.8	39.1

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Synopsis Table 4 - Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ assay cut-off				≥ 0.1 IU/mL				≥ 1.0 IU/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-D antibody	Hexa group	PIII(M5)	142	142	100	97.4	100	142	100	97.4	100	112	78.9	71.2	85.3	1.777	1.551	2.036
	Pedia group	PIII(M5)	144	144	100	97.5	100	144	100	97.5	100	105	72.9	64.9	80.0	1.648	1.440	1.886
	Penta group	PIII(M5)	149	149	100	97.6	100	149	100	97.6	100	88	59.1	50.7	67.0	1.249	1.095	1.425
anti-T antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	146	100	97.5	100	130	89.0	82.8	93.6	2.458	2.195	2.753
	Pedia group	PIII(M5)	149	149	100	97.6	100	149	100	97.6	100	134	89.9	83.9	94.3	2.633	2.338	2.966
	Penta group	PIII(M5)	149	149	100	97.6	100	148	99.3	96.3	100	119	79.9	72.5	86.0	2.012	1.768	2.290

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 5 - Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), one month post primary vaccination
(Primary ATP cohort for immunogenicity)

				≥ 8 ED50				GMT		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Polio 1 antibody	Hexa group	PIII(M5)	137	137	100	97.3	100	546.9	447.7	668.0
	Pedia group	PIII(M5)	134	134	100	97.3	100	604.1	495.9	736.0
	Penta group	PIII(M5)	136	135	99.3	96.0	100	319.5	256.8	397.5
anti-Polio 2 antibody	Hexa group	PIII(M5)	133	133	100	97.3	100	483.5	394.2	593.0
	Pedia group	PIII(M5)	131	131	100	97.2	100	567.7	448.8	718.1
	Penta group	PIII(M5)	134	134	100	97.3	100	283.0	229.4	349.2
anti-Polio 3 antibody	Hexa group	PIII(M5)	129	129	100	97.2	100	722.2	577.4	903.4
	Pedia group	PIII(M5)	132	132	100	97.2	100	927.0	740.7	1160.3
	Penta group	PIII(M5)	126	124	98.4	94.4	99.8	294.6	221.6	391.7

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 6 - Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ assay cut-off				≥ 0.15 µg/mL				≥ 1.0 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – qualified assay	Hexa group	PIII(M5)	149	140	94.0	88.8	97.2	140	94.0	88.8	97.2	83	55.7	47.3	63.8	1.373	1.083	1.740
	Pedia group	PIII(M5)	153	151	98.7	95.4	99.8	151	98.7	95.4	99.8	144	94.1	89.1	97.3	10.327	8.127	13.122
	Penta group	PIII(M5)	153	151	98.7	95.4	99.8	151	98.7	95.4	99.8	126	82.4	75.4	88.0	6.485	4.922	8.544
anti-PRP – fully validated assay	Hexa group	PIII(M5)	154	152	98.7	95.4	99.8	146	94.8	90.0	97.7	85	55.2	47.0	63.2	1.348	1.076	1.688
	Pedia group	PIII(M5)	154	153	99.4	96.4	100	151	98.1	94.4	99.6	145	94.2	89.2	97.3	9.258	7.362	11.642
	Penta group	PIII(M5)	156	154	98.7	95.4	99.8	154	98.7	95.4	99.8	130	83.3	76.5	88.8	5.717	4.363	7.492

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 7 - Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ 6.2 mIU/mL				≥ 10 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-HBs antibody	Hexa group	PIII(M5)	134	134	100	97.3	100	134	100	97.3	100	2258.8	1910.7	2670.4
	Pedia group	PIII(M5)	138	138	100	97.4	100	138	100	97.4	100	1886.0	1565.6	2271.9
	Penta group	PIII(M5)	136	134	98.5	94.8	99.8	133	97.8	93.7	99.5	1053.4	780.2	1422.4

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 8 - Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), before and one month post booster vaccination (Booster ATP cohort for immunogenicity)

				≥ assay cut-off				GMC		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PT antibody	Hexa group	PRE-BST	131	107	81.7	74.0	87.9	5.3	4.6	6.2
		POST-BST	138	138	100	97.4	100	71.4	62.6	81.5
	Pedia group	PRE-BST	132	114	86.4	79.3	91.7	6.5	5.6	7.7
		POST-BST	136	136	100	97.3	100	87.6	76.6	100.2
	Penta group	PRE-BST	121	63	52.1	42.8	61.2	3.1	2.6	3.7
		POST-BST	126	126	100	97.1	100	55.5	47.4	65.1
anti-FHA antibody	Hexa group	PRE-BST	131	130	99.2	95.8	100	17.1	14.7	19.9
		POST-BST	138	138	100	97.4	100	186.9	165.1	211.5
	Pedia group	PRE-BST	132	130	98.5	94.6	99.8	21.8	18.3	26.1
		POST-BST	136	136	100	97.3	100	250.4	220.4	284.6
	Penta group	PRE-BST	121	113	93.4	87.4	97.1	8.1	6.6	9.9
		POST-BST	126	126	100	97.1	100	101.0	86.2	118.3
anti-PRN antibody	Hexa group	PRE-BST	131	110	84.0	76.5	89.8	6.8	5.5	8.3
		POST-BST	137	136	99.3	96.0	100	208.0	172.3	251.1
	Pedia group	PRE-BST	132	104	78.8	70.8	85.4	5.5	4.5	6.6
		POST-BST	136	136	100	97.3	100	215.6	176.1	263.8
	Penta group	PRE-BST	120	91	75.8	67.2	83.2	6.0	4.8	7.5
		POST-BST	125	124	99.2	95.6	100	130.5	105.9	160.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 9 - Booster response for anti-PT, anti-FHA and anti-PRN antibodies, one month post booster vaccination (Booster ATP cohort for immunogenicity)

				Booster response			
						95% CI	
Antibody	**Group**	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
anti-PT antibody (IU/mL)	Hexa group	S-	24	22	91.7	73.0	99.0
		S+ (<4*cut_off IU/mL)	78	75	96.2	89.2	99.2
		S+ (≥4*cut_off IU/mL)	29	29	100	88.1	100
		Total	131	126	96.2	91.3	98.7
	Pedia group	S-	18	18	100	81.5	100
		S+ (<4*cut_off IU/mL)	86	81	94.2	87.0	98.1
		S+ (≥4*cut_off IU/mL)	26	22	84.6	65.1	95.6
		Total	130	121	93.1	87.3	96.8
	Penta group	S-	56	52	92.9	82.7	98.0
		S+ (<4*cut_off IU/mL)	46	45	97.8	88.5	99.9
		S+ (≥4*cut_off IU/mL)	14	14	100	76.8	100
		Total	116	111	95.7	90.2	98.6
anti-FHA antibody (IU/mL)	Hexa group	S-	1	1	100	2.5	100
		S+ (<4*cut_off IU/mL)	27	27	100	87.2	100
		S+ (≥4*cut_off IU/mL)	103	102	99.0	94.7	100
		Total	131	130	99.2	95.8	100
	Pedia group	S-	2	2	100	15.8	100
		S+ (<4*cut_off IU/mL)	17	17	100	80.5	100
		S+ (≥4*cut_off IU/mL)	111	108	97.3	92.3	99.4
		Total	130	127	97.7	93.4	99.5
	Penta group	S-	8	8	100	63.1	100
		S+ (<4*cut_off IU/mL)	57	56	98.2	90.6	100
		S+ (≥4*cut_off IU/mL)	51	50	98.0	89.6	100
		Total	116	114	98.3	93.9	99.8
anti-PRN antibody (IU/mL)	Hexa group	S-	21	20	95.2	76.2	99.9
		S+ (<4*cut_off IU/mL)	54	54	100	93.4	100
		S+ (≥4*cut_off IU/mL)	55	54	98.2	90.3	100
		Total	130	128	98.5	94.6	99.8
	Pedia group	S-	28	27	96.4	81.7	99.9
		S+ (<4*cut_off IU/mL)	55	54	98.2	90.3	100
		S+ (≥4*cut_off IU/mL)	47	47	100	92.5	100
		Total	130	128	98.5	94.6	99.8
	Penta group	S-	28	26	92.9	76.5	99.1
		S+ (<4*cut_off IU/mL)	40	39	97.5	86.8	99.9
		S+ (≥4*cut_off IU/mL)	47	47	100	92.5	100
		Total	115	112	97.4	92.6	99.5

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
Booster response to PT, FHA and PRN antigens is defined as:
ubjects: For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration ≥ 4 times the assay cut-off
<4*cut_off IU/mL) subjects: For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration
S+ (≥4*cut_off IU/mL) subjects: For subjects with pre-vaccination antibody concentration equal or above 4 times the assay cut off,

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

post-vaccination antibody concentration equal or above 2 times the pre-vaccination antibody concentration
N = number of subjects with pre- and post-vaccination results available
n/% = number/percentage of subjects with booster response
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Synopsis Table 10 - Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), before and one month post booster vaccination (Booster ATP cohort for immunogenicity)

				≥ assay cut-off				≥ 0.1 IU/mL				≥ 1.0 IU/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-D antibody	Hexa group	PRE-BST	131	131	100	97.2	100	128	97.7	93.5	99.5	43	32.8	24.9	41.6	0.701	0.597	0.825
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	138	100	97.4	100	8.334	7.479	9.286
	Pedia group	PRE-BST	132	129	97.7	93.5	99.5	123	93.2	87.5	96.8	48	36.4	28.2	45.2	0.622	0.514	0.753
		POST-BST	136	136	100	97.3	100	136	100	97.3	100	136	100	97.3	100	7.886	6.972	8.920
	Penta group	PRE-BST	121	118	97.5	92.9	99.5	115	95.0	89.5	98.2	51	42.1	33.2	51.5	0.764	0.629	0.928
		POST-BST	126	126	100	97.1	100	126	100	97.1	100	126	100	97.1	100	8.537	7.524	9.687
anti-T antibody	Hexa group	PRE-BST	131	130	99.2	95.8	100	118	90.1	83.6	94.6	16	12.2	7.1	19.1	0.327	0.281	0.380
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	138	100	97.4	100	9.212	7.863	10.793
	Pedia group	PRE-BST	132	129	97.7	93.5	99.5	123	93.2	87.5	96.8	17	12.9	7.7	19.8	0.402	0.340	0.474
		POST-BST	136	136	100	97.3	100	136	100	97.3	100	133	97.8	93.7	99.5	8.870	7.668	10.261
	Penta group	PRE-BST	121	119	98.3	94.2	99.8	107	88.4	81.3	93.5	19	15.7	9.7	23.4	0.340	0.281	0.410
		POST-BST	126	126	100	97.1	100	125	99.2	95.7	100	125	99.2	95.7	100	6.880	5.905	8.015

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 11 - Number and percentage of subjects with anti-PRP antibody concentration equal to or above 0.066 µg/mL, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), before and one month post booster vaccination (Booster ATP cohort for immunogenicity)

				≥ 0.066 µg/mL				≥ 0.15 µg/mL				≥ 1.0 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – fully validated assay	Hexa group	PRE-BST	131	118	90.1	83.6	94.6	91	69.5	60.8	77.2	23	17.6	11.5	25.2	0.301	0.242	0.373
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	136	98.6	94.9	99.8	39.365	31.520	49.164
	Pedia group	PRE-BST	132	129	97.7	93.5	99.5	122	92.4	86.5	96.3	71	53.8	44.9	62.5	0.987	0.775	1.256
		POST-BST	139	139	100	97.4	100	139	100	97.4	100	138	99.3	96.1	100	51.140	41.954	62.339
	Penta group	PRE-BST	121	111	91.7	85.3	96.0	94	77.7	69.2	84.8	47	38.8	30.1	48.1	0.614	0.458	0.822
		POST-BST	131	130	99.2	95.8	100	129	98.5	94.6	99.8	128	97.7	93.5	99.5	27.318	21.140	35.302

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

Synopsis Table 12 - Number and percentage of subjects with anti-Polio 1, 2 and 3 antibody titers equal to or above 8 and geometric mean titers (GMT), before the booster vaccination (Booster ATP cohort for immunogenicity)

				≥ 8 ED50				GMT		
						95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-Polio 1 antibody	Hexa group	PRE-BST	128	124	96.9	92.2	99.1	99.5	79.4	124.8
	Pedia group	PRE-BST	128	121	94.5	89.1	97.8	107.4	83.7	137.9
	Penta group	PRE-BST	116	100	86.2	78.6	91.9	42.2	32.6	54.6
anti-Polio 2 antibody	Hexa group	PRE-BST	128	119	93.0	87.1	96.7	94.9	73.2	123.1
	Pedia group	PRE-BST	128	122	95.3	90.1	98.3	111.9	88.0	142.4
	Penta group	PRE-BST	117	109	93.2	87.0	97.0	51.2	40.8	64.3
anti-Polio 3 antibody	Hexa group	PRE-BST	127	123	96.9	92.1	99.1	122.1	95.1	156.9
	Pedia group	PRE-BST	129	126	97.7	93.4	99.5	160.4	125.8	204.6
	Penta group	PRE-BST	117	80	68.4	59.1	76.7	28.4	20.6	39.1

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Synopsis Table 13 - Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10 mIU/mL and geometric mean concentration (GMC), before the booster vaccination (Booster ATP cohort for immunogenicity)

				≥ 6.2 mIU/mL				≥ 10 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-HBs antibody	Hexa group	PRE-BST	133	132	99.2	95.9	100	131	98.5	94.7	99.8	328.7	261.5	413.2
	Pedia group	PRE-BST	131	130	99.2	95.8	100	128	97.7	93.5	99.5	235.8	188.2	295.5
	Penta group	PRE-BST	121	110	90.9	84.3	95.4	105	86.8	79.4	92.2	149.4	100.5	222.3

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Summary:

Immunogenicity results: Primary Vaccination Epoch

- The primary objective to demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody GMCs for pertussis antigens (PT, FHA and PRN) one month after the third dose of the primary vaccination was reached:
  - For PT, FHA and PRN, the upper limit of the 95% CI for the GMC ratio [Pedia group divided by Hexa group] was ≤ 1.5: For anti-PT antibody – 1.31; for anti-FHA antibody – 1.35; for anti-PRN antibody – 0.99 (Synopsis Table 2).
- *Anti-Diphtheria and anti-Tetanus antibody responses:* All subjects had anti-D antibody concentrations ≥ 0.1 IU/mL and at least 99.3% of subjects had anti-T antibody concentrations ≥ 0.1 IU/mL, indicating seroprotection against these diseases (Synopsis Table 4).
- *Anti-Polio 1, 2, and 3 antibody responses:* At least 99.3% of subjects had anti-Polio 1 antibody titer ≥8, all subjects had anti-Polio 2 antibody titer ≥8 and at least 98.4% of subjects had anti-Polio 3 antibody titer ≥8 (Synopsis Table 5).
- *Anti-PRP antibody responses:* Short-term seroprotection against *Haemophilus influenzae* type b disease (anti-PRP antibody concentrations ≥ 0.15 μg/mL) was met by at least 94.8% across groups using the fully validated assay (Synopsis Table 6).
- *Anti-HBs antibody responses:* Seroprotection against Hepatitis B virus (HBV) disease (anti-HBs ≥ 10 mIU/mL) was reached by at least 97.8% of subjects across the groups (Synopsis Table 7).

Name of company: GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	**Name of finished product:** *Infanrix hexa* vaccine	**Name of active substance:** Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine

Immunogenicity results: Booster Vaccination Epoch

- The proportion of subjects with an anti-Pertussis antibody booster response was:
  For anti-PT antibody: ≥93.1% across groups; for anti-FHA antibody: ≥97.7% across groups;
  for anti-PRN antibody: ≥97.4% across groups.
- *Anti-D and Anti-T immune response:* Seroprotection (≥ 0.1 IU/mL) was reached for at least 99.2% of subjects across groups and long-term seroprotection (antibody concentrations ≥1.0 IU/mL) was reached by all subjects for anti-D and for anti-T antibody by between 97.8-100% of subjects (Synopsis Table 10).
- *Anti-PRP immune response:* Short-term seroprotection (≥ 0.15 μg/mL): Between 98.5-100% of subjects across groups and long-term seroprotection (≥ 1.0 μg/mL) for between 97.7-99.3% of subjects across groups.

Safety results:

Primary Total vaccinated cohort - Safety summary

- *Any Symptom:* In all three groups (Hexa, Pedia and Penta) over the primary doses, symptoms (solicited and/or unsolicited, local and/or general) were reported for 93.4-96.4% of subjects.
- *Solicited local symptoms:* Pain was the most frequently reported solicited local symptom reported in 67.9% of subjects in the Hexa group, in 82.0% of subjects in the Pedia group and in 79.8% of subjects in the Penta group.
- Pain was also the most frequently reported Grade 3 solicited local symptom reported in 4.3% of subjects in the Hexa group, 18.0% of subjects in the Pedia group and 11.7% of subjects in the Penta group.
- Solicited *general symptoms:* Irritability / Fussiness was the most frequently reported solicited general symptom in all groups, reported in 87.7% of subjects in the Hexa group, in 96.3% of subjects in the Pedia group and in 94.1% of subjects in the Penta group overall.

  Irritability was also the most commonly reported grade 3 solicited general symptom, reported for 9.6% of subjects in the Hexa group, 18.5% of subjects in the Pedia group and 16.0% of subjects in the Penta group overall.
- *Unsolicited adverse events:* At least one unsolicited symptom within the 31-day post-vaccination period after each vaccination was reported for 57.9%, 55.7% and 49.0% of subjects in the Hexa, Pedia and Penta groups, respectively.

  The most commonly reported unsolicited symptom in the three groups was Upper Respiratory Tract Infection (URTI): Hexa group: 15.4%; Pedia group: 11.9%; Penta group: 13.3%.

  Grade 3 unsolicited symptoms were reported for 6.7%, 6.2% and 3.6% of subjects in Hexa, Pedia and Penta groups, respectively. The most commonly reported grade 3 unsolicited symptoms were: Hexa group: URTI and Otitis media (1.5%);
  Pedia group: URTI, Conjunctivitis and Irritability (1.0%);
  Penta group: URTI (1.0%).
- *Adverse events of interest:* New Onset of Chronic Illness (NOCI) symptoms were reported for 7 subjects (3.6%) in the Hexa group, 11 subjects (5.7%) in the Pedia group and 10 subjects (5.1%) in the Penta group. The two reported symptoms in the Hexa group were Dermatitis atopic (2.6%) followed by Bronchial hyperreactivity (1.0%). In the Pedia group, the symptom reported by more than one subject was Dermatitis atopic (3.6%). In the Penta group, the symptoms reported by more than one subject were Dermatitis atopic (3.6%) and Asthma (1.0%).

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- *Serious adverse events:* Non-fatal SAEs from Dose 1 up to 6 months following priming doses were reported for 7 (3.6%) subjects in the Hexa group and Penta group, and 1 (0.5%) subject in the Pedia group. All SAE were considered recovered/resolved without sequelae at the end of the study except one non-causally related event of Choking in a 47-week-old female in the Hexa group which was considered recovered/resolved with sequelae.

  Three SAEs occurring in two subjects were considered causally related to primary vaccination by the investigator: An SAE of Lethargy in an 8-week-old female subject in the Hexa group which recovered/resolved after one day without sequelae; 2 SAEs in the same subject: one "Apparent life-threatening event" and one event of Leukocytosis were observed in a 10-week-old female subject in the Hexa group which recovered/resolved over 1-2 days without sequelae.

- No fatal SAEs were reported during the primary vaccination Epoch of the study.

- *Withdrawals due to AEs /SAEs:* Two subjects had adverse events leading to premature discontinuation during the primary vaccination period: one Hexa group subject with an SAE of Lethargy reported after the first vaccination; one Penta group subject with a Non-Serious Adverse Event of Seizure reported after the Month 2 dose.

Booster Total vaccinated cohort - Safety summary

- *Any Symptom:* At least one solicited or unsolicited symptom was reported during the Booster phase for 77.2% of Hexa group subjects, 81.6% of Pedia group subjects and 70.2% of Penta group subjects.

- *Solicited local symptoms:* Pain was the most frequently reported solicited local symptom reported in 46.8% of subjects in the Hexa group, 51.0% of Pedia group subjects and 39.3% of Penta group subjects.

  Redness was the most frequently reported Grade 3 solicited local symptom reported in 1.3-5.2% of subjects in the three groups.

- *Solicited general symptoms:* Irritability / Fussiness was the most frequently reported solicited general symptom in all the groups, reported in 56.2% of Hexa group subjects, in 62.7% of Pedia group subjects and in 50.3% of Penta group subjects.

  Irritability / Fussiness was also the most commonly reported grade 3 solicited general symptom reported for between 2.0 and 2.7% of subjects across groups.

- *Unsolicited adverse events:* At least one unsolicited symptom within the 31-day post-vaccination period after the booster vaccination was recorded for 22.2%, 22.2% and 25.5% of subjects in the Hexa, Pedia and Penta groups, respectively.

  The most commonly reported unsolicited symptoms were:
  Hexa group: Pyrexia (3.0%); Pedia group: Pyrexia, Otitis media and URTI (3.2%);
  Penta group: URTI (5.0%).

  A grade 3 unsolicited symptom was reported for 3.0%, 1.9% and 1.9% of subjects in Hexa, Pedia and Penta groups, respectively. No grade 3 unsolicited symptom was reported by more than one subject in any group.

- *Adverse events of interest:* NOCI were reported for 4 subjects (2.4%) in the Hexa group, 1 subject (0.6%) in the Pedia group and 1 subject (0.6%) in the Penta group. Only Seasonal allergy symptoms were reported by more than one subject in any group: 3 (1.8%) subjects.

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- *Large injection site reactions up to 4 days (D0-D3) after vaccination:* Two subjects (1.3%) in the Hexa group and one subject (0.7%) in the Pedia group had Local Swelling, and Diffuse Swelling was recorded in one subject (0.6%) in the Hexa group.
- *Serious adverse events within 31 days post booster:* Non-fatal SAEs within 31 days post-booster dose were reported for one (0.6%) subject in the Hexa group (Petechiae), for one (0.6%) subject in the Penta group (Seizure like phenomena), and no subject in the Pedia group. None of the two non-fatal SAEs were considered to be causally-related to vaccination and both were recorded to have an outcome of "recovered/resolved".
- *Withdrawals due to AEs /SAEs:* No subject was withdrawn due to an AE or SAE during the booster Epoch.
- ***SAEs for the full study***: There were no fatal SAEs throughout the study. SAEs were reported for 8 subjects in *the* Hexa group and Penta group, and for one subject in the Pedia group throughout the study.

Conclusion:

- The primary objective of the study was met: One month post-primary vaccination, *Infanrix hexa* was demonstrated to be non-inferior to *Pediarix+ACTHib* in terms of antibody GMCs for the three pertussis antigens (PT, FHA, and PRN).
- *One month after the primary vaccination:* The immune responses to *Infanrix hexa*, *Pediarix+ACTHib* and *Pentacel*/*Engerix-B* were similar between the different groups, in terms of seroprotection/seropositivity rates and GMCs.

  The lowest anti-PRP GMCs were observed after *Infanrix hexa* vaccination as compared to *Pediarix+ACTHib* and *Pentacel+Engerix-B*.
- *One month after the booster vaccination:* The immune responses to *Infanrix+Hiberix* (booster vaccines used after *Infanrix hexa* priming), *Infanrix+ActHIB* (booster vaccines used after *Pediarix+ActHIB* priming) and *Pentacel* were similar between the different groups, in terms of seroprotection/seropositivity rates and GMCs.

  Similar Anti-PRP long-term protection antibody levels were observed (≥1.0 µg/mL) between *Infanrix+Hiberix*, *Infanrix+ActHIB* and *Pentacel* after booster vaccination.
- *Safety, reactogenicity:* Clinically acceptable safety and reactogenicity profile in the different vaccination groups, aligned with the very well-known profiles of the study vaccines.

References: None.

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LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
ANCOVA	Analysis of Co-variance
ANOVA	Analysis of Variance
ATP	According-To-Protocol
CBER	Center for Biologics Evaluation and Research
$CCID_{50}$	median Cell Culture Infective Dose
CDC	Centers for Disease Control and Prevention (United States of America)
CEPL	Clinical and Epidemiology R&D Project Leader
CRDL	Clinical Research and Development Lead
CI	Confidence Interval
CLIA	ChemiLuminescence ImmunoAssay
CRO	Contract Reseach Organisation
CTSU	Clinical Trial Supply Unit
D	Diphtheria
DMEM	Dulbecco's Modified Eagle Medium
DTPa or DTaP	Combined diphtheria-tetanus-acellular pertussis vaccine
DTPa-HBV-IPV/Hib	Combined diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus and *Haemophilus influenzae* type b vaccine (*Infanrix hexa*).
eCRF	electronic Case Report Form
EL.U	ELISA unit(s)
ELISA	Enzyme-linked immunosorbent assay

ESFU	Extended safety follow-up
eTDF	electronic Temperature excursion Decision Form
FHA	Filamentous haemagglutinin
GCP	Good Clinical Practice
GMC	Geometric Mean Concentration
GMT	Geometric Mean Titer
GSK	GlaxoSmithKline
HBs	Hepatitis B surface antigen
HHE	Hypotonic Hyporesponsive Episode
Hib	*Haemophilus influenzae* (*H. influenzae*) type b
HRV	Human Rotavirus
IB	Investigators Brochure
ICF	Informed Consent Form
IM	Intramuscular
IND	Investigational New Drug
IRB	Institutional Review Board
IU	International unit(s)
LAR	Legally Acceptable Representative
MedDRA	Medical Dictionary for Regulatory Activities
NI	Non-inferiority
NOCI	New Onset of Chronic Illness; referred to as new-onset chronic diseases (NOCDs) in the protocol
Pa	Acellular *Bordetella pertussis* component
PI	Principal Investigator
Post-Bst	Post Booster
Post-Pri	Post Primary vaccination

Pre-Bst	Pre Booster
PRN	Pertactin
PRP	Polyribosyl-Ribitol-Phosphate: polysaccharide component of the Hib bacterium capsule
PT	Pertussis toxoid: a secreted exotoxin of the *Bordetella pertussis* bacterium
RCC	Reverse Cumulative Curve
pIMD	Potential Immune-Mediated Disease
SAE	Serious Adverse Event
SAS	Statistical Analysis Software
SBIR	Randomization System on Internet
SCID	Severe Combined Immunodeficiency Disease
SD	Standard Deviation
SDL	Study Delivery Lead
SM	Study Management
SMQ	Standardised MedDRA Queries
SOP	Standard Operating Procedures
SPC	Summary of Product Characteristics
T	Tetanus
TMF	Trial Master File (TMF)
TT	Tetanus Toxoid
TVC	Total Vaccinated cohort
US (USA)	United States (United States of America)
URTI	Upper Respiratory Tract Infection
WHO	World Health Organization

GLOSSARY OF TERMS

Adverse event:	Any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An adverse event (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 open-label study, no blind is used. Both the investigator and the subject know the identity of the treatment assigned.
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 legal guardian.
Eligible:	Qualified for enrolment into the study based upon strict adherence to inclusion/exclusion criteria.
Epoch:	An epoch is a self-contained set of consecutive timepoints or a single timepoint from a single protocol. Self-contained means that data collected for all subjects at all timepoints within that epoch allows to draw a complete conclusion to define or precise the targeted label of the product. Typical examples of epochs are primary vaccinations, boosters, yearly immunogenicity follow-ups, and surveillance periods for efficacy or safety.
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 (see Sections 5.6.2 and 5.10.4 for details on criteria for evaluability).
Immunological correlate of protection:	The defined humoral antibody response above which there is a high likelihood of protection in the absence of any host factors that might increase susceptibility to the infectious agent.
Intercurrent medical condition:	A condition that has the capability of altering a subject's immune response or are confirmed to have an immunodeficiency condition during the study.
Investigational vaccine/product: **(Synonym of Investigational Medicinal Product)**	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Primary completion date:	The date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.
Randomization:	Process of random attribution of treatment to subjects in order to reduce bias of selection.
Self-contained study:	Study with objectives not linked to the data of another study.
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:	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 contacted in order to participate or participates in the clinical study, either as a recipient of the vaccines or as a control.
Subject number:	A unique number identifying a subject, assigned to each subject consenting to participate in the study.

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.
Treatment number:	A number identifying a treatment to a subject, according to the study randomization or treatment allocation.
Unsolicited adverse event:	Any 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 will be written without the superscript symbol ™ or ® and in *italics*.

Trademarks of the GlaxoSmithKline group of companies	Generic description
Engerix-B	Hepatitis B vaccine (recombinant)
Hiberix	*Haemophilus influenzae* type b conjugate vaccine (tetanus toxoid conjugate)
Infanrix	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed
Infanrix hexa	Combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated polio vaccine and *Haemophilus influenzae* type b vaccine
Pediarix	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine
Rotarix	Rotavirus Vaccine, Live, Oral

Trademarks not owned by the GlaxoSmithKline group of companies	Generic description
ActHIB **(Sanofi Pasteur SA)**	*Haemophilus influenzae* type b conjugate vaccine (tetanus toxoid conjugate)
Pentacel **(Sanofi Pasteur SA)**	Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus influenzae* type b conjugate (tetanus toxoid conjugate)
Prevnar **(Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)**	Pneumococcal 7-valent conjugate vaccine (diphtheria CRM_{197} protein)
Prevnar13 **(Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)**	Pneumococcal 13-valent conjugate vaccine (diphtheria CRM_{197} protein)

1. ETHICS

1.1. Institutional Review Board (IRB)

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

1.3. Subject information and consent

Written informed consent was 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 study was conducted by multiple investigators across 43 centers in the United States (US). GSK Biologicals, King of Prussia, PA, US was responsible for administration of the study including clinical trial supply management and laboratory facilities.

Dr. Nicola Klein at the Kaiser Permanente Oakland, One Kaiser Plaza, Oakland, CA, USA was the principal investigator.

The following contract research organisations (CROs) were involved in this study:

Name of vendor	Address	Role
Q^2 Solutions	Global Headquarters 5827 South Miami Blvd Morrisville, NC 27560, USA	Sample management and Logistics
InVentiv Clinical Solutions	Corporate Headquarters 3201 Beechleaf Court Suite 600 Raleigh, NC 27604-1547, USA	Clinical Trial Administration, Study Management (SM), Contract support
Randstad North America	Randstad USA Corporate Office, 3625 Cumberland Blvd, Atlanta, Georgia 30339, USA	Clinical Trial Supply Unit (CTSU), and Cold Chain support
Bartech Group Inc	Corporate Headquarters The Bartech Group 27777 Franklin Road, Suite 600, Southfield, Michigan, USA 48034	Clinical Trial Supply Unit (CTSU), and Cold Chain support

Name of vendor	Address	Role
Novella Clinical Resourcing	USA Headquarters 1700 Perimeter Park Drive Morrisville, NC 27560, USA	Monitoring support
Quorum Review Inc	1501 Fourth Avenue Suite 800 Seattle, WA 98101, USA	Central Institutional Review Board (IRB)
Fisher Scientific	Headquarters Thermo Fisher Scientific 168 Third Avenue Waltham, MA, USA 02451	Non-vaccine supplies
Creative Edge Promotions	Email address: PPD	Non-vaccine supplies
McVeigh Associates	275 Dixon Ave Amityville, NY 11701, USA	Investigator Meeting Planners
United Parcel Service	UPS World Headquarters 55 Glenlake Parkway NE Atlanta, GA 30328, USA	Courier
Federal Express	FedEx, 7900 Legacy Drive Plano, TX 75024, USA	Courier
Henry Schein, Inc	Corporate Headquarters 135 Duryea Road Melville, NY 11747, USA	Vaccines purchased locally (Pentacel, ActHib)
Sanofi Pasteur Inc	U.S. Headquarters Discovery Drive Swiftwater, PA 18370, USA	Vaccine purchased locally (Pentacel)
Pfizer Inc	235 East 42nd Street NY, NY 10017, USA	Vaccines purchased locally (ActHib, Prevnar 13)
Tata Consultancy Services	Gopalan Global Axis Campus, Gopalan Enterprises, 152, EPIP Industrial Area, White Field, K R Puram Hobli, Bangalore, 560066, India	Data Management
Synteract, Inc.	Global Headquarters: 5909 Sea Otter Place Suite 100 Carlsbad, CA 92010, USA	Study Delivery Management (Study Delivery Lead (SDL)) Trial Master File (TMF) Management (TMF Specialist)
Syneos Health TM	Corporate Headquarters 3201 Beechleaf Court Suite 600 Raleigh, NC 27604-1547, USA	Study Delivery Management (Study Delivery Associate)

3. INTRODUCTION

Combination vaccines have been developed to provide multiple immunizations in a single injection. They can simplify vaccine administration and have the potential to promote compliance and cost-effectiveness by decreasing the number of injections needed to immunize a child [Zinke, 2010; Kalies, 2006]. Use of combination vaccines can alleviate concerns associated with the number of injections to be given at one time [ACIP, 2011].

GlaxoSmithKline (GSK) Biologicals' *Infanrix hexa* vaccine helps prevent six diseases in a single injection. *Infanrix hexa* is licensed for primary and booster vaccination in more than 98 countries around the globe, including the entire European Union. The vaccine complies with the World Health Organization (WHO) requirements for manufacture of biological substances for all of its antigenic components. The *Infanrix hexa* vaccine consists of a combination of GSK's *Pediarix* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined); STN 103907, approved in the US on December 13, 2002 and a *Haemophilus influenzae* (*H. influenzae*) type B (Hib) vaccine consisting of purified polyribosyl-ribitol-phosphate (PRP) capsular polysaccharide of *Haemophilus influenzae* type b covalently bound to tetanus toxoid (TT). The conjugated Hib-TT is the same as that used for the formulation of *Hiberix* [*Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate)] (licensed in the US as a booster dose in August 2009, and as a primary dose in January 2016), with the only difference that in *Infanrix hexa*, the Hib-conjugate is adsorbed onto aluminium phosphate.

The *Infanrix hexa* combination vaccine would provide an additional source of DTaP (combined diphtheria-tetanus-acellular pertussis vaccine), hepatitis B, poliovirus, and Hib containing vaccines for the US market and would potentially reduce the number of injections required to provide infants with recommended vaccinations.

GSK has an extensive clinical safety database for *Infanrix hexa*. The safety and immunogenicity data of the vaccine have been evaluated in numerous controlled studies [Dhillon, 2010; Zepp, 2009], of which 4 were conducted in the US with approximately 3000 US subjects exposed to a primary vaccination with *Infanrix hexa*.

3.1. Rationale for the study

Infanrix hexa was licensed in the European Union in 2000. More than 150 million doses have been distributed to date and the benefit/risk profile remains favorable. Licensure of *Infanrix hexa* combination vaccine in the US was to provide an additional option for vaccination within the routine US pediatric schedule with the fewest number of injections, which would create opportunities to add further injections in case other novel vaccines against important pediatric diseases become available. Furthermore, *Infanrix hexa* was to provide an additional source of DTaP, hepatitis B, poliovirus, and Hib-containing vaccine to the US market, which would help ensure a more stable supply.

The present study 117119 (DTPA-HBV-IPV-135) was intended to generate pivotal immunogenicity data demonstrating non-inferiority of the immune responses against pertussis antigens of *Infanrix hexa* compared to *Pediarix*, which is currently one of the DTaP combination vaccines widely used as a standard of care in the US. Additionally, this study was to also provide descriptive data with regard to the immunogenicity of the other vaccine antigens and the safety profile in US subjects. These pivotal immunogenicity non-inferiority data for pertussis and descriptive safety data were intended to support the registration of GSK Biologicals' combined DTPa-HBV-IPV/Hib (*Infanrix hexa*) vaccine in the US. A subsequent Phase III study was planned to provide pivotal data regarding lot-to-lot consistency, safety and the immunogenicity of the other vaccine antigens.

Comparison of immunogenicity data from separate clinical studies for *Infanrix hexa* and *Pentacel*, given on a 2-4-6 month schedule, suggests that the immune response to the Hib component of these vaccines is similar. This study was to provide descriptive information regarding the immune response to the Hib components of *Infanrix hexa* and *Pentacel* following a 3-dose primary series, prior to further evaluation in Phase III studies.

4. STUDY OBJECTIVES

4.1. Primary objective

4.1.1. Epoch 001 (Primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens was to be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] was ≤ 1.5.

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

4.2. Secondary objectives

4.2.1. Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D (Diphtheria), T (Tetanus), HBs (Hepatitis B surface antigen), pertussis, poliovirus types 1, 2 and 3 and PRP (Polyribosyl-Ribitol-Phosphate) antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa*, of *Pentacel* co-administered with *Engerix-B*, and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic illnesses (NOCIs; referred to as new-onset chronic diseases (NOCDs) in the protocol) and serious adverse events (SAEs).

4.2.2. Epoch 002 (Booster vaccination)

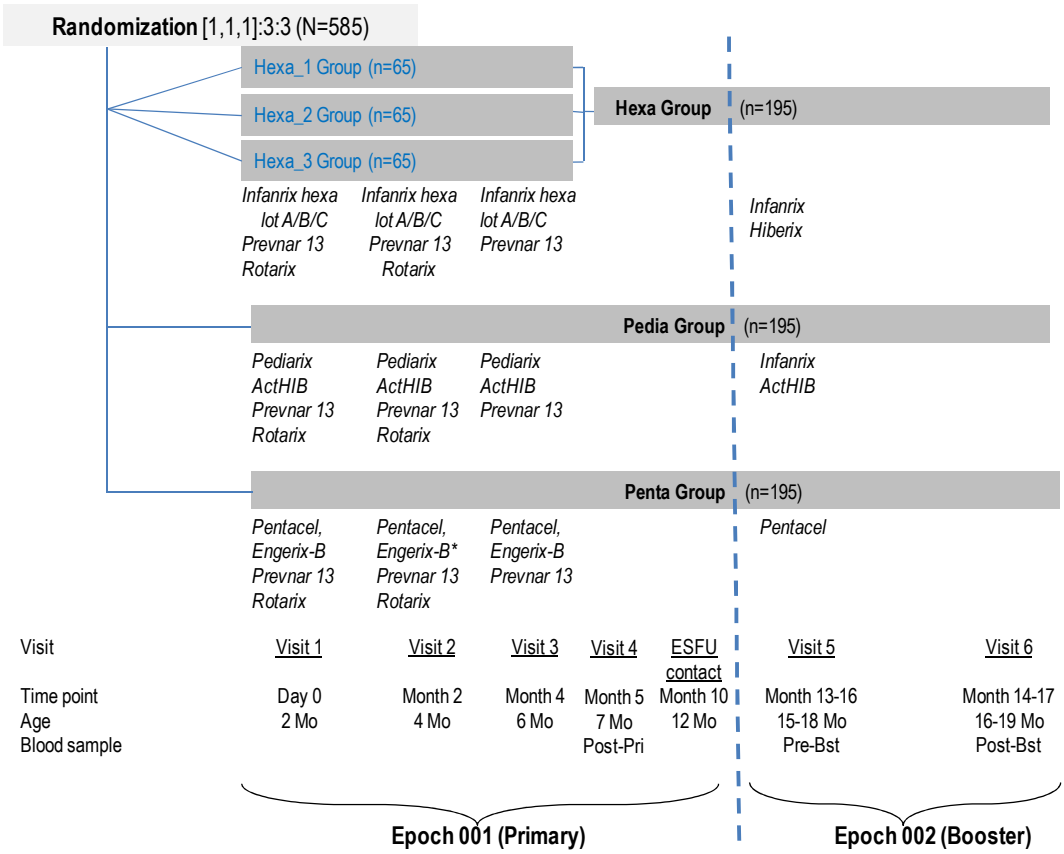
- To assess the immunogenicity of *Infanrix hexa*, *Pentacel*, *Engerix-B*, *Pediarix* and *ActHIB*, in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.
- To assess the immune response to *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*, in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix* and *Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix, Hiberix, ActHIB* and *Pentacel*.

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

5. INVESTIGATIONAL PLAN

5.1. Study design

5.1.1. Overview



N = number of subjects in the study; n = number of subjects in each group; Mo = months
Visit 3 should be conducted at least 8 weeks after Visit 2, with subjects at least 24 weeks of age, in order to comply with US recommendations on hepatitis B dosing
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002
* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group
ESFU = Extended safety follow-up

5.1.2. Overall study design – Description

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups.
- Duration of the study: The intended duration of the study per subject was approximately 14-17 months.
  - **Epoch 001**: Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10);
  - **Epoch 002**: Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).
- Study groups: The study groups and epochs foreseen in the study are presented in Table 1.

Table 1 Study groups and epochs foreseen in the study

Study groups	Number of subjects	Age (Min/Max) at Visit 1	Epochs	
			Epoch 001	Epoch 002
Hexa_1	65	6 weeks -12 weeks	x	x
Hexa_2	65	6 weeks -12 weeks	x	x
Hexa_3	65	6 weeks -12 weeks	x	x
Pedia	195	6 weeks -12 weeks	x	x
Penta	195	6 weeks -12 weeks	x	x

The study groups and treatment foreseen in the study are presented in Table 2.

Table 2 Study groups and treatment foreseen in the study

Treatment name	Vaccine/Product name	Study Groups				
		Hexa_1	Hexa_2	Hexa_3	Pedia	Penta
Epoch 001						
Infanrix hexa		x	x	x		
	Hib					
Pediarix					x	
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					
Engerix-B*	HBV					x
Prevnar13	Prevenar 13	x	x	x	x	x
Rotarix	HRV	x	x	x	x	x
	$CaCO_3$					
Epoch 002						
Infanrix	DTPa	x	x	x	x	
Hiberix	Hib	x	x	x		
	NaCl					
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					

* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group.

- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*;
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*.

  Vaccination schedules:

  Epoch 001

  - **Hexa Group**: Subjects in this group were to receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
    - Hexa_1 Group: Subjects were to receive lot A of *Infanrix hexa*;
    - Hexa_2 Group: Subjects were to receive lot B of *Infanrix hexa;*
    - Hexa_3 Group: Subjects were to receive lot C of *Infanrix hexa*.
  - **Pedia Group:** Subjects in this group were to receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - **Penta Group:** Subjects in this group were to receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

  *Subjects in the Penta Group who received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination were not to receive *Engerix-B* at 4 months of age (Visit 2).

  Epoch 002

  - **Hexa Group:** Subjects were to receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
  - **Pedia Group:** Subjects were to receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
  - **Penta Group:** Subjects were to receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

  The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls were given in this study at 15-18 months of age, the fourth dose of *Prevnar13* was not to be administered as part of the study protocol. Subject's parent(s)/LARs were to be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

- As the analyses were to be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups were pooled together for the analysis and were called the Hexa group.
- Treatment allocation: The subjects were randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This was done at study entry using GSK Biologicals' central randomization system on internet (SBIR).

- Blinding: The study was open-label for both epochs (Table 3) due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology 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 subject) to each sample.

The blinding of study epochs is presented in Table 3.

Table 3 Blinding of study epochs

Study Epochs	Blinding
Epoch 001	open
Epoch 002	open

- Sampling schedule: Blood samples were drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) was collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) was collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) was collected.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

5.1.3. Discussion of study design

5.1.3.1. Design of Epoch 001 (primary vaccination):

The study was designed as a randomized, controlled, open-label study with five parallel groups:

- The first three groups (Hexa_1, Hexa_2 and Hexa_3 group) were to receive three doses of the *Infanrix hexa* vaccine (either lot A, lot B or lot C, respectively). These three groups were pooled together for the analyses and the pooled group was called the Hexa group.
- The Pedia Group (Control 1) was to receive three doses of the US-licensed control vaccines, *Pediarix* and *ActHIB*.
- The Penta Group (Control 2) was to receive three doses of the US-licensed control vaccines, *Pentacel* and *Engerix-B* (only two doses of *Engerix-B* were to be administered if a subject had received a birth dose of hepatitis B vaccine).

Three distinct vaccine lots manufactured according to the same procedures were used in the Hexa group in order to obtain more representative data for the vaccine.

The study was open-label due to the differences in the number of injections and the appearance of the vaccines administered.

Vaccines (i.e., *Prevnar13* and *Rotarix*) that were recommended for children in the US during the first year of life were administered concomitantly with the other study vaccines as part of the study.

5.1.3.2. Design of Epoch 002 (booster vaccination):

In Epoch 002, the subjects were assessed for antibody persistence to the vaccine antigens of *Infanrix hexa*. This epoch was also to assess the adequacy of priming subjects with *Infanrix hexa* by evaluating the boostability of D, T, Pa (Acellular *Bordetella pertussis* component) and Hib antigens with the US-licensed vaccines. The pooled Hexa Group was to receive booster doses of *Infanrix* and *Hiberix* vaccines at 15 through 18 months of age, the subjects in the Penta Group were to receive *Pentacel* vaccine as a booster, and the subjects in the Pedia Group were to receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15 through 18 months of age.

The study was to continue to be open-label in Epoch 002.

5.2. Study procedures

Table 4 List of study procedures

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Informed consent	●						
Check inclusion/exclusion criteria	●						
Medical history	●						
Collect demography data	●						
Vaccination history including HepB vaccination history	●						
Informed consent for Tdap vaccination history of mother[α]	●						
Last Tdap vaccination history of mother[β]	●						
History directed physical examination including length and weight	●					●	
Study group and treatment number allocation (Randomization)	O						
Treatment number allocation for subsequent doses		O	O			O	
Recording of administered treatment number	●	●	●			●	
Pre-vaccination body temperature	●	●	●			●	
Blood sampling				●		●	●
Check warnings and precautions	O	O	O			O	
Check contraindications to subsequent vaccination		●	●			●	
Pre-vaccination measurement of circumference of limb(s) at site of injection by investigator[δ]						●	
Vaccination	●	● **	●			●	
Distribution of thermometer	O						
Distribution of measuring device	O					O	
Distribution of diary cards	O	O	O			O	

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Daily post-vaccination recording of solicited adverse events during the 4-day (Day 0–3) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of non-serious (unsolicited) adverse events during the 31-day (Day 0–30) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of any large injection site reactions in the eCRF by the investigator*						●	
Return of diary cards and transcription by the investigator		●	●	●			●
Record any concomitant medication and vaccination §	●	●	●	●	●	●	●
Record any intercurrent medical conditions‖		●	●	●	●	●	●
Recording of serious adverse events including related to study participation or to a concurrent GSK medication/vaccine	●	●	●	●	●	●	●
Recording of NOCIs‡	●	●	●	●	●	●	●
Investigator sign-off				●			●
Analysis of the Epoch 001 #				O			
Analysis of the Epoch 002 #							O
Study Conclusion							●

Note: The double-line border indicated the analyses which were performed on all data obtained up to that visit or contact.

● was used to indicate a study procedure that required documentation in the individual eCRF

○ was used to indicate a study procedure that did not require documentation in the individual eCRF

Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001

Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002

Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

† Visit 3 was to be conducted at least 8 weeks after Visit 2 and when the subject was at least 24 weeks of age

$^{\alpha}$ The child could still continue in the study even if the mother did not wish to provide consent to record her Tdap vaccination history.

$^{\beta}$ Only the Tdap vaccination history (during the pregnancy of the enrolled child) from mothers who had given consent to provide this information, was obtained and recorded in the eCRF.

[δ] For the Penta group, which received only one vaccine at Visit 5, baseline measurement of only the limb receiving the vaccine was required
** If subject in the Penta Group received a birth dose of Hep B vaccine, no administration of *Engerix-B* was foreseen at Visit 2 (4-months of age)
* Refer to Section 5.9.2.1 and the study protocol (Section on Baseline measurement of limb circumference after booster vaccination at Visit 5) for detailed explanation on the reporting of large injection site reactions
§ Refer to Section 5.6 for details
‖ Refer to Section 5.7 for details
‡ New onset of chronic illness (NOCI) included events such as autoimmune disorders, asthma, type I diabetes and allergies
# Refer to Section 5.10.8 for details

It was the investigator's responsibility to ensure that intervals between visits were strictly followed. The intervals between study visits are presented in Table 5.

Table 5 Intervals between study visits

Interval	Optimal length of interval[1]
Birth→Visit 1	6-12 weeks (42-90 days) of age[2]
Visit 1 →Visit 2	49-83 days[2]
Visit 2 →Visit 3 *	56-90 days[2]
Visit 3 → Visit 4	30-48 days[2] †
Visit 3 → Phone call (ESFU contact)	180-210 days**
Birth→ Visit 5^	15-18 months of age[2]
Visit 5 → Visit 6	30-48 days[2] †

[1] Whenever possible the investigator was to arrange within this interval;
[2] Subjects were not to be eligible for inclusion in one or more cohorts for analysis if they made the study visit outside this interval. For Visit 3-Visit 4 and Visit 5-Visit 6, an interval of 21-48 days was considered for the According-to-protocol (ATP) cohort of immunogenicity. Refer to Section 5.10.4 for the definition of the cohorts for analysis;
* Advisory Committee on Immunization Practices (ACIP) recommendation stated that minimum age of last Hep B dose was 24 weeks and this last dose was to be administered at least 8 weeks after the previous dose. So, Visit 3 was to be conducted at least 8 weeks after Visit 2 and when the subject was at least 24 weeks of age
† It was preferred that subjects came in for Visit 4 and Visit 6, at least 30 days after Visits 3 and 5, respectively. If subjects returned for the visit prior to 30 days, they were to take home the diary card and continue to record unsolicited safety information until 30 days post-vaccination and mail/send it upon completion. Investigators were to make an attempt to retrieve diary cards from subjects who had not mailed/sent them in.
^ Visit 5 was to occur after the ESFU. ESFU was to occur prior to vaccination if Visit 5 coincided with the 6 months post-Visit 3 time-point.
** Adherence to the interval pertaining to phone contact was only indicative and was not to determine a subject's eligibility for inclusion for ATP analysis. However, the interval was to be respected in order to obtain safety information over the complete 6 months extended safety follow up period.

5.3. Selection of study population

5.3.1. Number of subjects/centers

Target enrolment was 585 subjects (65 each in Hexa_1, Hexa_2, Hexa_3 groups and 195 each in Pedia and Penta groups). Enrolment was to be terminated when the target number of subjects had been enrolled. Refer to Section 5.10.3 for a detailed description of the criteria used in the estimation of sample size.

This study was conducted at multiple centers (43 centers) in the US.

Actual numbers of subjects enrolled versus target was monitored by the site monitor using SBIR.

5.3.2. Inclusion criteria for enrolment

Deviations from inclusion criteria were not allowed because they could potentially jeopardize the scientific integrity of the study, regulatory acceptability or subject safety. Therefore, adherence to the criteria as specified in the protocol was essential.

All subjects were to satisfy ALL the following criteria at study entry:

- Subjects' parent(s)/ LAR(s) 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).
- A male or female between, and including, 6 and 12 weeks of age at the time of the first vaccination.
- Born full-term (i.e. after a gestation period of 37 weeks to less than 42 completed weeks [259 to 293 days]).
- Written informed consent obtained from parent(s)/LAR(s) of the subject.
- Healthy subjects as established by medical history and clinical examination before entering into the study.
- Infants who had not received a previous dose of hepatitis B vaccine or those who had received only 1 dose of hepatitis B vaccine administered at least 30 days prior to enrolment.

5.3.3. Exclusion criteria

Deviations from exclusion criteria were not allowed because they could potentially jeopardize the scientific integrity of the study, regulatory acceptability or subject safety. Therefore, adherence to the criteria as specified in the protocol was essential.

The following criteria were to be checked at the time of study entry. If ANY exclusion criterion applied, the subject must not be included in the study:

- Child in care

  Please 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 vaccines within 30 days preceding the first dose of study vaccines, or planned use during the study period.
- Chronic administration (defined as more than 14 days in total) of immunosuppressants or other immune-modifying drugs since birth. For corticosteroids, this meant prednisone ≥ 0.5 mg/kg/day, or equivalent. Inhaled and topical steroids were allowed.

- Planned administration/administration of a vaccine not foreseen by the study protocol within the period starting from 30 days before the first vaccination until 30 days after Dose 3 (Epoch 001, primary vaccination) and from 30 days before the booster Dose 4 until 30 days after booster Dose 4 (Epoch 002, booster vaccination), i.e. the end of the study:
  - Inactivated influenza and hepatitis A vaccines were allowed throughout the study.
  - Routine administration(s) of vaccines were allowed from 30 days after the last dose of primary vaccination until 30 days before the booster dose and after post-booster blood sampling. Routine administration of measles-mumps-rubella vaccine, varicella, pneumococcal vaccines were allowed from 30 days after last dose of primary vaccine until 30 days before booster dose and from post-booster blood sampling, as well as according to the recommended immunization schedule in US.
- Concurrently participating in another clinical study, at any time during the study period, in which the subject had been or was to be exposed to an investigational or a non-investigational product (pharmaceutical product or device).
- History of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and hepatitis B diseases.
- Previous vaccination against Hib, diphtheria, tetanus, pertussis, pneumococcus, rotavirus and/or poliovirus; more than one previous dose of hepatitis B vaccine.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
- Family history of congenital or hereditary immunodeficiency.
- History of any reaction or hypersensitivity likely to be exacerbated by any component of the vaccines (including yeast).
- Hypersensitivity to latex.
- Major congenital defects or serious chronic illness.
- History of any neurological disorders including seizures.
- Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period.
- History of intussusception or of any uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception.
- History of Severe Combined Immunodeficiency Disease (SCID).
- Acute disease and/or fever at the time of enrolment.
  - Fever was defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study was rectal for Epoch 001 and axillary for Epoch 002.
  - Subjects with a minor illness (such as mild diarrhea, mild upper respiratory infection) without **fever** could be enrolled at the discretion of the investigator.

5.3.4. Withdrawal criteria

5.3.4.1. Subject completion

Any subject who returned for the concluding visit / was available for the concluding contact foreseen in the protocol, was considered to have completed the study.

5.3.4.2. Subject withdrawal

Withdrawals were not to be replaced.

5.3.4.2.1. Subject withdrawal from the study

From an analysis perspective, a 'withdrawal' from the study referred to any subject who did not come back for the concluding visit/was not available for the concluding contact foreseen in the protocol.

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

A subject 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/last contact.

Investigators were to make an attempt to contact those subjects who did not return for scheduled visits or follow-up.

Information relative to the withdrawal was 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)

*In case a subject was withdrawn from the study because the subject's parent(s) had withdrawn consent, the investigator was to document the reason for withdrawal of consent, if specified by the parents/ LARs, in the eCRF.

Subjects who were withdrawn from the study because of SAEs/AEs were to be clearly distinguished from subjects who were withdrawn for other reasons. Investigators were to follow subjects who were withdrawn from the study as result of a SAE/AE until resolution of the event (see Section 5.9.8.2).

5.3.4.2.2. Subject withdrawal from investigational vaccine

A 'withdrawal' from the investigational vaccine referred to any subject who did not receive the complete treatment, i.e. when no further planned dose was administered from the date of withdrawal. A subject withdrawn from the investigational vaccine could not necessarily be withdrawn from the study as further study procedures or follow-up could be performed (safety or immunogenicity) if planned in the study protocol.

Information relative to premature discontinuation of the investigational vaccine was to be documented on the Vaccine Administration screen of the eCRF. The investigator was to document whether the decision to discontinue further vaccination/treatment 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.
- Other (specify).

5.4. Composition and administration of vaccine(s)

5.4.1. Description of vaccines

All candidate vaccines that were used were developed and manufactured by GSK Biologicals, except for the following four marketed vaccines with name of manufacturer provided in brackets: *ActHIB* (Sanofi Pasteur SA), *Pentacel* (Sanofi Pasteur SA), *Prevnar* (Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.), and *Prevnar13* (Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.).

The Quality Control Standards and Requirements for each candidate vaccine were described in separate Quality Assurance documents (e.g. release protocols, certificate of analysis) and the required approvals were obtained.

The vaccines were labelled and packed according to applicable regulatory requirements.

Commercial vaccines were assumed to comply with the specifications given in the manufacturer's Summary of Product Characteristics (SPC).

Table 6 Study vaccines

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix hexa Lot A: AC21VB448C and AHIBC950C; Lot B: AC21B514A and AHIBC907D; Lot C: AC21B510B and AHIBC954A.	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+	The DTPa-HBV-IPV component was presented as a turbid white suspension in a pre-filled syringe.	full volume^	3
	Hib	PRP=10µg; TT~=25µg Aluminum as salts = 0.12 mg	The lyophilized Hib component was presented as a white pellet in a glass vial; it was reconstituted before use with the DTPa-HBV-IPV component.		
Pediarix Lot no.: AC21VB448C	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+	The DTPa-HBV-IPV component was presented as a turbid white suspension in a pre-filled syringe.	0.5 mL	3
ActHIB Lot no.: DLOCA106AZ (Alternative Lot no. UH971AA), DLOCA150AZ (Alternative Lot no. UI117AA; only for Epoch 2). Lot no.: DLOCA106AY (Alternative Lot no. UH954AB), DLOCA150AY (Alternative Lot no. UI128AA; only for Epoch 2).	ActHIB	Hib=10µg TT, TT=24µg	White lyophilized pellet in a single dose vial, it was reconstituted before use with sterile 0.4% saline solution	0.5 mL*	4
	NaCl	NaCl=60mM	Sterile 0.4% saline solution		

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Pentacel First Lot: Lot no. DLOCA102AY (Alternative Lot no. C4507AA) Lot no.: DLOCA102AZ (Alternative Lot no. C4557AA) Second Lot: Lot no. DLOCA108AY (Alternative Lot no. C4517BA) Lot no.: DLOCA108AZ (Alternative Lot no. C4574AA) Third Lot Lot no. DLOCA144AY (Alternative Lot. No. C4724AA) DLOCA144AZ (Alternative Lot. No.C4642AA)	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial. The lyophilized Hib component was presented as a white pellet in a separate glass vial. It was reconstituted with the liquid DTaP-IPV component before use.	0.5 mL*	4
	Hib	PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+			
Engerix-B Lot no.: AHBVC253A	HBV	HBsAg=10µg; $Al(OH)_3$=250µg Al3+	Suspension pre-filled syringe	0.5 mL	2 or 3**
Infanrix Lot no.: AC14B195A	DTPa	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; $AlPO_4$=500µg Al3+	Homogeneous, turbid, white suspension in a pre-filled syringe	0.5 mL	1
Hiberix Lot no.: AHIBC875A Lot no.: DEXTA517AZ	Hib	PRP=10µg; TT~=25µg	The lyophilized Hib component was presented as a white pellet in a glass vial; it was reconstituted before use with sterile 0.9% saline solution.	0.5 mL*	1
	NaCl	NaCl=150mM	Sterile 0.9% saline solution		

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Prevnar13 Lot no.: DLOCA107A (Alternative Lot no. H39264)	Prevenar 13	PS1=2.2µg CRM197; PS3=2.2µg CRM197; PS4=2.2µg CRM197; PS5=2.2µg CRM197; PS6A=2.2µg CRM197; PS6B=4.4µg CRM197; PS7F=2.2µg CRM197; PS9V=2.2µg CRM197; PS14=2.2µg CRM197; PS18C=2.2µg CRM197; PS19A=2.2µg CRM197; PS19F=2.2µg CRM197; PS23F=2.2µg CRM197; $AlPO_4$=125µg Al3+	Suspension for injection in a pre-filled syringe.	0.5 mL	3
Rotarix Lot no.: AROTVA291D Lot no. AD05VA833A	HRV	HRV RIX4414=$10^{6.0}$ $CCID_{50}$	Lyophilized vaccine in a monodose glass vial was reconstituted with the calcium carbonate buffer diluent	1.0 mL*	2
	$CaCO_3$	$CaCO_3$=60µg	Diluent (calcium carbonate liquid buffer) supplied separately in prefilled syringe		

$CCID_{50}$ = median Cell Culture Infective Dose; DMEM = Dulbecco's Modified Eagle Medium
* After reconstitution
** Subjects in the Penta Group who received a birth dose of hepatitis B vaccine were not to receive *Engerix-B* at the Month 4 visit (Visit 2)
^ Full volume after reconstitution (0.5 mL) to be administered

5.4.2. Dosage and administration of study vaccines

The injectable vaccines must be administered intramuscularly, at a 90-degree angle into the anterolateral side of the thigh [Centers for Disease Control and Prevention (CDC), 2002] on the side stated in Table 7. The buttock was not to be used.

In order to ensure proper intramuscular injection of the vaccines, a needle of at least 1 inch (2.54 cm) length, 25 gauge was used [Diggle, 2006; Zuckerman, 2000].

For reconstitution of *Infanrix hexa* vaccine, an appropriate needle was attached to the prefilled syringe containing the DTPa-HBV-IPV liquid vaccine and inserted into the vial containing the lyophilized Hib vaccine. The entire contents of the syringe were to be transferred to the vial. With needle still inserted, the vial was to be vigorously shaken. After reconstitution, the full volume of the vial (0.5 mL) was then withdrawn using the same syringe. A new needle was then to be affixed to the syringe for administration of the vaccine.

NOTE: After reconstitution, *Infanrix hexa* was to be injected immediately. However the vaccine might have been kept for up to 8 hours at room temperature (21°C).

The vaccinees were 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.

Rotarix must be exclusively administered orally. DO NOT INJECT.

The contraindications and warnings/precautions to vaccination were specified in the protocol (see protocol for details).

Table 7 Dosage and administration

Visit	Study Group	Treatment name	Route [1]	Site [2]	Side [3]
Epoch 001					
1, 2, 3	Hexa Group	*Infanrix hexa* (lot A, lot B or lot C)	IM	T	R
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
1, 2, 3	Pedia Group	*Pediarix*	IM	T	R
1, 2, 3		*ActHIB*	IM	T	UpL
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
1, 2, 3	Penta Group	*Pentacel*	IM	T	R
1, 2, 3		*Engerix-B*†	IM	T	UpL
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
Epoch 002*					
5	Hexa Group	*Infanrix*	IM	T	R
		Hiberix	IM	T	L
5	Pedia Group	*Infanrix*	IM	T	R
		ActHIB	IM	T	L
5	Penta Group	*Pentacel*	IM	T	R

[1]Oral (O), Intramuscular (IM); [2]Thigh (T), [3]Left (L), Right (R), Upper Left (UpL), Lower Left (LoL)
Note: Vaccination could be performed in the opposite side in case of medical indication preventing vaccination in the side stated in the table, as judged by the investigator
†Subjects in the Penta Group who received a birth dose of hepatitis B vaccine were not to receive *Engerix-B* at the Month 4 visit (Visit 2).
* Toddlers (12 Months through 2 Years): For toddlers, the vastus lateralis muscle in the anterolateral thigh was preferred. The needle was at least 1-inch long. The deltoid muscle could be used if the muscle mass was adequate.

5.4.3. Treatment allocation and randomisation

5.4.3.1. Subject identification

After checking the inclusion/exclusion criteria, subject numbers were assigned sequentially to subjects whose parent(s)/LAR(s) gave consent for their child to participate in the study, according to the range of subject numbers allocated to each study center. Subject numbers were also to be used to identify blood samples collected during the study.

5.4.3.2. Randomization of treatment

5.4.3.2.1. Randomization of supplies

The numbering of supplies was performed at GSK Biologicals, using MATerial EXcellence (MATEX), a program developed for use in Statistical Analysis System (SAS®) (Cary, NC, USA) by GSK Biologicals.

To allow GSK Biologicals to take advantage of greater rates of recruitment than anticipated at individual centers in this multi-center study and to thus reduce the overall study recruitment period, an over-randomization of supplies was prepared.

Epoch 001

A first list based on a randomization blocking scheme using a [1:1:1]:3:3 randomization ratio was used to number the following vaccines for Doses 1, 2 and 3.

- DTPa-HBV-IPV/Hib lot A
- DTPa-HBV-IPV/Hib lot B
- DTPa-HBV-IPV/Hib lot C
- *Pediarix*
- *Pentacel*

The vaccines from this list were distributed to the study center while respecting the randomization block size.

ActHIB, *Engerix-B*, *Prevnar13* and *Rotarix* were numbered independently using a sequential numbering.

Epoch 002

Four sequential lists (one for *Infanrix*, one for *Hiberix*, one for *ActHIB* and one for *Pentacel*) were used to number the vaccine doses for the Epoch 002.

The study staff members in charge of the vaccine administration were to access SBIR, provide the subject identification number and the dose number. The system was to provide a new treatment number for all the vaccines to be administered to a subject (*Pentacel*, *Infanrix* + *ActHIB* or *Infanrix* + *Hiberix*). This was consistent with the allocated study group.

5.4.3.2.2. Treatment allocation to the subject

The treatment numbers were allocated by dose.

Study group and treatment number allocation

The target was to enroll 585 subjects to be randomly assigned to five study groups in a [1:1:1]:3:3 ratio (195 subjects in the pooled lots group).

Allocation of each subject to a study group at the investigator site was performed using SBIR. The randomization algorithm was to use a minimization procedure accounting for the study as a whole and for each of the centers with equal weight.

After obtaining the signed and dated Informed Consent Form (ICF) from the subject's parent(s)/LAR(s) and having checked the eligibility of the subject, the site staff member in charge of the vaccine administration was to access SBIR. Upon providing the subject identification number, the randomization system was to ask whether the subject had a previous hepatitis B vaccination and was to use the minimization algorithm to determine the group allocation and the appropriate treatment number for *Pentacel*, *Pediarix* or for *Infanrix hexa* (lot A, lot B or lot C) to be used for the subject.

SBIR was to also provide treatment numbers for co-administered vaccines *Engerix B*, *ActHib*, *Prevnar13* vaccine and a *Rotarix* vaccine, each one labelled with a different treatment number. Therefore a subject was to have three or four different treatment numbers allocated at dose 1.

The number of each administered treatment had to be recorded in the eCRF on the Vaccine Administration screen.

When SBIR was not available, study staff members were referred to the SBIR user guide or the SPM for specific instructions.

Treatment number allocation for subsequent doses

For each dose subsequent to the first dose, the study staff member in charge of the vaccine administration was to access SBIR, provide the subject identification number, the dose number and the system was to provide new treatment numbers consistent with the allocated study group.

Each vaccine was to be labelled with a different treatment number.

The number of each administered treatment must be recorded in the eCRF on the Vaccine Administration screen.

Note that in the Penta Group, the investigator was to be reminded that *Engerix-B* was not allowed at dose 2, for subjects with previous hepatitis B vaccination. So for these subjects, the treatment identified by SBIR for dose 2 was not to be used.

5.5. Blinding

The study was open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing was to be blinded to the treatment, and codes were used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

5.6. Prior and concomitant medication /vaccinations

At each study visit/contact, the investigator was to question the subject's parent(s)/LAR(s) about any medication/product taken and vaccination received by the subject.

5.6.1. Recording of concomitant medications/products and concomitant vaccination

The following concomitant medications/products/vaccines must be recorded in the eCRF if administered during the indicated recording period:

- All concomitant medications/products, except vitamins and dietary supplements, administered within 30 days following each dose of study vaccine.
- Any concomitant vaccination administered since birth and ending 30 days after the booster dose (Visit 6). Vaccinations listed prior to the first dose of study vaccine were to be recorded as vaccination history. The fourth dose of *Prevnar13* was to be recorded as concomitant vaccination.
- Prophylactic medication (i.e. medication administered in the absence of ANY symptom and in anticipation of a reaction to the vaccination).

  E.g. an anti-pyretic was considered to be prophylactic when it was given in the absence of fever and any other symptom, to prevent fever from occurring [fever was defined as temperature ≥ 38.0°C/100.4°F by any route].
- Any concomitant medications/products/vaccines listed in Section 5.6.2.
- Any concomitant medication/product/vaccine relevant to a SAE* or administered at any time during the study period for the treatment of a SAE*.

  * Refer to those SAEs that are required to be reported per protocol.

5.6.2. Concomitant medications/products/vaccines that may lead to the elimination of a subject from ATP analyses

The use of the following concomitant medications/products/vaccines was not to require withdrawal of the subject from the study but may determine a subject's evaluability in the ATP analysis. See Section 5.10.4 for study cohorts/ data sets to be analysed.

- Any investigational or non-registered product (drug or vaccine) other than the study vaccines used during the study period (starting from Visit 1 and ending at Visit 6).
- Immunosuppressants or other immune-modifying drugs administered chronically (i.e. more than 14 days) during the study period until the final blood sample (Visit 6). For corticosteroids, this meant prednisone ≥ 0.5 mg/kg/day, or equivalent. Inhaled and topical steroids were allowed.
- A vaccine not foreseen by the study protocol administered during the period starting from 30 days before the first vaccination until Post-Pri blood sampling i.e. approximately 30 days after Dose 3 (Epoch 001) and from 30 days before Pre-Bst until Post-Bst blood sampling i.e. approximately 30 days after Dose 4 (Epoch 002). Thus, routine administration(s) of measles-mumps-rubella, varicella and pneumococcal vaccines were allowed from 30 days after the last dose of primary vaccination (after Post-Pri blood sampling) until 30 days before the booster dose and from 30 days after the booster dose (after Post-Bst blood sampling), as well as according to the recommended immunization schedule in the US.
- Exceptions:
  - Inactivated influenza vaccine and hepatitis A vaccines were allowed throughout the study.

    In case an emergency mass vaccination for an unforeseen public health threat (e.g.: a pandemic) was organized by the public health authorities, outside the routine immunization program, the time period described above could be reduced if necessary for that vaccine provided it is licensed and used according to its SPC or Product Information and according to the local governmental recommendations and provided a written approval of the Sponsor was obtained.
- Immunoglobulins and/or any blood products administered during the study period until the final blood sample (Visit 6).

5.7. Intercurrent medical conditions that may lead to elimination of a subject from ATP analyses

At each study visit subsequent to the first vaccination visit, it had to be verified if the subject had experienced or was experiencing any intercurrent medical condition. If it was the case, the condition(s) had to be recorded in the eCRF.

- Subjects could be eliminated from the ATP cohort for immunogenicity if they incurred a condition that had the capability of altering their immune response or were confirmed to have an immunodeficiency condition.
- Subjects were to be eliminated from the ATP cohort for immunogenicity if they experienced intercurrent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and/or Hib prior to the post-dose 3 blood draw and diphtheria, tetanus, pertussis and/or Hib post-dose 4 blood draw.

5.8. Assessment of immunogenicity variables

5.8.1. Biological samples

Table 8 Biological samples

Sample type	Quantity*	Unit	Timepoint
Blood	5	mL	Month 5 (Post-Pri)
Blood	5	mL	Month 13-16 (Pre-Bst)
Blood	3.5	mL	Month 14-17 (Post-Bst)

* Approximate quantity
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

5.8.2. Laboratory assays

At Visits 4, 5 and 6, blood was to be collected for measurement of immune response. Total blood volume to be taken from each subject over the study period was approximately 13.5 mL (approximately 5.0 mL of whole blood to provide approximately 1.7 mL of serum at Visits 4 and 5 and at least 3.5 mL of whole blood to provide approximately 1.2 mL of serum at Visit 6). All serology was to be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized procedures with adequate controls. All serology for primary endpoints were to be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized, validated procedures with adequate controls.

The laboratory assays for humoral immunity are presented in Table 9.

Table 9 Humoral Immunity (Antibody determination)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off	Laboratory
Serum	*Bordetella pertussis*. Pertussis Toxin Ab.IgG	ELISA	In-house*	IU/mL	2.693	GSK Biologicals§
Serum	*Bordetella pertussis*. Filamentous Hemaglutinin Ab.IgG	ELISA	In-house*	IU/mL	2.046	GSK Biologicals§
Serum	*Bordetella pertussis*. Pertactin Ab.IgG	ELISA	In-house*	IU/mL	2.187	GSK Biologicals§
Serum	*Corynebacterium diphtheriae*. Diphtheria Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.057	GSK Biologicals§
Serum	*Clostridium tetani*. Tetanus Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.043	GSK Biologicals§
Serum	Hepatitis B Virus.Surface Ab	CLIA	Centaur (Siemens Healthcare)	mIU/mL	6.2	GSK Biologicals§
Serum	Poliovirus Sabin Types 1, 2 and 3	NEUTRA	In-house*	ED_{50}	8	GSK Biologicals§
Serum	*Haemophilus influenzae* type b. Polyribosyl Ribitol Phosphate Ab ‡	ELISA	In-house*	µg/mL	0.15 (qualified assay) 0.066 (fully validated assay)	GSK Biologicals§

*In-house refers to assays developed internally by GSK which could be performed at GSK Biologicals' laboratories or external laboratory designated by GSK.
§GSK Biologicals laboratory referred to the Global Vaccines Clinical Laboratories (GVCL) (current name: Clinical Laboratory Sciences) in Rixensart and Wavre, Belgium.
‡For anti-PRP post-dose 3, the primary vaccination results were presented using the qualified assay and the fully validated assay. The booster vaccination results were presented only using the fully validated assay.
ELISA = Enzyme-Linked Immunosorbent Assay
NEUTRA = Neutralization Assay
CLIA = ChemiLuminescence ImmunoAssay

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.

5.8.3. Biological samples evaluation

5.8.3.1. Immunological read-outs

The immunological read-outs are presented in Table 10.

Table 10 Immunological read-outs

Blood sampling time point		No. of subjects	Components and priority rank
Type of contact and time point	Sampling time point		
Visit 4 (Month 5)	Post-Pri	585 (All)	PRN, FHA, PT, PRP, D, T, HBs, Poliovirus type 1, Poliovirus type 2, Poliovirus type 3
Visit 5 (Month 13-16)	Pre-Bst	585 (All)	PRN, FHA, PT, PRP, D, T, HBs, Poliovirus type 1, Poliovirus type 2, Poliovirus type 3
Visit 6 (Month 14-17)	Post-Bst	585 (All)	PRN, FHA, PT, PRP, D, T

Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

In case of insufficient blood sample volume to perform assays for all antibodies, the samples were analysed according to priority ranking provided in Table 10.

5.8.4. Immunological correlates of protection

The following cut-offs were accepted as immunological correlates of protection:

- Specific antibodies against diphtheria toxoid (anti-diphtheria) and tetanus toxoid (anti-tetanus) were to be measured by enzyme-linked immunosorbent assay (ELISA). An antibody concentration ≥0.1 International Units per ml (IU/ml) was considered a conservative estimate of the percentage of subjects deemed to be protected [Camargo, 1984; Melville-Smith, 1983].
- Antibodies to the hepatitis B surface antigen (anti-HBs) were measured using ChemiLuminescence ImmunoAssay (CLIA). An antibody concentration ≥10 mIU/ml defined seroprotection [Centers for Disease Control and Prevention (CDC), 1991; WHO, 1988].
- Antibodies against poliovirus types 1, 2 and 3 were determined by a virus micro-neutralization test adapted from the WHO Guidelines for WHO/EPI Collaborative Studies on Poliomyelitis [WHO, 1993]. The lowest dilution at which serum samples were tested was 1:8, from which a test was considered positive. Titers were expressed in terms of the reciprocal of the dilution resulting in 50% inhibition. Antibody titers greater than or equal to this value were considered as protective.
- Data from subjects given unconjugated Hib vaccine suggested that, in the absence of induction of immunological memory, a concentration of 0.15 µg/mL was indicative of short-term protection, with 1 µg/mL considered indicative of long-term protection [Käyhty, 1983; Anderson, 1984].

- No serological correlate of protection against pertussis has been established [Granström, 1987; Karpinsky, 1987]. Antibodies against the pertussis components PT, FHA and PRN were measured by ELISA. The assay cut-off values were: 2.693 IU/mL for anti-PT (pertussis toxoid), 2.046 IU/mL for anti-FHA (filamentous haemagglutinin), and 2.187 IU/mL for anti-PRN (pertactin). Subjects with antibody concentration below the cut-off were considered seronegative.

For the purpose of identification of sub-optimal responders and communication to the investigators, anti-HBs and anti-poliovirus types 1, 2 and 3 assessment of the protection level were done for each subject on samples taken approximately 4 weeks after the 3rd dose of the primary vaccination. For PRP, D and T antigens, the assessment of the protection level was done for each subject on samples taken approximately 4 weeks after the administration of the booster dose. In addition a listing of subjects who did not seroconvert to anti-PT, anti-FHA and anti-PRN was provided.

The immunological assay results were communicated to the investigator (Visit 4 for HBV and poliovirus; Visit 6 for PRP, D, T and pertussis antigens).

The investigator was encouraged to share the immunological assay results for non-responders with the study subjects' parent(s)/LAR(s).

For the study subjects identified as non-responders, it remained the responsibility of the study investigator in charge of the subject's clinical management to determine the medical need for re-vaccination and to re-vaccinate the subjects as per local/regional practices.

5.9. Assessment of safety variables

The investigator or site staff was/were responsible for the detection, documentation and reporting of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE) as provided in the protocol.

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

5.9.1. Safety definitions

5.9.1.1. Definition of an adverse event

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 unfavourable 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 an AE included:

- Significant or unexpected worsening or exacerbation of the condition/indication under study.
- New conditions detected or diagnosed after investigational vaccines 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 vaccines or a concurrent medication (overdose per se was not to be reported as an AE/SAE).
- Signs, symptoms temporally associated with vaccine administration.
- Significant failure of expected pharmacological or biological action.
- Pre- or post-treatment events that occurred as a result of protocol-mandated procedures (i.e. invasive procedures, modification of subject's previous therapeutic regimen).

AEs to be recorded as endpoints (solicited AEs) are described in Section 5.9.2. All other AEs were recorded as UNSOLICITED AEs.

Examples of an AE DO NOT include:

- Medical or surgical procedures (e.g. endoscopy, appendectomy); the condition that led to the procedure was an AE/SAE.
- Situations where an untoward medical occurrence did not occur (e.g. social and/or 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 did not worsen.
- Pre-existing conditions or signs and/or symptoms present in a subject prior to the first study vaccination. These events were recorded in the medical history section of the eCRF**.**

5.9.1.2. Definition of a serious adverse event

A serious adverse event was any untoward medical occurrence that:

a. Resulted in death,

b. Was 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 did not refer to an event, which hypothetically might have caused death, had it been more severe.

c. Required hospitalisation or prolongation of existing hospitalisation,

   Note: In general, hospitalisation signified that the subject had 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 occurred during hospitalisation were also considered AEs. If a complication prolonged hospitalisation or fulfilled any other serious criteria, the event was also to be considered serious. When in doubt as to whether 'hospitalisation' occurred or was necessary, the AE was to be considered serious.

Hospitalisation for elective treatment of a pre-existing condition (known or diagnosed prior to informed consent signature) that did not worsen from baseline was NOT considered an AE.

d. Resulted in disability/incapacity,

Note: The term disability meant a substantial disruption of a person's ability to conduct normal life functions. This definition was 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 could interfere or prevent everyday life functions but did not constitute a substantial disruption.

Medical or scientific judgement was to be exercised in deciding whether reporting was appropriate in other situations, such as important medical events that were not immediately life-threatening or resulted in death or hospitalisation but could jeopardise the subject or could require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These were also to be considered serious. Examples of such events were invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalisation.

5.9.2. Solicited adverse events

A 4-day follow-up (Day 0-Day 3) of solicited local (at each injection site) and general AEs was performed after administration of the vaccine. Data concerning the following AEs were solicited using diary cards provided by the sponsor.

5.9.2.1. Solicited local (injection-site) adverse events

The following local (injection-site) AEs were solicited (Table 11):

Table 11 Solicited local adverse events

Pain at injection site
Redness at injection site
Swelling at injection site
Post-dose 4 measurements of circumference of limbs (arm or leg according to where vaccine was administered)

N.B. If parent(s) /LAR(s) of infants observed any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of limb circumference) after the booster dose at Visit 5, they were to contact study personnel and to visit the investigator's office for evaluation as soon as possible and bring

the diary card with them. The investigator was to record detailed information describing the AE on a specific large injection site reaction form in the eCRF. In addition to the diameter of the swelling and the circumference of the limb that were reported as solicited symptoms the parent(s)/LAR(s) were to record additional symptoms/characteristics as mentioned in the protocol (Section on Recording of AEs, SAEs and NOCIs).

Note: local AEs were not solicited for co-administered vaccines like *Prevnar 13*.

5.9.2.2. Solicited general adverse events

The following general AEs were solicited (Table 12):

Table 12 Solicited general adverse events

Drowsiness
Fever
Irritability/Fussiness
Loss of appetite

Note: Temperature was recorded in the evening. Should additional temperature measurements be performed at other times of day, the highest temperature was recorded. Fever was defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study was rectal for Epoch 001 and axillary for Epoch 002.

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

In absence of diagnosis, abnormal laboratory findings (e.g. clinical chemistry, haematology, urinalysis) or other abnormal assessments (e.g. vital signs etc.) that were judged by the investigator to be clinically significant were recorded as AE or SAE if they met the definition of an AE or SAE (refer to Sections 5.9.1.1 and 5.9.1.2). Clinically significant abnormal laboratory findings or other abnormal assessments that were present at baseline and significantly worsened following the start of the study were also reported as AEs or SAEs. However, clinically significant abnormal laboratory findings or other abnormal assessments that were associated with the disease being studied, unless judged by the investigator as more severe than expected for the subject's condition, or that were present or detected at the start of the study and did not worsen, were not reported as AEs or SAEs.

The investigator was to exercise his or her medical and scientific judgement in deciding whether an abnormal laboratory finding or other abnormal assessment was clinically significant.

5.9.4. Adverse events of specific interest

Adverse events of specific interest (i.e. NOCIs such as autoimmune disorders, asthma, type I diabetes and allergies) were recorded from Day 0 up to 6 months after the last primary vaccination (Epoch 001) and from booster dose up to one month after booster vaccination (Epoch 002). NOCIs were reported as either AEs or SAEs, as appropriate in the eCRF.

5.9.5. Detecting and recording adverse events and serious adverse events

5.9.5.1. Time period for detecting and recording adverse events and serious adverse events

All AEs starting within 30 days following administration of each dose of study vaccine/comparator were recorded into the appropriate section of the eCRF, irrespective of intensity or whether or not they were considered vaccination-related.

The time period for collecting and recording SAEs and AEs of specific interest was to begin at the first receipt of study vaccine/comparator and to end 180 days following administration of the last dose of study vaccine/comparator of the primary vaccination course for each subject and 30 days following administration of the booster dose. Instructions on reporting of SAEs were specified in the protocol (see protocol for details).

All AEs/SAEs leading to withdrawal from the study were collected and recorded from the time of the first receipt of study vaccine/comparator.

In addition to the above-mentioned reporting requirements and in order to fulfil 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 were collected and recorded from the time the subject consented to participate in the study until she/he was discharged from the study.

Note: With the exception of AEs/SAEs leading to withdrawal, study participation and concurrent GSK medications or vaccines, there was no reporting of SAEs from the time of the Epoch 1 extended safety follow-up (ESFU) phone contact and administration of dose 4 (approximately three months).

An overview of the protocol-required reporting periods for AEs and SAEs is given in Table 13.

Table 13 Reporting periods for adverse events and serious adverse events

Study activity	C.O	V1	4-days post vac	31-days post-vac	V2	4-days post vac	31-days post-vac	V3	4-days post- vac	31-days post-vac	Phone call 6 months post-V3	V5	4-days post- vac	31-days post-vac
Age of subject		2 months			4 months			6 months		7 months	12 months	15-18 months		16-19 months
Solicited local and general AEs														
Large injection site reactions														
Unsolicited AEs														
AEs/SAEs leading to withdrawal from the study														
NOCIs														
SAEs														
SAEs related to study participation or concurrent GSK medication/vaccine														

NOCI: New Onset of Chronic Illnesses; C.O: consent obtained; V: Visit; Post-V: Post-Visit; vac: vaccination

5.9.6. Post-Study adverse events and serious adverse events

A post-study AE/SAE was defined as any event that occurred outside of the AE/SAE reporting period defined in Table 13. Investigators were not obligated to actively seek AEs or SAEs in former study participants. 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 vaccine/product, the investigator was to promptly notify the Study Contact for Reporting SAEs.

5.9.7. Evaluation of adverse events and serious adverse events

5.9.7.1. Active questioning to detect adverse events and serious adverse events

As a consistent method of collecting AEs, the subject's parent(s)/LAR(s) were to 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 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 in the eCRF. The investigator was not allowed to send photocopies of the subject's medical records to GSK Biologicals instead of appropriately completing 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 blinded on the copies of the medical records prior to submission to GSK Biologicals.

The investigator was to 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.

5.9.7.2. Assessment of adverse events

5.9.7.2.1. Assessment of intensity

The intensity of the following solicited AEs were assessed as described:

Table 14 Intensity scales for solicited symptoms in infants/toddlers

Infant/Toddler (15–24 months)		
Adverse Event	**Intensity grade**	**Parameter**
Pain at injection site	0	None
	1	Mild: Minor reaction to touch
	2	Moderate: Cries/protests on touch
	3	Severe: Cries when limb is moved/spontaneously painful
Redness at injection site		Record greatest surface diameter in mm
Swelling at injection site		Record greatest surface diameter in mm
Increase in limb circumference post-dose 4 (arm or leg according to where vaccine was administered)		Record the limb circumference at the level of the injection site
Fever*		Record temperature in °C/°F
Irritability/Fussiness	0	Behaviour as usual
	1	Mild: Crying more than usual/no effect on normal activity
	2	Moderate: Crying more than usual/interferes with normal activity
	3	Severe: Crying that cannot be comforted/prevents normal activity
Drowsiness	0	Behaviour as usual
	1	Mild: Drowsiness easily tolerated
	2	Moderate: Drowsiness that interferes with normal activity
	3	Severe: Drowsiness that prevents normal activity
Loss of appetite	0	Appetite as usual
	1	Mild: Eating less than usual/no effect on normal activity
	2	Moderate: Eating less than usual/interferes with normal activity
	3	Severe: Not eating at all

* Fever was defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study was rectal for Epoch 001 and axillary for Epoch 002.

The maximum intensity of local injection site redness/swelling/fever was scored at GSK Biologicals as follows:

0 : Absent
1 : ≤ 5 mm
2 : > 5 mm and ≤ 20 mm
3 : > 20 mm

The maximum intensity of fever was scored at GSK Biologicals as follows:

0	=	<100.4°F	<38.0°C
1	=	≥100.4°F to ≤102.2°F	≥38.0°C to ≤39.0°C
2	=	>102.2°F to ≤104.0°F	>39.0°C to ≤40.0°C
3	=	> 104.0°F	> 40.0°C

Following each vaccination (3 doses during the primary vaccination course and one booster dose) during the 4 days after the vaccine dose had been administered (day of vaccination and subsequent 3 days), the child's temperature was screened each evening, at bedtime, for signs of fever by means of the rectal/axillary thermometer. Children < 15 months were to have their temperature taken rectally and children ≥ 15 months were to have their temperature taken by the axillary route. Rectal/axillary temperatures were recorded on the diary card. Temperatures measured by any route were presented in 0.5°C increments starting at 38°C/100.4°F.

Prior to analysis, the increase in limb circumference of each limb as compared to the baseline pre-vaccination measurement was scored at GSK Biologicals for each subject with large injection site reaction as follows:

Grade 0 = Increase in limb circumference ≤5 mm

1 = Increase in limb circumference >5 mm but ≤20 mm

2 = Increase in limb circumference >20 mm but ≤40 mm

3 = Increase in limb circumference >40 mm

The investigator was to assess the maximum intensity that occurred over the duration of the event for all unsolicited AEs (including SAEs) recorded during the study. The assessment was based on the investigator's clinical judgement.

For unsolicited symptoms and adverse events associated with large injection site reactions (e.g. pruritus, induration and functional impairment), the intensity was 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 child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center 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 a SAE. Grade 3 was a category used 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 Section 5.9.1.2.

5.9.7.2.2. Assessment of causality

The investigator was obligated to assess the relationship between investigational vaccines and the occurrence of each AE/SAE. The investigator used clinical judgement to determine the relationship. Alternative plausible causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors, and the temporal relationship of the event to the investigational vaccines were considered and investigated. The investigator was also to consult the IB (Investigators Brochure) and/or Product Information for marketed products to determine his/her assessment. Investigational vaccines included vaccines such as *Infanrix hexa*, *Pediarix*, *Pentacel*, *ActHIB*, *Engerix-B*, *Rotarix*, *Prevnar 13*, *Infanrix* and *Hiberix*.

There could be situations when a 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 report to GSK Biologicals. The investigator could change his/her opinion of causality in light of follow-up information and update the SAE information accordingly. The causality assessment was one of the criteria used when determining regulatory reporting requirements.

Due to concomitant administration of multiple vaccines, it might not be possible to determine the causal relationship of general AEs to the individual vaccines administered. The investigator was to, therefore, assess whether the AE could be causally related to vaccination rather than to the individual vaccines.

All solicited local (injection site) reactions were considered causally related to vaccination. As the individual vaccines were administered to separate sites, the investigator was to make an assessment of local reactogenicity at the vaccine level e.g. *Infanrix* or *Hiberix*. Causality of all other AEs were assessed by the investigator using the following question:

Is there a reasonable possibility that the AE could have been caused by the investigational vaccines?

YES	:	There was a reasonable possibility that the vaccines contributed to the AE.
NO	:	There was no reasonable possibility that the AE was causally related to the 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.

If an event met the criteria to be determined as ‘serious’ (see Section 5.9.1.2), additional examinations/tests were performed by the investigator in order to determine ALL possible contributing factors for each SAE.

Possible contributing factors included:

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

5.9.7.3. Assessment of outcomes

The investigator was to assess the outcome of all unsolicited AEs (including SAEs) recorded during the study as:

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

5.9.7.4. Medically attended visits

For each solicited and unsolicited symptom the subject experienced, the subject's parent(s)/LAR(s) were asked if the subject received medical attention defined as hospitalisation, or an otherwise unscheduled visit to or from medical personnel for any reason, including emergency room visits. This information was recorded in the eCRF.

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

5.9.8.1. Follow-up during the study

After the initial AE/SAE report, the investigator was required to proactively follow each subject and provide additional relevant information on the subject's condition to GSK Biologicals (within 24 hours for SAEs; refer to the protocol for further details).

All SAEs documented at a previous visit/contact and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until the end of the study.

All AEs documented at a previous visit/contact and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until 30 days after the last vaccination.

New onset of chronic diseases (such as autoimmune disorders, asthma, type I diabetes and allergies) documented at a previous visit/contact and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until end of the study.

5.9.8.2. Follow-up after the subject was discharged from the study

The investigator was to follow 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.
- with other non-serious AEs of specific interest, i.e. NOCIs, such as autoimmune disorders, asthma, type I diabetes and allergies, until the end of the study period or they were lost to follow-up.

If the investigator received additional relevant information on a previously reported SAE, he/she was to provide this information to GSK Biologicals using a paper SAE form.

GSK Biologicals could request that the investigator perform or arrange the conduct of additional clinical examinations/tests and/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 would provide any available post-mortem findings, including histopathology.

5.10. Statistical methods

The statistical analyses were performed using the SAS version 9. Refer to Section 5.12.2 for a description of differences with planned statistical methods.

5.10.1. Primary endpoint

5.10.1.1. Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

5.10.2. Secondary endpoints

5.10.2.1. Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

5.10.2.2. Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).

- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1.0 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1.0 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1.0 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1.0 µg/mL one month after the booster dose (Dose 4)
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

5.10.3. Determination of sample size

Target enrolment was 585 subjects. Assuming 65% of the subjects were evaluable post-dose 3, this would provide approximately 378 subjects (126 subjects in each group) evaluable for immunogenicity in the Epoch 001.

The sample size was estimated in order to obtain at least 94% power to demonstrate the primary inferential objective (i.e. non-inferiority of the response to the pertussis antigens). The power associated to the target sample size for the conclusion on the inferential primary objective of this study is detailed in the next section.

5.10.3.1. Control on type I error

A 2.5% nominal type I error was used for each pertussis non-inferiority (NI) evaluation. Since NI was to be met simultaneously for the 3 pertussis antigens, the global type I error would be below 2.5%.

5.10.3.2. References for sample size

References were chosen based on observed standard deviations (SDs) observed in studies Hib-MenCY-TT-005 (101858) and Hib-MenCY-TT-009 (103813) one month post-dose 3 from the subjects that received *ActHIB* co-administered with *Pediarix* and *Prevnar*, and from study DTPa-HBV-IPV-027 (217744/027) one month post-dose 3 from the DTPa-HBV-IPV/Hib pooled groups. All these studies enrolled subjects in the US.

The standard deviation for $\log_{10}$ transformed concentrations post vaccination for pertussis antigens is presented in Table 15.

Table 15 Standard deviation for $\log_{10}$ transformed concentration post vaccination

Study	Antigen					
	PT		FHA		PRN	
	N	SD	N	SD	N	SD
Hib-MenCY-TT-005-US	215	0.274	213	0.312	217	0.392
Hib-MenCY-TT-009 – US cohort	100	0.258	97	0.252	101	0.482
DTPa-HBV-IPV-027-US	865	0.274	802	0.254	869	0.376
Reference taken		0.274		0.307		0.392

N: Number of subjects; SD: standard deviation

5.10.3.3. Power computation

Out of the 585 subjects enrolled, 65% (126 in each pooled group) were expected to be evaluable post-Dose 3.

The individual type II error for each pertussis antigen was obtained using PASS 2005, one-sided non-inferiority test for 2 means from normal data with common variance between groups, under the alternative of equal means and alpha=2.5% (Table 16).

To account for the multiplicity of comparisons, the global type II error was conservatively estimated as the sum of individual type II errors, ensuring a global power for the study of 94.02% as presented in Table 16.

Table 16 Power for pertussis NI post-Dose 3

Antigen	Margin	SD on log_{10} transformed titer	Type I error	N evaluable per pooled group	Type II error
PT	1.5	0.274	2.5%	126	0.08%
FHA	1.5	0.307	2.5%	126	0.48%
PRN	1.5	0.392	2.5%	126	5.42%
Global Power = 100-(0.08+0.48+5.42) % = 94.02%					

5.10.4. Study cohorts /data sets analyzed

Six cohorts were defined for the purpose of the analysis:

- Primary Total Vaccinated cohort (TVC)
- Primary ATP cohort for analysis of safety
- Primary ATP cohort for analysis of immunogenicity
- Booster Total Vaccinated cohort
- Booster ATP cohort for analysis of safety
- Booster ATP cohort for analysis of immunogenicity

5.10.4.1. Primary Total vaccinated cohort

The Primary Total Vaccinated cohort (TVC) included all vaccinated subjects for whom data were available.

- A safety analysis based on the Primary TVC included all subjects with at least one vaccine administration documented.
- An immunogenicity analysis based on the Primary TVC included all vaccinated subjects for whom data concerning at least one immunogenicity endpoint measure was available.

5.10.4.2. Primary ATP cohort for analysis of safety

The Primary ATP cohort for safety consisted of all subjects from the Primary TVC who complied with the protocol up to the end of Epoch 001, namely all subjects:

- who met all inclusion criteria and no exclusion criteria for the study;
- who had received all planned study vaccines for each completed vaccination visit in Epoch 001;
- for whom administration site of study vaccines was known and was according to protocol;
- who did not receive a product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in the study protocol.

Note that for the purpose of ATP cohort definition, the Epoch 001 ended at Visit 4.

Adherence to the interval related to ESFU phone contact was not to be taken into account for inclusion in the ATP cohort for safety.

5.10.4.3. Primary ATP cohort for analysis of immunogenicity

The Primary ATP cohort for immunogenicity consisted of all subjects from the Primary ATP cohort for safety who complied with eligibility criteria and study procedures (see the protocol for the definition of the intervals) up to the post-dose 3 blood sample and had immunogenicity results for the post-dose 3 blood sample. The analysis was performed per treatment (first dose) actually administered.

More specifically, the analysis post-dose 3 based on the ATP cohort for immunogenicity included all eligible subjects:

- who received all the study vaccines up to dose 3 as per the vaccination schedule;
- for whom administration site and route of study vaccines up to dose 3 was as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 4 (Month 5) which led to elimination from an ATP analysis as listed in the protocol;
- who did not present with a medical condition before the blood sampling at Visit 4 (Month 5) which led to elimination from an ATP analysis as listed in the protocol.
- who complied with the post-dose 3 blood sample schedule, i.e. 21-48 days post-dose 3.
- who were not administered a vaccine not foreseen by the study protocol before the corresponding post-vaccination blood sample.
- who had immunogenicity results post-dose 3.

In addition for Hep-B analysis, hemolysed samples were excluded from the Primary ATP cohort for immunogenicity.

5.10.4.4. Booster Total vaccinated cohort

The Booster TVC included all subjects from the primary TVC that received the booster vaccine dose.

- For the Booster-TVC analysis of safety, this included all subjects with booster vaccine administration documented.
- For the Booster-TVC analysis of immunogenicity, this included vaccinated subjects for whom data concerning immunogenicity endpoint measures were available.

5.10.4.5. Booster ATP cohort for analysis of safety

The Booster ATP cohort for safety consisted of all subjects from the Booster TVC who complied with the protocol up to the end of Epoch 002, namely all subjects:

- who met all inclusion criteria and no exclusion criteria for the study;
- who had received the planned booster dose at 15-18 months of age;
- who received 3 doses in Epoch 001;
- for whom administration site of study vaccines was known and was according to protocol;
- who did not receive a product before the blood sampling at Visit 6 (Months 14-17) which led to elimination from an ATP analysis as listed in the protocol.

5.10.4.6. Booster ATP cohort for analysis of immunogenicity

The Booster ATP cohort for immunogenicity consisted of all subjects from the Booster ATP cohort for safety who complied with eligibility criteria and study procedures (see the protocol for the definition of the intervals) up to the post-dose 4 blood sample and had immunogenicity results for the post-dose 4 blood sample.

More specifically, the analysis pre- and post-dose 4 based on the Booster ATP cohort for immunogenicity included all eligible subjects:

- who received all the study vaccines up to dose 4 as per the vaccination schedule;
- for whom administration site and route of the study vaccines up to dose 4 was as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 6 (Months 14-17) which led to elimination from an ATP analysis (see the protocol);
- who did not present with a medical condition before the blood sampling at Visit 6 (Months 14-17) which led to elimination from an ATP analysis (see the protocol);
- who complied with the booster vaccination schedule at 15-18 months of age and with the post-dose 4 blood sample schedule i.e. 21-48 days for post-dose 4;
- who had immunogenicity results post-dose 4.

5.10.5. Derived and transformed data

5.10.5.1. Demography

For a given subject and a given demographic variable, missing measurements were not to be replaced except for age.

Age was to be calculated as the number of years between the date of birth and the date of vaccination.

5.10.5.2. Immunogenicity

- A seronegative subject was a subject whose antibody concentration/titer was below the assay cut-off (see Section 5.8.2 for cut-off details).
- A seropositive subject was a subject whose antibody concentration/titer was greater than or equal to the assay cut-off.
- A seroprotected subject was a subject whose antibody concentration/titer was greater than or equal to the level defining clinical protection. The following seroprotection thresholds were applicable:
  - Anti-diphtheria antibody concentrations ≥ 0.1 IU/mL.
  - Anti-tetanus antibody concentrations ≥ 0.1 IU/mL.
  - Anti-HBs antibody concentrations ≥ 10 mIU/mL.
  - Anti-poliovirus types 1, 2 and 3 antibody titers ≥ 8.
  - Anti-PRP antibody concentrations ≥ 0.15 µg/mL.
- Other cut-offs were to be considered:
  - Anti-PRP antibody concentrations ≥ 1.0 µg/mL.
  - Anti-diphtheria and anti-tetanus antibody concentrations ≥ 1.0 IU/mL
- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies were defined as:
  - initially seronegative subjects (pre-booster antibody concentration below the assay cut-off) presenting an increase of at least four times the assay cut-off one month after vaccination;
  - initially seropositive subjects with antibody concentration < four times the assay cut-off presenting an increase of at least four times the pre-booster antibody concentration one month after vaccination;
  - initially seropositive subjects with anti-body concentration ≥ four times the assay cut-off presenting an increase of at least two times the pre-booster antibody concentration one month after vaccination.

- The GMC/geometric mean titer (GMT) calculations were performed by taking the anti-log of the mean of the log_{10} titer/ concentration transformations. Antibody titers/concentrations below the cut-off of the assay were given an arbitrary value of half the cut-off for the purpose of GMC/GMT calculation.
- Handling of missing data - For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements were not to be replaced.

5.10.5.3. Safety/reactogenicity:

- For a given subject and the analysis of solicited symptom within 4 days post-vaccination, missing or non-evaluable measurements were not to be replaced. Therefore the analysis of the solicited symptoms based on the Total Vaccinated cohort was to include only vaccinated subjects and doses with documented safety data (i.e. symptom screen completed).
- For analysis of unsolicited adverse events, such as serious adverse events or adverse events by primary MedDRA term, and for the analysis of concomitant medications, all vaccinated subjects were considered. Subjects who did not report the event or the concomitant medication were considered as subjects without the event or the concomitant medication, respectively.
- For analysis of convulsion, the adverse event was to be identified by using narrow standard MedDRA query.
- For analysis of Hypotonic Hyporesponsive Episode (HHE), the adverse event was identified by using broad standard MedDRA query.
- For analysis of NOCI, the adverse event was identified by using narrow standard MedDRA query.
- For summaries reporting both solicited and unsolicited adverse events, all vaccinated subjects were considered. Subjects for whom the event was not reported were considered as subjects without the event.
- Large injection site reactions were defined as either swelling with a diameter of >50 mm or a >50 mm increase in the circumference of any limb when compared to the baseline (pre-vaccination) measurement, or any diffuse swelling that interferred with or prevented everyday activities (for example, active playing, eating, sleeping).

5.10.6. Final analysis of the Epoch 001

5.10.6.1. Analysis of demographics

Demographic characteristics (age [weeks], gender, geographical ancestry, height in length [cm], weight [kg] at first dose, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status were summarised by group using descriptive statistics:

- Frequency tables were generated for categorical variables such as center;
- Mean, median and standard error were provided for continuous data such as age.

The distribution of subjects enrolled among the study sites was tabulated as a whole and per group.

5.10.6.2. Analysis of immunogenicity

The primary analysis was based on the Primary ATP cohort for immunogenicity. An analysis on the Primary Total Vaccinated cohort was performed only if, in any vaccine group and at any time point, more than 5% of the vaccinated subjects with immunological data post-dose 3 were excluded from the Primary ATP cohort for immunogenicity.

The following sections describe the analyses that were performed.

5.10.6.2.1. Within group assessment

For each group, one month post-dose 3 and for each assay for which a serological result was available:

- Seropositivity and seroprotection rates with exact 95% CIs were calculated.
- GMCs/GMTs with 95% CIs were tabulated.
- For each antigen, antibody concentration or titer distribution one month post-vaccination was tabulated and displayed using reverse cumulative curves (RCCs).
- For anti-PRP post primary vaccination at Visit 4 using the qualified assay and the fully validated assay, seropositivity and seroprotection rates and GMCs were calculated per *Infanrix hexa* lot.

All the above within group analysis for Epoch 001, except the reverse cumulative curves and the presentation per *Infanrix hexa* lot, were also to be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and by Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

5.10.6.2.2. Between group assessment

At one month post-dose 3,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection rates was computed for each antigen.

Antigen	Threshold considered for protection
• Anti-D	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-T	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-polio	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (short term protection) • 1.0 µg/mL (long term protection)
• Anti-HBs	• 10 mIU/mL

- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) was computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers. The ANOVA model was to include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as continuous regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B vaccine birth dose status was also to be used as regressor leading to an ANCOVA model. The model was to include the data from the 3 groups compared. For analysis purpose, DTP vaccination of the mother during pregnancy and Hepatitis B vaccination at birth were considered as continuous variables. More specifically 2 continuous indicator variables were to be used for Tdap vaccination of mother during pregnancy (an indicator for no Tdap vaccination at birth and an indicator for unknown vaccination at birth) while one indicator of hepatitis B vaccination at birth was used.

5.10.6.2.3. Interpretation of analyses

Except for analyses addressing criteria specified in the primary objective, comparative analyses were descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses were not to be interpreted for formal conclusions since there was no adjustment for multiplicity of endpoints.

5.10.6.3. Analysis of safety

The primary analysis was based on the primary Total Vaccinated cohort. If, in any vaccine group and at any time point of the Epoch 001, the percentage of vaccinated subjects excluded from the primary ATP cohort for safety was more than 5%, a second

analysis based on the primary ATP cohort for safety was to be performed to complement the primary Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period was tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period was tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses with local AEs (solicited and unsolicited) were calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered) during the 4-day follow-up period was tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses reporting each individual solicited local and general AE during the 4-day follow-up period were tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

  The exact 95% CIs were calculated assuming independence between doses.
- All computations mentioned above were done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects/doses reporting each individual solicited local symptom (any grade, grade 2, grade 3, medical advice) during the 4-day follow-up period were also to be tabulated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines with exact 95% CI after each vaccine dose and overall where the same row on the table was used for all vaccines given at the same site across the three study groups (e.g. *Infanrix hexa*, *Pentacel* and *Pediarix* together were in one row and *ActHIB* and *Engerix-B* together were in one row). The percentage of subjects/doses reporting each individual general solicited symptom (any grade, Grade ≥2, Grade 3, causally related, Grade 3 causally related, medical advice) during the 4-day follow-up period were also to be tabulated with exact 95% CI. For fever, the analyses were also to be performed by 0.5°C increments.

- The percentage of subjects/doses with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination was tabulated after each dose and over the Epoch 001.
- The verbatim reports of unsolicited AEs were reviewed by a Clinical Research and Development Lead and the signs and symptoms were coded according to MedDRA. Every verbatim term was matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI was tabulated by Preferred Term. Similar tabulations were done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.
- Subjects who experienced AEs of specific interest (i.e. convulsions, Hypotonic Hyporesponsive Episode) during 31 days with exact 95% CI were tabulated by Preferred Term. Similar tabulations were done for AEs considered related to vaccination. Subjects who experienced AEs of specific interest were also to be described in detail.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination were tabulated by Preferred Term.
- Subjects who experienced at least one SAE with onset from Dose 1 up to six months post primary vaccination were tabulated with MedDRA primary preferred term.
- All reactogenicity analyses and analyses for unsolicited symptoms were also to be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry).

5.10.7. Final analysis of the Epoch 002

5.10.7.1. Analysis of demographics/baseline characteristics

Demographic characteristics (age [months] at Visit 5, gender, geographical ancestry, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status were summarized by group using descriptive statistics:

- Frequency tables were generated for categorical variables such as race/ethnicity;
- Mean, median and standard error were provided for continuous data such as age.

The distribution of subjects vaccinated at Visit 5 among the study sites was tabulated as a whole and per group.

For enrolled subjects that did not participate in the Epoch 002, the reason for not participating was summarized.

5.10.7.2. Analysis of immunogenicity

The primary analysis was based on the booster ATP cohort for immunogenicity. An analysis on the booster Total Vaccinated cohort was to be performed only if, in any vaccine group and at any time point of the Epoch 002, more than 5% of the vaccinated subjects with immunological data were excluded from the booster ATP cohort for immunogenicity.

The following section describes the analyses that were performed.

5.10.7.2.1. Within group assessment

For each group, prior to the booster dose and one month post-booster dose and for each assay, for which a serological result was available:

- Seropositivity and seroprotection rates and booster response rates for pertussis with exact 95% CIs were calculated.
- GMCs/GMTs with 95% CIs were tabulated.
- For each antigen, antibody concentration or titer distribution before and one month Post-booster (when available) were tabulated and displayed using RCCs.

All the above within group analysis for Epoch 002 except the reverse cumulative curves were also to be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

5.10.7.2.2. Between group assessment

At pre-booster and at one month post-booster,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection rates was computed for each antigen except for group difference (Penta group minus Hexa group).

Antigen	Threshold considered for protection
• Anti-D	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-T	• 0.1 IU/mL (short term protection) • 1.0 IU/mL (long term protection)
• Anti-polio (Pre-Booster)	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (short term protection) • 1.0 µg/mL (long term protection)
• Anti-HBs (Pre-Booster)	• 10 mIU/mL

- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) were computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model was to include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as regressor leading to an ANCOVA. For hepatitis B antigen, the hepatitis B vaccine birth dose status was also to be used as regressor leading to an ANCOVA model. The model was also to include the data from the 3 groups compared. For analysis purpose, DTP vaccination of the mother during pregnancy and Hepatitis B vaccination at birth were considered as continuous variables. More specifically 2 continuous indicator variables were used for Tdap vaccination of mother during pregnancy (an indicator for no Tdap vaccination at birth and an indicator for unknown vaccination at birth) while one indicator of hepatitis B vaccination at birth was used.

5.10.7.2.3. Interpretation of analyses

In Epoch 002, all comparative analyses were descriptive/exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses were not to be interpreted for formal conclusions since there was no adjustment for multiplicity of endpoints.

5.10.7.3. Analysis of safety

The primary analysis for the Epoch 002 was based on the booster Total Vaccinated cohort and was only to look at the booster dose. If, in any vaccine group, the percentage of vaccinated subjects excluded from the booster ATP cohort for safety was more than 5%, a second analysis based on the booster ATP cohort for safety was to be performed to complement the booster Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose, were tabulated with exact 95% CI for each group.
- The incidence of local AEs (solicited and unsolicited) was calculated at each injection site as well as overall (all sites considered) for each group during the 4-day (Days 0-3) follow-up period after the booster dose.
- The percentage of subjects reporting each individual solicited local and general AE during the 4-day follow-up period was tabulated with its exact 95% CI for each group.
- All computations mentioned above were to be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects reporting each individual solicited local symptoms (any grade, Grade ≥2, Grade 3, medical advice) during the 4-day follow-up period were also to be tabulated at each injection site for *Infanrix, Hiberix, ActHIB* and *Pentacel*

vaccines with exact 95% CI after each vaccine dose and overall where vaccination with same vaccine site was considered together (e.g. *Infanrix* and *Pentacel* together were on one row and *ActHIB* and *Hiberix* together were on one row). The percentage of subjects reporting each individual general solicited symptom (any grade, Grade ≥2, Grade 3, causally related, Grade 3 causally related, medical advice) during the 4-day follow-up period was also to be tabulated with exact 95% CI. For fever, analyses were also to be performed by 0.5°C increments.

- The percentage of subjects with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination were tabulated for each group.
- The verbatim reports of unsolicited AEs were reviewed by a Clinical Research and Development Lead and the signs and symptoms were coded according to MedDRA. Every verbatim term was matched with the appropriate Preferred Term. The percentage of subjects with unsolicited AEs occurring within 31 days following the booster dose with its exact 95% CI was tabulated by Preferred Term. Similar tabulations were done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Additionally,

- Any large injection site reaction (defined as a swelling with a diameter > 50 mm, noticeable diffuse swelling or increase in limb circumference of greater than 50 mm) reported within 4 days (Days 0-3) following the booster dose was to be tabulated.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from booster dose up to one month after booster vaccination were tabulated by Preferred Term.
- Subjects who experienced at least one SAE from the booster dose up to one month after were tabulated with MedDRA primary preferred term. The same summary was provided for all SAEs reported from dose 1 up to study end.

All reactogenicity analyses and analyses for unsolicited symptoms were also to be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestry, namely White Caucasian versus any other geographical ancestry).

5.10.8. Sequence of analyses

The analyses were performed stepwise:

1. A partial analysis of Epoch 001 up to one month after the third primary vaccine dose was conducted. This analysis included the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis was displayed on the GSK clinical trial registry.
2. The final data analysis of the study covering both the epochs was conducted at the end of the study. All these analyses are presented in an integrated final clinical study report.

5.10.9. Interim analysis

All analyses were conducted on final data and therefore no statistical adjustment for interim analyses was required – see Section 5.10.8 and first bullet point for details of the interim analysis.

5.11. Data quality assurance at study level

To ensure that the study procedures conformed across all investigator sites, the protocol, 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 was held on 05-06 March 2014 Face to Face in Dallas, Texas, USA, 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 eCRF completion. All procedures were performed according to methodologies detailed in GSK Biologicals Standard Operating Procedures (SOPs).

All protocol deviations collected during the study were reviewed by the GSK study team in order to identify important protocol deviations. Consistent with International Conference on Harmonisation 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 Table in Section 2 summarises the roles of the different CROs that were employed in this study. The CRO responsibilities were conducted according to SOPs agreed between GSK and the CRO.

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

5.12.1.1. Protocol Amendment 1

Protocol Amendment 1 was implemented at all study sites from the date of approval on 18-September-2014 onwards.

Rationale/background for changes:

- Clarification was provided that large injection site reactions and measurement of the injected limb was to be collected as a solicited symptom. Specific instructions regarding measurement of limb circumference and clinical details of large injection site reactions were added.
- Additional minor clarifications of study procedures and data analyses were made throughout the document.
- Instructions regarding interval between preparation and administration of vaccine was aligned with the stability data described in the current Investigator Brochure.
- Due to ongoing re-validation of serological assays for antibodies to diphtheria and tetanus toxoids, pertussis antigens, poliovirus, hepatitis B surface antigen and polyribosyl ribitol phosphate, the cut-offs for these assays could potentially change and hence a note was added in the protocol regarding this. The definition of booster response to pertussis antigens could also potentially have been revised.
- Sequence of reporting the results was clarified.
- The contributing authors and sponsor signatory were updated to reflect changes in the study team.

5.12.1.2. Protocol Amendment 2

Protocol Amendment 2 was implemented at all study sites from the date of approval on 17-April-2015 onwards.

Rationale/background for changes:

- The assay for testing antibodies against polyribosyl ribitol phosphate (anti-PRP) was re-developed but was not yet qualified or validated for testing the one month post dose-3 samples. This was clarified in the protocol in Table 7 Humoral immunity (antibody determination) and Section 5.7.3 Laboratory assays.
- Investigator sign-off on the patient identification (PIDS) was done after Visit 4 instead of ESFU. In Table 4 List of study procedures, the bullets pertaining to investigator sign-off and analysis of Epoch 001 were removed from the ESFU visit and retained at Visit 4 to reflect this change.
- The collection of baseline measurement of limb length was removed since it was not to be used in analysis; only limb circumference was used in the analysis. Accordingly, text related to this was amended in Table 4 List of study procedures, Sections 5.6.2.11, Baseline measurement of limb circumference after booster vaccination at Visit 5 and 5.6.2.13 Recording of AEs, SAEs and NOCIs.
- Errors in the vaccines dictionary of Study Master Repository were rectified for *Infanrix hexa*, *Pediarix* and *Pentacel* vaccines. The corresponding correction was made in Table 9 Study vaccines.
- The sequence of analysis in Section 10.9.1 Sequence of analyses, was amended to reflect that there would first be an analysis of immunogenicity for anti-PRP and safety for Epoch 001, followed by a final analysis covering both Epochs at the end of the study.

5.12.2. Other changes

5.12.2.1. Changes in the Statistical Analysis Plan (SAP) from the protocol

- During the course of the study, the assays used to measure the anti-D, -T, -PRP, -PT, -FHA and -PRN IgG concentrations were re-developed and re-validated and both assay units and assay cut-offs were adapted. The new ELISAs for PT, FHA and PRN were calibrated against the WHO International Standard (NIBSC 06/140). This allowed the expression of concentrations measured with the new ELISAs in International Units per milliliter (IU/mL) instead of the formerly used ELISA units per milliliter (EL.U/mL). The newly validated DTPa ELISA's had a lower assay cut-offs as compared to the ones described in the protocol. The current assay cut-off was 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T, 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, 2.187 IU/mL for anti-PRN and 0.066 µg/mL for the fully validated anti-PRP assay.
- Since for anti-D and anti-T, a threshold of 0.1 IU/mL provided a conservative estimate of the percentage of subjects deemed to be protected, the anti-D, anti-T seropositivity endpoints initially defined by the previous assay cut-off of 0.1 IU/mL were replaced by seroprotection rate endpoints defined as the percentage of subjects with concentration above 0.1 IU/mL.
- In the absence of a correlate of protection for the *B. pertussis* antigens, the pertussis vaccine response endpoints were redefined based on the assay cut-off (see Section 5.10.1 and 5.10.2 for the definition of the endpoints).
- Subgroup analyses by gender and geographical ancestry was added for summaries of solicited symptoms and for summaries of unsolicited symptoms.
- During the review of protocol deviations, hemolysed samples were identified among blood samples obtained one month post dose 3. Not knowing the impact on the anti-HBs assay the samples were conservatively excluded from the Primary ATP cohort for immunogenicity analyses of anti-HBs. This concerned 36 subjects (14 in the Penta group and 11 in each of Pedia and Hexa groups).
- A descriptive summary per lot was added for anti-PRP post priming.
- The ANCOVA model was revised to include the 3 study groups rather than the 2 groups compared. This allowed identical adjusted GMC estimates regardless of the groups involved in the comparison.
- The DTPA-HBV-IPV-135 (117119) Abridged Interim Report Main (19-Oct-2015) included immunogenicity data against PRP antigen at Visit 4 using an assay which was not fully validated. For the final analysis, the Visit 4 samples were retested together with the samples pre- and post-booster using a newly validated assay. In the final analysis, the results of both assays are descriptively presented at Visit 4.
- Analyses of HHE within the 31-day (Days 0-30) post-vaccination period and of convulsion within 31-day (Days 0-30) post vaccination were added following a request from CBER [GlaxoSmithKline Vaccines, 2014].
- The distribution of vaccinated subjects by center and the summary of reason for withdrawal were performed for the full study rather than by Epoch.

6. STUDY POPULATION RESULTS

6.1. Study dates

Primary vaccination epoch

The first subject was enrolled in the primary vaccination study on 16-April-2014 and the last visit for the primary epoch took place on 31-March-2015. The last contact (ESFU) of the primary vaccination epoch was made on 12-August-2015.

Booster vaccination epoch

The first subject first visit for the Booster vaccination epoch was on 14-May-2015 and the last contact (ESFU) of the booster vaccination epoch was made on 13-November-2015.

6.2. Subject disposition

The number of subjects enrolled in the study at each centre is presented in Table 6.1. The deviations from specifications for age and intervals between study visits is presented in Table 6.5 (Primary Total vaccinated cohort) and Table 6.6 (Booster Total vaccinated cohort).

Table 17 represents the number of subjects who were vaccinated, completed and withdrawn at visit 6 (Month 14-17) with reason for withdrawal from the study.

A total of 585 subjects were vaccinated and 476 subjects completed the study. The most frequent reasons for withdrawal were: migrated/moved from the study area (21 subjects) and consent withdrawal (not due to an AE; 20 subjects).

Table 17 Number of subjects vaccinated, completed and withdrawn at visit 6 (Month 14-17) with reason for withdrawal (Primary Total vaccinated cohort)

	Hexa group	Pedia group	Penta group	Total
Number of subjects vaccinated	195	194	196	585
Number of subjects completed	161	158	157	476
Number of subjects withdrawn	34	36	39	109
Reasons for withdrawal :				
Subject died	0	0	0	0
Serious Adverse Event	1	0	0	1
Non-Serious Adverse Event	0	0	1	1
Eligibility criteria not fulfilled (inclusion and exclusion criteria)	0	0	0	0
Protocol violation	7	2	8	17
Consent withdrawal (not due to an adverse event)	5	7	8	20
Migrated/moved from study area	6	10	5	21
Lost to follow-up (subjects with incomplete vaccination course)	5	8	6	19
Lost to follow-up (subjects with complete vaccination course)	3	0	4	7
Sponsor study termination	0	0	1	1
Other - change their doctor	1	0	0	1
Other - loss of kaiser coverage	3	8	2	13
Other - medical history updated information	0	1	0	1
Other - received vaccines in injection clinic	0	0	1	1
Other - refuses blood draws	0	0	1	1
Other - subject got a new doctor	1	0	0	1
Other - subject unable to complete visit 5 during the gsk shortened window for visit 5	0	0	1	1
Other - subject was discontiued due to non-compliance	0	0	1	1
Other - terminated by pi due to non-compliance with appointment schedules	1	0	0	1
Other - unknown	1	0	0	1

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
pi = Principal Investigator

6.3. Important Protocol deviations at subject level

6.3.1. Protocol Deviations leading to elimination from ATP analyses

The details on number of subjects excluded from Primary ATP analysis with reasons for exclusion are presented in Table 18.

For Hepatitis B / anti-HBs analysis, hemolysed samples were excluded from the Primary ATP cohort for immunogenicity – see Section 5.12.2.1 for further details of which subjects were excluded.

The details on number of subjects excluded from Booster ATP analysis with reasons for exclusion are presented in Table 19.

Table 18 Number of subjects enrolled into the study as well as number excluded from Primary ATP analyses with reasons for exclusion

	Total			Hexa group		Pedia group		Penta group	
Title	**n**	**s**	**%**	**n**	**s**	**n**	**s**	**n**	**s**
Primary Total vaccinated cohort	585		100	195		194		196	
Administration of vaccine(s) forbidden in the protocol (code 1040)	7	7		1	1	1	1	5	5
Study vaccine dose not administered according to protocol (code 1070)	0	2		0	0	0	0	0	2
ATP cohort for safety	578		98.8	194		193		191	
Underlying medical condition forbidden by the protocol (code 2050)	2	2		0	0	0	0	2	2
Concomitant infection related to the vaccine which may influence immune response (code 2060)	0	2		0	0	0	0	0	2
Non compliance with vaccination schedule (including wrong and unknown dates) (code 2080)	19	20		5	5	8	8	6	7
Non compliance with blood sampling schedule (including wrong and unknown dates (code 2090)	6	9		4	6	2	3	0	0
Essential serological data missing (code 2100)	85	93		31	34	27	27	27	32
ATP cohort for immunogenicity *	466		79.7	154		156		156	

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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 Primary Total vaccinated cohort
* Subjects with hemolysed samples were excluded from the Primary ATP cohort for immunogenicity – see Section 5.12.2.1 for further details of which subjects were excluded.

Table 19 Number of subjects who received a booster dose as well as number excluded from Booster ATP analyses with reasons for exclusion

	Total			Hexa group		Pedia group		Penta group	
Title	**n**	**s**	**%**	**n**	**s**	**n**	**s**	**n**	**s**
Booster Total vaccinated cohort	486		100	167		158		161	
Administration of vaccine(s) forbidden in the protocol (code 1040)	1	1		0	0	0	0	1	1
ATP cohort for safety	485		99.8	167		158		160	
Administration of any medication forbidden by the protocol (code 2040)	2	2		0	0	0	0	2	2
Non compliance with vaccination schedule (including wrong and unknown dates) (code 2080)	6	6		4	4	0	0	2	2
Non compliance with blood sampling schedule (including wrong and unknown dates (code 2090)	17	17		8	8	2	2	7	7
Essential serological data missing (code 2100)	52	57		17	20	17	17	18	20
ATP cohort for immunogenicity	408		84.0	138		139		131	

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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 Booster Total vaccinated cohort

6.3.2. Protocol Deviations not leading to elimination from ATP analyses

None

6.4. Demographic characteristics and other baseline characteristics

The demographic characteristics are summarised for the Primary ATP cohort for immunogenicity in Table 20 and for the Booster ATP cohort for immunogenicity in Table 21.

In the Primary ATP cohort for immunogenicity, the mean age of the subjects was 8.6 weeks at the time of first vaccination (SD = 1.0; Table 20). There were more males (52.8%) compared to females (47.2%). The majority of the subjects were of White - Caucasian / European Heritage (62.9%), with African Heritage / African American (8.2%) and American Indian or Alaskan Native (7.7%) racial categories being the next two most frequent categories.

In the Booster ATP cohort for immunogenicity, the mean age of the subjects was 15.3 months at the time of vaccination (SD = 0.7; Table 21). There were more males (56.6%) compared to females (43.4%). The distribution of Booster phase subjects in the racial categories remained similar to the corresponding Primary cohort.

Table 20 Summary of demographic characteristics (Primary ATP cohort for immunogenicity)

		Hexa group N = 154		Pedia group N = 156		Penta group N = 156		Total N = 466	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age [Weeks] at first primary dose	Mean	8.6	-	8.6	-	8.6	-	8.6	-
	SD	0.9	-	1.1	-	1.0	-	1.0	-
	Median	8.0	-	9.0	-	9.0	-	9.0	-
	Minimum	6.0	-	6.0	-	6.0	-	6.0	-
	Maximum	12.0	-	12.0	-	11.0	-	12.0	-
Gender	Female	85	55.2	61	39.1	74	47.4	220	47.2
	Male	69	44.8	95	60.9	82	52.6	246	52.8
Race	African Heritage / African American	13	8.4	8	5.1	17	10.9	38	8.2
	American Indian or Alaskan Native	12	7.8	8	5.1	16	10.3	36	7.7
	Asian - Central/South Asian Heritage	1	0.6	1	0.6	0	0.0	2	0.4
	Asian - East Asian Heritage	1	0.6	2	1.3	0	0.0	3	0.6
	Asian - Japanese Heritage	1	0.6	0	0.0	1	0.6	2	0.4
	Asian - South East Asian Heritage	5	3.2	8	5.1	5	3.2	18	3.9
	Native Hawaiian or Other Pacific Islander	1	0.6	0	0.0	2	1.3	3	0.6
	White - Arabic / North African Heritage	0	0.0	1	0.6	0	0.0	1	0.2
	White - Caucasian / European Heritage	98	63.6	106	67.9	89	57.1	293	62.9
	Other	22	14.3	22	14.1	26	16.7	70	15.0
Height	Mean	58.0	-	58.2	-	59.0	-	58.4	-
	SD	3.5	-	3.8	-	3.1	-	3.5	-
	Median	58.0	-	58.0	-	58.0	-	58.0	-
	Minimum	38.0	-	37.0	-	51.0	-	37.0	-
	Maximum	65.0	-	69.0	-	66.0	-	69.0	-
Weight	Mean	5.3	-	5.4	-	5.4	-	5.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-
	Median	5.2	-	5.4	-	5.5	-	5.4	-
	Minimum	3.4	-	3.6	-	3.7	-	3.4	-
	Maximum	7.9	-	7.1	-	7.4	-	7.9	-
Hepatitis B vaccination at birth	Yes	143	92.9	136	87.2	144	92.3	423	90.8
	No	11	7.1	20	12.8	12	7.7	43	9.2

		Hexa group N = 154		Pedia group N = 156		Penta group N = 156		Total N = 466	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%	Value or n	%
Tdap vaccination of mother	Yes	83	66.4	79	64.8	81	61.4	243	64.1
	No	42	33.6	43	35.2	51	38.6	136	35.9
	Missing	29	-	34	-	24	-	87	-

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = number of subjects
n = number of subjects in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
SD = Standard deviation

Table 21 Summary of demographic characteristics (Booster ATP cohort for immunogenicity)

		Hexa group N = 138		Pedia group N = 139		Penta group N = 131		Total N = 408	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%	Value or n	%
Age [months] at booster dose	Mean	15.3	-	15.3	-	15.3	-	15.3	-
	SD	0.6	-	0.6	-	0.7	-	0.7	-
	Median	15.0	-	15.0	-	15.0	-	15.0	-
	Minimum	15.0	-	15.0	-	15.0	-	15.0	-
	Maximum	18.0	-	18.0	-	18.0	-	18.0	-
Gender	Female	72	52.2	47	33.8	58	44.3	177	43.4
	Male	66	47.8	92	66.2	73	55.7	231	56.6
Race	African Heritage / African American	12	8.7	8	5.8	12	9.2	32	7.8
	American Indian or Alaskan Native	11	8.0	10	7.2	14	10.7	35	8.6
	Asian - Central/South Asian Heritage	1	0.7	2	1.4	0	0.0	3	0.7
	Asian - East Asian Heritage	3	2.2	2	1.4	0	0.0	5	1.2
	Asian - Japanese Heritage	0	0.0	0	0.0	1	0.8	1	0.2
	Asian - South East Asian Heritage	5	3.6	8	5.8	5	3.8	18	4.4
	Native Hawaiian or Other Pacific Islander	1	0.7	0	0.0	2	1.5	3	0.7

		Hexa group N = 138		Pedia group N = 139		Penta group N = 131		Total N = 408	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
	White - Arabic / North African Heritage	0	0.0	1	0.7	0	0.0	1	0.2
	White - Caucasian / European Heritage	84	60.9	90	64.7	72	55.0	246	60.3
	Other	21	15.2	18	12.9	25	19.1	64	15.7
Height	Mean	58.0	-	58.5	-	59.0	-	58.5	-
	SD	3.6	-	4.6	-	3.2	-	3.9	-
	Median	58.0	-	58.0	-	58.0	-	58.0	-
	Minimum	38.0	-	37.0	-	48.0	-	37.0	-
	Maximum	64.0	-	86.0	-	66.0	-	86.0	-
Weight	Mean	5.3	-	5.4	-	5.4	-	5.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-
	Median	5.3	-	5.4	-	5.5	-	5.4	-
	Minimum	4.0	-	4.0	-	3.7	-	3.7	-
	Maximum	7.9	-	7.1	-	7.4	-	7.9	-
Hepatitis B vaccination at birth	Yes	129	93.5	122	87.8	120	91.6	371	90.9
	No	9	6.5	17	12.2	11	8.4	37	9.1
Tdap vaccination of mother	Yes	79	69.9	75	68.2	73	62.9	227	67.0
	No	34	30.1	35	31.8	43	37.1	112	33.0
	Missing	25	-	29	-	15	-	69	-

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = number of subjects
n = number of subjects in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
SD = Standard deviation

7. IMMUNOGENICITY RESULTS

The primary analysis of immunogenicity was performed on the Primary ATP cohort for analysis of immunogenicity and the Booster ATP cohort for analysis of immunogenicity. Refer to Section 5.10.4 for the definition of the cohorts identified for analyses.

7.1. Primary Vaccination Epoch

7.1.1. Non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB* - Immunogenicity of study vaccine pertussis antigens (PT, FHA and PRN)

The primary objective to demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens (PT, FHA and PRN) one month after the third dose of the primary vaccination was reached (Table 22) – see Section 4.1.1 for the definition of the primary objective.

For each of the three pertussis antigens, the upper limit of the 95% confidence interval (CI) for the GMC ratio [Pedia group divided by Hexa group] was ≤ 1.5 (Table 22):

- For anti-PT antibody – 1.31;
- For anti-FHA antibody – 1.35;
- For anti-PRN antibody – 0.99.

Table 22 Ratio of GMCs for anti-PT, anti-FHA and anti-PRN between groups (Pedia group divided by Hexa group), one month post primary vaccination (Primary ATP cohort for immunogenicity)

					Adjusted GMC ratio (Pedia group / Hexa group)		
	Pedia group		Hexa group			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PT antibody (IU/mL)	149	47.9	146	43.6	1.10	0.92	1.31
anti-FHA antibody (IU/mL)	149	122.6	146	107.3	1.14	0.97	1.35
anti-PRN antibody (IU/mL)	149	46.1	146	58.2	0.79	0.63	0.99

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
Adjusted GMC = geometric mean antibody concentration adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

7.1.2. Immune response to the Primary vaccinations

7.1.2.1. Anti-Pertussis (PT, FHA, PRN) antibody responses

The percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentrations ≥ the assay cut-off and GMC are presented in Table 23.

One month after primary vaccination for subjects in the Hexa, Pedia and Penta groups:

- At least 99.3% of subjects had anti-PT antibody concentrations ≥2.693 IU/mL (assay cut-off) and also anti-PRN antibody concentrations ≥2.187 IU/mL (assay cut-off).
- All subjects had an anti-FHA antibody concentrations ≥2.046 IU/mL (assay cut-off).
- GMC values across the three groups ranged for anti-PT antibody from 24.2-48.3, for anti-FHA antibody from 59.9-122.7, and for anti-PRN antibody from 33.0-57.4.

Table 23 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ assay cut-off				GMC		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	43.2	38.1	48.9
	Pedia group	PIII(M5)	149	148	99.3	96.3	100	48.3	42.7	54.5
	Penta group	PIII(M5)	149	148	99.3	96.3	100	24.2	21.1	27.7
anti-FHA antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	106.3	95.0	119.0
	Pedia group	PIII(M5)	149	149	100	97.6	100	122.7	109.9	137.0
	Penta group	PIII(M5)	149	149	100	97.6	100	59.9	51.7	69.3
anti-PRN antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	57.4	49.5	66.6
	Pedia group	PIII(M5)	149	148	99.3	96.3	100	46.9	39.9	55.3
	Penta group	PIII(M5)	149	148	99.3	96.3	100	33.0	27.8	39.1

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

The corresponding data is also presented by gender (Table 7.1), geographical ancestry (Table 7.2) and Tdap vaccination of mother (Table 7.3).

Reverse cumulative distribution curves for anti-PT concentrations one month post primary vaccination is provided in Figure 7.1, with corresponding curves for anti-FHA concentrations in Figure 7.2, and anti-PRN concentrations in Figure 7.3.

7.1.2.2. Anti-Diphtheria (D) and anti-Tetanus (Anti-T) antibody responses

The percentage of subjects with anti-D and anti-T antibody concentrations ≥ the assay cut-off, ≥ 0.1 IU/mL, ≥ 1.0 IU/mL and GMC are presented in Table 24.

One month after primary vaccination for subjects in the Hexa, Pedia and Penta groups:

- All subjects had anti-D antibody concentrations ≥ 0.1 IU/mL and at least 99.3% of subjects had anti-T antibody concentrations ≥ 0.1 IU/mL, which were the protocol-defined levels of seroprotection against these diseases (see Section 5.8.4 and 5.10.5.2).

The corresponding data is also presented by gender (Table 7.4), geographical ancestry (Table 7.5) and Tdap vaccination of mother (Table 7.6).

Reverse cumulative distribution curves for anti-D concentrations one month post primary vaccination is provided in Figure 7.4, with a corresponding curve for anti-T concentrations in Figure 7.5.

Table 24 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ cut-off				≥ 0.1 IU/mL				≥ 1.0 IU/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	PIII(M5)	142	142	100	97.4	100	142	100	97.4	100	112	78.9	71.2	85.3	1.777	1.551	2.036
	Pedia group	PIII(M5)	144	144	100	97.5	100	144	100	97.5	100	105	72.9	64.9	80.0	1.648	1.440	1.886
	Penta group	PIII(M5)	149	149	100	97.6	100	149	100	97.6	100	88	59.1	50.7	67.0	1.249	1.095	1.425
anti-T antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	146	100	97.5	100	130	89.0	82.8	93.6	2.458	2.195	2.753
	Pedia group	PIII(M5)	149	149	100	97.6	100	149	100	97.6	100	134	89.9	83.9	94.3	2.633	2.338	2.966
	Penta group	PIII(M5)	149	149	100	97.6	100	148	99.3	96.3	100	119	79.9	72.5	86.0	2.012	1.768	2.290

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

7.1.2.3. Anti-Polio 1, 2, and 3 antibody responses

The percentage of subjects with anti-Polio 1, 2, and 3 antibody titer ≥ 8 - the protocol-defined seroprotection level (see Section 5.8.4 and 5.10.5.2) and GMT are e presented in Table 25.

One month after primary vaccination for subjects in the Hexa, Pedia and Penta groups:

- At least 99.3% of subjects had anti-Polio 1 antibody titer ≥8,
  all subjects had anti-Polio 2 antibody titer ≥8 and
  at least 98.4% of subjects had anti-Polio 3 antibody titer ≥8.

The corresponding data is also presented by gender (Table 7.7), geographical ancestry (Table 7.8) and Tdap vaccination of mother (Table 7.9).

Reverse cumulative distribution curves for anti-Polio 1 titres one month post primary vaccination is provided in Figure 7.6, with corresponding curves for anti-Polio 2 titres in Figure 7.7 and anti-Polio 3 titres in Figure 7.8.

Table 25 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ 8 ED50				GMT		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	PIII(M5)	137	137	100	97.3	100	546.9	447.7	668.0
	Pedia group	PIII(M5)	134	134	100	97.3	100	604.1	495.9	736.0
	Penta group	PIII(M5)	136	135	99.3	96.0	100	319.5	256.8	397.5
anti-Polio 2 antibody	Hexa group	PIII(M5)	133	133	100	97.3	100	483.5	394.2	593.0
	Pedia group	PIII(M5)	131	131	100	97.2	100	567.7	448.8	718.1
	Penta group	PIII(M5)	134	134	100	97.3	100	283.0	229.4	349.2
anti-Polio 3 antibody	Hexa group	PIII(M5)	129	129	100	97.2	100	722.2	577.4	903.4
	Pedia group	PIII(M5)	132	132	100	97.2	100	927.0	740.7	1160.3
	Penta group	PIII(M5)	126	124	98.4	94.4	99.8	294.6	221.6	391.7

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

7.1.2.4. Anti-PRP antibody responses

The percentage of subjects with anti-PRP antibody concentrations ≥ the assay cut-off, ≥ 0.1 µg/mL, ≥ 1.0 µg/mL and GMC are presented in Table 26.

One month after primary vaccination for subjects in the Hexa, Pedia and Penta groups:

- Short-term seroprotection against *Haemophilus influenzae* type b disease is defined as an anti-PRP antibody concentrations ≥ 0.15 µg/mL (see Section 5.8.4 and 5.10.5.2). This level of seroprotection was reached by at least 94.0% of subjects across the groups using the qualified assay and at least 94.8% across groups using the fully validated assay.

Table 26 Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ assay cut-off				≥ 0.15 µg/mL				≥ 1.0 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-PRP – qualified assay	Hexa group	PIII(M5)	149	140	94.0	88.8	97.2	140	94.0	88.8	97.2	83	55.7	47.3	63.8	1.373	1.083	1.740
	Pedia group	PIII(M5)	153	151	98.7	95.4	99.8	151	98.7	95.4	99.8	144	94.1	89.1	97.3	10.327	8.127	13.122
	Penta group	PIII(M5)	153	151	98.7	95.4	99.8	151	98.7	95.4	99.8	126	82.4	75.4	88.0	6.485	4.922	8.544
anti-PRP – fully validated assay	Hexa group	PIII(M5)	154	152	98.7	95.4	99.8	146	94.8	90.0	97.7	85	55.2	47.0	63.2	1.348	1.076	1.688
	Pedia group	PIII(M5)	154	153	99.4	96.4	100	151	98.1	94.4	99.6	145	94.2	89.2	97.3	9.258	7.362	11.642
	Penta group	PIII(M5)	156	154	98.7	95.4	99.8	154	98.7	95.4	99.8	130	83.3	76.5	88.8	5.717	4.363	7.492

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

The corresponding data is also presented by study lot (Table 7.10), by gender (Table 7.11), geographical ancestry (Table 7.12) and Tdap vaccination of mother (Table 7.13).

Reverse cumulative distribution curves for anti-PRP (fully validated assay) concentrations one month post primary vaccination is provided in Figure 7.9, with a corresponding curve for anti-PRP (qualified assay) concentrations in Figure 7.10.

7.1.2.5. Anti-HBs antibody responses

The percentage of subjects with anti-HBs antibody concentrations ≥ assay cut-off of 6.2 mIU/mL or seroprotection threshold of ≥ 10.0 mIU/mL and GMC are presented in Table 27.

One month after primary vaccination for subjects in the Hexa, Pedia and Penta groups:

- Seroprotection against Hepatitis B virus (HBV) disease is defined as anti-HBs antibody concentrations greater than or equal to 10 mIU/mL (see Section 5.8.4 and 5.10.5.2). This level of seroprotection was met by at least 97.8% of subjects across the groups.

  The results were re-presented this time by either receiving a HepB vaccination at birth or not (Table 28).

Table 27 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				≥ 6.2 mIU/mL				≥ 10 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-HBs antibody	Hexa group	PIII(M5)	134	134	100	97.3	100	134	100	97.3	100	2258.8	1910.7	2670.4
	Pedia group	PIII(M5)	138	138	100	97.4	100	138	100	97.4	100	1886.0	1565.6	2271.9
	Penta group	PIII(M5)	136	134	98.5	94.8	99.8	133	97.8	93.7	99.5	1053.4	780.2	1422.4

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

The corresponding data is also presented by gender (Table 7.14), geographical ancestry (Table 7.15) and Tdap vaccination of mother (Table 7.16).

Reverse cumulative distribution curves for anti-HBs concentrations one month post primary vaccination is provided in Figure 7.11.

Table 28 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination – by Hepatitis B vaccination at birth (Primary ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	HepB at birth Yes	PIII(M5)	124	124	100	97.1	100	124	100	97.1	100	2322.2	1951.3	2763.6
		HepB at birth No	PIII(M5)	10	10	100	69.2	100	10	100	69.2	100	1602.9	799.9	3212.1
	Pedia group	HepB at birth Yes	PIII(M5)	122	122	100	97.0	100	122	100	97.0	100	2026.9	1681.8	2442.9
		HepB at birth No	PIII(M5)	16	16	100	79.4	100	16	100	79.4	100	1088.7	506.6	2339.6
	Penta group	HepB at birth Yes	PIII(M5)	126	124	98.4	94.4	99.8	123	97.6	93.2	99.5	1043.4	755.4	1441.2
		HepB at birth No	PIII(M5)	10	10	100	69.2	100	10	100	69.2	100	1188.2	755.3	1869.1

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

7.1.3. Primary Total Vaccinated cohort analysis

A total of 119 (20.3%) subjects, out of 585 vaccinated subjects were eliminated from the Primary ATP cohort for immunogenicity (466 subjects; Table 18). As more than 5% of the vaccinated subjects with immunological data post-dose 3 were excluded from the Primary ATP cohort for immunogenicity, a complementary analysis was carried out on the Primary Total Vaccinated cohort (see Section 5.10.6.2).

No apparent or clinically meaningful differences were observed between the immunogenicity results for the Primary Total Vaccinated cohort and the Primary ATP cohort for immunogenicity.

The results of the Primary Total Vaccinated cohort analyses are presented in Table 7.53 to Table 7.58.

7.2. Booster Vaccination Epoch

7.2.1. Immune response to the Booster vaccinations

7.2.1.1. Anti-Pertussis (PT, FHA, PRN) antibody persistence and booster response

The percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentrations ≥ the assay cut-off and GMC are presented in Table 29.

Before the Booster vaccination for subjects in the Hexa, Pedia and Penta groups:

- Between 52.1-86.4% of subjects had anti-PT antibody concentrations ≥2.693 IU/mL, between 93.4-99.2% of subjects had anti-FHA antibody concentrations ≥2.046 IU/mL, and between 75.8-84.0% of subjects had anti-PRN antibody concentrations ≥2.187 IU/mL.
- The most pronounced anti-pertussis antibody levels decay (especially PT and FHA) between the primary and booster vaccinations is observed after *Pentacel+Engerix-B* vaccination.

One month after Booster vaccination for subjects in the Hexa, Pedia and Penta groups:

- All subjects had anti-PT antibody concentrations ≥2.693 IU/mL, all subjects had anti-FHA antibody concentrations ≥2.046 IU/mL, and all Pedia group subjects had anti-PRN antibody concentrations ≥2.187 IU/mL. The other anti-PRN antibody concentrations results were both above 99%.

The corresponding data is also presented by gender (Table 7.24), geographical ancestry (Table 7.25) and Tdap vaccination of mother (Table 7.26).

Reverse cumulative distribution curves for anti-PT concentrations, before and one month post booster vaccination is provided in Figure 7.12, with corresponding curves for anti-FHA concentrations in Figure 7.13, and anti-PRN concentrations in Figure 7.14.

Table 29 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), before and one month post booster vaccination (Booster ATP cohort for immunogenicity)

				≥ assay cut-off				GMC		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	PRE-BST	131	107	81.7	74.0	87.9	5.3	4.6	6.2
		POST-BST	138	138	100	97.4	100	71.4	62.6	81.5
	Pedia group	PRE-BST	132	114	86.4	79.3	91.7	6.5	5.6	7.7
		POST-BST	136	136	100	97.3	100	87.6	76.6	100.2
	Penta group	PRE-BST	121	63	52.1	42.8	61.2	3.1	2.6	3.7
		POST-BST	126	126	100	97.1	100	55.5	47.4	65.1
anti-FHA antibody	Hexa group	PRE-BST	131	130	99.2	95.8	100	17.1	14.7	19.9
		POST-BST	138	138	100	97.4	100	186.9	165.1	211.5
	Pedia group	PRE-BST	132	130	98.5	94.6	99.8	21.8	18.3	26.1
		POST-BST	136	136	100	97.3	100	250.4	220.4	284.6
	Penta group	PRE-BST	121	113	93.4	87.4	97.1	8.1	6.6	9.9
		POST-BST	126	126	100	97.1	100	101.0	86.2	118.3
anti-PRN antibody	Hexa group	PRE-BST	131	110	84.0	76.5	89.8	6.8	5.5	8.3
		POST-BST	137	136	99.3	96.0	100	208.0	172.3	251.1
	Pedia group	PRE-BST	132	104	78.8	70.8	85.4	5.5	4.5	6.6
		POST-BST	136	136	100	97.3	100	215.6	176.1	263.8
	Penta group	PRE-BST	120	91	75.8	67.2	83.2	6.0	4.8	7.5
		POST-BST	125	124	99.2	95.6	100	130.5	105.9	160.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

7.2.1.2. Booster responses for anti-PT, anti-FHA, and anti-PRN antibodies

The proportion of subjects with an anti-Pertussis antibody booster response was:

- For anti-PT antibody: ≥93.1% across groups;
- For anti-FHA antibody: ≥97.7% across groups;
- For anti-PRN antibody: ≥97.4% across groups (Table 30).

Table 30 Booster response for anti-PT, anti-FHA and anti-PRN antibodies, one month post booster vaccination (Booster ATP cohort for immunogenicity)

				Booster response			
						95% CI	
Antibody	Group	Pre-vaccination status	N	n	%	LL	UL
anti-PT antibody (IU/mL)	Hexa group	S-	24	22	91.7	73.0	99.0
		S+ (<4*cut_off IU/mL)	78	75	96.2	89.2	99.2
		S+ (≥4*cut_off IU/mL)	29	29	100	88.1	100
		Total	131	126	96.2	91.3	98.7
	Pedia group	S-	18	18	100	81.5	100
		S+ (<4*cut_off IU/mL)	86	81	94.2	87.0	98.1
		S+ (≥4*cut_off IU/mL)	26	22	84.6	65.1	95.6
		Total	130	121	93.1	87.3	96.8
	Penta group	S-	56	52	92.9	82.7	98.0
		S+ (<4*cut_off IU/mL)	46	45	97.8	88.5	99.9
		S+ (≥4*cut_off IU/mL)	14	14	100	76.8	100
		Total	116	111	95.7	90.2	98.6
anti-FHA antibody (IU/mL)	Hexa group	S-	1	1	100	2.5	100
		S+ (<4*cut_off IU/mL)	27	27	100	87.2	100
		S+ (≥4*cut_off IU/mL)	103	102	99.0	94.7	100
		Total	131	130	99.2	95.8	100
	Pedia group	S-	2	2	100	15.8	100
		S+ (<4*cut_off IU/mL)	17	17	100	80.5	100
		S+ (≥4*cut_off IU/mL)	111	108	97.3	92.3	99.4
		Total	130	127	97.7	93.4	99.5
	Penta group	S-	8	8	100	63.1	100
		S+ (<4*cut_off IU/mL)	57	56	98.2	90.6	100
		S+ (≥4*cut_off IU/mL)	51	50	98.0	89.6	100
		Total	116	114	98.3	93.9	99.8
anti-PRN antibody (IU/mL)	Hexa group	S-	21	20	95.2	76.2	99.9
		S+ (<4*cut_off IU/mL)	54	54	100	93.4	100
		S+ (≥4*cut_off IU/mL)	55	54	98.2	90.3	100
		Total	130	128	98.5	94.6	99.8
	Pedia group	S-	28	27	96.4	81.7	99.9
		S+ (<4*cut_off IU/mL)	55	54	98.2	90.3	100
		S+ (≥4*cut_off IU/mL)	47	47	100	92.5	100
		Total	130	128	98.5	94.6	99.8
	Penta group	S-	28	26	92.9	76.5	99.1
		S+ (<4*cut_off IU/mL)	40	39	97.5	86.8	99.9
		S+ (≥4*cut_off IU/mL)	47	47	100	92.5	100
		Total	115	112	97.4	92.6	99.5

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines

Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines

Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine

Booster response to PT, FHA and PRN antigens is defined as:

S- subjects: For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration ≥ 4 times the assay cut-off

S+ (<4*cut_off IU/mL) subjects: For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration

S+ (≥4*cut_off IU/mL) subjects: For subjects with pre-vaccination antibody concentration equal or above 4 times the assay cut off, post-vaccination antibody concentration equal or above 2 times the pre-vaccination antibody concentration
N = number of subjects with pre- and post-vaccination results available
n/% = number/percentage of subjects with booster response
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

The corresponding data is also presented by gender (Table 7.27), geographical ancestry (Table 7.28) and Tdap vaccination of mother (Table 7.29).

7.2.1.3. Anti-D and anti-T antibody persistence and booster response

The percentage of subjects with anti-D and anti-T antibody concentrations ≥ the assay cut-off, ≥ 0.1 IU/mL, ≥ 1.0 IU/mL and GMC are presented in Table 31.

Antibody persistence data before the Booster vaccination for subjects in the Hexa, Pedia and Penta groups:

- Between 93.2-97.7% of subjects had anti-D antibody concentrations ≥ 0.1 IU/mL and between 88.4-93.2% of subjects had anti-T antibody concentrations ≥ 0.1 IU/mL, which were the protocol-defined levels of seroprotection against these diseases.

One month after Booster vaccination for subjects in the Hexa, Pedia and Penta groups:

- All subjects had anti-D antibody concentrations and anti-T antibody concentrations ≥ 0.1 IU/mL, except for the Penta group for which anti-T antibody concentration was ≥ 0.1 IU/mL for 99.2% of subjects.
- The conservative level of ≥ 1.0 IU/mL seroprotection was exhibited for anti-D antibody by all subjects and for anti-T antibody by between 97.8-100% of subjects.

The corresponding data is also presented by gender (Table 7.30), geographical ancestry (Table 7.31) and Tdap vaccination of mother (Table 7.32).

Reverse cumulative distribution curves for anti-D concentrations, before and one month post booster vaccination is provided in Figure 7.15, with a corresponding curve for anti-T concentrations in Figure 7.16.

Table 31 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), before and one month post booster vaccination (Booster ATP cohort for immunogenicity)

				≥ assay cut-off				≥ 0.1 IU/mL				≥ 1.0 IU/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-D antibody	Hexa group	PRE-BST	131	131	100	97.2	100	128	97.7	93.5	99.5	43	32.8	24.9	41.6	0.701	0.597	0.825
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	138	100	97.4	100	8.334	7.479	9.286
	Pedia group	PRE-BST	132	129	97.7	93.5	99.5	123	93.2	87.5	96.8	48	36.4	28.2	45.2	0.622	0.514	0.753
		POST-BST	136	136	100	97.3	100	136	100	97.3	100	136	100	97.3	100	7.886	6.972	8.920
	Penta group	PRE-BST	121	118	97.5	92.9	99.5	115	95.0	89.5	98.2	51	42.1	33.2	51.5	0.764	0.629	0.928
		POST-BST	126	126	100	97.1	100	126	100	97.1	100	126	100	97.1	100	8.537	7.524	9.687
anti-T antibody	Hexa group	PRE-BST	131	130	99.2	95.8	100	118	90.1	83.6	94.6	16	12.2	7.1	19.1	0.327	0.281	0.380
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	138	100	97.4	100	9.212	7.863	10.793
	Pedia group	PRE-BST	132	129	97.7	93.5	99.5	123	93.2	87.5	96.8	17	12.9	7.7	19.8	0.402	0.340	0.474
		POST-BST	136	136	100	97.3	100	136	100	97.3	100	133	97.8	93.7	99.5	8.870	7.668	10.261
	Penta group	PRE-BST	121	119	98.3	94.2	99.8	107	88.4	81.3	93.5	19	15.7	9.7	23.4	0.340	0.281	0.410
		POST-BST	126	126	100	97.1	100	125	99.2	95.7	100	125	99.2	95.7	100	6.880	5.905	8.015

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

7.2.1.4. Anti-PRP antibody persistence and booster response

The percentage of subjects with anti-PRP antibody concentration ≥ 0.066 µg/mL, ≥ 0.15 µg/mL and ≥ 1.0 µg/mL and GMC are presented in Table 32.

Antibody persistence data before the Booster vaccination for subjects in the Hexa, Pedia and Penta groups:

- Between 69.5-92.4% of subjects had anti-PRP antibody concentrations ≥ 0.15 µg/mL, which indicated short-term seroprotection.
- Between 17.6-53.8% of subjects had anti-PRP antibody concentrations ≥ 1.0 µg/mL, which indicated long-term seroprotection.
- The most pronounced Anti-PRP antibody levels decay between the primary and booster vaccinations is observed after *Infanrix hexa* vaccination.

One month after Booster vaccination for subjects in the Hexa, Pedia and Penta groups:

- Between 98.5-100% of subjects had anti-PRP antibody concentrations ≥ 0.15 µg/mL.
- Between 97.7-99.3% of subjects had anti-PRP antibody concentrations ≥ 1.0 µg/mL.

The corresponding data is also presented by gender (Table 7.33), geographical ancestry (Table 7.34) and Tdap vaccination of mother (Table 7.35).

Reverse cumulative distribution curves for anti-PRP (fully validated assay) concentrations, before and one month post booster vaccination is provided in Figure 7.20.

Table 32 Number and percentage of subjects with anti-PRP antibody concentration equal to or above 0.066 µg/mL, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), before and one month post booster vaccination (Booster ATP cohort for immunogenicity)

				≥ 0.066 µg/mL				≥ 0.15 µg/mL				≥ 1.0 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – fully validated assay	Hexa group	PRE-BST	131	118	90.1	83.6	94.6	91	69.5	60.8	77.2	23	17.6	11.5	25.2	0.301	0.242	0.373
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	136	98.6	94.9	99.8	39.365	31.520	49.164
	Pedia group	PRE-BST	132	129	97.7	93.5	99.5	122	92.4	86.5	96.3	71	53.8	44.9	62.5	0.987	0.775	1.256
		POST-BST	139	139	100	97.4	100	139	100	97.4	100	138	99.3	96.1	100	51.140	41.954	62.339
	Penta group	PRE-BST	121	111	91.7	85.3	96.0	94	77.7	69.2	84.8	47	38.8	30.1	48.1	0.614	0.458	0.822
		POST-BST	131	130	99.2	95.8	100	129	98.5	94.6	99.8	128	97.7	93.5	99.5	27.318	21.140	35.302

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

7.2.1.5. Anti-Polio antibody persistence

The percentage of subjects with anti-Polio 1, 2, and 3 antibody titers ≥ 8 – the protocol-defined seroprotection level (see Section 5.8.4 and 5.10.5.2) and GMT are e presented in Table 33.

Antibody persistence data at the Month 13-16 or Pre-Bst timepoint (Visit 5; Section 5.1.1) for the Hexa, Pedia and Penta groups:

- Between 86.2-96.9% of subjects had anti-Polio 1 antibody titer ≥8, between 93.0-95.3% of subjects had anti-Polio 2 antibody titer ≥8, and between 68.4-97.7% of subjects had anti-Polio 3 antibody titer ≥8.
- The most pronounced anti-polio antibody levels decay (especially polio 1 and polio 3) between the primary and booster vaccinations is observed after *Pentacel+Engerix-B* vaccination.

The corresponding data is also presented by gender (Table 7.36), geographical ancestry (Table 7.37) and Tdap vaccination of mother (Table 7.38).

Reverse cumulative distribution curves for anti-Polio 1 antibody titres before booster vaccination is provided in Figure 7.17, with corresponding curves for anti-Polio 2 titres in Figure 7.18 and anti-Polio 3 titres in Figure 7.19.

Table 33 Number and percentage of subjects with anti-Polio 1, 2 and 3 antibody titers equal to or above 8 and geometric mean titers (GMT), before the booster vaccination (Booster ATP cohort for immunogenicity)

				≥ 8 ED50				GMT		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	PRE-BST	128	124	96.9	92.2	99.1	99.5	79.4	124.8
	Pedia group	PRE-BST	128	121	94.5	89.1	97.8	107.4	83.7	137.9
	Penta group	PRE-BST	116	100	86.2	78.6	91.9	42.2	32.6	54.6
anti-Polio 2 antibody	Hexa group	PRE-BST	128	119	93.0	87.1	96.7	94.9	73.2	123.1
	Pedia group	PRE-BST	128	122	95.3	90.1	98.3	111.9	88.0	142.4
	Penta group	PRE-BST	117	109	93.2	87.0	97.0	51.2	40.8	64.3
anti-Polio 3 antibody	Hexa group	PRE-BST	127	123	96.9	92.1	99.1	122.1	95.1	156.9
	Pedia group	PRE-BST	129	126	97.7	93.4	99.5	160.4	125.8	204.6
	Penta group	PRE-BST	117	80	68.4	59.1	76.7	28.4	20.6	39.1

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

7.2.1.6. Anti-HBs antibody persistence

The percentage of subjects with anti-HBs antibody concentration ≥ the assay cut-off of 6.2 mIU/mL or ≥ 10.0 mIU/mL which was the protocol-defined seroprotection level (see Section 5.8.4 and 5.10.5.2), and GMC are presented in Table 34.

Antibody persistence data at the Month 13-16 or Pre-Bst timepoint (Visit 5; Section 5.1.1) for the Hexa, Pedia and Penta groups:

- Between 86.8-98.5% of subjects had anti-HBs antibody concentrations ≥ 10.0 mIU/mL.
- The most pronounced anti-HBs antibody levels decay between the primary and booster vaccinations is observed after *Pentacel+Engerix-B* vaccination.

The corresponding data is also presented by gender (Table 7.39), geographical ancestry (Table 7.40), Tdap vaccination of mother (Table 7.41) and by Hepatitis B vaccination of subject (Table 7.42).

Reverse cumulative distribution curves for anti-HBs antibody concentrations before booster vaccination is provided in Figure 7.21.

Table 34 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10 mIU/mL and geometric mean concentration (GMC), before the booster vaccination (Booster ATP cohort for immunogenicity)

				≥ 6.2 mIU/mL				≥ 10 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-HBs antibody	Hexa group	PRE-BST	133	132	99.2	95.9	100	131	98.5	94.7	99.8	328.7	261.5	413.2
	Pedia group	PRE-BST	131	130	99.2	95.8	100	128	97.7	93.5	99.5	235.8	188.2	295.5
	Penta group	PRE-BST	121	110	90.9	84.3	95.4	105	86.8	79.4	92.2	149.4	100.5	222.3

Hexa group = Subjects who received primary doses of *Infanrix* hexa and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

7.2.2. Booster Total Vaccinated cohort analysis

A total of 78 (16.1%) subjects, out of 486 booster vaccinated subjects were eliminated from the Booster ATP cohort for immunogenicity (408 subjects; Table 19). As more than 5% of the booster vaccinated subjects with immunological data post-booster were excluded from the Booster ATP cohort for immunogenicity, a complementary analysis was carried out on the Booster Total Vaccinated cohort (see Section 5.10.7.2).

No apparent or clinically meaningful differences were observed between the immunogenicity results for the Booster Total Vaccinated cohort and the Booster ATP cohort for immunogenicity.

The results of the Booster Total Vaccinated cohort analyses are presented in Table 7.59 to Table 7.64.

7.3. Immunogenicity summary

7.3.1. Primary Vaccination Epoch

The primary objective to demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody GMCs for pertussis antigens (PT, FHA and PRN) one month after the third dose of the primary vaccination was reached:

- For PT, FHA and PRN, the upper limit of the 95% CI for the GMC ratio [Pedia group divided by Hexa group] was ≤ 1.5: For anti-PT antibody – 1.31; for anti-FHA antibody – 1.35; for anti-PRN antibody – 0.99.

- *Anti-Diphtheria and anti-Tetanus antibody responses:* All subjects had anti-D antibody concentrations ≥ 0.1 IU/mL and at least 99.3% of subjects had anti-T antibody concentrations ≥ 0.1 IU/mL, indicating seroprotection against these diseases.
- *Anti-Polio 1, 2, and 3 antibody responses:* At least 99.3% of subjects had anti-Polio 1 antibody titer ≥8, all subjects had anti-Polio 2 antibody titer ≥8 and at least 98.4% of subjects had anti-Polio 3 antibody titer ≥8.
- *Anti-PRP antibody responses:* Short-term seroprotection against *Haemophilus influenzae* type b disease (anti-PRP antibody concentrations ≥ 0.15 μg/mL) was met by at least 94.8% across groups using the fully validated assay.
- *Anti-HBs antibody responses:* Seroprotection against Hepatitis B virus (HBV) disease (anti-HBs ≥ 10 mIU/mL) was reached by at least 97.8% of subjects across the groups.

7.3.2. Booster Vaccination Epoch

- The proportion of subjects with an anti-Pertussis antibody booster response was:
  For anti-PT antibody: ≥93.1% across groups;
  for anti-FHA antibody: ≥97.7% across groups;
  for anti-PRN antibody: ≥97.4% across groups.
- *Anti-D and Anti-T immune response:* Seroprotection (≥ 0.1 IU/mL) was reached for at least 99.2% of subjects across groups and long-term seroprotection (antibody concentrations ≥1.0 IU/mL) was reached by all subjects for anti-D and for anti-T antibody by between 97.8-100% of subjects.
- *Anti-PRP immune response:* Short-term seroprotection (≥ 0.15 μg/mL): Between 98.5-100% of subjects across groups and long-term seroprotection (≥ 1.0 μg/mL) for between 97.7-99.3% of subjects across groups.

8. SAFETY RESULTS

8.1. Primary Total vaccinated cohort analysis

8.1.1. Primary vaccination doses received

All enrolled subjects received at least one dose of study vaccine (Table 35):

- For the Hexa group, the correct number of doses of *Infanrix hexa*, *Prevnar13* and *Rotarix* were received by 93.8%, 93.8% and 95.4%, respectively.
- For the Pedia group, the correct number of doses of *ActHIB*, *Pediarix*, *Prevnar13* and *Rotarix* were received by 95.4%, 95.4%, 95.4% and 96.9%, respectively.
- For the Penta group, the correct number of doses of *Engerix-B, Pentacel*, *Prevnar13* and *Rotarix* were received by 91.8%, 91.8%, 91.8%, and 96.4%, respectively.

Table 35 Number and percentage of subjects who received priming doses by vaccine (Primary Total vaccinated cohort)

	Hexa group INFANRIX HEXA N = 195		Hexa group PREVNAR 13 N = 195		Hexa group ROTARIX N = 195		Pedia group ACTHIB N = 194		Pedia group PEDIARIX N = 194		Pedia group PREVNAR 13 N = 194		Pedia group ROTARIX N = 194		Penta group ENGERIX-B N = 196		Penta group PENTACEL N = 196		Penta group PREVNAR 13 N = 196		Penta group ROTARIX N = 196	
Total number of doses received	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
1	9	4.6	9	4.6	9	4.6	6	3.1	6	3.1	6	3.1	6	3.1	16	8.2	9	4.6	7	3.6	7	3.6
2	3	1.5	3	1.5	186	95.4	3	1.5	3	1.5	3	1.5	188	96.9	167	85.2	7	3.6	9	4.6	189	96.4
3	183	93.8	183	93.8	0	0.0	185	95.4	185	95.4	185	95.4	0	0.0	13	6.6	180	91.8	180	91.8	0	0.0
Any	195	100	195	100	195	100	194	100	194	100	194	100	194	100	196	100	196	100	196	100	196	100

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the specified total number of doses
Any = number and percentage of subjects receiving at least one dose

8.1.2. Symptom eCRF screen compliance

Compliance in recording general symptom eCRF screens or local symptom eCRF screens was typically very high across groups for each of the three scheduled doses i.e. total results per group were at least 95% and results per treatment group across doses were at least 94% (Table 36).

Table 36 Compliance in returning symptom sheets for priming doses (Primary Total vaccinated cohort)

Dose	Group	Number of doses	Doses NOT according to protocol	Number of general SS	Compliance % general SS	Number of local SS	Compliance % local SS
1	Hexa group	195	1	185	94.9	185	94.9
	Pedia group	194	0	189	97.4	189	97.4
	Penta group	196	1	188	95.9	188	95.9
2	Hexa group	186	0	182	97.8	182	97.8
	Pedia group	188	0	184	97.9	184	97.9
	Penta group	189	0	179	94.7	180	95.2
3	Hexa group	183	2	172	94.0	172	94.0
	Pedia group	185	0	175	94.6	175	94.6
	Penta group	180	0	170	94.4	171	95.0
Total	Hexa group	564	3	539	95.6	539	95.6
	Pedia group	567	0	548	96.6	548	96.6
	Penta group	565	1	537	95.0	539	95.4

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.1.3. Overall incidence of adverse events

Please refer to the following Tables:

1. Incidence and nature of symptoms (solicited and unsolicited): Table 37;
   - In all three groups (Hexa, Pedia and Penta) over the primary doses, symptoms (solicited and/or unsolicited, local and/or general) were reported for 93.4-96.4% of subjects.
2. Incidence and nature of grade 3 symptoms (solicited and unsolicited): Table 38;
   - In all three groups (Hexa, Pedia and Penta) over the primary doses, grade 3 symptoms (solicited and/or unsolicited, local and/or general) were reported for 17.4-37.1% of subjects.
3. Incidence of local symptoms (solicited and unsolicited) reported for *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B* vaccines: Table 39;
   - Overall local symptoms (solicited and unsolicited) over the primary doses, were recorded for subjects receiving: Infanrix hexa (76.4%); Pediarix (82.0%), ActHIB (84.5%), Pentacel (79.6%), and *Engerix-B* (74.0%).
4. Incidence of grade 3 local symptoms (solicited and unsolicited) reported for *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B* vaccines: Table 40;
   - Overall grade 3 local symptoms (solicited and unsolicited) over the primary doses, were recorded for subjects receiving: Infanrix hexa (8.2%); Pediarix (18.6%), ActHIB (19.6%), Pentacel (17.3%), and *Engerix-B* (9.7%).

Please also refer to the following Tables:

1. Incidence and nature of symptoms (solicited and unsolicited) that were causally related to vaccination reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall: Table 8.1.
2. Incidence and nature of grade 3 symptoms (solicited and unsolicited) that were causally related to vaccination reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall: Table 8.2.
3. Incidence and nature of symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall: Table 8.3.
4. Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall: Table 8.4.
5. Incidence and nature of symptoms (solicited and unsolicited) that were causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall: Table 8.5.
6. Incidence and nature of grade 3 symptoms (solicited and unsolicited) that were causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall: Table 8.6.

Table 37 Incidence and nature of symptoms (solicited and unsolicited) reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	165	84.6	78.8	89.4	195	153	78.5	72.0	84.0	195	111	56.9	49.7	64.0
	Pedia group	194	182	93.8	89.4	96.8	194	179	92.3	87.6	95.6	194	144	74.2	67.5	80.2
	Penta group	196	178	90.8	85.9	94.5	196	173	88.3	82.9	92.4	196	128	65.3	58.2	71.9
Dose 2	Hexa group	186	161	86.6	80.8	91.1	186	151	81.2	74.8	86.5	186	105	56.5	49.0	63.7
	Pedia group	188	167	88.8	83.4	93.0	188	160	85.1	79.2	89.9	188	135	71.8	64.8	78.1
	Penta group	189	162	85.7	79.9	90.4	189	156	82.5	76.4	87.7	189	117	61.9	54.6	68.9
Dose 3	Hexa group	183	152	83.1	76.8	88.2	183	142	77.6	70.9	83.4	183	103	56.3	48.8	63.6
	Pedia group	185	161	87.0	81.3	91.5	185	155	83.8	77.7	88.8	185	118	63.8	56.4	70.7
	Penta group	180	146	81.1	74.6	86.5	180	138	76.7	69.8	82.6	180	107	59.4	51.9	66.7
Overall/dose	Hexa group	564	478	84.8	81.5	87.6	564	446	79.1	75.5	82.4	564	319	56.6	52.4	60.7
	Pedia group	567	510	89.9	87.2	92.3	567	494	87.1	84.1	89.8	567	397	70.0	66.1	73.8
	Penta group	565	486	86.0	82.9	88.8	565	467	82.7	79.3	85.7	565	352	62.3	58.2	66.3
Overall/subject	Hexa group	195	185	94.9	90.8	97.5	195	182	93.3	88.9	96.4	195	151	77.4	70.9	83.1
	Pedia group	194	187	96.4	92.7	98.5	194	186	95.9	92.0	98.2	194	168	86.6	81.0	91.1
	Penta group	196	183	93.4	88.9	96.4	196	182	92.9	88.3	96.0	196	162	82.7	76.6	87.7

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines

Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines

Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine

For each dose and overall/subject:

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered

For overall/dose:

N = number of administered doses

n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 38 Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	17	8.7	5.2	13.6	195	10	5.1	2.5	9.2	195	12	6.2	3.2	10.5
	Pedia group	194	41	21.1	15.6	27.6	194	22	11.3	7.2	16.7	194	32	16.5	11.6	22.5
	Penta group	196	35	17.9	12.8	23.9	196	24	12.2	8.0	17.7	196	22	11.2	7.2	16.5
Dose 2	Hexa group	186	17	9.1	5.4	14.2	186	13	7.0	3.8	11.7	186	5	2.7	0.9	6.2
	Pedia group	188	26	13.8	9.2	19.6	188	19	10.1	6.2	15.3	188	13	6.9	3.7	11.5
	Penta group	189	16	8.5	4.9	13.4	189	12	6.3	3.3	10.8	189	10	5.3	2.6	9.5
Dose 3	Hexa group	183	9	4.9	2.3	9.1	183	8	4.4	1.9	8.4	183	1	0.5	0.0	3.0
	Pedia group	185	27	14.6	9.8	20.5	185	20	10.8	6.7	16.2	185	13	7.0	3.8	11.7
	Penta group	180	20	11.1	6.9	16.6	180	15	8.3	4.7	13.4	180	8	4.4	1.9	8.6
Overall/dose	Hexa group	564	43	7.6	5.6	10.1	564	31	5.5	3.8	7.7	564	18	3.2	1.9	5.0
	Pedia group	567	94	16.6	13.6	19.9	567	61	10.8	8.3	13.6	567	58	10.2	7.9	13.0
	Penta group	565	71	12.6	9.9	15.6	565	51	9.0	6.8	11.7	565	40	7.1	5.1	9.5
Overall/subject	Hexa group	195	34	17.4	12.4	23.5	195	24	12.3	8.0	17.8	195	16	8.2	4.8	13.0
	Pedia group	194	72	37.1	30.3	44.3	194	45	23.2	17.5	29.8	194	46	23.7	17.9	30.3
	Penta group	196	54	27.6	21.4	34.4	196	39	19.9	14.5	26.2	196	35	17.9	12.8	23.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines

Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines

Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine

For each dose and overall/subject:

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered

For overall/dose:

N = number of administered doses

n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 39 Incidence of local symptoms (solicited and unsolicited) reported for *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B* vaccines during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

		INFANRIX HEXA					PEDIARIX					ACTHIB					PENTACEL					ENGERIX-B				
					95% CI					95% CI					95% CI					95% CI					95% CI	
	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Hexa group	195	111	56.9	49.7	64.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	131	67.5	60.4	74.1	194	139	71.6	64.8	77.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	123	62.8	55.6	69.5	196	118	60.2	53.0	67.1
Dose 2	Hexa group	186	104	55.9	48.5	63.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	188	127	67.6	60.4	74.2	188	122	64.9	57.6	71.7	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	187	116	62.0	54.7	69.0	13	7	53.8	25.1	80.8
Dose 3	Hexa group	183	101	55.2	47.7	62.5	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	185	108	58.4	50.9	65.6	185	113	61.1	53.7	68.1	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	180	98	54.4	46.9	61.9	180	95	52.8	45.2	60.2
Overall/dose	Hexa group	564	316	56.0	51.8	60.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	567	366	64.6	60.5	68.5	567	374	66.0	61.9	69.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	563	337	59.9	55.7	63.9	389	220	56.6	51.5	61.5
Overall/subject	Hexa group	195	149	76.4	69.8	82.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	159	82.0	75.8	87.1	194	164	84.5	78.7	89.3	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	156	79.6	73.3	85.0	196	145	74.0	67.2	80.8

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 40 Incidence of grade 3 local symptoms (solicited and unsolicited) reported for *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B* vaccines during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

		INFANRIX HEXA					PEDIARIX					ACTHIB					PENTACEL					ENGERIX-B				
					95% CI					95% CI					95% CI					95% CI					95% CI	
	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Hexa group	195	12	6.2	3.2	10.5	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	21	10.8	6.8	16.1	194	28	14.4	9.8	20.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	22	11.2	7.2	16.5	196	13	6.6	3.6	11.1
Dose 2	Hexa group	186	5	2.7	0.9	6.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	188	11	5.9	3.0	10.2	188	10	5.3	2.6	9.6	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	187	10	5.3	2.6	9.6	13	0	0.0	0.0	24.7
Dose 3	Hexa group	183	1	0.5	0.0	3.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	185	11	5.9	3.0	10.4	185	9	4.9	2.2	9.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	180	7	3.9	1.6	7.8	180	7	3.9	1.6	7.8
Overall/dose	Hexa group	564	18	3.2	1.9	5.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	567	43	7.6	5.5	10.1	567	47	8.3	6.2	10.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	563	39	6.9	5.0	9.3	389	20	5.1	3.2	7.8
Overall/subject	Hexa group	195	16	8.2	4.8	13.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	36	18.6	13.3	24.8	194	38	19.6	14.2	25.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	34	17.3	12.3	23.4	196	19	9.7	5.9	14.7

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.1.4. Solicited local adverse events

Incidence of solicited local symptoms is summarized in Table 41.

Pain was the most frequently reported solicited local symptom reported in 67.9% of subjects in the Hexa group, in 82.0% of subjects in the Pedia group and in 79.8% of subjects in the Penta group.

Pain was also the most frequently reported Grade 3 solicited local symptom reported in 4.3% of subjects in the Hexa group, 18.0% of subjects in the Pedia group and 11.7% of subjects in the Penta group.

Medical advice was sought for not more than 1.1% of subjects following any one local symptom.

Please also refer to the following Tables:

1. Incidence of local symptoms (solicited and unsolicited) that were causally related to vaccination reported for *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B* vaccines during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall: Table 8.7.
2. Incidence of grade 3 local symptoms (solicited and unsolicited) that were causally related to vaccination reported for *Infanrix hexa*, *Pediarix*, *ActHIB*, *Pentacel* and *Engerix-B* vaccines during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall: Table 8.8.

The incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period for the Primary Total Vaccinated Cohort by gender and by geographical ancestry is presented in Table 8.9 and Table 8.10, respectively.

Table 41 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																	
Pain	Total	All	185	94	50.8	43.4	58.2	189	128	67.7	60.6	74.3	188	119	63.3	56.0	70.2
		Grade 2 or 3	185	40	21.6	15.9	28.3	189	75	39.7	32.7	47.0	188	56	29.8	23.4	36.9
		Grade 3	185	8	4.3	1.9	8.3	189	24	12.7	8.3	18.3	188	12	6.4	3.3	10.9
		Medical advice	185	1	0.5	0.0	3.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	123	65.1	57.8	71.9	188	100	53.2	45.8	60.5
		Grade 2 or 3						189	66	34.9	28.1	42.2	188	45	23.9	18.0	30.7
		Grade 3						189	22	11.6	7.4	17.1	188	10	5.3	2.6	9.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	185	94	50.8	43.4	58.2	189	113	59.8	52.4	66.8	188	115	61.2	53.8	68.2
		Grade 2 or 3	185	40	21.6	15.9	28.3	189	65	34.4	27.6	41.6	188	51	27.1	20.9	34.1
		Grade 3	185	8	4.3	1.9	8.3	189	17	9.0	5.3	14.0	188	12	6.4	3.3	10.9
		Medical advice	185	1	0.5	0.0	3.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Redness (mm)	Total	All	185	47	25.4	19.3	32.3	189	73	38.6	31.6	46.0	188	67	35.6	28.8	42.9
		>5	185	15	8.1	4.6	13.0	189	27	14.3	9.6	20.1	188	27	14.4	9.7	20.2
		>20	185	3	1.6	0.3	4.7	189	10	5.3	2.6	9.5	188	4	2.1	0.6	5.4
		Medical advice	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	63	33.3	26.7	40.5	188	55	29.3	22.9	36.3
		>5						189	19	10.1	6.2	15.3	188	12	6.4	3.3	10.9
		>20						189	8	4.2	1.8	8.2	188	1	0.5	0.0	2.9
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	185	47	25.4	19.3	32.3	189	56	29.6	23.2	36.7	188	57	30.3	23.8	37.4
		>5	185	15	8.1	4.6	13.0	189	15	7.9	4.5	12.8	188	20	10.6	6.6	16.0
		>20	185	3	1.6	0.3	4.7	189	4	2.1	0.6	5.3	188	3	1.6	0.3	4.6
		Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Swelling (mm)	Total	All	185	31	16.8	11.7	22.9	189	46	24.3	18.4	31.1	188	53	28.2	21.9	35.2
		>5	185	10	5.4	2.6	9.7	189	18	9.5	5.7	14.6	188	24	12.8	8.4	18.4
		>20	185	2	1.1	0.1	3.9	189	7	3.7	1.5	7.5	188	11	5.9	3.0	10.2
		Medical advice	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	41	21.7	16.0	28.3	188	39	20.7	15.2	27.2

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>5						189	14	7.4	4.1	12.1	188	14	7.4	4.1	12.2
		>20						189	6	3.2	1.2	6.8	188	3	1.6	0.3	4.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	185	31	16.8	11.7	22.9	189	35	18.5	13.3	24.8	188	45	23.9	18.0	30.7
		>5	185	10	5.4	2.6	9.7	189	14	7.4	4.1	12.1	188	24	12.8	8.4	18.4
		>20	185	2	1.1	0.1	3.9	189	3	1.6	0.3	4.6	188	11	5.9	3.0	10.2
		Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Dose 2																	
Pain	Total	All	182	84	46.2	38.8	53.7	184	112	60.9	53.4	68.0	180	93	51.7	44.1	59.2
		Grade 2 or 3	182	25	13.7	9.1	19.6	184	54	29.3	22.9	36.5	180	32	17.8	12.5	24.2
		Grade 3	182	1	0.5	0.0	3.0	184	10	5.4	2.6	9.8	180	6	3.3	1.2	7.1
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	180	0	0.0	0.0	2.0
	ActHIB/Engerix B	All						184	104	56.5	49.0	63.8	13	6	46.2	19.2	74.9
		Grade 2 or 3						184	47	25.5	19.4	32.5	13	2	15.4	1.9	45.4
		Grade 3						184	9	4.9	2.3	9.1	13	0	0.0	0.0	24.7
		Medical advice						184	0	0.0	0.0	2.0	13	0	0.0	0.0	24.7
	Hexa/Pediarix/Pentacel	All	182	84	46.2	38.8	53.7	184	108	58.7	51.2	65.9	180	93	51.7	44.1	59.2
		Grade 2 or 3	182	25	13.7	9.1	19.6	184	44	23.9	17.9	30.7	180	31	17.2	12.0	23.5
		Grade 3	182	1	0.5	0.0	3.0	184	7	3.8	1.5	7.7	180	6	3.3	1.2	7.1
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	180	0	0.0	0.0	2.0
Redness (mm)	Total	All	182	59	32.4	25.7	39.7	184	77	41.8	34.6	49.3	180	64	35.6	28.6	43.0
		>5	182	15	8.2	4.7	13.2	184	22	12.0	7.6	17.5	180	16	8.9	5.2	14.0
		>20	182	3	1.6	0.3	4.7	184	3	1.6	0.3	4.7	180	2	1.1	0.1	4.0
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	180	0	0.0	0.0	2.0
	ActHIB/Engerix B	All						184	66	35.9	28.9	43.3	13	5	38.5	13.9	68.4
		>5						184	17	9.2	5.5	14.4	13	1	7.7	0.2	36.0
		>20						184	1	0.5	0.0	3.0	13	0	0.0	0.0	24.7
		Medical advice						184	0	0.0	0.0	2.0	13	0	0.0	0.0	24.7
	Hexa/Pediarix/Pentacel	All	182	59	32.4	25.7	39.7	184	61	33.2	26.4	40.5	180	64	35.6	28.6	43.0
		>5	182	15	8.2	4.7	13.2	184	12	6.5	3.4	11.1	180	15	8.3	4.7	13.4
		>20	182	3	1.6	0.3	4.7	184	3	1.6	0.3	4.7	180	2	1.1	0.1	4.0
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	180	0	0.0	0.0	2.0
Swelling (mm)	Total	All	182	41	22.5	16.7	29.3	184	51	27.7	21.4	34.8	180	44	24.4	18.4	31.4

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>5	182	10	5.5	2.7	9.9	184	16	8.7	5.1	13.7	180	7	3.9	1.6	7.8
		>20	182	2	1.1	0.1	3.9	184	2	1.1	0.1	3.9	180	3	1.7	0.3	4.8
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	180	0	0.0	0.0	2.0
	ActHIB/Engerix B	All						184	40	21.7	16.0	28.4	13	3	23.1	5.0	53.8
		>5						184	11	6.0	3.0	10.4	13	0	0.0	0.0	24.7
		>20						184	1	0.5	0.0	3.0	13	0	0.0	0.0	24.7
		Medical advice						184	0	0.0	0.0	2.0	13	0	0.0	0.0	24.7
	Hexa/Pediarix/Pentacel	All	182	41	22.5	16.7	29.3	184	40	21.7	16.0	28.4	180	42	23.3	17.4	30.2
		>5	182	10	5.5	2.7	9.9	184	12	6.5	3.4	11.1	180	7	3.9	1.6	7.8
		>20	182	2	1.1	0.1	3.9	184	2	1.1	0.1	3.9	180	3	1.7	0.3	4.8
		Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	180	0	0.0	0.0	2.0
Dose 3																	
Pain	Total	All	172	67	39.0	31.6	46.7	175	98	56.0	48.3	63.5	171	83	48.5	40.8	56.3
		Grade 2 or 3	172	18	10.5	6.3	16.0	175	45	25.7	19.4	32.9	171	28	16.4	11.2	22.8
		Grade 3	172	0	0.0	0.0	2.1	175	8	4.6	2.0	8.8	171	7	4.1	1.7	8.3
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	171	0	0.0	0.0	2.1
	ActHIB/Engerix B	All						175	93	53.1	45.5	60.7	169	75	44.4	36.8	52.2
		Grade 2 or 3						175	41	23.4	17.4	30.4	169	25	14.8	9.8	21.1
		Grade 3						175	7	4.0	1.6	8.1	169	5	3.0	1.0	6.8
		Medical advice						175	1	0.6	0.0	3.1	169	0	0.0	0.0	2.2
	Hexa/Pediarix/Pentacel	All	172	67	39.0	31.6	46.7	175	90	51.4	43.8	59.0	170	76	44.7	37.1	52.5
		Grade 2 or 3	172	18	10.5	6.3	16.0	175	39	22.3	16.4	29.2	170	20	11.8	7.3	17.6
		Grade 3	172	0	0.0	0.0	2.1	175	7	4.0	1.6	8.1	170	7	4.1	1.7	8.3
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Redness (mm)	Total	All	172	63	36.6	29.4	44.3	175	81	46.3	38.7	54.0	171	65	38.0	30.7	45.7
		>5	172	7	4.1	1.7	8.2	175	14	8.0	4.4	13.1	171	16	9.4	5.4	14.7
		>20	172	1	0.6	0.0	3.2	175	4	2.3	0.6	5.7	171	2	1.2	0.1	4.2
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	171	0	0.0	0.0	2.1
	ActHIB/Engerix B	All						175	69	39.4	32.1	47.1	169	51	30.2	23.4	37.7
		>5						175	7	4.0	1.6	8.1	169	9	5.3	2.5	9.9
		>20						175	1	0.6	0.0	3.1	169	2	1.2	0.1	4.2
		Medical advice						175	0	0.0	0.0	2.1	169	0	0.0	0.0	2.2
	Hexa/Pediarix/Pentacel	All	172	63	36.6	29.4	44.3	175	66	37.7	30.5	45.3	170	56	32.9	25.9	40.6

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>5	172	7	4.1	1.7	8.2	175	12	6.9	3.6	11.7	170	11	6.5	3.3	11.3
		>20	172	1	0.6	0.0	3.2	175	3	1.7	0.4	4.9	170	0	0.0	0.0	2.1
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Swelling (mm)	Total	All	172	43	25.0	18.7	32.2	175	53	30.3	23.6	37.7	171	44	25.7	19.4	33.0
		>5	172	7	4.1	1.7	8.2	175	12	6.9	3.6	11.7	171	8	4.7	2.0	9.0
		>20	172	1	0.6	0.0	3.2	175	3	1.7	0.4	4.9	171	0	0.0	0.0	2.1
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	171	0	0.0	0.0	2.1
	ActHIB/Engerix B	All						175	42	24.0	17.9	31.0	169	37	21.9	15.9	28.9
		>5						175	7	4.0	1.6	8.1	169	7	4.1	1.7	8.3
		>20						175	1	0.6	0.0	3.1	169	0	0.0	0.0	2.2
		Medical advice						175	0	0.0	0.0	2.1	169	0	0.0	0.0	2.2
	Hexa/Pediarix/Pentacel	All	172	43	25.0	18.7	32.2	175	44	25.1	18.9	32.2	170	35	20.6	14.8	27.5
		>5	172	7	4.1	1.7	8.2	175	10	5.7	2.8	10.3	170	4	2.4	0.6	5.9
		>20	172	1	0.6	0.0	3.2	175	3	1.7	0.4	4.9	170	0	0.0	0.0	2.1
		Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Overall/dose																	
Pain	Total	All	539	245	45.5	41.2	49.8	548	338	61.7	57.5	65.8	539	295	54.7	50.4	59.0
		Grade 2 or 3	539	83	15.4	12.5	18.7	548	174	31.8	27.9	35.8	539	116	21.5	18.1	25.2
		Grade 3	539	9	1.7	0.8	3.1	548	42	7.7	5.6	10.2	539	25	4.6	3.0	6.8
		Medical advice	539	1	0.2	0.0	1.0	548	2	0.4	0.0	1.3	539	0	0.0	0.0	0.7
	ActHIB/Engerix B	All						548	320	58.4	54.1	62.6	370	181	48.9	43.7	54.1
		Grade 2 or 3						548	154	28.1	24.4	32.1	370	72	19.5	15.5	23.9
		Grade 3						548	38	6.9	5.0	9.4	370	15	4.1	2.3	6.6
		Medical advice						548	2	0.4	0.0	1.3	370	0	0.0	0.0	1.0
	Hexa/Pediarix/Pentacel	All	539	245	45.5	41.2	49.8	548	311	56.8	52.5	60.9	538	284	52.8	48.5	57.1
		Grade 2 or 3	539	83	15.4	12.5	18.7	548	148	27.0	23.3	30.9	538	102	19.0	15.7	22.5
		Grade 3	539	9	1.7	0.8	3.1	548	31	5.7	3.9	7.9	538	25	4.6	3.0	6.8
		Medical advice	539	1	0.2	0.0	1.0	548	1	0.2	0.0	1.0	538	0	0.0	0.0	0.7
Redness (mm)	Total	All	539	169	31.4	27.5	35.5	548	231	42.2	38.0	46.4	539	196	36.4	32.3	40.6
		>5	539	37	6.9	4.9	9.3	548	63	11.5	8.9	14.5	539	59	10.9	8.4	13.9
		>20	539	7	1.3	0.5	2.7	548	17	3.1	1.8	4.9	539	8	1.5	0.6	2.9
		Medical advice	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	539	0	0.0	0.0	0.7
	ActHIB/Engerix B	All						548	198	36.1	32.1	40.3	370	111	30.0	25.4	35.0

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>5						548	43	7.8	5.7	10.4	370	22	5.9	3.8	8.9
		>20						548	10	1.8	0.9	3.3	370	3	0.8	0.2	2.4
		Medical advice						548	1	0.2	0.0	1.0	370	0	0.0	0.0	1.0
	Hexa/Pediarix/Pentacel	All	539	169	31.4	27.5	35.5	548	183	33.4	29.5	37.5	538	177	32.9	28.9	37.0
		>5	539	37	6.9	4.9	9.3	548	39	7.1	5.1	9.6	538	46	8.6	6.3	11.2
		>20	539	7	1.3	0.5	2.7	548	10	1.8	0.9	3.3	538	5	0.9	0.3	2.2
		Medical advice	539	0	0.0	0.0	0.7	548	1	0.2	0.0	1.0	538	0	0.0	0.0	0.7
Swelling (mm)	Total	All	539	115	21.3	17.9	25.0	548	150	27.4	23.7	31.3	539	141	26.2	22.5	30.1
		>5	539	27	5.0	3.3	7.2	548	46	8.4	6.2	11.0	539	39	7.2	5.2	9.8
		>20	539	5	0.9	0.3	2.2	548	12	2.2	1.1	3.8	539	14	2.6	1.4	4.3
		Medical advice	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	539	0	0.0	0.0	0.7
	ActHIB/Engerix B	All						548	123	22.4	19.0	26.2	370	79	21.4	17.3	25.9
		>5						548	32	5.8	4.0	8.1	370	21	5.7	3.5	8.5
		>20						548	8	1.5	0.6	2.9	370	3	0.8	0.2	2.4
		Medical advice						548	1	0.2	0.0	1.0	370	0	0.0	0.0	1.0
	Hexa/Pediarix/Pentacel	All	539	115	21.3	17.9	25.0	548	119	21.7	18.3	25.4	538	122	22.7	19.2	26.5
		>5	539	27	5.0	3.3	7.2	548	36	6.6	4.6	9.0	538	35	6.5	4.6	8.9
		>20	539	5	0.9	0.3	2.2	548	8	1.5	0.6	2.9	538	14	2.6	1.4	4.3
		Medical advice	539	0	0.0	0.0	0.7	548	1	0.2	0.0	1.0	538	0	0.0	0.0	0.7
Overall/subject																	
Pain	Total	All	187	127	67.9	60.7	74.5	189	155	82.0	75.8	87.2	188	150	79.8	73.3	85.3
		Grade 2 or 3	187	58	31.0	24.5	38.2	189	104	55.0	47.6	62.3	188	88	46.8	39.5	54.2
		Grade 3	187	8	4.3	1.9	8.3	189	34	18.0	12.8	24.2	188	22	11.7	7.5	17.2
		Medical advice	187	1	0.5	0.0	2.9	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	148	78.3	71.7	84.0	188	127	67.6	60.4	74.2
		Grade 2 or 3						189	96	50.8	43.4	58.1	188	62	33.0	26.3	40.2
		Grade 3						189	30	15.9	11.0	21.9	188	14	7.4	4.1	12.2
		Medical advice						189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	187	127	67.9	60.7	74.5	189	151	79.9	73.5	85.4	188	147	78.2	71.6	83.9
		Grade 2 or 3	187	58	31.0	24.5	38.2	189	93	49.2	41.9	56.6	188	80	42.6	35.4	50.0
		Grade 3	187	8	4.3	1.9	8.3	189	27	14.3	9.6	20.1	188	22	11.7	7.5	17.2
		Medical advice	187	1	0.5	0.0	2.9	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
Redness (mm)	Total	All	187	94	50.3	42.9	57.6	189	120	63.5	56.2	70.4	188	106	56.4	49.0	63.6

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		>5	187	27	14.4	9.7	20.3	189	49	25.9	19.8	32.8	188	45	23.9	18.0	30.7
		>20	187	7	3.7	1.5	7.6	189	15	7.9	4.5	12.8	188	8	4.3	1.9	8.2
		Medical advice	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	108	57.1	49.8	64.3	188	77	41.0	33.9	48.3
		>5						189	38	20.1	14.6	26.5	188	20	10.6	6.6	16.0
		>20						189	10	5.3	2.6	9.5	188	3	1.6	0.3	4.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	187	94	50.3	42.9	57.6	189	98	51.9	44.5	59.2	188	97	51.6	44.2	58.9
		>5	187	27	14.4	9.7	20.3	189	32	16.9	11.9	23.1	188	37	19.7	14.3	26.1
		>20	187	7	3.7	1.5	7.6	189	9	4.8	2.2	8.8	188	5	2.7	0.9	6.1
		Medical advice	187	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
Swelling (mm)	Total	All	187	73	39.0	32.0	46.4	189	88	46.6	39.3	53.9	188	81	43.1	35.9	50.5
		>5	187	20	10.7	6.7	16.0	189	34	18.0	12.8	24.2	188	29	15.4	10.6	21.4
		>20	187	4	2.1	0.6	5.4	189	11	5.8	2.9	10.2	188	12	6.4	3.3	10.9
		Medical advice	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	ActHIB/Engerix B	All						189	78	41.3	34.2	48.6	188	64	34.0	27.3	41.3
		>5						189	25	13.2	8.7	18.9	188	18	9.6	5.8	14.7
		>20						189	7	3.7	1.5	7.5	188	3	1.6	0.3	4.6
		Medical advice						189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	187	73	39.0	32.0	46.4	189	70	37.0	30.1	44.3	188	72	38.3	31.3	45.7
		>5	187	20	10.7	6.7	16.0	189	26	13.8	9.2	19.5	188	26	13.8	9.2	19.6
		>20	187	4	2.1	0.6	5.4	189	7	3.7	1.5	7.5	188	12	6.4	3.3	10.9
		Medical advice	187	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	0	0.0	0.0	1.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

8.1.5. Solicited general adverse events

Incidence of solicited general symptoms are summarised in Table 42.

- Irritability / Fussiness was the most frequently reported solicited general symptom in all the groups, reported in 87.7% of subjects in the Hexa group, in 96.3% of subjects in the Pedia group and in 94.1% of subjects in the Penta group overall.
- Irritability was also the most commonly reported solicited general symptom graded 3 in intensity; reported for 9.6% of subjects in the Hexa group, 18.5% of subjects in the Pedia group and 16.0% of subjects in the Penta group overall.
- Grade 3 fever (>40.0°C rectal temperature) was reported for 0.0% of subjects in the Hexa and Penta groups, and 1.1% of subjects (2 subjects) in the Pedia group.
- Medical advice was sought in ≤ 1.6% of subjects following any one general symptom.
- The majority of solicited general symptoms following vaccination were considered by the investigator to be causally related to vaccination in the three groups.

The incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall for the Primary Total vaccinated cohort according to gender and geographical ancestry is presented in Table 8.11 and Table 8.12, respectively.

Table 42 Incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

		Hexa group					Pedia group					Penta group				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1																
Drowsiness	All	185	114	61.6	54.2	68.7	189	143	75.7	68.9	81.6	188	149	79.3	72.8	84.8
	Grade 2 or 3	185	36	19.5	14.0	25.9	189	56	29.6	23.2	36.7	188	53	28.2	21.9	35.2
	Grade 3	185	3	1.6	0.3	4.7	189	8	4.2	1.8	8.2	188	12	6.4	3.3	10.9
	Related	185	112	60.5	53.1	67.6	189	136	72.0	65.0	78.2	188	141	75.0	68.2	81.0
	Grade 3 Related	185	3	1.6	0.3	4.7	189	7	3.7	1.5	7.5	188	12	6.4	3.3	10.9
	Medical advice	185	1	0.5	0.0	3.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Irritability / Fussiness	All	185	115	62.2	54.8	69.2	189	165	87.3	81.7	91.7	188	153	81.4	75.1	86.7
	Grade 2 or 3	185	42	22.7	16.9	29.4	189	79	41.8	34.7	49.2	188	68	36.2	29.3	43.5
	Grade 3	185	9	4.9	2.2	9.0	189	17	9.0	5.3	14.0	188	15	8.0	4.5	12.8
	Related	185	113	61.1	53.7	68.1	189	163	86.2	80.5	90.8	188	147	78.2	71.6	83.9
	Grade 3 Related	185	9	4.9	2.2	9.0	189	17	9.0	5.3	14.0	188	15	8.0	4.5	12.8
	Medical advice	185	1	0.5	0.0	3.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Loss Of Appetite	All	185	53	28.6	22.3	35.7	189	76	40.2	33.2	47.6	188	80	42.6	35.4	50.0
	Grade 2 or 3	185	8	4.3	1.9	8.3	189	13	6.9	3.7	11.5	188	26	13.8	9.2	19.6
	Grade 3	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	4	2.1	0.6	5.4
	Related	185	48	25.9	19.8	32.9	189	73	38.6	31.6	46.0	188	77	41.0	33.9	48.3
	Grade 3 Related	185	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	4	2.1	0.6	5.4
	Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
Temperature/(Rectally) (°C)	All	185	22	11.9	7.6	17.4	189	34	18.0	12.8	24.2	188	29	15.4	10.6	21.4
	>38.5	185	2	1.1	0.1	3.9	189	4	2.1	0.6	5.3	188	5	2.7	0.9	6.1
	>39.0	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	2	1.1	0.1	3.8
	>39.5	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
	>40.0	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
	Related	185	15	8.1	4.6	13.0	189	31	16.4	11.4	22.5	188	27	14.4	9.7	20.2
	>40.0 Related	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9
	Medical advice	185	0	0.0	0.0	2.0	189	0	0.0	0.0	1.9	188	0	0.0	0.0	1.9

		Hexa group					Pedia group					Penta group				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 2																
Drowsiness	All	182	97	53.3	45.8	60.7	184	132	71.7	64.6	78.1	179	109	60.9	53.3	68.1
	Grade 2 or 3	182	31	17.0	11.9	23.3	184	43	23.4	17.5	30.2	179	39	21.8	16.0	28.6
	Grade 3	182	8	4.4	1.9	8.5	184	7	3.8	1.5	7.7	179	4	2.2	0.6	5.6
	Related	182	94	51.6	44.1	59.1	184	126	68.5	61.2	75.1	179	108	60.3	52.8	67.6
	Grade 3 Related	182	7	3.8	1.6	7.8	184	7	3.8	1.5	7.7	179	3	1.7	0.3	4.8
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
Irritability / Fussiness	All	182	128	70.3	63.1	76.9	184	147	79.9	73.4	85.4	179	136	76.0	69.0	82.0
	Grade 2 or 3	182	53	29.1	22.6	36.3	184	70	38.0	31.0	45.5	179	61	34.1	27.2	41.5
	Grade 3	182	6	3.3	1.2	7.0	184	14	7.6	4.2	12.4	179	11	6.1	3.1	10.7
	Related	182	125	68.7	61.4	75.3	184	143	77.7	71.0	83.5	179	133	74.3	67.2	80.5
	Grade 3 Related	182	6	3.3	1.2	7.0	184	13	7.1	3.8	11.8	179	11	6.1	3.1	10.7
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	2	1.1	0.1	4.0
Loss Of Appetite	All	182	56	30.8	24.2	38.0	184	55	29.9	23.4	37.1	179	56	31.3	24.6	38.6
	Grade 2 or 3	182	17	9.3	5.5	14.5	184	15	8.2	4.6	13.1	179	15	8.4	4.8	13.4
	Grade 3	182	1	0.5	0.0	3.0	184	1	0.5	0.0	3.0	179	2	1.1	0.1	4.0
	Related	182	52	28.6	22.1	35.7	184	51	27.7	21.4	34.8	179	55	30.7	24.1	38.0
	Grade 3 Related	182	1	0.5	0.0	3.0	184	1	0.5	0.0	3.0	179	2	1.1	0.1	4.0
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	1	0.6	0.0	3.1
Temperature/(Rectally)) (°C)	All	182	47	25.8	19.6	32.8	184	36	19.6	14.1	26.0	179	35	19.6	14.0	26.1
	>38.5	182	15	8.2	4.7	13.2	184	13	7.1	3.8	11.8	179	9	5.0	2.3	9.3
	>39.0	182	2	1.1	0.1	3.9	184	3	1.6	0.3	4.7	179	2	1.1	0.1	4.0
	>39.5	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	1	0.6	0.0	3.1
	>40.0	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	Related	182	37	20.3	14.7	26.9	184	32	17.4	12.2	23.7	179	33	18.4	13.0	24.9
	>40.0 Related	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0
	Medical advice	182	0	0.0	0.0	2.0	184	0	0.0	0.0	2.0	179	0	0.0	0.0	2.0

		Hexa group					Pedia group					Penta group				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 3																
Drowsiness	All	172	85	49.4	41.7	57.1	175	108	61.7	54.1	68.9	170	88	51.8	44.0	59.5
	Grade 2 or 3	172	23	13.4	8.7	19.4	175	37	21.1	15.3	27.9	170	25	14.7	9.7	20.9
	Grade 3	172	3	1.7	0.4	5.0	175	5	2.9	0.9	6.5	170	9	5.3	2.4	9.8
	Related	172	81	47.1	39.5	54.8	175	105	60.0	52.3	67.3	170	86	50.6	42.8	58.3
	Grade 3 Related	172	3	1.7	0.4	5.0	175	5	2.9	0.9	6.5	170	9	5.3	2.4	9.8
	Medical advice	172	0	0.0	0.0	2.1	175	2	1.1	0.1	4.1	170	1	0.6	0.0	3.2
Irritability / Fussiness	All	172	126	73.3	66.0	79.7	175	135	77.1	70.2	83.1	170	122	71.8	64.4	78.4
	Grade 2 or 3	172	46	26.7	20.3	34.0	175	58	33.1	26.2	40.6	170	58	34.1	27.0	41.8
	Grade 3	172	6	3.5	1.3	7.4	175	15	8.6	4.9	13.7	170	11	6.5	3.3	11.3
	Related	172	121	70.3	62.9	77.1	175	129	73.7	66.5	80.1	170	120	70.6	63.1	77.3
	Grade 3 Related	172	6	3.5	1.3	7.4	175	13	7.4	4.0	12.4	170	11	6.5	3.3	11.3
	Medical advice	172	0	0.0	0.0	2.1	175	3	1.7	0.4	4.9	170	1	0.6	0.0	3.2
Loss Of Appetite	All	172	45	26.2	19.8	33.4	175	58	33.1	26.2	40.6	170	53	31.2	24.3	38.7
	Grade 2 or 3	172	11	6.4	3.2	11.2	175	13	7.4	4.0	12.4	170	15	8.8	5.0	14.1
	Grade 3	172	1	0.6	0.0	3.2	175	2	1.1	0.1	4.1	170	2	1.2	0.1	4.2
	Related	172	44	25.6	19.2	32.8	175	56	32.0	25.2	39.5	170	52	30.6	23.8	38.1
	Grade 3 Related	172	1	0.6	0.0	3.2	175	2	1.1	0.1	4.1	170	2	1.2	0.1	4.2
	Medical advice	172	0	0.0	0.0	2.1	175	1	0.6	0.0	3.1	170	0	0.0	0.0	2.1
Temperature/(Rectally)) (°C)	All	172	40	23.3	17.2	30.3	175	45	25.7	19.4	32.9	170	37	21.8	15.8	28.7
	>38.5	172	12	7.0	3.7	11.9	175	21	12.0	7.6	17.8	170	15	8.8	5.0	14.1
	>39.0	172	4	2.3	0.6	5.8	175	11	6.3	3.2	11.0	170	7	4.1	1.7	8.3
	>39.5	172	1	0.6	0.0	3.2	175	3	1.7	0.4	4.9	170	1	0.6	0.0	3.2
	>40.0	172	0	0.0	0.0	2.1	175	2	1.1	0.1	4.1	170	0	0.0	0.0	2.1
	Related	172	35	20.3	14.6	27.1	175	39	22.3	16.4	29.2	170	35	20.6	14.8	27.5
	>40.0 Related	172	0	0.0	0.0	2.1	175	2	1.1	0.1	4.1	170	0	0.0	0.0	2.1
	Medical advice	172	1	0.6	0.0	3.2	175	2	1.1	0.1	4.1	170	1	0.6	0.0	3.2

		Hexa group					Pedia group					Penta group				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Overall/dose																
Drowsiness	All	539	296	54.9	50.6	59.2	548	383	69.9	65.9	73.7	537	346	64.4	60.2	68.5
	Grade 2 or 3	539	90	16.7	13.6	20.1	548	136	24.8	21.3	28.7	537	117	21.8	18.4	25.5
	Grade 3	539	14	2.6	1.4	4.3	548	20	3.6	2.2	5.6	537	25	4.7	3.0	6.8
	Related	539	287	53.2	48.9	57.5	548	367	67.0	62.9	70.9	537	335	62.4	58.1	66.5
	Grade 3 Related	539	13	2.4	1.3	4.1	548	19	3.5	2.1	5.4	537	24	4.5	2.9	6.6
	Medical advice	539	1	0.2	0.0	1.0	548	2	0.4	0.0	1.3	537	1	0.2	0.0	1.0
Irritability / Fussiness	All	539	369	68.5	64.4	72.4	548	447	81.6	78.1	84.7	537	411	76.5	72.7	80.1
	Grade 2 or 3	539	141	26.2	22.5	30.1	548	207	37.8	33.7	42.0	537	187	34.8	30.8	39.0
	Grade 3	539	21	3.9	2.4	5.9	548	46	8.4	6.2	11.0	537	37	6.9	4.9	9.4
	Related	539	359	66.6	62.4	70.6	548	435	79.4	75.7	82.7	537	400	74.5	70.6	78.1
	Grade 3 Related	539	21	3.9	2.4	5.9	548	43	7.8	5.7	10.4	537	37	6.9	4.9	9.4
	Medical advice	539	1	0.2	0.0	1.0	548	3	0.5	0.1	1.6	537	3	0.6	0.1	1.6
Loss Of Appetite	All	539	154	28.6	24.8	32.6	548	189	34.5	30.5	38.6	537	189	35.2	31.2	39.4
	Grade 2 or 3	539	36	6.7	4.7	9.1	548	41	7.5	5.4	10.0	537	56	10.4	8.0	13.3
	Grade 3	539	2	0.4	0.0	1.3	548	4	0.7	0.2	1.9	537	8	1.5	0.6	2.9
	Related	539	144	26.7	23.0	30.7	548	180	32.8	28.9	37.0	537	184	34.3	30.3	38.4
	Grade 3 Related	539	2	0.4	0.0	1.3	548	4	0.7	0.2	1.9	537	8	1.5	0.6	2.9
	Medical advice	539	0	0.0	0.0	0.7	548	1	0.2	0.0	1.0	537	1	0.2	0.0	1.0
Temperature/(Rectally)) (°C)	All	539	109	20.2	16.9	23.9	548	115	21.0	17.6	24.6	537	101	18.8	15.6	22.4
	>38.5	539	29	5.4	3.6	7.6	548	38	6.9	5.0	9.4	537	29	5.4	3.6	7.7
	>39.0	539	6	1.1	0.4	2.4	548	14	2.6	1.4	4.2	537	11	2.0	1.0	3.6
	>39.5	539	1	0.2	0.0	1.0	548	3	0.5	0.1	1.6	537	2	0.4	0.0	1.3
	>40.0	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	537	0	0.0	0.0	0.7
	Related	539	87	16.1	13.1	19.5	548	102	18.6	15.4	22.1	537	95	17.7	14.6	21.2
	>40.0 Related	539	0	0.0	0.0	0.7	548	2	0.4	0.0	1.3	537	0	0.0	0.0	0.7
	Medical advice	539	1	0.2	0.0	1.0	548	2	0.4	0.0	1.3	537	1	0.2	0.0	1.0
Overall/subject																
Drowsiness	All	187	147	78.6	72.0	84.3	189	172	91.0	86.0	94.7	188	168	89.4	84.0	93.4
	Grade 2 or 3	187	66	35.3	28.5	42.6	189	88	46.6	39.3	53.9	188	81	43.1	35.9	50.5
	Grade 3	187	11	5.9	3.0	10.3	189	19	10.1	6.2	15.3	188	22	11.7	7.5	17.2
	Related	187	144	77.0	70.3	82.8	189	169	89.4	84.1	93.4	188	166	88.3	82.8	92.5
	Grade 3 Related	187	11	5.9	3.0	10.3	189	18	9.5	5.7	14.6	188	21	11.2	7.0	16.6

		Hexa group					Pedia group					Penta group				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
	Medical advice	187	1	0.5	0.0	2.9	189	2	1.1	0.1	3.8	188	1	0.5	0.0	2.9
Irritability / Fussiness	All	187	164	87.7	82.1	92.0	189	182	96.3	92.5	98.5	188	177	94.1	89.8	97.0
	Grade 2 or 3	187	96	51.3	43.9	58.7	189	128	67.7	60.6	74.3	188	120	63.8	56.5	70.7
	Grade 3	187	18	9.6	5.8	14.8	189	35	18.5	13.3	24.8	188	30	16.0	11.0	22.0
	Related	187	161	86.1	80.3	90.7	189	180	95.2	91.2	97.8	188	175	93.1	88.5	96.3
	Grade 3 Related	187	18	9.6	5.8	14.8	189	34	18.0	12.8	24.2	188	30	16.0	11.0	22.0
	Medical advice	187	1	0.5	0.0	2.9	189	3	1.6	0.3	4.6	188	3	1.6	0.3	4.6
Loss Of Appetite	All	187	95	50.8	43.4	58.2	189	111	58.7	51.4	65.8	188	117	62.2	54.9	69.2
	Grade 2 or 3	187	28	15.0	10.2	20.9	189	32	16.9	11.9	23.1	188	39	20.7	15.2	27.2
	Grade 3	187	2	1.1	0.1	3.8	189	3	1.6	0.3	4.6	188	6	3.2	1.2	6.8
	Related	187	91	48.7	41.3	56.1	189	108	57.1	49.8	64.3	188	116	61.7	54.3	68.7
	Grade 3 Related	187	2	1.1	0.1	3.8	189	3	1.6	0.3	4.6	188	6	3.2	1.2	6.8
	Medical advice	187	0	0.0	0.0	2.0	189	1	0.5	0.0	2.9	188	1	0.5	0.0	2.9
Temperature/(Rectally)) (°C)	All	187	72	38.5	31.5	45.9	189	78	41.3	34.2	48.6	188	72	38.3	31.3	45.7
	>38.5	187	24	12.8	8.4	18.5	189	34	18.0	12.8	24.2	188	26	13.8	9.2	19.6
	>39.0	187	6	3.2	1.2	6.9	189	14	7.4	4.1	12.1	188	10	5.3	2.6	9.6
	>39.5	187	1	0.5	0.0	2.9	189	3	1.6	0.3	4.6	188	2	1.1	0.1	3.8
	>40.0	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	Related	187	61	32.6	26.0	39.8	189	74	39.2	32.2	46.5	188	69	36.7	29.8	44.0
	>40.0 Related	187	0	0.0	0.0	2.0	189	2	1.1	0.1	3.8	188	0	0.0	0.0	1.9
	Medical advice	187	1	0.5	0.0	2.9	189	2	1.1	0.1	3.8	188	1	0.5	0.0	2.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

8.1.6. Unsolicited adverse events

The percentage of subjects who recorded the occurrence of unsolicited symptoms and grade 3 unsolicited symptoms within the 31-day (Days 0-30) post-vaccination period for the Primary Total vaccinated cohort is presented in Table 43 and Table 44, respectively.

- At least one unsolicited symptom within the 31-day post-vaccination period after each vaccination, classified by MedDRA Primary System Organ Class and Preferred Term was reported for 57.9%, 55.7% and 49.0% of subjects in the Hexa, Pedia and Penta groups, respectively (Table 43). The corresponding unsolicited symptoms within the 31-day (Days 0-30) post vaccination period following priming doses is provided in Table 8.13.
- The most commonly reported unsolicited symptoms in the Hexa group was Upper Respiratory Tract Infection (URTI) (15.4%) followed by Cough (7.7%) and Pyrexia (6.2%). In the Pedia group, the most commonly reported symptom was URTI (11.9%) followed by Conjunctivitis, Gastrooesophageal reflux disease, Teething, and Vomiting (4.1%). The most commonly reported symptoms in the Penta group were URTI (13.3%) followed by Pyrexia (7.7%), Diarrhoea (5.1%) and Vomiting (5.1%).
- A grade 3 unsolicited symptom was reported for 6.7%, 6.2% and 3.6% of subjects in Hexa, Pedia and Penta groups, respectively (Table 44). The most commonly reported grade 3 unsolicited symptom in the Hexa group were URTI and Otitis media (1.5%) followed by Pyrexia and Vomiting (1.0%). In the Pedia group, grade 3 unsolicited symptoms reported in more than one subject were URTI, Conjunctivitis and Irritability (1.0%). In the Penta group, grade 3 unsolicited symptoms reported in more than one subject were URTI (1.0%). The corresponding grade 3 unsolicited symptoms within the 31-day (Days 0-30) post vaccination period following priming doses is provided in Table 8.14.
- The investigator assessed a causal relationship between at least one unsolicited symptom and primary vaccination for 12.3%, 14.4% and 17.3% of subjects in the Hexa, Pedia and Penta groups, respectively – Table 8.15.

The percentage of doses followed by an unsolicited symptom with causal relationship to vaccination, grade 3 unsolicited symptom with causal relationship to primary vaccination, and doses followed by a grade 3 unsolicited symptom with causal relationship to primary vaccination, within the 31-day (Days 0-30) post-vaccination period for the Primary Total vaccinated cohort are presented in Table 8.16, Table 8.17 and Table 8.18.

The following data are summarised in the following tables:

- The percentage of subjects who reported the occurrence of unsolicited symptoms by gender (Table 8.19), and of unsolicited symptoms by geographical ancestry (Table 8.20).
- The percentage of subjects who reported the occurrence of grade 3 unsolicited symptoms by gender (Table 8.21), and of grade 3 unsolicited symptoms by geographical ancestry (Table 8.22).
- The percentage of subjects who reported the occurrence of unsolicited symptoms with causal relationship to primary vaccination by gender (Table 8.23), and of unsolicited symptoms with causal relationship to primary vaccination by geographical ancestry (Table 8.24).
- The percentage of subjects who reported the occurrence of grade 3 unsolicited symptoms with causal relationship to primary vaccination by gender (Table 8.25), and of grade 3 unsolicited symptoms with causal relationship to primary vaccination by geographical ancestry (Table 8.26).
- The percentage of subjects who reported the occurrence of unsolicited symptoms following priming doses by gender (Table 8.27), and of unsolicited symptoms following priming doses by geographical ancestry (Table 8.28).
- The percentage of subjects who reported the occurrence of grade 3 unsolicited symptoms following priming doses by gender (Table 8.29), and of grade 3 unsolicited symptoms following priming doses by geographical ancestry (Table 8.30).
- The percentage of subjects who reported the occurrence of unsolicited symptoms with causal relationship to vaccination following priming doses by gender (Table 8.31), and of unsolicited symptoms with causal relationship to vaccination following priming doses by geographical ancestry (Table 8.32).
- The percentage of subjects who reported the occurrence of grade 3 unsolicited symptoms with causal relationship to vaccination following priming doses by gender (Table 8.33), and of grade 3 unsolicited symptoms with causal relationship to vaccination following priming doses by geographical ancestry (Table 8.34).

Table 43 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		113	57.9	50.7	65.0	108	55.7	48.4	62.8	96	49.0	41.8	56.2
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Leukocytosis (10024378)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Lymphadenopathy (10025197)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6
Congenital, familial and genetic disorders (10010331)	Congenital skin dimples (10072978)	0	0.0	0.0	1.9	3	1.5	0.3	4.5	1	0.5	0.0	2.8
	Dermoid cyst (10012522)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Hydrocele (10020488)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Hypospadias (10021093)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Macrocephaly (10050183)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Plagiocephaly (10048586)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	2	1.0	0.1	3.6
	Ear disorder (10014004)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Ear pain (10014020)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Anal fistula (10002156)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Constipation (10010774)	1	0.5	0.0	2.8	2	1.0	0.1	3.7	5	2.6	0.8	5.9
	Diarrhoea (10012735)	6	3.1	1.1	6.6	5	2.6	0.8	5.9	10	5.1	2.5	9.2
	Flatulence (10016766)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Frequent bowel movements (10017367)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.9	8	4.1	1.8	8.0	1	0.5	0.0	2.8
	Inguinal hernia (10022016)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Teething (10043183)	6	3.1	1.1	6.6	8	4.1	1.8	8.0	9	4.6	2.1	8.5
	Vomiting (10047700)	9	4.6	2.1	8.6	8	4.1	1.8	8.0	10	5.1	2.5	9.2
	Vomiting projectile (10047708)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Crying (10011469)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	0	0.0	0.0	1.9

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ill-defined disorder (10061520)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site bruising (10022052)	2	1.0	0.1	3.7	2	1.0	0.1	3.7	5	2.6	0.8	5.9
	Injection site erythema (10022061)	4	2.1	0.6	5.2	2	1.0	0.1	3.7	5	2.6	0.8	5.9
	Injection site induration (10022075)	3	1.5	0.3	4.4	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Injection site mass (10022081)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Injection site pain (10022086)	4	2.1	0.6	5.2	6	3.1	1.1	6.6	7	3.6	1.4	7.2
	Injection site pruritus (10022093)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site rash (10022094)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	2	1.0	0.1	3.6
	Injection site swelling (10053425)	4	2.1	0.6	5.2	1	0.5	0.0	2.8	4	2.0	0.6	5.1
	Injection site warmth (10022112)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Oedema peripheral (10030124)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Peripheral swelling (10048959)	0	0.0	0.0	1.9	3	1.5	0.3	4.5	0	0.0	0.0	1.9
	Pyrexia (10037660)	12	6.2	3.2	10.5	5	2.6	0.8	5.9	15	7.7	4.3	12.3
	Swelling (10042674)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Vaccination site bruising (10069484)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	1	0.5	0.0	2.8
	Vaccination site erythema (10059079)	2	1.0	0.1	3.7	4	2.1	0.6	5.2	3	1.5	0.3	4.4
	Vaccination site induration (10065117)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Vaccination site pain (10068879)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	3	1.5	0.3	4.4
	Vaccination site swelling (10069620)	3	1.5	0.3	4.4	1	0.5	0.0	2.8	2	1.0	0.1	3.6
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Milk allergy (10027633)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Infections and infestations (10021881)	Acute sinusitis (10001076)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Anal abscess (10048946)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Bronchiolitis (10006448)	3	1.5	0.3	4.4	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Bronchitis (10006451)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Candida infection (10074170)	2	1.0	0.1	3.7	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Candida nappy rash (10007135)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Cellulitis (10007882)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Conjunctivitis (10010741)	10	5.1	2.5	9.2	8	4.1	1.8	8.0	1	0.5	0.0	2.8
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Conjunctivitis viral (10010755)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Croup infectious (10011416)	2	1.0	0.1	3.7	2	1.0	0.1	3.7	0	0.0	0.0	1.9

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ear infection (10014011)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Eczema herpeticum (10014197)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Exanthema subitum (10015586)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Fungal infection (10017533)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Fungal skin infection (10017543)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Gastric infection (10056663)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Gastroenteritis (10017888)	1	0.5	0.0	2.8	2	1.0	0.1	3.7	1	0.5	0.0	2.8
	Hand-foot-and-mouth disease (10019113)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Herpangina (10019936)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Impetigo (10021531)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	2	1.0	0.1	3.6
	Influenza (10022000)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Nasopharyngitis (10028810)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	3	1.5	0.3	4.4
	Oral candidiasis (10030963)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Otitis externa (10033072)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Otitis media (10033078)	9	4.6	2.1	8.6	7	3.6	1.5	7.3	9	4.6	2.1	8.5
	Otitis media acute (10033079)	1	0.5	0.0	2.8	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Otitis media chronic (10033081)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Pertussis (10034738)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Pharyngitis (10034835)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Pneumonia (10035664)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Respiratory syncytial virus infection (10061603)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Respiratory tract infection (10062352)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Rhinitis (10039083)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Roseola (10039222)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Sinusitis (10040753)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Skin candida (10054152)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Upper respiratory tract infection (10046306)	30	15.4	10.6	21.2	23	11.9	7.7	17.3	26	13.3	8.9	18.8
	Urinary tract infection (10046571)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	1	0.5	0.0	2.8
	Viraemia (10058874)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral infection (10047461)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	3	1.5	0.3	4.4
	Viral rash (10047476)	3	1.5	0.3	4.4	0	0.0	0.0	1.9	3	1.5	0.3	4.4
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Arthropod sting (10003402)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Clavicle fracture (10009245)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Concussion (10010254)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Corneal abrasion (10010984)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Craniocerebral injury (10070976)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Fall (10016173)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Foreign body (10070245)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Head injury (10019196)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6
	Nasal injury (10078651)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Thermal burn (10053615)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Investigations (10022891)	Body temperature increased (10005911)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Cardiac murmur (10007586)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Weight decreased (10047895)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Musculoskeletal and connective tissue disorders (10028395)	Asymmetric gluteal fold (10072189)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Pain in extremity (10033425)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Positional plagiocephaly (10068711)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma (10018814)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Lethargy (10024264)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Poor quality sleep (10062519)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Tremor (10044565)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Psychiatric disorders (10037175)	Irritability (10022998)	4	2.1	0.6	5.2	3	1.5	0.3	4.5	1	0.5	0.0	2.8
	Screaming (10039740)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Renal and urinary disorders (10038359)	Urethral meatus stenosis (10058463)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Genital labial adhesions (10064162)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Penile adhesion (10059636)	3	1.5	0.3	4.4	3	1.5	0.3	4.5	0	0.0	0.0	1.9

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Penile erythema (10070655)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Bronchial hyperreactivity (10066091)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Cough (10011224)	15	7.7	4.4	12.4	7	3.6	1.5	7.3	7	3.6	1.4	7.2
	Dysphonia (10013952)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Epistaxis (10015090)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Nasal congestion (10028735)	2	1.0	0.1	3.7	6	3.1	1.1	6.6	2	1.0	0.1	3.6
	Respiratory arrest (10038669)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Respiratory disorder (10038683)	1	0.5	0.0	2.8	2	1.0	0.1	3.7	1	0.5	0.0	2.8
	Rhinitis allergic (10039085)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Rhinorrhoea (10039101)	3	1.5	0.3	4.4	2	1.0	0.1	3.7	4	2.0	0.6	5.1
	Sinus congestion (10040742)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Sneezing (10041232)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Upper respiratory tract congestion (10052252)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Wheezing (10047924)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	2	1.0	0.1	3.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	3	1.5	0.3	4.4	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Dermatitis atopic (10012438)	2	1.0	0.1	3.7	3	1.5	0.3	4.5	5	2.6	0.8	5.9
	Dermatitis contact (10012442)	1	0.5	0.0	2.8	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Dermatitis diaper (10012444)	2	1.0	0.1	3.7	3	1.5	0.3	4.5	9	4.6	2.1	8.5
	Dry skin (10013786)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Eczema (10014184)	4	2.1	0.6	5.2	5	2.6	0.8	5.9	4	2.0	0.6	5.1
	Erythema (10015150)	0	0.0	0.0	1.9	3	1.5	0.3	4.5	0	0.0	0.0	1.9
	Hair growth abnormal (10019044)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Hypertrichosis (10020864)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Intertrigo (10022622)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Post inflammatory pigmentation change (10036229)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Rash (10037844)	4	2.1	0.6	5.2	4	2.1	0.6	5.2	6	3.1	1.1	6.5
	Rash macular (10037867)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Seborrhoea (10039792)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Seborrhoeic dermatitis (10039793)	3	1.5	0.3	4.4	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Urticaria (10046735)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 44 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		13	6.7	3.6	11.1	12	6.2	3.2	10.6	7	3.6	1.4	7.2
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Diarrhoea (10012735)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Teething (10043183)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Vomiting (10047700)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	0	0.0	0.0	1.9
General disorders and administration site conditions (10018065)	Crying (10011469)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Ill-defined disorder (10061520)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site erythema (10022061)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site pain (10022086)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Injection site swelling (10053425)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site warmth (10022112)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Pyrexia (10037660)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Infections and infestations (10021881)	Bronchiolitis (10006448)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Conjunctivitis (10010741)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Croup infectious (10011416)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Gastroenteritis (10017888)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Hand-foot-and-mouth disease (10019113)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Nasopharyngitis (10028810)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Otitis media (10033078)	3	1.5	0.3	4.4	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Pharyngitis (10034835)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Respiratory syncytial virus infection (10061603)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Rhinitis (10039083)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Sinusitis (10040753)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Upper respiratory tract infection (10046306)	3	1.5	0.3	4.4	2	1.0	0.1	3.7	2	1.0	0.1	3.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Cough (10011224)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Respiratory arrest (10038669)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Wheezing (10047924)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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

8.1.7. According-to-protocol cohort analysis

In the Hexa, Pedia and Penta groups less than 5% of subjects who received a vaccine dose were excluded from the Primary ATP cohort for safety: 0.5%, 0.5% and 2.6%, respectively (Table 18). Thus a complementary analysis was not carried out on the Primary ATP cohort for safety.

8.1.8. Serious adverse events

The SAE Summary Table(s) are in Section 12.1 (Table 8.46) and the SAE Clinical Narratives reports are in Section 12.2.

8.1.8.1. Fatal events

No fatal SAEs were reported during the course of the study.

8.1.8.2. Non-fatal events

Non-fatal SAEs from Dose 1 up to 6 months following priming doses were reported for 7 (3.6%) subjects in the Hexa group and Penta group, and 1 (0.5%) subject in the Pedia group (Table 45). Only two SAEs were reported by more than one subject in any group: 2 subjects (1.0%) with Respiratory distress in the Hexa group and 2 subjects with Parainfluenzae virus infection in the Penta group.

All subjects who experienced an SAE were considered recovered/ resolved at the end of the study except one non-causally related event of Choking in a 47-week-old female in the Hexa group which was considered recovered/ resolved with sequelae (Table 8.46).

Three SAEs occurring in two subjects were considered causally related to primary vaccination by the investigator:

- An SAE of Lethargy in an 8-week-old female subject in the Hexa group which recovered/resolved after one day.
- Two SAEs in the same subject: one “Apparent life-threatening event” and one event of Leukocytosis were observed in a 10-week-old female subject in the Hexa group which recovered/resolved over 1-2 days.

The percentage of subjects for whom the occurrence of SAEs was reported following priming doses by gender and geographical ancestry are presented in Table 8.44 and Table 8.45.

Table 45 Number (%) of subjects with serious adverse events (SAE) from Dose 1 up to 6 months following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		7	3.6	1.5	7.3	1	0.5	0.0	2.8	7	3.6	1.4	7.2
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Gastrointestinal disorders (10017947)	Gastrooesophageal reflux disease (10017885)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Infections and infestations (10021881)	Gastroenteritis viral (10017918)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Meningitis viral (10027260)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6
	Pneumonia (10035664)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Injury, poisoning and procedural complications (10022117)	Road traffic accident (10039203)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Lethargy (10024264)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Seizure (10039906)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Psychiatric disorders (10037175)	Mental status changes (10048294)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Choking (10008589)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Hypoxia (10021143)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Respiratory distress (10038687)	2	1.0	0.1	3.7	0	0.0	0.0	1.9	0	0.0	0.0	1.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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

8.1.9. Adverse events leading to premature discontinuation of study vaccine and/or study

Two subjects had adverse events leading to premature discontinuation of the study (Table 6.2):

- One Hexa group subject with an SAE of Lethargy reported after the first vaccination;
- One Penta group subject with a Non-Serious Adverse Event of Seizure reported after the Month 2 dose.

8.1.10. Other significant adverse events

8.1.10.1. New Onset of Chronic Illness (NOCI)

NOCI symptoms were reported for 7 subjects (3.6%) in the Hexa group, 11 subjects (5.7%) in the Pedia group and 10 subjects (5.1%) in the Penta group (Table 46).

- The two reported symptoms in the Hexa group were Dermatitis atopic (2.6%) followed by Bronchial hyperreactivity (1.0%). In the Pedia group, the symptom reported by more than one subject was Dermatitis atopic (3.6%). In the Penta group, the symptoms reported by more than one subject were Dermatitis atopic (3.6%) and Asthma (1.0%).

The percentage of subjects for whom the occurrence of NOCI classified by MedDRA Primary System Organ Class and Preferred Term was reported following priming doses by gender and geographical ancestry are presented in Table 8.41 and Table 8.42.

8.1.10.2. Hypotonic-Hyporesponsive Episode (HHE) and Convulsion

A search of the study data for symptoms which could be related to HHE within 31 days post-vaccination was conducted (broad MedDRA SMQ (Standardised MedDRA Queries) hypotonic-hyporesponsive episode) and 2 subjects with Cyanosis in the Penta group were identified (Table 8.35), who were both female (Table 8.37) and of the White Caucasian geographical ancestry (Table 8.38). After medical review of the cases, both of them were assessed as not meeting criteria for HHE.

A similar search this time for the narrow MedDRA SMQ “convulsion” with 31 days post-vaccination did not identify any subjects (Table 8.36, Table 8.39, Table 8.40).

Table 46 Number % of subjects with adverse events of New Onset of Chronic Illness (NOCI) from Dose 1 up to 6 months following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		7	3.6	1.5	7.3	11	5.7	2.9	9.9	10	5.1	2.5	9.2
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Food allergy (10016946)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	1	0.5	0.0	2.8
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6
	Bronchial hyperreactivity (10066091)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Rhinitis allergic (10039085)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	5	2.6	0.8	5.9	7	3.6	1.5	7.3	7	3.6	1.4	7.2
	Urticaria (10046735)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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

8.1.11. Concomitant medications /vaccinations

The intake of any concomitant medication was reported for between 60.0-75.8% of subjects in all three groups (Hexa, Pedia and Penta) during the 4-day (Day 0-3) post-vaccination period (Table 47).

- Between 54.9-69.1% of subjects across groups received any antipyretic and between 12.8-13.9% of subjects across groups received a prophylactic antipyretic concomitant medication.

The corresponding concomitant medication results during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall are provided in Table 8.43.

Table 47 Number and percentage of subjects with concomitant medication during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

	Hexa group					Pedia group					Penta group				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1															
Any	195	69	35.4	28.7	42.5	194	107	55.2	47.9	62.3	196	83	42.3	35.3	49.6
Any antipyretic	195	63	32.3	25.8	39.4	194	99	51.0	43.8	58.3	196	79	40.3	33.4	47.5
Prophylactic antipyretic	195	17	8.7	5.2	13.6	194	16	8.2	4.8	13.0	196	12	6.1	3.2	10.5
Dose 2															
Any	186	78	41.9	34.8	49.4	188	87	46.3	39.0	53.7	189	70	37.0	30.1	44.3
Any antipyretic	186	75	40.3	33.2	47.7	188	86	45.7	38.5	53.2	189	64	33.9	27.2	41.1
Prophylactic antipyretic	186	12	6.5	3.4	11.0	188	9	4.8	2.2	8.9	189	10	5.3	2.6	9.5
Dose 3															
Any	183	65	35.5	28.6	42.9	185	91	49.2	41.8	56.6	180	67	37.2	30.1	44.7
Any antipyretic	183	60	32.8	26.0	40.1	185	82	44.3	37.0	51.8	180	63	35.0	28.1	42.4
Prophylactic antipyretic	183	13	7.1	3.8	11.8	185	9	4.9	2.2	9.0	180	10	5.6	2.7	10.0
Overall/dose															
Any	564	212	37.6	33.6	41.7	567	285	50.3	46.1	54.5	565	220	38.9	34.9	43.1
Any antipyretic	564	198	35.1	31.2	39.2	567	267	47.1	42.9	51.3	565	206	36.5	32.5	40.6
Prophylactic antipyretic	564	42	7.4	5.4	9.9	567	34	6.0	4.2	8.3	565	32	5.7	3.9	7.9
Overall/subject															
Any	195	117	60.0	52.8	66.9	194	147	75.8	69.1	81.6	196	121	61.7	54.5	68.6
Any antipyretic	195	107	54.9	47.6	62.0	194	134	69.1	62.1	75.5	196	114	58.2	50.9	65.2
Prophylactic antipyretic	195	26	13.3	8.9	18.9	194	27	13.9	9.4	19.6	196	25	12.8	8.4	18.3

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period
For overall/dose:
N = number of administered doses

n/% = number/percentage of doses after which the specified concomitant medication was started at least once during the mentioned period
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.1.12. Clinical laboratory evaluations

Not applicable

8.1.13. Pregnancy

Not applicable

8.1.14. Important safety information received after the data lock point (database freeze date)

None

8.1.15. Primary Total vaccinated cohort - Safety summary

- *Any Symptom:* In all three groups (Hexa, Pedia and Penta) over the primary doses, symptoms (solicited and/or unsolicited, local and/or general) were reported for 93.4-96.4% of subjects.
- *Solicited local symptoms:* Pain was the most frequently reported solicited local symptom reported in 67.9% of subjects in the Hexa group, in 82.0% of subjects in the Pedia group and in 79.8% of subjects in the Penta group.

  Pain was also the most frequently reported Grade 3 solicited local symptom reported in 4.3% of subjects in the Hexa group, 18.0% of subjects in the Pedia group and 11.7% of subjects in the Penta group.
- *Solicited general symptoms:* Irritability / Fussiness was the most frequently reported solicited general symptom in all groups, reported in 87.7% of subjects in the Hexa group, in 96.3% of subjects in the Pedia group and in 94.1% of subjects in the Penta group overall.

  Irritability was also the most commonly reported grade 3 solicited general symptom, reported for 9.6% of subjects in the Hexa group, 18.5% of subjects in the Pedia group and 16.0% of subjects in the Penta group overall.
- *Unsolicited adverse events:* At least one unsolicited symptom within the 31-day post-vaccination period after each vaccination was reported for 57.9%, 55.7% and 49.0% of subjects in the Hexa, Pedia and Penta groups, respectively.

  The most commonly reported unsolicited symptom in the three groups was URTI: Hexa group:15.4%; Pedia group: 11.9%; Penta group: 13.3%.

Grade 3 unsolicited symptoms were reported for 6.7%, 6.2% and 3.6% of subjects in Hexa, Pedia and Penta groups, respectively. The most commonly reported grade 3 unsolicited symptoms were:
Hexa group: URTI and Otitis media (1.5%);
Pedia group: URTI, Conjunctivitis and Irritability (1.0%);
Penta group: URTI (1.0%).

- *Adverse events of interest:* NOCI symptoms were reported for 7 subjects (3.6%) in the Hexa group, 11 subjects (5.7%) in the Pedia group and 10 subjects (5.1%) in the Penta group. The two reported symptoms in the Hexa group were Dermatitis atopic (2.6%) followed by Bronchial hyperreactivity (1.0%). In the Pedia group, the symptom reported by more than one subject was Dermatitis atopic (3.6%). In the Penta group, the symptoms reported by more than one subject were Dermatitis atopic (3.6%) and Asthma (1.0%).
- *Serious adverse events:* Non-fatal SAEs from Dose 1 up to 6 months following priming doses were reported for 7 (3.6%) subjects in the Hexa group and Penta group, and 1 (0.5%) subject in the Pedia group. All SAE were considered recovered/resolved without sequelae at the end of the study except one non-causally related event of Choking in a 47-week-old female in the Hexa group which was considered recovered/resolved with sequelae.

  Three SAEs occurring in two subjects were considered causally related to primary vaccination by the investigator: An SAE of Lethargy in an 8-week-old female subject in the Hexa group which recovered/resolved after one day without sequelae; 2 SAEs in the same subject: one “Apparent life-threatening event” and one event of Leukocytosis were observed in a 10-week-old female subject in the Hexa group which recovered/resolved over 1-2 days without sequelae.
- No fatal SAEs were reported during the primary vaccination Epoch of the study.
- *Withdrawals due to AEs /SAEs:* Two subjects had adverse events leading to premature discontinuation during the primary vaccination period: one Hexa group subject with an SAE of Lethargy reported after the first vaccination; one Penta group subject with a Non-Serious Adverse Event of Seizure reported after the Month 2 dose.

8.2. Booster Total vaccinated cohort analysis

8.2.1. Booster vaccination doses received

All subjects in the Booster Total vaccinated cohort received the planned booster vaccine doses as shown in Table 48.

Table 48 Number and percentage of subjects who received the study vaccine dose by vaccine (Booster Total vaccinated cohort)

Hexa group HIBERIX N = 167		Hexa group INFANRIX N = 167		Pedia group ACTHIB N = 158		Pedia group INFANRIX N = 158		Penta group PENTACEL N = 161	
n	%	n	%	n	%	n	%	n	%
167	100	167	100	158	100	158	100	161	100

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = number of subjects in each group included in the considered cohort
n/% = number/percentage of subjects receiving the dose

8.2.2. Symptom eCRF screen compliance

Compliance in recording general symptom eCRF screens or local symptom eCRF screens was typically very high across groups: at least 91.6% and at least 92.2%, respectively (Table 49).

Table 49 Compliance in returning symptom sheets for the booster dose (Booster 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
Hexa group	167	0	153	91.6	154	92.2
Pedia group	158	0	150	94.9	151	95.6
Penta group	161	0	151	93.8	150	93.2

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.2.3. Overall incidence of adverse events

At least one solicited or unsolicited symptom was reported during the Booster phase for 77.2% of Hexa group subjects, 81.6% of Pedia group subjects and 70.2% of Penta group subjects (Table 50). General symptoms were reported by between 62.7-69.6% of subjects across groups and local symptoms were reported by between 47.2-63.3% of subjects across groups.

1. Incidence of local symptoms (solicited and unsolicited) reported for *Infanrix*, *Hiberix*, *ActHIB*, and *Pentacel* vaccines: Table 51;

   – Overall local symptoms (solicited and unsolicited) were recorded for subjects receiving: *Infanrix* (52.7% for Hexa group and 60.1% for Pedia group); *Hiberix* (47.9% for Hexa group), *ActHIB* (52.5% for Pedia group) and *Pentacel* (47.2% for Penta group).

2. Incidence and nature of grade 3 symptoms (solicited and unsolicited): Table 52;

   – In all three groups (Hexa, Pedia and Penta) grade 3 symptoms (solicited and/or unsolicited, local and/or general) were reported for 6.2-10.8% of subjects.

3. Incidence of grade 3 local symptoms (solicited and unsolicited) reported for *Infanrix*, *Hiberix*, *ActHIB*, and *Pentacel* vaccines: Table 53;

   – Overall local symptoms (solicited and unsolicited) were recorded for subjects receiving: *Infanrix* (6.0% for Hexa group and 7.0% for Pedia group); *Hiberix* (0.6% for Hexa group), *ActHIB* (3.2% for Pedia group) and *Pentacel* (3.7% for Penta group).

Please also refer to the following Tables:

1. Incidence and nature of grade 3 symptoms (solicited and unsolicited) that were causally related to Booster vaccination: Table 8.49.
2. Incidence and nature of symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following the booster dose: Table 8.50.
3. Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following the booster dose: Table 8.51.
4. Incidence and nature of symptoms (solicited and unsolicited) that were causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following the booster dose: Table 8.52.
5. Incidence and nature of grade 3 symptoms (solicited and unsolicited) that were causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following the booster dose: Table 8.53.
6. Incidence of local symptoms (solicited and unsolicited) that were causally related to vaccination reported for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose: Table 8.54.
7. Incidence of grade 3 local symptoms (solicited and unsolicited) that were causally related to vaccination reported for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose: Table 8.55.

Table 50 Incidence and nature of symptoms (solicited and unsolicited) reported during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster 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
Hexa group	167	129	77.2	70.1	83.4	167	105	62.9	55.1	70.2	167	95	56.9	49.0	64.5
Pedia group	158	129	81.6	74.7	87.3	158	110	69.6	61.8	76.7	158	100	63.3	55.3	70.8
Penta group	161	113	70.2	62.5	77.1	161	101	62.7	54.8	70.2	161	76	47.2	39.3	55.2

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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 51 Incidence of local symptoms (solicited and unsolicited) reported for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

	ACTHIB					PENTACEL					INFANRIX					HIBERIX				
				95% CI					95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Hexa group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	167	88	52.7	44.8	60.5	167	80	47.9	40.1	55.8
Pedia group	158	83	52.5	44.4	60.5	0	0	0.0	0.0	0.0	158	95	60.1	52.0	67.8	0	0	0.0	0.0	0.0
Penta group	0	0	0.0	0.0	0.0	161	76	47.2	39.3	55.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 52 Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster 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
Hexa group	167	13	7.8	4.2	12.9	167	3	1.8	0.4	5.2	167	10	6.0	2.9	10.7
Pedia group	158	17	10.8	6.4	16.7	158	6	3.8	1.4	8.1	158	12	7.6	4.0	12.9
Penta group	161	10	6.2	3.0	11.1	161	5	3.1	1.0	7.1	161	6	3.7	1.4	7.9

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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 53 Incidence of grade 3 local symptoms (solicited and unsolicited) reported for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

	ACTHIB					PENTACEL					INFANRIX					HIBERIX				
				95% CI					95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Hexa group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	167	10	6.0	2.9	10.7	167	1	0.6	0.0	3.3
Pedia group	158	5	3.2	1.0	7.2	0	0	0.0	0.0	0.0	158	11	7.0	3.5	12.1	0	0	0.0	0.0	0.0
Penta group	0	0	0.0	0.0	0.0	161	6	3.7	1.4	7.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

8.2.4. Solicited local adverse events

Incidence of solicited local symptoms are summarized in Table 54.

Pain was the most frequently reported solicited local symptom reported in 46.8% of subjects in the Hexa group, in 51.0% of subjects in the Pedia group and in 39.3% of subjects in the Penta group.

Redness was the most frequently reported Grade 3 (>20; Section 5.9.2.1) solicited local symptom reported in 5.2% of subjects in the Hexa group, 4.0% of subjects in the Pedia group and 1.3% of subjects in the Penta group.

Medical advice was sought for not more than 1.3% of subjects following any one symptom.

Please also refer to the following Tables:

1. Incidence of local symptoms (solicited and unsolicited) that were causally related to vaccination reported for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose: Table 8.54.
2. Incidence of grade 3 local symptoms (solicited and unsolicited) that were causally related to vaccination reported for *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel* vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose: Table 8.55.

The incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose by gender and by geographical ancestry are presented in Table 8.56 and Table 8.57, respectively.

The incidence of large injection site reaction reported during the 4-day (Days 0-3) post-vaccination period following the booster dose is presented in Table 8.58. A total of two subjects (1.3%) in the Hexa group and one subject (0.7%) in the Pedia group had Local Swelling, and Diffuse Swelling was recorded in one subject (0.6%) in the Hexa group. See Section 5.9.2.1 and Section 5.10.5.3 for the definition of large injection site reactions defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of limb circumference, with details of how these events were recorded.

Table 54 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

			Hexa group					Pedia group					Penta group				
						95 % CI					95 % CI					95 % CI	
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Pain	Total	All	154	72	46.8	38.7	55.0	151	77	51.0	42.7	59.2	150	59	39.3	31.5	47.6
		Grade 2 or 3	154	13	8.4	4.6	14.0	151	22	14.6	9.4	21.2	150	16	10.7	6.2	16.7
		Grade 3	154	2	1.3	0.2	4.6	151	3	2.0	0.4	5.7	150	2	1.3	0.2	4.7
		Medical advice	154	1	0.6	0.0	3.6	151	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4
	ActHIB/Hiberix	All	153	61	39.9	32.1	48.1	151	64	42.4	34.4	50.7					
		Grade 2 or 3	153	11	7.2	3.6	12.5	151	15	9.9	5.7	15.9					
		Grade 3	153	1	0.7	0.0	3.6	151	2	1.3	0.2	4.7					
		Medical advice	153	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4					
	Infanrix/Pentacel	All	154	62	40.3	32.4	48.5	151	74	49.0	40.8	57.3	150	59	39.3	31.5	47.6
		Grade 2 or 3	154	12	7.8	4.1	13.2	151	19	12.6	7.7	19.0	150	16	10.7	6.2	16.7
		Grade 3	154	2	1.3	0.2	4.6	151	3	2.0	0.4	5.7	150	2	1.3	0.2	4.7
		Medical advice	154	1	0.6	0.0	3.6	151	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4
Redness (mm)	Total	All	154	55	35.7	28.2	43.8	151	66	43.7	35.7	52.0	150	47	31.3	24.0	39.4
		>5	154	19	12.3	7.6	18.6	151	16	10.6	6.2	16.6	150	13	8.7	4.7	14.4
		>20	154	8	5.2	2.3	10.0	151	6	4.0	1.5	8.4	150	2	1.3	0.2	4.7
		Medical advice	154	2	1.3	0.2	4.6	151	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4
	ActHIB/Hiberix	All	153	42	27.5	20.6	35.2	151	49	32.5	25.1	40.5					
		>5	153	7	4.6	1.9	9.2	151	4	2.6	0.7	6.6					
		>20	153	0	0.0	0.0	2.4	151	2	1.3	0.2	4.7					
		Medical advice	153	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4					
	Infanrix/Pentacel	All	154	49	31.8	24.6	39.8	151	60	39.7	31.9	48.0	150	47	31.3	24.0	39.4
		>5	154	17	11.0	6.6	17.1	151	14	9.3	5.2	15.1	150	13	8.7	4.7	14.4
		>20	154	8	5.2	2.3	10.0	151	4	2.6	0.7	6.6	150	2	1.3	0.2	4.7
		Medical advice	154	2	1.3	0.2	4.6	151	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4
Swelling (mm)	Total	All	154	47	30.5	23.4	38.4	151	50	33.1	25.7	41.2	150	35	23.3	16.8	30.9
		>5	154	17	11.0	6.6	17.1	151	18	11.9	7.2	18.2	150	14	9.3	5.2	15.2
		>20	154	5	3.2	1.1	7.4	151	7	4.6	1.9	9.3	150	4	2.7	0.7	6.7
		Medical advice	154	2	1.3	0.2	4.6	151	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4
	ActHIB/Hiberix	All	153	29	19.0	13.1	26.1	151	29	19.2	13.3	26.4					
		>5	153	7	4.6	1.9	9.2	151	6	4.0	1.5	8.4					
		>20	153	0	0.0	0.0	2.4	151	2	1.3	0.2	4.7					
		Medical advice	153	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4					
	Infanrix/Pentacel	All	154	42	27.3	20.4	35.0	151	44	29.1	22.0	37.1	150	35	23.3	16.8	30.9
		>5	154	13	8.4	4.6	14.0	151	17	11.3	6.7	17.4	150	14	9.3	5.2	15.2
		>20	154	5	3.2	1.1	7.4	151	7	4.6	1.9	9.3	150	4	2.7	0.7	6.7
		Medical advice	154	2	1.3	0.2	4.6	151	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.2.5. Solicited general adverse events

Incidence of solicited general symptoms are summarised in Table 55.

- Irritability / Fussiness was the most frequently reported solicited general symptom in all the groups, reported in 56.2% of subjects in the Hexa group, in 62.7% of subjects in the Pedia group and in 50.3% of subjects in the Penta group.
- Irritability / Fussiness was also the most commonly reported solicited general symptom graded 3 in intensity; reported for 2.0% of subjects in the Hexa group, 2.7% of subjects in the Pedia group and 2.6% of subjects in the Penta group.
- Grade 3 fever (>40.0°C rectal temperature) was reported for none of the subjects in any group.
- Medical advice was sought by only 2 subjects in the Pedia group and 2 subjects in the Penta group.
- The majority of solicited general symptoms following vaccination were considered by the investigator to be causally related to vaccination in the three groups.

The incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose by gender and geographical ancestry are presented in Table 8.59 and Table 8.60, respectively.

Table 55 Incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group					Pedia group					Penta group				
					95 % CI					95 % CI					95 % CI	
Symptom	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	153	59	38.6	30.8	46.8	150	67	44.7	36.6	53.0	151	65	43.0	35.0	51.3
	Grade 2 or 3	153	18	11.8	7.1	18.0	150	20	13.3	8.3	19.8	151	17	11.3	6.7	17.4
	Grade 3	153	1	0.7	0.0	3.6	150	3	2.0	0.4	5.7	151	2	1.3	0.2	4.7
	Related	153	55	35.9	28.4	44.1	150	65	43.3	35.3	51.7	151	61	40.4	32.5	48.7
	Grade 3 Related	153	1	0.7	0.0	3.6	150	3	2.0	0.4	5.7	151	2	1.3	0.2	4.7
	Medical advice	153	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4
Irritability / Fussiness	All	153	86	56.2	48.0	64.2	150	94	62.7	54.4	70.4	151	76	50.3	42.1	58.6
	Grade 2 or 3	153	26	17.0	11.4	23.9	150	35	23.3	16.8	30.9	151	23	15.2	9.9	22.0
	Grade 3	153	3	2.0	0.4	5.6	150	4	2.7	0.7	6.7	151	4	2.6	0.7	6.6
	Related	153	85	55.6	47.3	63.6	150	92	61.3	53.0	69.2	151	68	45.0	36.9	53.3
	Grade 3 Related	153	3	2.0	0.4	5.6	150	4	2.7	0.7	6.7	151	4	2.6	0.7	6.6
	Medical advice	153	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4	151	1	0.7	0.0	3.6
Loss Of Appetite	All	153	47	30.7	23.5	38.7	150	47	31.3	24.0	39.4	151	46	30.5	23.2	38.5
	Grade 2 or 3	153	8	5.2	2.3	10.0	150	9	6.0	2.8	11.1	151	11	7.3	3.7	12.7
	Grade 3	153	1	0.7	0.0	3.6	150	2	1.3	0.2	4.7	151	2	1.3	0.2	4.7
	Related	153	44	28.8	21.7	36.6	150	44	29.3	22.2	37.3	151	41	27.2	20.2	35.0
	Grade 3 Related	153	1	0.7	0.0	3.6	150	2	1.3	0.2	4.7	151	2	1.3	0.2	4.7
	Medical advice	153	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4
Temperature/(Axillary) (°C)	All	153	4	2.6	0.7	6.6	150	10	6.7	3.2	11.9	151	11	7.3	3.7	12.7
	>38.5	153	2	1.3	0.2	4.6	150	5	3.3	1.1	7.6	151	4	2.6	0.7	6.6
	>39.0	153	1	0.7	0.0	3.6	150	1	0.7	0.0	3.7	151	1	0.7	0.0	3.6
	>39.5	153	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4
	>40.0	153	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4
	Related	153	2	1.3	0.2	4.6	150	10	6.7	3.2	11.9	151	9	6.0	2.8	11.0
	>40.0 Related	153	0	0.0	0.0	2.4	150	0	0.0	0.0	2.4	151	0	0.0	0.0	2.4
	Medical advice	153	0	0.0	0.0	2.4	150	2	1.3	0.2	4.7	151	1	0.7	0.0	3.6

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.2.6. Unsolicited adverse events

The percentage of subjects for whom the occurrence of unsolicited symptoms and grade 3 unsolicited symptoms within the 31-day (Days 0-30) post-vaccination period for the Primary Total vaccinated cohort is presented in Table 56 and Table 57, respectively.

- At least one unsolicited symptom within the 31-day post-vaccination period after the booster vaccination, classified by MedDRA Primary System Organ Class and Preferred Term was reported for 22.2%, 22.2% and 25.5% of subjects in the Hexa, Pedia and Penta groups, respectively (Table 56).
- The most commonly reported unsolicited symptoms in the Hexa group was Pyrexia (3.0%) followed by Teething (2.4%) and Vomiting (2.4%). In the Pedia group, the most commonly reported symptoms were Pyrexia (3.2%), Otitis Media (3.2%) and URTI (3.2%). The most commonly reported symptoms in the Penta group were URTI (5.0%) followed by Viral Infection (3.1%), Otitis Media (1.9%), Diarrhoea (1.9%) and Teething (1.9%).
- A grade 3 unsolicited symptom was reported for 3.0%, 1.9% and 1.9% of subjects in Hexa, Pedia and Penta groups, respectively (Table 57). No grade 3 unsolicited symptom was reported by more than one subject in any group.
- The investigator assessed a causal relationship between at least one unsolicited symptom and booster vaccination for 1.8%, 1.9% and 1.9% of subjects in the Hexa, Pedia and Penta groups, respectively – Table 8.61. None of these unsolicited symptoms were reported by more than one subject in any group.

No subject reported a grade 3 unsolicited symptom with causal relationship to booster vaccination (Table 8.62).

The following data are summarised in the following tables:

- The percentage of subjects who reported the occurrence of unsolicited symptoms by gender (Table 8.63), and of unsolicited symptoms by geographical ancestry (Table 8.64).
- The percentage of subjects who reported the occurrence of grade 3 unsolicited symptoms by gender (Table 8.65), and of grade 3 unsolicited symptoms by geographical ancestry (Table 8.66).
- The percentage of subjects who reported the occurrence of unsolicited symptoms with causal relationship to booster vaccination by gender (Table 8.67), and of unsolicited symptoms with causal relationship to booster vaccination by geographical ancestry (Table 8.68).
- No subjects reported the occurrence of grade 3 unsolicited symptoms with causal relationship to booster vaccination by gender (Table 8.69), or of grade 3 unsolicited symptoms with causal relationship to primary vaccination by geographical ancestry (Table 8.70).

Table 56 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		37	22.2	16.1	29.2	35	22.2	15.9	29.4	41	25.5	18.9	32.9
Blood and lymphatic system disorders (10005329)	Iron deficiency anaemia (10022972)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Congenital, familial and genetic disorders (10010331)	Dacryostenosis congenital (10011850)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Phimosis (10034878)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Tympanic membrane perforation (10045210)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Eye disorders (10015919)	Chalazion (10008388)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	2.2	2	1.3	0.2	4.5	3	1.9	0.4	5.3
	Nausea (10028813)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Stomatitis (10042128)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Teething (10043183)	4	2.4	0.7	6.0	2	1.3	0.2	4.5	3	1.9	0.4	5.3
	Vomiting (10047700)	4	2.4	0.7	6.0	3	1.9	0.4	5.4	2	1.2	0.2	4.4
General disorders and administration site conditions (10018065)	Injection site induration (10022075)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Injection site nodule (10057880)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Injection site scab (10066210)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Pyrexia (10037660)	5	3.0	1.0	6.8	5	3.2	1.0	7.2	2	1.2	0.2	4.4
	Vaccination site erythema (10059079)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
Immune system disorders (10021428)	Seasonal allergy (10048908)	3	1.8	0.4	5.2	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Cellulitis (10007882)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Conjunctivitis (10010741)	0	0.0	0.0	2.2	2	1.3	0.2	4.5	0	0.0	0.0	2.3
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Croup infectious (10011416)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	2	1.2	0.2	4.4
	Eye infection (10015929)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Folliculitis (10016936)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Gastroenteritis (10017888)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	1	0.6	0.0	3.4
	Herpangina (10019936)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Hordeolum (10020377)	2	1.2	0.1	4.3	1	0.6	0.0	3.5	1	0.6	0.0	3.4
	Nasopharyngitis (10028810)	2	1.2	0.1	4.3	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Otitis media (10033078)	1	0.6	0.0	3.3	5	3.2	1.0	7.2	3	1.9	0.4	5.3
	Otitis media acute (10033079)	1	0.6	0.0	3.3	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Pharyngitis (10034835)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Rhinitis (10039083)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	2	1.2	0.2	4.4
	Sinusitis (10040753)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Staphylococcal infection (10058080)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Upper respiratory tract infection (10046306)	3	1.8	0.4	5.2	5	3.2	1.0	7.2	8	5.0	2.2	9.6
	Viral infection (10047461)	2	1.2	0.1	4.3	2	1.3	0.2	4.5	5	3.1	1.0	7.1
	Viral rash (10047476)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Contusion (10050584)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Corneal abrasion (10010984)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Foreign body (10070245)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	2.2	2	1.3	0.2	4.5	1	0.6	0.0	3.4
	Head injury (10019196)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Mouth injury (10049294)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Skin abrasion (10064990)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Speech disorder developmental (10041467)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Reproductive system and breast disorders (10038604)	Genital labial adhesions (10064162)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Cough (10011224)	2	1.2	0.1	4.3	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Nasal congestion (10028735)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Rhinitis allergic (10039085)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Rhinorrhoea (10039101)	2	1.2	0.1	4.3	2	1.3	0.2	4.5	1	0.6	0.0	3.4
	Wheezing (10047924)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Dermatitis atopic (10012438)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Dermatitis contact (10012442)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Dermatitis diaper (10012444)	2	1.2	0.1	4.3	1	0.6	0.0	3.5	1	0.6	0.0	3.4
	Eczema (10014184)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Ingrowing nail (10022013)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Petechiae (10034754)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Pruritus (10037087)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Rash (10037844)	2	1.2	0.1	4.3	4	2.5	0.7	6.4	0	0.0	0.0	2.3
	Rash erythematous (10037855)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Rash generalised (10037858)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Urticaria (10046735)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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 57 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		5	3.0	1.0	6.8	3	1.9	0.4	5.4	3	1.9	0.4	5.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Vomiting (10047700)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Infections and infestations (10021881)	Croup infectious (10011416)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Sinusitis (10040753)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Upper respiratory tract infection (10046306)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Viral infection (10047461)	1	0.6	0.0	3.3	1	0.6	0.0	3.5	0	0.0	0.0	2.3
Injury, poisoning and procedural complications (10022117)	Corneal abrasion (10010984)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Head injury (10019196)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.2.7. According-to-protocol cohort analysis

In the Hexa, Pedia and Penta groups less than 5% of subjects who received a vaccine dose were excluded from the Primary ATP cohort for safety: 0.0%, 0.0% and 0.6%, respectively (Table 19). Thus a complementary analysis was not carried out on the Booster ATP cohort for safety.

8.2.8. Serious adverse events

The SAE Summary Table(s) are in Section 12.1 (Table 8.80) and the SAE Clinical Narratives reports are in Section 12.2.

8.2.8.1. Fatal events

No fatal SAEs were reported during the course of the study.

8.2.8.2. Non-fatal events

Non-fatal SAEs within 31 days post-booster were recorded for one (0.6%) subject in the Hexa group (Petechiae), for one (0.6%) subject in the Penta group (Seizure like phenomena), and no subject in the Pedia group during the booster vaccination epoch of the study (Table 58 and Table 8.46). None of the two non-fatal SAEs were considered to be causally-related to vaccination and both were recorded to have an outcome of "recovered/resolved" (Table 8.46).

The percentage of subjects for whom the occurrence of SAEs was reported following the booster dose by gender is presented in Table 8.80.

8.2.8.3. SAEs for the full study

There were no fatal SAEs throughout the study. Non-fatal SAEs were reported for 8 subjects in the Hexa group and Penta group, and one subject in the Pedia group throughout the study (Table 45 and Table 58). Only two SAEs were reported by more than one subject in a group during the primary epoch: 2 subjects (1.0%) with Respiratory distress in the Hexa group and 2 subjects with Parainfluenzae virus infection in the Penta group (Table 45). See Section 8.1.8.2 for details of non-fatal SAEs which were not considered fully recovered/resolved and were causally-related to primary vaccination in the primary Epoch.

Table 58 Number (%) of subjects reporting the occurrence of serious adverse event (SAE) within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	0.6	0.0	3.3	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Skin and subcutaneous tissue disorders (10040785)	Petechiae (10034754)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.2.9. Adverse events leading to premature discontinuation of study vaccine and/or study

None

8.2.10. Other significant adverse events

8.2.10.1. New Onset of Chronic Illness (NOCI)

NOCI symptoms were reported for 4 subjects (2.4%) in the Hexa group, 1 subject (0.6%) in the Pedia group and 1 subject (0.6%) in the Penta group (Table 8.77). Only Seasonal allergy symptoms were reported by more than one subject in any group: 3 (1.8%) subjects.

The percentage of subjects for whom the occurrence of NOCI classified by MedDRA Primary System Organ Class and Preferred Term was reported following booster dose by gender and geographical ancestry are presented in Table 8.78 and Table 8.79.

8.2.10.2. Hypotonic-Hyporesponsive Episode and Convulsion

A search of the study data for symptoms reported within 31 days post-vaccination which could be related to HHE was conducted (broad MedDRA SMQ hypotonic-hyporesponsive episode) and no subjects were identified (Table 8.71, Table 8.73, Table 8.75).

A search of the study data for symptoms reported within 31 days post-vaccination which could be related to "convulsion" was conducted (narrow MedDRA SMQ 'convulsion') and 1 subject that developed seizure like phenomena in the Penta group was identified (Table 8.72), who was female (Table 8.74) and of the "Other" geographical ancestry (Table 8.76). The case narrative suggested that the subject was suspected of having frontal lobe epilepsy and up to the end of follow-up was undergoing treatment with Levetiracetam.

8.2.11. Concomitant medications /vaccinations

The intake of any concomitant medication was reported for between 23.4-28.5% of subjects in all three groups (Hexa, Pedia and Penta) during the 4-day (Day 0-3) post-booster vaccination period (Table 59).

Between 21.1-27.2% of subjects across groups received any antipyretic and between 3.8-7.2% of subjects across groups received a prophylactic antipyretic concomitant medication.

Table 59 Number and percentage of subjects starting a concomitant medication during the 4-day (Days 0-3) post-vaccination period (Booster Total vaccinated cohort)

	Hexa group					Pedia group					Penta group				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Any	167	39	23.4	17.2	30.5	158	45	28.5	21.6	36.2	161	38	23.6	17.3	30.9
Any antipyretic	167	36	21.6	15.6	28.6	158	43	27.2	20.4	34.9	161	34	21.1	15.1	28.2
Prophylactic antipyretic	167	12	7.2	3.8	12.2	158	6	3.8	1.4	8.1	161	7	4.3	1.8	8.8

Hexa group = Subjects who received primary doses of *Infanrix hexa* and a booster dose of *Infanrix* and *Hiberix* vaccines
Pedia group = Subjects who received primary doses of *Pediarix* and *ActHIB* and a booster dose of *Infanrix* and *ActHIB* vaccines
Penta group = Subjects who received primary doses of *Pentacel* and *Engerix-B* and a booster dose of *Pentacel* vaccine
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

8.2.12. Clinical laboratory evaluations

Not applicable

8.2.13. Pregnancy

Not applicable

8.2.14. Important safety information received after the data lock point (database freeze date)

None

8.2.15. Booster Total vaccinated cohort - Safety summary

- *Any Symptom:* At least one solicited or unsolicited symptom was reported during the Booster phase for 77.2% of Hexa group subjects, 81.6% of Pedia group subjects and 70.2% of Penta group subjects.
- *Solicited local symptoms:* Pain was the most frequently reported solicited local symptom reported in 46.8% of subjects in the Hexa group, 51.0% of Pedia group subjects and 39.3% of Penta group subjects.

  Redness was the most frequently reported Grade 3 solicited local symptom reported in 1.3-5.2% of subjects in the three groups.
- *Solicited general symptoms:* Irritability / Fussiness was the most frequently reported solicited general symptom in all the groups, reported in 56.2% of Hexa group subjects, in 62.7% of Pedia group subjects and in 50.3% of Penta group subjects.

  Irritability / Fussiness was also the most commonly reported grade 3 solicited general symptom, reported for between 2.0 and 2.7% of subjects across groups.
- *Unsolicited adverse events:* At least one unsolicited symptom within the 31-day post-vaccination period after the booster vaccination was recorded for 22.2%, 22.2% and 25.5% of subjects in the Hexa, Pedia and Penta groups, respectively.

  The most commonly reported unsolicited symptoms were:
  Hexa group: Pyrexia (3.0%); Pedia group: Pyrexia, Otitis media and URTI (3.2%); Penta group: URTI (5.0%).

  A grade 3 unsolicited symptom was reported for 3.0%, 1.9% and 1.9% of subjects in Hexa, Pedia and Penta groups, respectively. No grade 3 unsolicited symptom was reported by more than one subject in any group.
- *Adverse events of interest:* NOCI were reported for 4 subjects (2.4%) in the Hexa group, 1 subject (0.6%) in the Pedia group and 1 subject (0.6%) in the Penta group. Only Seasonal allergy symptoms were reported by more than one subject in any group: 3 (1.8%) subjects.
- *Large injection site reactions up to 4 days (D0-D3) after vaccination:* Two subjects (1.3%) in the Hexa group and one subject (0.7%) in the Pedia group had Local Swelling, and Diffuse Swelling was recorded in one subject (0.6%) in the Hexa group.

- *Serious adverse events within 31 days post booster:* Non-fatal SAEs within 31 days post-booster dose were reported for one (0.6%) subject in the Hexa group (Petechiae), for one (0.6%) subject in the Penta group (Seizure like phenomena), and no subject in the Pedia group. None of the two non-fatal SAEs were considered to be causally-related to vaccination and both were recorded to have an outcome of "recovered/resolved".
- *Withdrawals due to AEs /SAEs:* No subject was withdrawn due to an AE or SAE during the booster Epoch.
- ***SAEs for the full study:*** There were no fatal SAEs throughout the study. SAEs were reported for 8 subjects in the Hexa group and Penta group, and for one subject in the Pedia group throughout the study

9. OVERALL CONCLUSIONS

- The primary objective of the study was met: One month post-primary vaccination, *Infanrix hexa* was demonstrated to be non-inferior to *Pediarix+ACTHib* in terms of antibody GMCs for the three pertussis antigens (PT, FHA, and PRN).
- *One month after the primary vaccination:* The immune responses to *Infanrix hexa*, *Pediarix+ACTHib* and *Pentacel*/*Engerix-B* were similar between the different groups, in terms of seroprotection/seropositivity rates and GMCs.

  The lowest anti-PRP GMCs were observed after *Infanrix hexa* vaccination as compared to *Pediarix+ACTHib* and *Pentacel+Engerix-B*.
- *One month after the booster vaccination:* The immune responses to *Infanrix+Hiberix* (booster vaccines used after *Infanrix hexa* priming), *Infanrix+ActHIB* (booster vaccines used after *Pediarix+ActHIB* priming) and *Pentacel* were similar between the different groups, in terms of seroprotection/seropositivity rates and GMCs.

  Similar Anti-PRP long-term protection antibody levels were observed (≥1.0 µg/mL) between *Infanrix+Hiberix*, *Infanrix+ActHIB* and *Pentacel* after booster vaccination.
- *Safety, reactogenicity:* Clinically acceptable safety and reactogenicity profile in the different vaccination groups, aligned with the very well-known profiles of the study vaccines.

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11. STUDY REPORT AUTHORS /CONTRIBUTING AUTHORS

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12. SERIOUS ADVERSE EVENTS / OTHER SIGNIFICANT ADVERSE EVENTS / PREGNANCY

12.1. SAE Listing(s)

Table 8.46 and Table 8.80

12.2. Clinical narratives for SAEs

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: PPD Respiratory distress, Hyponatraemia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 15-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Infanrix hexa (intramuscular) on 15th October 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 15th October 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 15th August 2014, for prophylaxis.

On PPD 277 days after receiving Infanrix hexa and Prevnar 13 and 338 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed moderate - grade 2 respiratory distress. Serious criteria included hospitalization, GSK medically significant and life threatening. Additional event(s) included moderate - grade 2 hyponatremia on 19th July 2015 with serious criteria of hospitalization and life threatening and moderate - grade 2 PPD on 19th July 2015 19:30 with serious criteria of hospitalization, GSK medically significant and life threatening. The subject was treated with oxygen. The outcome of respiratory distress was recovered/resolved on 20th July 2015. The outcome(s) of the additional event(s) included hyponatremia (recovered/resolved on 20th July 2015) and PPD (recovered/resolved on 20th July 2015 14:30).

The investigator considered that there was no reasonable possibility that the respiratory distress, hyponatremia and PPD may have been caused by Infanrix hexa, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: Chest X-Ray 07/19/2015: "CXR looks pretty clear but does have mild metabolic acidosis...."

Diagnostic results (unless otherwise stated, normal values were not provided): On 19th July 2015, Alanine aminotransferase result was 36 IU/L (normal low: 10, normal high: 35), Base excess result was -7 mmol/L (normal low: -2.5, normal high: 2.5), Blood bicarbonate result was 19 mmol/L (normal low: 22, normal high: 28), Blood creatine result was 0.25 mg/dL (normal low: 0.4, normal high: 0.7), Blood creatine result was less than 0.2 mg/dL (normal low: 0.4, normal high: 0.7), Blood glucose result was 112 mg/dL (normal low: 65, normal high: 99), Blood glucose result was 104 mg/dL (normal low: 65, normal high: 99),

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Clinical Narrative report with Both Serious & Non-Serious Events

Blood sodium result was 133 mmol/L (normal low: 135, normal high: 145), Blood sodium result was 134 mmol/L (normal low: 135, normal high: 145), Mean platelet volume result was 8.2 fL (normal low: 9, normal high: 12), Oxygen saturation result was 93 % (normal low: 60, normal high: 80), PCO2 result was 34 mmHg (normal low: 41, normal high: 51), PO2 result was 68 mmHg (normal low: 30, normal high: 45) and Red cell distribution width result was 34.3 fL (normal low: 38, normal high: 49). On 20th July 2015, Blood creatine result was 0.23 mg/dL (normal low: 0.4, normal high: 0.7), Blood glucose result was 80 mg/dL (normal low: 65, normal high: 99) and Blood sodium result was 140 mmol/L (normal low: 135, normal high: 145).

Investigator's text:
20JUL2015 subject's mother contacted the office. Mother stated that the subject suffered a PPD episode on 19JUL2015. The subject was PPD Subject was taken to the hospital. Subject was just discharged.
21JUL2015 Study Coordinator contacted parent for more information. Parent states that the episode took place 19JUL2015 at approximately 19:30. Subject was PPD was unconscious and required CPR. Subject was given oxygen and taken by helicopter to the hospital. At the hospital, mother states that subject had an initial blood test and a second blood test prior to discharge. Subject also had a chest X-ray and parent was told by the doctor and a nurse that there was a small amount of water in the lung/s. No medications were given, per mother. Subject was hospitalized for observation and discharged the next day on 20JUL2015. At the time of this conversation, mother states that subject is doing well. She will be seen in clinic on Friday 24JUL2015.
28JUL2015-Additional information: When subject suffered the PPD episode and arrived at the hospital, mild respiratory distress was present. Oxygen was already being administered. Hospital blood lab test indicated mild hyponatremia, which resolved by the next day13AUG2015 Update: Blood laboratory results on the initial arrival to hospital on 19JUL2015 also showed the following; high levels of BUN/Creatinine Ratio, ALT, PO2 VBG, O2 Sat VBG. Low levels of RDW-SD, MPV, Creatinine, PCO2 VBG, HCO3 (Bicarb) VBG, Base Excess VBG. Per hospital report, chemistry was considered normal limits except for the expected low TCO2 due to acidosis and the hyperglycemia which was a stress reaction. The glucose and sodium levels returned to normal limits by the following day of 20JUL201519AUG2015-Information from paper SAE report: Discharge notification states: "PPD No apparent Neuro deficits. Initial mild respiratory distress resolved quickly."
PPD 31.07.2015: No reasonable possibility of a causal association with Rotarix, 338 days after vaccination. No reasonable possibility to be related to Infanrix Hexa vaccination

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Parainfluenzae virus 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: [Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis B vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 5-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 2nd dose of Pentacel (intramuscular) on 3rd September 2014, for prophylaxis. The subject received the 1st dose of Hepatitis B vaccine (intramuscular) 10 µg on 30th June 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 3rd September 2014, for prophylaxis. The subject received the 2nd dose of Prevnar 13 (intramuscular) on 3rd September 2014, for prophylaxis.

On PPD 14:55, 5 days after receiving Pentacel, Rotavirus vaccine lyophilized formulation and Prevnar 13 and 70 days after receiving Hepatitis B vaccine, the subject developed moderate - grade 2 parainfluenzae virus infection. Serious criteria included hospitalization and GSK medically significant. The subject was treated with azithromycin. The outcome of parainfluenzae virus infection was recovered/resolved on 10th October 2014.

The investigator considered that there was no reasonable possibility that the parainfluenzae virus infection may have been caused by Pentacel, Hepatitis B vaccine, Rotavirus vaccine lyophilized formulation and Prevnar 13.

Relevant Tests: Respiratory Panel PCR positive for Parainfluenza. Rotavirus and bordetella pertussis testing negative. Workup in the ED include stool culture, urine culture, CBC and blood culture. CBC was reassuring, UA was normal, and cultures all returned negative Diagnostic results (unless otherwise stated, normal values were not provided): On 3rd October 2014, Blood calcium result was 10.6 mg/dL (normal low: 8.6, normal high: 10.5) and Blood urea result was 2 mg/dL (normal low: 5, normal high: 20).

Investigator comments:

Subject is a 5 month old female brought in to the ED today due to chronic diarrhea and dehydration. Per review of EMR, when baby was 4 month of age (Sep 3rd), child presented to our clinic for well child care. Mother reported concern of decreased po intake (breastfeeding per notes), thus mother started supplementing with formula. At that visit subject was immunized (including rotavirus) and was diagnosed with nasal congestion, but otherwise normal well child exam. One week later (Sep 10) she presented to primary care provider with complaint of vomiting and diarrhea x 2 days (onset sep 8), with report of 12 loose stools w/o blood in a 24 hr period and 6 episodes of non bloody emesis and temp to 103. Of note there are ill contacts with grandmother and sibling having cough and runny nose.
Child appeared well and playful on physical exam was sent home with diagnosis of acute gastroenteritis with reassurance and instructions to come back if fever persisted or if there were signs of dehydration. Subject remained ill, mother called PCC Sep 12 due to persistent symptoms, they direct them to the ED. In the ED parents report vomiting has resolved, but diarrhea persists consisting of 2 stools per hr, stools are mucosy and runny, and some upper respiratory symptoms including sneezing and mild cough. Her sibling also has URI. Workup in the ED include stool culture, urine culture, CBC and blood culture. CBC was reassuring, UA was normal, and cultures all returned negative, she was sent home with diagnosis of viral illness.

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Clinical Narrative report with Both Serious & Non-Serious Events

On sep 23 she returns to primary care provider with what is reported in EMR as new onset cough , rhinorrhea and fever x 3 days (however mother has reported to us in phone calls diarrhea and fever have persisted since onset September 8th). Today subject presents again to ED due to vomiting and diarrhea again, and admitted due to chronic diarrhea, concerns for pertussis and dehydration. More extensive testing is ordered today, O and P, rotavirus, viral culture, BMP and pertussis PCR and cultures. Child is being admitted on 10/3/14, was started on azythromycin and admitted for further observation.
Subject tested negative for bordetella pertussis and also rotavirus. Subject tested positive for parainfluenza. During hospitalization patient was stable on room air with stable vital signs. Patient did continue to have loose stool while in hospital but prior to discharge seemed to be decreasing in frequency/amount. At time of discharge on 10/5/2014 patient appeared well hydrated, stable vitals, on room air with improved feeding. Subject was instructed to continue Azithromycin course for 2 more days following discharge and follow up with PCP. Originally it was determined that the SAE was possibly related to the Investigational Product. Now that more tests have been run, a diagnosis of parainfluenza was made and more data gathered it has been decided by the PI that this SAE is not related the IP.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Respiratory syncytial virus bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Hepatitis B vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 11-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 2nd dose of Hepatitis B vaccine (intramuscular) 10 µg on 26th September 2014, for prophylaxis. The subject received the 3rd dose of Pentacel (intramuscular) on 26th September 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 8th July 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 26th September 2014, for prophylaxis.

On PPD 140 days after receiving Hepatitis B vaccine, Pentacel and Prevnar 13 and 220 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed mild - grade 1 respiratory syncytial virus bronchiolitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with prednisolone, salbutamol sulfate (Albuterol Sulfate), oxygen, amoxicillin and salbutamol (Albuterol). Pentacel was continued with no change. Prevnar 13 was continued with no change. The outcome of respiratory syncytial virus bronchiolitis was recovered/resolved on 23rd

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Clinical Narrative report with Both Serious & Non-Serious Events

February 2015.

The investigator considered that there was no reasonable possibility that the respiratory syncytial virus bronchiolitis may have been caused by Hepatitis B vaccine, Pentacel, Rotavirus vaccine lyophilized formulation and Prevnar 13.

Relevant Tests: WBC - 2/14/15 - 13.0 T/MM3; Influenza A and B Swab - 2/14/15 - Negative; Respiratory Virus Antigen Screen - 2/14/15 - Positive; CXR - 2/14/15 - No Focal Pneumonia

INVESTIGATOR TEXT
Pt presented to hospital with fever, cough and respiratory distress. Pt found to be RSV positive and hypoxic. Subject was admitted to hospital on 2/14/15. She was started on O2, breathing treatments, steroids and IV fluids. Subject improved overnight and was discharged from hospital on 2/15/15. Upon discharge subject continued nebulizer treatments and steroids. RSV resolved 2/23/15.
PPD 04.02.2016: TTO 220 days makes causal relationship between Rotarix and LRTI unlikely.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Febrile convulsion

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis B vaccine]:[Solution for injection] 10 mcg <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 29-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 2nd dose of Pentacel (intramuscular) on 15th August 2014, for prophylaxis. The subject received the 1st dose of Hepatitis B vaccine (intramuscular) 10 mcg on 30th May 2014, for prophylaxis. The subject received the 2nd dose of Prevnar 13 (intramuscular) on 15th August 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 15th August 2014, for prophylaxis.

Concurrent medical conditions included fever and urinary tract infection.

On PPD 33 days after receiving Pentacel, Prevnar 13 and Rotavirus vaccine lyophilized formulation, 110 after the 1st dose of Hepatitis B vaccine, the subject developed severe - grade 3 febrile seizure. Serious criteria included hospitalization and GSK medically significant. The subject was treated

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Clinical Narrative report with Both Serious & Non-Serious Events

with ceftriaxone (Rocephin), paracetamol (Tylenol) and cefdinir (Omnicef). The outcome of febrile seizure was recovered/resolved on 18th September 2014.

The investigator considered that there was no reasonable possibility that the febrile seizure may have been caused by Pentacel, Hepatitis B vaccine, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: Urine Culture 18SEP2014 positive for greater than 100,000 colonies of E.Coli Renal Sonogram 19SEP2014 Trace perihepatic fluid found and minimal debris found within the bladder. Diagnostic results (unless otherwise stated, normal values were not provided): On 18th September 2014, White blood cell count result was 31.3 k/mcl (normal low: 4.8, normal high: 10.8).

INVESTIGATOR TEXT
Subject had fever starting 9/17/14. Febrile seizure on the morning of 9/18/14 and was admitted to the hospital for futher workup.Fever started 09/17/2014-went to ER was diagnosed with viral infection. Baby had a Febrile Seizure 09/18/2014-mom called PPD and went back to ER. Blood work(CBC) showed high WBC. Urinalysis was abnormal. Baby was admitted to the hospital 09/18/2014. Started IV fluids and Rocephin IV. Tylenol po for fever. Renal sonogram performed-debris found with in bladder and trace perihepatic fluid found-seen with UTI. Baby was discharged on 09/19/2014 with fever resolved. Sent home on Omnicef for UTI. Rechecked in clinic after finishing abx-UTI resolved 29SEP2014 after finishing Omnicef. -
Likely causation intercurrent febrile medical condition_UTI

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Gastroenteritis viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 8-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Infanrix hexa (intramuscular) on 4th November 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 4th November 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 2nd September 2014, for prophylaxis.

On PPD 64 days after receiving Infanrix hexa and Prevnar 13 and 127 days after receiving

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Clinical Narrative report with Both Serious & Non-Serious Events

Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 viral gastroenteritis. Serious criteria included hospitalization. The subject was treated with paracetamol (Tylenol), ondansetron (Zofran), sodium chloride and glucose, potassium nos, sodium chloride (Dextrose + Sodium + Potassium). The outcome of viral gastroenteritis was recovered/resolved on 12th January 2015.

The investigator considered that there was no reasonable possibility that the viral gastroenteritis may have been caused by Infanrix hexa, Prevnar 13 and Rotavirus vaccine lyophilized formulation. Diagnostic results (unless otherwise stated, normal values were not provided): On 8th January 2015, Blood calcium result was 9.6 mg/dL (normal low: 9, normal high: 11), Blood chloride result was 105.00 mmol/L (normal low: 96, normal high: 105), Blood creatine result was 0.3 mg/dL (normal low: 0.4, normal high: 1.1), Blood glucose result was 73 mg/dL (normal low: 60, normal high: 100), Blood potassium result was 5.1 mmol/L (normal low: 3.7, normal high: 5.6), Blood sodium result was 138 mmol/L (normal low: 132, normal high: 140), Blood urea result was 14 mg/dL (normal low: 10, normal high: 18) and Carbon dioxide result was 21.0 mmol/L (normal low: 20, normal high: 28).

Investigator Comments:
Patient presented to the ER on 1/8/2015 with a 1 day history of decreased po intake, decreased urine output, 2 episodes of emesis and about 6 loose stools in 24 hours. Based on the history and physical exam, the ER physician diagnosed the patient with viral gastroenteritis and admitted her for IV fluids. In the ER, they gave her a normal saline bolus and then started her on maintenance IV fluids. They also gave her Zofran as needed for nausea/vomiting and Tylenol as needed for fever. The patient was discharged on 1/9/2015
No data on laboratory testing.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Seizure, Gastrooesophageal reflux disease, Choking

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 10-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Infanrix hexa on 25th September 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 on 25th September 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation on 30th July 2014, for prophylaxis.

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Clinical Narrative report with Both Serious & Non-Serious Events

On PPD 23:00, 140 days after receiving Infanrix hexa and Prevnar 13 and 197 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed moderate - grade 2 seizure. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included moderate - grade 2 gastroesophageal reflux on 19th February 2015 23:00 with serious criteria of hospitalization and moderate - grade 2 choking on 19th February 2015 23:00 with serious criteria of hospitalization and GSK medically significant. The outcome of seizure was recovered/resolved on 13th February 2015 16:23. The outcome(s) of the additional event(s) included gastroesophageal reflux (recovered/resolved on 21st February 2015 14:30) and choking (resolved with sequelae on 21st February 2015 14:30).

The investigator considered that there was no reasonable possibility that the seizure, gastroesophageal reflux and choking may have been caused by Infanrix hexa, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: CXR normal, Abdominal x-ray normal. EKG normal. Head CT normal. All completed on 2/13/15 GI series without KUB: Gastroesophageal reflux intermittent to the midesophagus (2/21/15). EEG normal (2/21/15)

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Petechiae

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Haemophilus influenzae type b vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 1st dose of DTPa vaccine (intramuscular) on 13th July 2015, for prophylaxis. The subject received the 1st dose of Haemophilus influenzae type b vaccine (intramuscular) on 13th July 2015, for prophylaxis. The subject received the 3rd dose of Infanrix hexa (intramuscular) on 25th September 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 30th July 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 25th September 2014, for prophylaxis.

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Clinical Narrative report with Both Serious & Non-Serious Events

The subject's past medical history included seizures, gastroesophageal reflux, alte and choking.

On PPD 12:40, 19 days after receiving DTPa vaccine and Haemophilus influenzae type b vaccine, 310 days after receiving Infanrix hexa and Prevnar 13 and 1 year and 2 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed moderate - grade 2 petechial rash. Serious criteria included hospitalization. The outcome of petechial rash was recovered/resolved on 13th October 2015 10:15.

The investigator considered that there was no reasonable possibility that the petechial rash may have been caused by DTPa vaccine, Haemophilus influenzae type b vaccine, Infanrix hexa, Rotavirus vaccine lyophilized formulation and Prevnar 13.
Diagnostic results (unless otherwise stated, normal values were not provided): On 1st August 2015, Full blood count result was normal, Metabolic function test result was normal, Platelet count result was normal and Prothrombin time ratio result was normal.

Investigator Text:
Subject seen in our office on 8/1/15 for petechial rash. Sent to ER for work up and further evaluation and admission. All labs WNL. Discharged 8/3/15.Subject was seen in our office on 10/13/15 for a routine scheduled exam. Petechial rash was resolved, healthy exam noted. Subjects admission date was on 01Aug2015, discharge date of 03Aug15.Reported SAE of possible seizure on 2/12/15 is possibly related to ALTE on same date. All diagnostic testing were within normal limits
There is no description on the location of the petechial rash, nevertheless, laboratory results do not indicate a low platelet count nor other abnormal values PT/PTT, blood count, or alteration in other biochemichal parameters, these results argue against an immune mediated thrombocytopenia PPD
17.01.2016: unlikely causal relationship with Rotarix over a year after vaccination

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Respiratory syncytial virus infection, Parainfluenzae virus infection, Pneumonia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [Hepatitis B vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 11-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 2nd dose of Hepatitis B

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Clinical Narrative report with Both Serious & Non-Serious Events

vaccine (intramuscular) 10 µg on 29th September 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 29th July 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13. (intramuscular) on 29th September 2014, for prophylaxis. The subject received the 3rd dose of Pentacel (intramuscular) on 29th September 2014, for prophylaxis.

On PPD 152 days after receiving Hepatitis B vaccine, Prevnar 13. and Pentacel and 214 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 respiratory syncytial virus infection. Serious criteria included hospitalization. Additional event(s) included moderate - grade 2 parainfluenzae virus infection on 28th February 2015 with serious criteria of hospitalization and GSK medically significant and moderate - grade 2 community acquired pneumonia on 6th March 2015 with serious criteria of hospitalization and GSK medically significant. The subject was treated with glucose + potassium chloride + sodium chloride (5% Dextrose 1/2 Normal Saline With 20 Meq Of Kcl), amoxicillin, ampicillin, oxygen, ibuprofen (Children'S Motrin), ketorolac trometamol (Toradol), salbutamol (Albuterol) and paracetamol (Tylenol Childrens). The outcome of respiratory syncytial virus infection was recovered/resolved on 13th March 2015. The outcome(s) of the additional event(s) included parainfluenzae virus infection (recovered/resolved on 11th March 2015) and community acquired pneumonia (recovered/resolved on 11th March 2015).

The investigator considered that there was no reasonable possibility that the respiratory syncytial virus infection, parainfluenzae virus infection and community acquired pneumonia may have been caused by Hepatitis B vaccine, Rotavirus vaccine lyophilized formulation, Prevnar 13. and Pentacel.

Relevant Tests: chest x-ray results suggested a possible right sided perihelia pneumonia. Blood Culture was done with no growth in nine hours. This was done on 3/6/2015 Diagnostic results (unless otherwise stated, normal values were not provided): On 7th March 2015, Band neutrophil count result was 18 %, C-reactive protein result was 7.6 % (normal low: 1, normal high: 3), Haematocrit result was 32.3 % (normal low: 33, normal high: 39), Haemoglobin result was 10.6 g (normal low: 10.5, normal high: 13.5), Neutrophil count result was 37 % (normal low: 1.5, normal high: 5), Platelet count result was 396 cells/mm3 (normal low: 300, normal high: 750) and White blood cell count result was 13.5 cells/mm3 (normal low: 6, normal high: 17).

INVESTIGATOR COMMENTS
Per mom symptoms started on 28FEB2015 and became sever enough that they took subject to the hospital on 06MAR2015 where subject was treated and diagnosed with Respiratory Syncytial Virus, Para Influenza, Pneumonia. Subject was released on 11MAR2015 from the hospital. Per mom subject is feeling much better and symptoms are resolved today on 13MAR2015.Symptoms on admit were Respiratory distress, hypoxia, bronchiolitis. Was placed on oxygen via nasal- cannula. Patient was placed on a Biphasic Intermittent Positive Airway Pressure and nasal gastric tube. Then was placed on continuous positive airway pressure and then went to high flow nasal cannula for 3 days. Then improved and was returned to regular nasal cannula. patient was discharged to home on room air and oral antibiotics.
The time to onset is not consistent with a vaccine-related effect.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

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Clinical Narrative report with Both Serious & Non-Serious Events

Case ID: PPD

Serious Events: Gastroenteritis viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[ActHIB]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 8-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of DTPa-HBV-IPV vaccine (intramuscular) on 5th November 2014, for prophylaxis. The subject received the 3rd dose of ActHIB (intramuscular) on 5th November 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 5th November 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 29th August 2014, for prophylaxis.

On PPD 63 days after receiving DTPa-HBV-IPV vaccine, ActHIB and Prevnar 13 and 131 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 viral gastroenteritis. Serious criteria included hospitalization. The subject was treated with paracetamol (Acetaminophen), ondansetron (Zofran) and d5 1/2 normal saline + potassium chloride. The outcome of viral gastroenteritis was recovered/resolved on 12th January 2015.

The investigator considered that there was no reasonable possibility that the viral gastroenteritis may have been caused by DTPa-HBV-IPV vaccine, ActHIB, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: BUN/CREATININE RATIO on10JAN2015 was 48.00 (Normal 7.00-25.00) Diagnostic results (unless otherwise stated, normal values were not provided): On 10th January 2015, Blood chloride result was 123 mmol/L (normal low: 97, normal high: 109), Blood creatine result was 0.50 mg/dL (normal low: 0.7, normal high: 1.2), Blood glucose result was 44 mg/dL (normal low: 65, normal high: 125), Blood sodium result was 144 mmol/L (normal low: 135, normal high: 145) and Blood urea result was 24 mg/dL (normal low: 4, normal high: 15).

Investigator comments:
Subject started having Vomiting, diaarhea and dehydration on January 7, 2015. Subject admitted to ER on January 10, 2015 with a diagnosis of Viiral Gastroenteritis and Dehydration. Subject discharged from hospital on January 12, 2015. -
Report of dehydration from acute gastroenteritis 4.4 months after 2nd dose Rotarix vaccination. Recovery under a week with medical intervention. Viral cause diagnosed. No stool test confirmation.

Study Number: 117119

Study Center ID: PPD

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Dehydration

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis B vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 6-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 2nd dose of Pentacel (intramuscular) on 4th August 2014, for prophylaxis. The subject received the 2nd dose of Prevnar 13 (intramuscular) on 4th August 2014, for prophylaxis. The subject received the 1st dose of Hepatitis B vaccine (intramuscular) 10 on 2nd June 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (intramuscular) on 4th August 2014, for prophylaxis.

Concurrent medical conditions included gastroenteritis.

On PPD 68 days after receiving Pentacel, Prevnar 13 and Rotavirus vaccine lyophilized formulation and 131 days after receiving Hepatitis B vaccine, the subject developed moderate - grade 2 dehydration. Serious criteria included hospitalization. The subject was treated with Iv Fluids-Sodium Chloride. The outcome of dehydration was recovered/resolved on 14th October 2014.

The investigator considered that there was no reasonable possibility that the dehydration may have been caused by Pentacel, Prevnar 13, Hepatitis B vaccine and Rotavirus vaccine lyophilized formulation.

Relevant Tests: Viral panel positive for pertussis, adenovirus, rhinovirus. the date for this was 10/13/14.

Investigator Comment:
Per mom child has been vomiting quite a bit lately(11 Oct 2014).Child was taken to the ER last night (12 Oct 2014). They ran some tests there.(We are awaiting the results of these tests at this time). Per mother Diaper has been dry for the last 5 hours or so. Per mother child is listless and lethargic. Therefore Dr. felt it was in the best interest of the child to admit to the hospital for IV therapy for dehydration. will report other information as we receive it.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Lethargy

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This female subject was enrolled in the prophylactic open study 117119 (DTPA-HBV-IPV-135). On 01 July 2014, she received a 1st dose of combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio, Haemophilus influenzae type b vaccine (Infanrix hexa), Pfizer's 13 valent pneumococcal vaccine (Prevenar 13) and rotavirus vaccine (Rotarix lyophilized formulation).

On PPD approximately 6 hours after the 1st dose of Infanrix hexa, approximately 6 hours after the 1st dose of Prevnar 13, and approximately 6 hours after the 1st dose of Rotarix lyophilized formulation, this two-month-old subject developed lethargy event. The subject was hospitalised. The event resolved on 01 July 2014. The investigator considered that there was a reasonable possibility that the lethargy event may have been caused by Infanrix hexa, Prevnar 13 and Rotarix lyophilized formulation. The subject was withdrawn from the study due to this event.

Investigator text :
Baby was given vaccines at 10:20 this morning. At approximately 16:00. Baby was noted by mother to be blue around the lips baby was aroused, and then had 2 more times that this happened and at that time mother noted baby appeared to have some floppiness . Mother also noted some short breathing patterns and it appeared that the baby was having a hard time expelling air. Brought into the Clinic to be examined by the MD. Per exam, it was normal at that time. Baby was admitted to the hospital for observation at this time. No treatment or labs completed. It was observation only. Per the Principal Investigator this SAE is possibly related as there is noted to be a possibility of an lethargic event after episodes that can be traumatic to infants under 3 months of age. It was not a cyanosis , the baby was somewhat hyporesponsive and there was some hypotonia. There is no seizure disorder noted or a family history of seizure disorder.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Dehydration

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: [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Haemophilus influenzae type b vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>;[DTPa vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 16-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Infanrix hexa (intramuscular) on 10th November 2014, for prophylaxis. The subject received the 1st dose of Haemophilus influenzae type b vaccine (intramuscular) on 30th July 2015, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 15th September 2014, for prophylaxis. The subject received the 1st dose of DTPa vaccine (intramuscular) on 30th July 2015, for prophylaxis. The subject received the 3rd dose of Prevnar 13. (intramuscular) on 10th November 2014, for prophylaxis.

Concomitant products included paracetamol (Tylenol).

On PPD 303 days after receiving Infanrix hexa and Prevnar 13., 41 days after receiving Haemophilus influenzae type b vaccine and DTPa vaccine and 359 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 dehydration. Serious criteria included hospitalization. The subject was treated with glucose + potassium chloride + sodium chloride (5% Dextrose + 0.9% Sodium Chloride + 20 Meq Potassium Chloride), sodium chloride (Normal Saline Bolus) and ondansetron (Zofran). The outcome of dehydration was recovered/resolved on 11th September 2015.

The investigator considered that there was no reasonable possibility that the dehydration may have been caused by Infanrix hexa, Haemophilus influenzae type b vaccine, Rotavirus vaccine lyophilized formulation, DTPa vaccine and Prevnar 13..

Relevant Tests: CBC was with in normal limits.

Investigator comments :
Patient fell and hit head on the evening of 9/8/2015. Was acting fine that night . on the morning of 9/9/2015 patient started vomiting. Seen in clinic about noon and physician told mother to call with concerns if not improved later in the evening. Mother call into the clinic and talked to MD. and patient was admitted to the hospital for dehydration. Patient was started on IV therapy. Per physician he feels the dehydration is a stomach virus as there are other family members that are starting to exhibit the same symptoms today (9/10/2015). The head injury and vomiting will be listed as A/E. Patient was discharged from the hospital 9/11/2015.
PPD 15.09.2015: Onset about a year after Rotarix makes causal relationship unlikely. The report suggests a gastroenteritis due to an infectious agent may be responsible for the child's symptoms.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Confidential
Clinical Narrative report with Both Serious & Non-Serious Events

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Apparent life threatening event, Leukocytosis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency: [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 2-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 1st dose of DTPa-HBV-IPV+Hib vaccine (intramuscular) on 9th July 2014, for prophylaxis. The subject received the 1st dose of Prevnar 13 (intramuscular) on 9th July 2014, for prophylaxis. The subject received the 1st dose of Rotavirus vaccine lyophilized formulation (oral) on 9th July 2014, for prophylaxis.

On PPD less than a day after receiving DTPa-HBV-IPV+Hib vaccine, Prevnar 13 and Rotavirus vaccine lyophilized formulation, the subject developed moderate - grade 2 apparent life threatening event. Serious criteria included hospitalization, GSK medically significant and life threatening. Additional event(s) included mild - grade 1 leukocytosis on 9th July 2014 with serious criteria of hospitalization and life threatening. DTPa-HBV-IPV+Hib vaccine was continued with no change. Prevnar 13 was continued with no change. The action taken with Rotavirus vaccine lyophilized formulation was unknown. The outcome of apparent life threatening event was recovered/resolved on 9th July 2014. The outcome(s) of the additional event(s) included leukocytosis (recovered/resolved on 10th July 2014).

The investigator considered that there was a reasonable possibility that the apparent life threatening event and leukocytosis may have been caused by DTPa-HBV-IPV+Hib vaccine, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: CBC with manual Difficile which showed white blood count that was slightly elevated at 20,000 and a little mildly elevated lactic acid. and urine culture and blood culture was negative so far. CRP was 20 but on the normal level would be 2. Diagnostic results (unless otherwise stated, normal values were not provided): On an unknown date, Blood culture result was negative unknown. On an unknown date, C-reactive protein result was 20 unknown. On an unknown date, Culture urine result was negative unknown. On an unknown date, White blood cell count result was 20000 unknown.

Investigator comments: On the evening of the 09 July 2014 baby was very irritable then finally went to sleep. Mom went to check on the baby and the skin was pale and the lips were pale, breathing was noted to be very shallow and baby tried to go back to sleep. Lips were not blue at all. Mom states that the baby acts like she is trying to let out a big cry and can't quite get it out. Was instructed by the afterhours nurse on call to take baby to the ER to be evaluated. Baby was taken in and from there admitted to the hospital. Baby did well with some mild fussiness and decreased stooling. Was discharged from the hospital on 10 July 2014. Baby is to return to the clinic for a check up on 11 July 2014. Mom also reported limp floppy extremities. This didn't occur after breast feeding or immediately after.No relevant medical history. No history of seizure disorder in family. No x-rays taken. Due to the time frame of onset and the test results it

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Clinical Narrative report with Both Serious & Non-Serious Events

is determined by the PI to be related.
Report of life-threathening event occuring in 2 month old within 24 hours of Rotavirus vaccination. Co-administered vaccines DTPa-HBV-IPV+Hib and Prevenar. Clinical picture vague, but included limp floppy extremities, irritability and leucocytosis of 20,000 (unit of measure unknown). Hospitalised and discharged the next day with review to follow at subsequent outpatient visit. No information about intervention measures or treatment. Insufficient information for case definition/causality assessment

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Respiratory distress, Hypoxia

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 11-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Infanrix hexa (intramuscular) on 11th November 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 11th November 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 11th September 2014, for prophylaxis.

Concurrent medical conditions included bronchiolitis.

On PPD 163 days after receiving Infanrix hexa and Prevnar 13 and 224 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 respiratory distress. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included severe - grade 3 hypoxia on 24th April 2015 with serious criteria of hospitalization and GSK medically significant. The subject was treated with salbutamol (Albuterol), prednisolone sodium phosphate (Orapred), oxygen, glucose, potassium nos, sodium chloride (Dextrose + Saline + Potassium), methylprednisolone sodium succinate (Solumedrol) and paracetamol (Tylenol). The outcome of respiratory distress was recovered/resolved on 30th April 2015. The outcome(s) of the additional event(s) included hypoxia (recovered/resolved on 25th April 2015).

The investigator considered that there was no reasonable possibility that the respiratory distress and hypoxia may have been caused by Infanrix hexa, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

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Clinical Narrative report with Both Serious & Non-Serious Events

Relevant Tests: Chest x-ray on 04/24/2015: Defined opacity in right lower lung concerning for pneumonia. Respiratory Film Array PCR: Rhinovirus is detected.

INVESTIGATOR TEXT
Subject was admitted to hospital on 04/24/2015 after he was treated in the emergency room on 04/24/2015. Medical history: 1-2 days prior had history of congestion, cough and started wheezing. Parent brought subject into the clinic and subject has low oxygen saturations of 70 to 80. Nurse practioner sent subject to the emergency room after giving a albuterol nebulizer treatment. At the emergency room subject was stabilized with continuous albuterol treatments and admitted to the hospital for continued care. Once admitted, albuterol treatments and oxygen were continuous for approximately 12 hours then subject was weaned down to albuterol treatments every 2 hours and oxygen was rapidly weaned to room air. At discharge, parent was to continue albuterol treatments every 4 hours as needed. No oxygen for home. Subject discharged to home on 04/25/2015.
The time to onset from vaccination of 163 days is not consistent with a vaccine-related effect.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Seizure like phenomena

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Hepatitis B vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>

Narrative: This 15-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 4th dose of Pentacel (intramuscular) on 30th July 2015, for prophylaxis. The subject received the 2nd dose of Hepatitis B vaccine (intramuscular) 10 ug on 30th October 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 30th October 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (intramuscular) on 19th August 2014, for prophylaxis.

On PPD 25 days after receiving Pentacel, 298 days after receiving Hepatitis B vaccine and Prevnar 13 and 1 year and 5 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed moderate - grade 2 seizure like phenomena. Serious criteria included hospitalization and GSK medically significant. The subject was treated with lidocaine, levetiracetam (Keppra (Levetiracetam)), Keppra, glucose, sodium chloride (5% Dextrose + Sodium Chloride Solution), ketamine and dexmedetomidine hydrochloride (Precedex). The outcome of seizure like phenomena was

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recovered/resolved on 1st September 2015.

The investigator considered that there was no reasonable possibility that the seizure like phenomena may have been caused by Pentacel, Hepatitis B vaccine, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: Renal Function Panel Results: Abnormal, Albumin 5.0 (H), range (3.0- 4.8 g/dL) test date: 08/27/2015 unremarkable. EKG and ECHO returned unremarkable test, EKG showed sinus rhythm, no deltas appreciated date: 08/28/2015. EEG on 08/27/15 interpretation: this video EEG tracing in the awake, drowsey and asleep state is normal. There were no electroclinical seizures. No evidence of any epileptiform or focal abnormalities. EEG on 08/28/15 Interepretation: This EEG tracing in the awake, drowsey and asleep state with photic stimulation is normal. Clinical correlation is recommended. MRI Head without contrast on 08/28/2015: Impression: Unremarkable MRI of the brain.

Investigator Text:
The subject is a 15 month old born by induced vaginal delivery at 37 weeks due to intrauterine growth restriction with a history of neonatal hyperbilirubinemia treated with phototherapy and seasonal allergies formerly trated with claritin who presents to the emergency room with 4 episodes of seizure-like activity. During these episodes, she tenses up, makes choking noises, and her eyes deviate upwards. After these episodes on the first two nights and again this morning(08/27/15), she cried, appeared temporarily disoriented, and then acted fussy for a few minutes. During the episode last night (08/26/15) she did not seem to be post-ictal. Nursing reports that the subject had an observed 1-minute period of tachycardia to 240 bpm accompanied by inactivity but no obvious change in mental status. She was breathing during this episode. Her immunizations are up to date. She has been out of daycare since 07/28/2015 and no known sick contacts or recent travel. There is no family history of
arrhythmia or epilepsy. She eats table food and drinks milk, juice, and water. She has been making 5-7 wet and 2-3 dirty diapers a day. Child remains in the hospital at the initial SAE report on 08/28/2015. Study staff spoke with parent today to inquire about the start date, parent reported via telephone started having first episode on Monday evening at home on 08/24/2015. Child admitted to the hospital on the afternoon of 08/27/2015.
Follow up report as of 09/01/15: Hospital course: Upon admission child remained stable without any seizure like activity observed. She continued on KEPPRA 15mg/kg twice a day. Neurological evaluation with EEG and MRI returned unremarkable. Cardiology consultation was placed given tachycardia in ED, concerning fr underlying arrhytmia. Cardiac evaluation with EKG and ECHO returned unremarkable. Decision was made to discharge child as she remained clinically stable without any noted seizure like activity and adequate appetite and oral intake. The child has undergone EEG which was normal. At this point and time impression was that this child is likely having frontal lobe seizures resulting in these events. These episodes are not related to reflux, choking, or obstructive sleep apnea. KEPPRA was started. Family educated about seizures. Suggested primary care MD to make referral to pediatric sleep medicine to evaluate snoring. Child was discharged home with seizure like activity nocturnal
partial seizures, and placed on KEPPRA. Discharged from hospital on 08/29/2015. Parent took the child back to the ED on 08/31/15. Mom stated she noticed an episode of twitching of her right arm andone leg in her sleep lasting 20 seconds and self resolving. The child's eyes were closed. Neuro was consulted in the ED who deferred change in medication at this visit. Parent was instructed to follow up with primary MD. Child was discharged from the ED on 08/31/15. Chil went to primary MD office for ER follow up on 09/01/15. Plan from the follow up visit: child referred to sleep medicine on 08/31/15 for snoring, continue KEPPRA as prescribed. Mom was requested by primary MD to call neurology to schedule an appointment as soon as possible. There is no more information available. Update on 09/25/2015, spoke with parent today she reports the child has not experienced any new seizure like episodes since the follow up visit on

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09/01/2015, initial hospitalized event has resolved per parent report.
TTO implausible for causality due to Hepatitis B or Rotavirus vaccine

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Respiratory distress, Respiratory syncytial virus bronchiolitis

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 6-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Infanrix hexa (intramuscular) on 3rd November 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 3rd November 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 8th September 2014, for prophylaxis.

On PPD 28 days after receiving Infanrix hexa, 28 days after receiving Prevnar 13 and 84 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 respiratory syncytial virus bronchiolitis. Serious criteria included hospitalization and GSK medically significant. Additional event(s) included severe - grade 3 respiratory distress on 7th December 2014 with serious criteria of hospitalization and GSK medically significant. The subject was treated with furosemide (Lasix), paracetamol (Tylenol), salbutamol (Albuterol), 5% dextrose + normal saline solution, ibuprofen and sucrose (Sucrose Oral Solution). The outcome of respiratory syncytial virus bronchiolitis was recovered/resolved on 12th December 2014. The outcome(s) of the additional event(s) included respiratory distress (recovered/resolved on 12th December 2014).

The investigator considered that there was no reasonable possibility that the respiratory syncytial virus bronchiolitis and respiratory distress may have been caused by Infanrix hexa, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: Respiratory Panel: 07Dec2014, RSV positive, Flu negative.
Chest X-ray: 07Dec2014, showed viral illness Blood culture: 07Dec2014, no growth Urine culture: 07Dec2014: no growth

Investigator Comment:
On 07 Dec 2014, subject's mother brought her to the ER with a 1-week history of cough, congestion, and

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rhinorrhea. Approximately 3 days prior, fever, worsening cough, decreased intake and decreased urine output as well as loose stools and increased sleepiness and increased work of breathing was noted by the mother. Mother brought the subject to the ER in the early morning hours of 07Dec2014 due to those worsening symptoms. In the ER, subject presented with grunting, lethargy, oxygen saturation of 84%, and was treated with suctioning, oxygen by mask. Work of breathing was still increased and subject's temperature was 105F. Subject was then admitted to the hospital service for 23-hour observation. No familial risk factors were noted. Care included nasal suctioning, breathing treatments and supportive care. In the morning of 08Dec2014, increased work of breathing and tachypnea was noted, and subject was transferred to the Pediatric Intensive Care Unit for increased care and management.Respiratory panel returned with positive for Repiratory Syncitial Virus. While in the Pediatric Intensive Care Unit, subject required up to 15 liters of 100% Oxygen via Vapotherm, and was weaned down to 5L of 28%. Subject was transferred to the general care floor on 10Dec2014 and was weaned to room air on the evening of 11Dec2014. She continued to require suctioning until 24 hours prior to discharge. Subject was discharged on 12Dec2014. Subject was well at discharge.
RSV bronchiolitis 28 days after multiple vaccines. RSV bronchiolitis is a risk for infants of this age, regardless of the vaccination administered. In this case, due to co-administration of several vaccines, an individual assessment of causality cannot be made.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Mental status changes

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis B vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 9-month-old male subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 3rd dose of Pentacel (intramuscular) on 11th November 2014, for prophylaxis. The subject received the 2nd dose of Hepatitis B vaccine (intramuscular) 10 ug on 11th November 2014, for prophylaxis. The subject received the 3rd dose of Prevnar 13 (intramuscular) on 11th November 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 15th September 2014, for prophylaxis.

On PPD 108 days after receiving Pentacel, Hepatitis B vaccine and Prevnar 13 and 165 days after receiving Rotavirus vaccine lyophilized formulation, the subject developed severe - grade 3 mental status changes. Serious criteria included hospitalization. The subject was treated with sodium

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chloride (Sodium Chloride Infusion), lidocaine (Lidocain) and naloxone hydrochloride (Narcan (Naloxone)). The outcome of mental status changes was recovered/resolved on 28th February 2015.

The investigator considered that there was no reasonable possibility that the mental status changes may have been caused by Pentacel, Hepatitis B vaccine, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: The following blood tests were also conducted: Ethanol: Negative. Salicylate: less tha 1.0 mg/dl (range 2-20). Valproic Acid: less tha 10.0 ug/mL (range 50-150). Diff-Cells Counted: 114. Atypical lymph%: 11 10*3/ul (range 0-8). Atypical lymph#: 1.3, (range 0-1.4). Poikilocytes: 1+(A). Ovalocytes: 1+(A). Platelet Estimate: Adequate. Urine Culture: Rpt. Acetaminophen: less tha 10.0 ug/ml (range 10-30). Amphetamine - Urine screen: Negative. Barbiturate - Urine Screen: Negative. Benzodiazepine Screen - Urine: Negative. Cocaine/Metab-Urine Screen: Negative.Opiates - Urine: Negative. Cannabinoids - Urine Screen: Negative. Tricyclics - Urine Screen: Negative. Diagnostic results (unless otherwise stated, normal values were not provided): On 27th February 2015, Alanine aminotransferase result was 40 u/L (normal low: 13, normal high: 69), Amylase result was 130 u/L (normal low: 30, normal high: 110), Aspartate aminotransferase result was 48 u/L (normal low: 15, normal high: 46), Basophil count result was 1 % (normal low: 0.00, normal high: 2), Basophil count result was 0.12 unknown (normal low: 0.00, normal high: 0.4), Blood albumin result was 4.3 g/dL (normal low: 3, normal high: 4.8), Blood alkaline phosphatase result was 252 u/L (normal low: 80, normal high: 270), Blood bilirubin result was 0.3 mg/dL (normal low: 0.00, normal high: 0.9), Blood calcium result was 10.0 mg/dL (normal low: 8.6, normal high: 11.2), Blood chloride result was 103 NA (normal low: 98, normal high: 107), Blood creatinine result was 0.3 mg/dL (normal low: 0.3, normal high: 0.5), Blood glucose result was 99 mg/dL (normal low: 60, normal high: 100), Blood potassium result was 4.4 NA (normal low: 3.5, normal high: 5.1), Blood sodium result was 138 NA (normal low: 132, normal high: 142), Blood urea result was 8 mg/dL (normal low: 4, normal high: 15), Carbon dioxide result was 20 NA (normal low: 18, normal high: 27), Eosinophil count result was 1 % (normal low: 0.00, normal high: 7), Eosinophil count result was 0.12 unknown (normal low: 0.00, normal high: 1.2), Haematocrit result was 38.2 % (normal low: 30, normal high: 42), Haemoglobin result was 12.8 g/dL (normal low: 10.5, normal high: 13.5), Lymphocyte count result was 62 % (normal low: 35, normal high: 74), Lymphocyte count result was 7.17 unknown (normal low: 2.1, normal high: 13), Mean cell haemoglobin result was 25.0 pg (normal low: 25, normal high: 31), Mean cell haemoglobin concentration result was 33.5 g/dL (normal low: 29, normal high: 37), Mean cell volume result was 74.6 fL (normal low: 70, normal high: 86), Mean platelet volume result was 9.5 fL (normal low: 6.7, normal high: 10.8), Monocyte count result was 14 % (normal low: 0.00, normal high: 15), Monocyte count result was 1.62 unknown (normal low: 0.00, normal high: 2.6), Neutrophil count result was 11 % (normal low: 16, normal high: 48), Neutrophil count result was 1.27 unknown (normal low: 1, normal high: 8.4), Platelet count result was 292 unknown (normal low: 140, normal high: 440), Protein total result was 6.8 g/dL (normal low: 5, normal high: 7.5), Red blood cell count result was 5.12 unknown (normal low: 3.7, normal high: 5.3), Red cell distribution width result was 13.3 % (normal low: 14.1, normal high: 21.6) and White blood cell count result was 11.57 unknown (normal low: 6, normal high: 17.5).

Investigator text:
On 27Feb2015, subject was in the care of grandparents for the day. When the subject's mother arrived to pick him up, around 0810 PM, he was drowsy and not acting like himself. Grandparents reported that the subject had slept 6-7 hours straight that afternoon. No known injury or ingestion was reported by the grandparents. Subject was taken to an Immediate Care Center and was minimally responsive there, so subject was transported via ambulance to the local children's hospital Emergency Department. There, he was minimally responsive to sternal rubs and had fixed pupils. Vital signs were stable. He did not respond when the IV was placed. After receipt of 1 gm of Narcan, he immediately began to respond, and within 15

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minutes was back to normal behavior. Urine and serum toxicity screenings were negative, and EKG shows sinus arrhythmia. Subject was sent to the floor for observation and the remainder of the hospitalization was unremarkable. He was discharged on 28 February 2015 after the shorthospital stay.Final discharge diagnosis was Altered Mental State. Per mother's report today (02Mar2015) subject is doing fine. She reported that they feel that the subject must have ingested one of the many pills that the grandparents have in their home. The start date 27 FEB 2015= date of first signs and symptoms.

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: PPD

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [Pentacel]:[Solution for injection] <Blank> <Blank> <Blank>;[Hepatitis B vaccine]:[Solution for injection] 10 mcg <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 5-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. The subject received the 2nd dose of Pentacel (intramuscular) on 13th August 2014, for prophylaxis. The subject received the 1st dose of Hepatitis B vaccine (intramuscular) 10 mcg on 18th June 2014, for prophylaxis. The subject received the 2nd dose of Prevnar 13 (intramuscular) on 13th August 2014, for prophylaxis. The subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) on 13th August 2014, for prophylaxis.

On PPD 32 days after receiving Pentacel, Prevnar 13 and Rotavirus vaccine lyophilized formulation and 88 days after receiving Hepatitis B vaccine, the subject developed moderate - grade 2 PPD Serious criteria included hospitalization. The outcome of PPD was recovered/resolved on 15th September 2014.

The investigator considered that there was no reasonable possibility that the PPD may have been caused by Pentacel, Hepatitis B vaccine, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: chest xray Negative

INVESTIGATOR TEXT
Subject involved in PPD on 14Sep2014. Admitted to ICU for observation on 14Sep2014. Subject released in good condition on 15Sep2014. Multiple trauma ruled out.

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Subject involved in PPD on 14Sep2014. Admitted to ICU for observation on 14Sep2014. Subject released in good condition on 15Sep2014 -

Study Number: 117119

Study Center ID: PPD

Subject ID: PPD

Randomization Number: UNKNOWN

Case ID: PPD

Serious Events: Meningitis viral

Non Serious Events:

Suspect Product Name With Formulation, Dose, Units and Frequency**:** [DTPa-HBV-IPV+Hib vaccine]:[Solution for injection] <Blank> <Blank> <Blank>;[Prevnar 13]:[Solution for injection] <Blank> <Blank> <Blank>;[Rotavirus vaccine lyophilized formulation]:[Oral drops] <Blank> <Blank> <Blank>

Narrative: This 7-month-old female subject was enrolled in an open label study titled A phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa' vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age. On 21st August 2014, the subject received the 3rd dose of Infanrix hexa (intramuscular) for prophylaxis and the 3rd dose of Prevnar 13 (intramuscular) for prophylaxis. On 26th June 2014, the subject received the 2nd dose of Rotavirus vaccine lyophilized formulation (oral) for prophylaxis.

The subject's past medical history included allergic reaction to antibiotics.

On PPD 31 days after receiving Infanrix hexa and Prevnar 13 and 87 days after receiving Rotavirus vaccine lyophilized formulation the subject developed moderate - grade 2 viral meningitis. Serious criteria included hospitalization and GSK medically significant. The subject was treated with PARACETAMOL (ACETAMINOPHEN), LIDOCAINE, vancomycin, ceftriaxone, (Naci 0.9% (Sodium Chloride)), ibuprofen and D5w 0.45% Sodium Choride + 20 Meq Potassium Chloride. The outcome of viral meningitis was recovered/resolved on 25th September 2014.

The investigator considered that there was no reasonable possibility that the viral meningitis may have been caused by Infanrix hexa, Prevnar 13 and Rotavirus vaccine lyophilized formulation.

Relevant Tests: cerebrospinal fluid culture negative. Urine culture negative. Erythrocyte sedimentation rate 25 mm/hr (high) Normal range = 0-20 mm/hr. C-reactive protein 8.8 mg/L (high) Normal range =0.0-8.0 mg/L

INVESTIGATOR TEXT
Patient developed fever and rash on 21Sep2014. Patient seen in emergency department on 21Sep2014 (two times) and admitted to outside medical facility on 21Sep2014 to be treated for viral meningitis. During

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the course of hospitalization, patient had a post-vancomycin infusion allergic reaction. Patient was discharged on 24Sep2014 in good condition. Patient seen for follow-up in clinic on 25Sep2014, patient afebrile and clinically stable.
Patient develop 31 days postvacciantion with Infanrix hexa viral meningitis. There is no causal relationship to relate this event with vaccination.

Overall Case Count : 19

13. POST-TEXT TABLES AND FIGURES

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

	Hexa group	Pedia group	Penta group	Total	
Center	n	n	n	n	%
PPD	4	3	4	11	1.9
	4	3	3	10	1.7
	4	5	5	14	2.4
	2	2	1	5	0.9
	4	5	3	12	2.1
	1	2	3	6	1.0
	2	4	4	10	1.7
	3	3	1	7	1.2
	1	0	1	2	0.3
	1	1	1	3	0.5
	7	6	6	19	3.2
	4	2	3	9	1.5
	0	1	2	3	0.5
	1	1	1	3	0.5
	2	2	2	6	1.0
	4	3	3	10	1.7
	4	3	4	11	1.9
	0	1	1	2	0.3
	1	1	0	2	0.3
	3	2	2	7	1.2
	3	5	6	14	2.4
	3	3	3	9	1.5
	5	2	3	10	1.7
	4	4	3	11	1.9
	7	7	7	21	3.6
	5	3	3	11	1.9
	0	2	0	2	0.3
	8	6	6	20	3.4
	3	3	5	11	1.9
	3	2	2	7	1.2
	5	5	5	15	2.6
	2	5	4	11	1.9
	14	15	16	45	7.7
	10	11	12	33	5.6
	15	13	14	42	7.2
	5	8	6	19	3.2
	11	9	7	27	4.6
	4	2	2	8	1.4
	16	16	17	49	8.4
	6	7	6	19	3.2
	8	7	8	23	3.9
	3	5	5	13	2.2
	3	4	6	13	2.2
All	195	194	196	585	100

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 (Primary Total vaccinated cohort)

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
Hexa group	VISIT 1 D0 DOSE	195		
			no.PPD	Lost to follow-up
			no.	Migrated / moved from the study area
			no.	Terminated by PI due to non-compliance with appointment schedules
			no.	loss of kaiser coverage
			no.	loss of kaiser coverage
			no.	Consent withdrawal
			no.	Consent withdrawal
			no.	Serious Adverse Event
			no.	Consent withdrawal
	VISIT 2 M2 DOSE	186		
			no.PPD	Migrated / moved from the study area
			no.	Lost to follow-up
	VISIT 3 M4 DOSE	184		
			no.PPD	Lost to follow-up
	VISIT 4 M5 POST	183		
			no.PPD	Protocol violation*Lost to follow-up
	ESFU CONTACT	182		
			no.PPD	loss of kaiser coverage
			no.	Lost to follow-up
			no.	Protocol violation
			no.	Protocol violation
			no.	Protocol violation
			no.	Protocol violation
			no.	unknown
			no.	subject got a new doctor
			no.	Migrated / moved from the study area
			no.	Protocol violation
			no.	Migrated / moved from the study area
			no.	Protocol violation
			no.	Migrated / moved from the study area
			no.	Lost to follow-up
			no.	Consent withdrawal / not willing to participate, not due to a (S)AE
	VISIT 5 M 13-16	167		
			noPPD	Consent withdrawal
			no	Lost to follow-up
			no	Migrated / moved from the study area
			no	change their doctor
			no	Lost to follow-up
			no	Lost to follow-up
	VISIT 6 M 14-17	161		

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
Pedia group	VISIT 1 D0 DOSE	194		
			no.PPD	loss of kaiser coverage
			no.	loss of kaiser coverage
			no.	loss of kaiser coverage
			no.	Consent withdrawal
			no.	Consent withdrawal
			no.	Migrated / moved from the study area
	VISIT 2 M2 DOSE	188		
			no.PPD	Migrated / moved from the study area
			no.	Migrated / moved from the study area
			no.	Consent withdrawal
	VISIT 3 M4 DOSE	185		
			noPPD	Consent withdrawal
			no	Consent withdrawal
	VISIT 4 M5 POST	183		
			no.PPD	Lost to follow-up
	ESFU CONTACT	182		
			noPPD	medical history updated information
			no	Migrated / moved from the study area
			no	Protocol violation
			no	Lost to follow-up
			no	Lost to follow-up
			no	loss of kaiser coverage
			no	Migrated / moved from the study area
			no	Migrated / moved from the study area
			no	Lost to follow-up
			no	loss of kaiser coverage
			no	loss of kaiser coverage
			no	loss of kaiser coverage
			no	loss of kaiser coverage
			no	Consent withdrawal / not willing to participate, not due to a (S)AE
			no	Migrated / moved from the study area
			no	Lost to follow-up
			no	Lost to follow-up
			no	Migrated / moved from the study area
			no	Lost to follow-up
			no	Migrated / moved from the study area
			no	Lost to follow-up
			no	Protocol violation
			no	Consent withdrawal / not willing to participate, not due to a (S)AE
			no	Migrated / moved from the study area
	VISIT 5 M 13-16	158		
	VISIT 6 M 14-17	158		
Penta group	VISIT 1 D0 DOSE	196		
			noPPD	Consent withdrawal
			no	Consent withdrawal
			no	Consent withdrawal
			no	Consent withdrawal
			no	loss of kaiser coverage
	VISIT 2 M2 DOSE	191		
			noPPD	Lost to follow-up

Group	VISIT	N	Withdrawn Subject numbers	Reason for withdrawal
			no.PPD	loss of kaiser coverage
			no.	subject was discontiued due to non-compliance
			no.	Consent withdrawal
			no.	Protocol violation
			no.	Non-Serious Adverse Event
			no.	Protocol violation
			no.	Lost to follow-up
			no.	Protocol violation
	VISIT 3 M4 DOSE	182		
	VISIT 4 M5 POST	182		
			noPPD	Migrated / moved from the study area
	ESFU CONTACT	181		
			noPPD	Migrated / moved from the study area
			no.	Protocol violation
			no.	Lost to follow-up
			no.	received vaccines in injection clinic
			no.	refuses blood draws
			no.	Lost to follow-up
			no.	Protocol violation
			no.	Protocol violation
			no.	Consent withdrawal / not willing to participate, not due to a (S)AE
			no.	Lost to follow-up
			no.	Consent withdrawal / not willing to participate, not due to a (S)AE
			no.	Migrated / moved from the study area
			no.	subject unable to complete visit 5 during the GSK shortened window for visit 5
			no.	Migrated / moved from the study area
			no.	Lost to follow-up
			no.	Sponsor study termination
			no.	Protocol violation
			no.	Migrated / moved from the study area
	VISIT 5 M 13-16	163		
			no.PPD	Lost to follow-up
			no.	Lost to follow-up
			no.	Lost to follow-up
			no.	Consent withdrawal
			no.	Lost to follow-up
			no.	Protocol violation
	VISIT 6 M 14-17	157		

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 Summary of demographic characteristics (Primary Total vaccinated cohort)

		Hexa group N = 195		Pedia group N = 194		Penta group N = 196		Total N = 585	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age [Weeks] at first primary dose	Mean	8.5	-	8.6	-	8.6	-	8.6	-
	SD	1.0	-	1.1	-	1.1	-	1.1	-
	Median	8.0	-	9.0	-	8.0	-	8.0	-
	Minimum	6.0	-	6.0	-	6.0	-	6.0	-
	Maximum	12.0	-	12.0	-	12.0	-	12.0	-
Gender	Female	101	51.8	80	41.2	95	48.5	276	47.2
	Male	94	48.2	114	58.8	101	51.5	309	52.8
Race	African Heritage / African American	16	8.2	9	4.6	20	10.2	45	7.7
	American Indian or Alaskan Native	15	7.7	15	7.7	17	8.7	47	8.0
	Asian - Central/South Asian Heritage	2	1.0	2	1.0	1	0.5	5	0.9
	Asian - East Asian Heritage	3	1.5	2	1.0	0	0.0	5	0.9
	Asian - Japanese Heritage	1	0.5	0	0.0	1	0.5	2	0.3
	Asian - South East Asian Heritage	9	4.6	9	4.6	8	4.1	26	4.4
	Native Hawaiian or Other Pacific Islander	2	1.0	1	0.5	2	1.0	5	0.9
	White - Arabic / North African Heritage	0	0.0	1	0.5	0	0.0	1	0.2
	White - Caucasian / European Heritage	118	60.5	128	66.0	115	58.7	361	61.7
	Other	29	14.9	27	13.9	32	16.3	88	15.0
Height	Mean	58.0	-	58.6	-	58.8	-	58.5	-
	SD	4.1	-	4.7	-	3.1	-	4.0	-
	Median	58.0	-	58.0	-	58.0	-	58.0	-
	Minimum	32.0	-	37.0	-	48.0	-	32.0	-
	Maximum	74.0	-	86.0	-	69.0	-	86.0	-
Weight	Mean	5.3	-	5.4	-	5.4	-	5.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-
	Median	5.2	-	5.4	-	5.4	-	5.3	-
	Minimum	3.4	-	3.6	-	3.7	-	3.4	-
	Maximum	7.9	-	7.1	-	7.5	-	7.9	-
Hepatitis B vaccination at birth	Yes	181	92.8	172	88.7	180	91.8	533	91.1
	No	14	7.2	22	11.3	16	8.2	52	8.9
Tdap vaccination of mother	Yes	102	66.7	94	62.7	98	60.9	294	63.4
	No	51	33.3	56	37.3	63	39.1	170	36.6
	Missing	42	-	44	-	35	-	121	-

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects
n = number of subjects in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
SD = Standard deviation

Table 6.4 Summary of demographic characteristics (Booster Total vaccinated cohort)

		Hexa group N = 167		Pedia group N = 158		Penta group N = 161		Total N = 486	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age [months] at booster dose	Mean	15.3	-	15.3	-	15.3	-	15.3	-
	SD	0.7	-	0.6	-	0.7	-	0.7	-
	Median	15.0	-	15.0	-	15.0	-	15.0	-
	Minimum	14.0	-	15.0	-	14.0	-	14.0	-
	Maximum	18.0	-	18.0	-	18.0	-	18.0	-
Gender	Female	87	52.1	58	36.7	73	45.3	218	44.9
	Male	80	47.9	100	63.3	88	54.7	268	55.1
Race	African Heritage / African American	14	8.4	9	5.7	16	9.9	39	8.0
	American Indian or Alaskan Native	12	7.2	14	8.9	16	9.9	42	8.6
	Asian - Central/South Asian Heritage	2	1.2	2	1.3	0	0.0	4	0.8
	Asian - East Asian Heritage	3	1.8	2	1.3	0	0.0	5	1.0
	Asian - Japanese Heritage	1	0.6	0	0.0	1	0.6	2	0.4
	Asian - South East Asian Heritage	8	4.8	9	5.7	5	3.1	22	4.5
	Native Hawaiian or Other Pacific Islander	2	1.2	0	0.0	2	1.2	4	0.8
	White - Arabic / North African Heritage	0	0.0	1	0.6	0	0.0	1	0.2
	White - Caucasian / European Heritage	101	60.5	101	63.9	94	58.4	296	60.9
	Other	24	14.4	20	12.7	27	16.8	71	14.6
Height	Mean	58.0	-	58.6	-	58.9	-	58.5	-
	SD	3.7	-	4.6	-	3.2	-	3.9	-
	Median	58.0	-	58.0	-	58.0	-	58.0	-
	Minimum	38.0	-	37.0	-	48.0	-	37.0	-
	Maximum	74.0	-	86.0	-	69.0	-	86.0	-
Weight	Mean	5.3	-	5.4	-	5.4	-	5.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-
	Median	5.3	-	5.4	-	5.5	-	5.4	-
	Minimum	3.4	-	4.0	-	3.7	-	3.4	-
	Maximum	7.9	-	7.1	-	7.5	-	7.9	-
Hepatitis B vaccination at birth	Yes	153	91.6	139	88.0	149	92.5	441	90.7
	No	14	8.4	19	12.0	12	7.5	45	9.3
Tdap vaccination of mother	Yes	90	67.7	85	68.0	82	59.9	257	65.1
	No	43	32.3	40	32.0	55	40.1	138	34.9
	Missing	34	-	33	-	24	-	91	-

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects
n = number of subjects in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
SD = Standard deviation

Table 6.5 Deviations from specifications for age and intervals between study visits (Primary Total vaccinated cohort)

		Age	Dose:1-Dose:2	Dose:2-Dose:3	Dose:3-PIII(M5)	
Group		**Protocol**	**Protocol**	**Protocol**	**Protocol**	**Adapted**
		from 42 to 90 days	from 49 to 83 days	from 56 to 90 days	from 30 to 48 days	from 21 to 48 days
Hexa group	N	195	186	183	161	161
	n	0	1	4	7	6
	%	0.0	0.5	2.2	4.3	3.7
	range	44 to 85	49 to 98	56 to 119	29 to 88	29 to 88
Pedia group	N	194	188	185	167	167
	n	0	5	3	5	3
	%	0.0	2.7	1.6	3.0	1.8
	range	42 to 89	49 to 95	56 to 113	28 to 69	28 to 69
Penta group	N	196	189	180	164	164
	n	0	2	5	1	0
	%	0.0	1.1	2.8	0.6	0.0
	range	42 to 87	49 to 96	56 to 98	28 to 48	28 to 48

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adapted = interval used for defining the ATP cohorts for immunogenicity
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 6.6 Deviations from specifications for age and intervals between study visits (Booster Total vaccinated cohort)

		age	Dose:4-POST-BST	
Group		**Protocol**	**Protocol**	**Adapted**
		from 15 to 18 months	from 30 to 48 days	from 21 to 48 days
Hexa group	N	167	150	150
	n	4	10	8
	%	2.4	6.7	5.3
	range	14 to 18	28 to 78	28 to 78
Pedia group	N	158	146	146
	n	0	2	2
	%	0.0	1.4	1.4
	range	15 to 18	30 to 60	30 to 60
Penta group	N	161	146	146
	n	2	8	8
	%	1.2	5.5	5.5
	range	14 to 18	30 to 103	30 to 103

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adapted = interval used for defining the ATP cohorts for immunogenicity
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
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

Table 6.7 Summary of demographic characteristics (Primary ATP cohort for safety)

		Hexa group N = 194		Pedia group N = 193		Penta group N = 191		Total N = 578	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age [Weeks] at first primary dose	Mean	8.5	-	8.6	-	8.6	-	8.6	-
	SD	1.0	-	1.1	-	1.1	-	1.0	-
	Median	8.0	-	9.0	-	8.0	-	8.0	-
	Minimum	6.0	-	6.0	-	6.0	-	6.0	-
	Maximum	12.0	-	12.0	-	12.0	-	12.0	-
Gender	Female	101	52.1	80	41.5	90	47.1	271	46.9
	Male	93	47.9	113	58.5	101	52.9	307	53.1
Race	African Heritage / African American	16	8.2	9	4.7	19	9.9	44	7.6
	American Indian or Alaskan Native	15	7.7	15	7.8	17	8.9	47	8.1
	Asian - Central/South Asian Heritage	2	1.0	1	0.5	1	0.5	4	0.7
	Asian - East Asian Heritage	3	1.5	2	1.0	0	0.0	5	0.9
	Asian - Japanese Heritage	1	0.5	0	0.0	1	0.5	2	0.3
	Asian - South East Asian Heritage	9	4.6	9	4.7	8	4.2	26	4.5
	Native Hawaiian or Other Pacific Islander	2	1.0	1	0.5	2	1.0	5	0.9
	White - Arabic / North African Heritage	0	0.0	1	0.5	0	0.0	1	0.2
	White - Caucasian / European Heritage	117	60.3	128	66.3	112	58.6	357	61.8
	Other	29	14.9	27	14.0	31	16.2	87	15.1
Height	Mean	58.0	-	58.6	-	58.8	-	58.5	-
	SD	4.1	-	4.7	-	3.1	-	4.0	-
	Median	58.0	-	58.0	-	58.0	-	58.0	-
	Minimum	32.0	-	37.0	-	48.0	-	32.0	-
	Maximum	74.0	-	86.0	-	69.0	-	86.0	-
Weight	Mean	5.3	-	5.4	-	5.4	-	5.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-
	Median	5.2	-	5.4	-	5.4	-	5.3	-
	Minimum	3.4	-	3.6	-	3.7	-	3.4	-
	Maximum	7.9	-	7.1	-	7.5	-	7.9	-
Hepatitis B vaccination at birth	Yes	180	92.8	171	88.6	177	92.7	528	91.3
	No	14	7.2	22	11.4	14	7.3	50	8.7
Tdap vaccination of mother	Yes	101	66.4	93	62.4	96	61.1	290	63.3
	No	51	33.6	56	37.6	61	38.9	168	36.7
	Missing	42	-	44	-	34	-	120	-

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects
n = number of subjects in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
SD = Standard deviation

Table 6.8 Summary of demographic characteristics (Booster ATP cohort for safety)

		Hexa group N = 167		Pedia group N = 158		Penta group N = 160		Total N = 485	
Characteristics	**Parameters or Categories**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**	**Value or n**	**%**
Age [months] at booster dose	Mean	15.3	-	15.3	-	15.3	-	15.3	-
	SD	0.7	-	0.6	-	0.7	-	0.7	-
	Median	15.0	-	15.0	-	15.0	-	15.0	-
	Minimum	14.0	-	15.0	-	14.0	-	14.0	-
	Maximum	18.0	-	18.0	-	18.0	-	18.0	-
Gender	Female	87	52.1	58	36.7	72	45.0	217	44.7
	Male	80	47.9	100	63.3	88	55.0	268	55.3
Race	African Heritage / African American	14	8.4	9	5.7	16	10.0	39	8.0
	American Indian or Alaskan Native	12	7.2	14	8.9	16	10.0	42	8.7
	Asian - Central/South Asian Heritage	2	1.2	2	1.3	0	0.0	4	0.8
	Asian - East Asian Heritage	3	1.8	2	1.3	0	0.0	5	1.0
	Asian - Japanese Heritage	1	0.6	0	0.0	1	0.6	2	0.4
	Asian - South East Asian Heritage	8	4.8	9	5.7	5	3.1	22	4.5
	Native Hawaiian or Other Pacific Islander	2	1.2	0	0.0	2	1.3	4	0.8
	White - Arabic / North African Heritage	0	0.0	1	0.6	0	0.0	1	0.2
	White - Caucasian / European Heritage	101	60.5	101	63.9	93	58.1	295	60.8
	Other	24	14.4	20	12.7	27	16.9	71	14.6
Height	Mean	58.0	-	58.6	-	58.9	-	58.5	-
	SD	3.7	-	4.6	-	3.2	-	3.9	-
	Median	58.0	-	58.0	-	58.0	-	58.0	-
	Minimum	38.0	-	37.0	-	48.0	-	37.0	-
	Maximum	74.0	-	86.0	-	69.0	-	86.0	-
Weight	Mean	5.3	-	5.4	-	5.4	-	5.4	-
	SD	0.7	-	0.7	-	0.7	-	0.7	-
	Median	5.3	-	5.4	-	5.5	-	5.4	-
	Minimum	3.4	-	4.0	-	3.7	-	3.4	-
	Maximum	7.9	-	7.1	-	7.5	-	7.9	-
Hepatitis B vaccination at birth	Yes	153	91.6	139	88.0	148	92.5	440	90.7
	No	14	8.4	19	12.0	12	7.5	45	9.3
Tdap vaccination of mother	Yes	90	67.7	85	68.0	82	59.9	257	65.1
	No	43	32.3	40	32.0	55	40.1	138	34.9
	Missing	34	-	33	-	23	-	90	-

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects
n = number of subjects in a given category
Value = value of the considered parameter
% = n / Number of subjects with available results x 100
SD = Standard deviation

7. IMMUNOGENICITY

Table 7.1 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), one month post primary vaccination - by gender (Primary ATP cohort for immunogenicity)

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	Female	PIII(M5)	81	81	100	95.5	100	41.1	34.9	48.5
		Male	PIII(M5)	65	65	100	94.5	100	45.8	37.7	55.8
	Pedia group	Female	PIII(M5)	56	56	100	93.6	100	43.0	35.2	52.6
		Male	PIII(M5)	93	92	98.9	94.2	100	51.8	44.4	60.4
	Penta group	Female	PIII(M5)	71	71	100	94.9	100	23.1	19.3	27.6
		Male	PIII(M5)	78	77	98.7	93.1	100	25.3	20.6	31.1
anti-FHA antibody	Hexa group	Female	PIII(M5)	81	81	100	95.5	100	98.9	85.1	114.9
		Male	PIII(M5)	65	65	100	94.5	100	116.4	98.0	138.3
	Pedia group	Female	PIII(M5)	56	56	100	93.6	100	114.7	95.0	138.4
		Male	PIII(M5)	93	93	100	96.1	100	127.9	111.5	146.7
	Penta group	Female	PIII(M5)	71	71	100	94.9	100	54.0	43.6	66.9
		Male	PIII(M5)	78	78	100	95.4	100	65.8	53.8	80.5
anti-PRN antibody	Hexa group	Female	PIII(M5)	81	81	100	95.5	100	56.6	46.9	68.3
		Male	PIII(M5)	65	65	100	94.5	100	58.5	45.9	74.5
	Pedia group	Female	PIII(M5)	56	55	98.2	90.4	100	52.9	39.9	70.3
		Male	PIII(M5)	93	93	100	96.1	100	43.7	35.7	53.4
	Penta group	Female	PIII(M5)	71	71	100	94.9	100	34.9	28.3	43.2
		Male	PIII(M5)	78	77	98.7	93.1	100	31.3	24.0	40.8

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.2 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), one month post primary vaccination – by geographical ancestry (Primary ATP cohort for immunogenicity)

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	White Caucasian	PIII(M5)	93	93	100	96.1	100	38.1	32.5	44.6
		other	PIII(M5)	53	53	100	93.3	100	53.7	44.0	65.6
	Pedia group	White Caucasian	PIII(M5)	101	100	99.0	94.6	100	43.8	37.5	51.2
		other	PIII(M5)	48	48	100	92.6	100	59.1	49.2	71.1
	Penta group	White Caucasian	PIII(M5)	84	83	98.8	93.5	100	21.6	17.8	26.2
		other	PIII(M5)	65	65	100	94.5	100	28.1	23.3	33.8
anti-FHA antibody	Hexa group	White Caucasian	PIII(M5)	93	93	100	96.1	100	95.8	83.2	110.5
		other	PIII(M5)	53	53	100	93.3	100	127.6	106.5	152.8
	Pedia group	White Caucasian	PIII(M5)	101	101	100	96.4	100	114.2	99.9	130.6
		other	PIII(M5)	48	48	100	92.6	100	142.8	117.6	173.4
	Penta group	White Caucasian	PIII(M5)	84	84	100	95.7	100	51.7	42.5	62.8
		other	PIII(M5)	65	65	100	94.5	100	72.4	58.2	90.1
anti-PRN antibody	Hexa group	White Caucasian	PIII(M5)	93	93	100	96.1	100	53.0	43.9	64.0
		other	PIII(M5)	53	53	100	93.3	100	66.1	51.9	84.2
	Pedia group	White Caucasian	PIII(M5)	101	100	99.0	94.6	100	44.0	35.7	54.3
		other	PIII(M5)	48	48	100	92.6	100	53.7	41.6	69.2
	Penta group	White Caucasian	PIII(M5)	84	83	98.8	93.5	100	29.5	23.4	37.2
		other	PIII(M5)	65	65	100	94.5	100	38.2	29.7	49.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.3 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), one month post primary vaccination – by Tdap vaccination of mother (Primary ATP cohort for immunogenicity)

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	81	81	100	95.5	100	37.7	31.5	45.1
		Tdap Vaccination No	PIII(M5)	40	40	100	91.2	100	51.2	41.9	62.5
		Tdap Vaccination Missing	PIII(M5)	25	25	100	86.3	100	51.2	37.5	69.9
	Pedia group	Tdap Vaccination Yes	PIII(M5)	74	74	100	95.1	100	41.2	35.6	47.6
		Tdap Vaccination No	PIII(M5)	42	41	97.6	87.4	99.9	59.8	45.6	78.5
		Tdap Vaccination Missing	PIII(M5)	33	33	100	89.4	100	52.5	39.8	69.4
	Penta group	Tdap Vaccination Yes	PIII(M5)	79	78	98.7	93.1	100	19.0	16.1	22.4
		Tdap Vaccination No	PIII(M5)	46	46	100	92.3	100	34.9	26.8	45.4
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	26.6	19.0	37.4
anti-FHA antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	81	81	100	95.5	100	94.3	80.4	110.6
		Tdap Vaccination No	PIII(M5)	40	40	100	91.2	100	136.0	111.5	165.8
		Tdap Vaccination Missing	PIII(M5)	25	25	100	86.3	100	105.9	82.5	135.9
	Pedia group	Tdap Vaccination Yes	PIII(M5)	74	74	100	95.1	100	108.6	94.1	125.4
		Tdap Vaccination No	PIII(M5)	42	42	100	91.6	100	166.3	133.6	207.0
		Tdap Vaccination Missing	PIII(M5)	33	33	100	89.4	100	109.6	86.0	139.6
	Penta group	Tdap Vaccination Yes	PIII(M5)	79	79	100	95.4	100	45.7	38.0	55.0
		Tdap Vaccination No	PIII(M5)	46	46	100	92.3	100	95.9	78.0	118.0
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	58.9	36.4	95.1
anti-PRN antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	81	81	100	95.5	100	48.8	40.1	59.3
		Tdap Vaccination No	PIII(M5)	40	40	100	91.2	100	71.2	55.2	92.0
		Tdap Vaccination Missing	PIII(M5)	25	25	100	86.3	100	68.9	44.6	106.4
	Pedia group	Tdap Vaccination Yes	PIII(M5)	74	74	100	95.1	100	34.4	28.0	42.3
		Tdap Vaccination No	PIII(M5)	42	41	97.6	87.4	99.9	55.2	38.0	80.1
		Tdap Vaccination Missing	PIII(M5)	33	33	100	89.4	100	76.4	58.3	100.1
	Penta group	Tdap Vaccination Yes	PIII(M5)	79	78	98.7	93.1	100	27.7	22.2	34.5
		Tdap Vaccination No	PIII(M5)	46	46	100	92.3	100	36.8	26.7	50.9
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	47.6	30.0	75.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.4 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), one month post primary vaccination - by gender (Primary ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	Female	PIII(M5)	79	79	100	95.4	100	79	100	95.4	100	60	75.9	65.0	84.9	1.689	1.389	2.054
		Male	PIII(M5)	63	63	100	94.3	100	63	100	94.3	100	52	82.5	70.9	90.9	1.893	1.567	2.288
	Pedia group	Female	PIII(M5)	55	55	100	93.5	100	55	100	93.5	100	40	72.7	59.0	83.9	1.866	1.492	2.333
		Male	PIII(M5)	89	89	100	95.9	100	89	100	95.9	100	65	73.0	62.6	81.9	1.526	1.287	1.810
	Penta group	Female	PIII(M5)	71	71	100	94.9	100	71	100	94.9	100	44	62.0	49.7	73.2	1.335	1.114	1.599
		Male	PIII(M5)	78	78	100	95.4	100	78	100	95.4	100	44	56.4	44.7	67.6	1.176	0.970	1.427
anti-T antibody	Hexa group	Female	PIII(M5)	81	81	100	95.5	100	81	100	95.5	100	74	91.4	83.0	96.5	2.342	2.041	2.688
		Male	PIII(M5)	65	65	100	94.5	100	65	100	94.5	100	56	86.2	75.3	93.5	2.610	2.157	3.159
	Pedia group	Female	PIII(M5)	56	56	100	93.6	100	56	100	93.6	100	50	89.3	78.1	96.0	2.384	1.941	2.928
		Male	PIII(M5)	93	93	100	96.1	100	93	100	96.1	100	84	90.3	82.4	95.5	2.796	2.414	3.238
	Penta group	Female	PIII(M5)	71	71	100	94.9	100	71	100	94.9	100	58	81.7	70.7	89.9	1.937	1.650	2.274
		Male	PIII(M5)	78	78	100	95.4	100	77	98.7	93.1	100	61	78.2	67.4	86.8	2.082	1.701	2.550

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.5 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), one month post primary vaccination – by geographical ancestry (Primary ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	White Caucasian	PIII(M5)	91	91	100	96.0	100	91	100	96.0	100	69	75.8	65.7	84.2	1.633	1.377	1.937
		other	PIII(M5)	51	51	100	93.0	100	51	100	93.0	100	43	84.3	71.4	93.0	2.065	1.645	2.593
	Pedia group	White Caucasian	PIII(M5)	99	99	100	96.3	100	99	100	96.3	100	67	67.7	57.5	76.7	1.408	1.205	1.644
		other	PIII(M5)	45	45	100	92.1	100	45	100	92.1	100	38	84.4	70.5	93.5	2.330	1.828	2.971
	Penta group	White Caucasian	PIII(M5)	84	84	100	95.7	100	84	100	95.7	100	44	52.4	41.2	63.4	1.085	0.927	1.271
		other	PIII(M5)	65	65	100	94.5	100	65	100	94.5	100	44	67.7	54.9	78.8	1.499	1.203	1.866
anti-T antibody	Hexa group	White Caucasian	PIII(M5)	93	93	100	96.1	100	93	100	96.1	100	79	84.9	76.0	91.5	2.009	1.759	2.295
		other	PIII(M5)	53	53	100	93.3	100	53	100	93.3	100	51	96.2	87.0	99.5	3.502	2.946	4.163
	Pedia group	White Caucasian	PIII(M5)	101	101	100	96.4	100	101	100	96.4	100	89	88.1	80.2	93.7	2.383	2.058	2.761
		other	PIII(M5)	48	48	100	92.6	100	48	100	92.6	100	45	93.8	82.8	98.7	3.247	2.668	3.952
	Penta group	White Caucasian	PIII(M5)	84	84	100	95.7	100	83	98.8	93.5	100	67	79.8	69.6	87.7	1.813	1.521	2.162
		other	PIII(M5)	65	65	100	94.5	100	65	100	94.5	100	52	80.0	68.2	88.9	2.301	1.901	2.785

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.6 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), one month post primary vaccination – by Tdap vaccination of mother (Primary ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	78	78	100	95.4	100	78	100	95.4	100	55	70.5	59.1	80.3	1.440	1.194	1.737
		Tdap Vaccination No	PIII(M5)	40	40	100	91.2	100	40	100	91.2	100	39	97.5	86.8	99.9	2.432	2.027	2.918
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	24	100	85.8	100	18	75.0	53.3	90.2	2.083	1.390	3.121
	Pedia group	Tdap Vaccination Yes	PIII(M5)	71	71	100	94.9	100	71	100	94.9	100	49	69.0	56.9	79.5	1.426	1.171	1.736
		Tdap Vaccination No	PIII(M5)	41	41	100	91.4	100	41	100	91.4	100	28	68.3	51.9	81.9	1.772	1.345	2.335
		Tdap Vaccination Missing	PIII(M5)	32	32	100	89.1	100	32	100	89.1	100	28	87.5	71.0	96.5	2.069	1.628	2.629
	Penta group	Tdap Vaccination Yes	PIII(M5)	79	79	100	95.4	100	79	100	95.4	100	37	46.8	35.5	58.4	1.005	0.837	1.208
		Tdap Vaccination No	PIII(M5)	46	46	100	92.3	100	46	100	92.3	100	35	76.1	61.2	87.4	1.680	1.349	2.092
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	24	100	85.8	100	16	66.7	44.7	84.4	1.449	1.061	1.978
anti-T antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	81	81	100	95.5	100	81	100	95.5	100	71	87.7	78.5	93.9	2.405	2.065	2.801
		Tdap Vaccination No	PIII(M5)	40	40	100	91.2	100	40	100	91.2	100	38	95.0	83.1	99.4	2.569	2.053	3.215
		Tdap Vaccination Missing	PIII(M5)	25	25	100	86.3	100	25	100	86.3	100	21	84.0	63.9	95.5	2.460	1.836	3.295
	Pedia group	Tdap Vaccination Yes	PIII(M5)	74	74	100	95.1	100	74	100	95.1	100	68	91.9	83.2	97.0	2.739	2.299	3.263
		Tdap Vaccination No	PIII(M5)	42	42	100	91.6	100	42	100	91.6	100	35	83.3	68.6	93.0	2.344	1.844	2.978
		Tdap Vaccination Missing	PIII(M5)	33	33	100	89.4	100	33	100	89.4	100	31	93.9	79.8	99.3	2.795	2.225	3.513
	Penta group	Tdap Vaccination Yes	PIII(M5)	79	79	100	95.4	100	78	98.7	93.1	100	66	83.5	73.5	90.9	2.180	1.804	2.633
		Tdap Vaccination No	PIII(M5)	46	46	100	92.3	100	46	100	92.3	100	33	71.7	56.5	84.0	1.850	1.456	2.351
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	24	100	85.8	100	20	83.3	62.6	95.3	1.815	1.405	2.345

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T

Table 7.7 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), one month post primary vaccination - by gender (Primary ATP cohort for immunogenicity)

					≥ 8 ED50				GMT		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	Female	PIII(M5)	76	76	100	95.3	100	730.9	564.8	945.8
		Male	PIII(M5)	61	61	100	94.1	100	381.0	283.0	513.1
	Pedia group	Female	PIII(M5)	51	51	100	93.0	100	846.6	631.0	1135.8
		Male	PIII(M5)	83	83	100	95.7	100	491.0	379.8	634.8
	Penta group	Female	PIII(M5)	66	66	100	94.6	100	461.0	342.5	620.3
		Male	PIII(M5)	70	69	98.6	92.3	100	226.1	166.9	306.4
anti-Polio 2 antibody	Hexa group	Female	PIII(M5)	74	74	100	95.1	100	551.7	409.8	742.8
		Male	PIII(M5)	59	59	100	93.9	100	409.7	311.7	538.5
	Pedia group	Female	PIII(M5)	49	49	100	92.7	100	660.6	443.6	984.0
		Male	PIII(M5)	82	82	100	95.6	100	518.5	386.0	696.6
	Penta group	Female	PIII(M5)	65	65	100	94.5	100	356.1	260.9	486.1
		Male	PIII(M5)	69	69	100	94.8	100	228.0	172.0	302.2
anti-Polio 3 antibody	Hexa group	Female	PIII(M5)	74	74	100	95.1	100	889.7	658.1	1202.9
		Male	PIII(M5)	55	55	100	93.5	100	545.5	392.6	757.9
	Pedia group	Female	PIII(M5)	52	52	100	93.2	100	1154.6	808.5	1648.8
		Male	PIII(M5)	80	80	100	95.5	100	803.8	601.0	1075.0
	Penta group	Female	PIII(M5)	63	63	100	94.3	100	458.7	322.4	652.6
		Male	PIII(M5)	63	61	96.8	89.0	99.6	189.2	123.2	290.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.8 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), one month post primary vaccination – by geographical ancestry (Primary ATP cohort for immunogenicity)

					≥ 8 ED50				GMT		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	White Caucasian	PIII(M5)	87	87	100	95.8	100	465.4	359.0	603.4
		other	PIII(M5)	50	50	100	92.9	100	724.1	533.1	983.6
	Pedia group	White Caucasian	PIII(M5)	91	91	100	96.0	100	506.2	393.1	651.7
		other	PIII(M5)	43	43	100	91.8	100	878.6	660.5	1168.7
	Penta group	White Caucasian	PIII(M5)	75	74	98.7	92.8	100	305.1	220.2	422.7
		other	PIII(M5)	61	61	100	94.1	100	338.2	254.0	450.2
anti-Polio 2 antibody	Hexa group	White Caucasian	PIII(M5)	84	84	100	95.7	100	396.4	303.7	517.4
		other	PIII(M5)	49	49	100	92.7	100	679.5	502.5	918.9
	Pedia group	White Caucasian	PIII(M5)	88	88	100	95.9	100	494.3	367.1	665.5
		other	PIII(M5)	43	43	100	91.8	100	753.7	515.9	1101.2
	Penta group	White Caucasian	PIII(M5)	76	76	100	95.3	100	265.3	199.8	352.2
		other	PIII(M5)	58	58	100	93.8	100	308.2	223.5	424.9
anti-Polio 3 antibody	Hexa group	White Caucasian	PIII(M5)	83	83	100	95.7	100	566.1	424.8	754.3
		other	PIII(M5)	46	46	100	92.3	100	1121.0	805.9	1559.2
	Pedia group	White Caucasian	PIII(M5)	91	91	100	96.0	100	721.6	543.8	957.6
		other	PIII(M5)	41	41	100	91.4	100	1616.3	1188.0	2199.1
	Penta group	White Caucasian	PIII(M5)	67	65	97.0	89.6	99.6	244.3	160.9	371.1
		other	PIII(M5)	59	59	100	93.9	100	364.4	247.6	536.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.9 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), one month post primary vaccination – by Tdap vaccination of mother (Primary ATP cohort for immunogenicity)

					≥ 8 ED50				GMT		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	76	76	100	95.3	100	526.1	396.3	698.5
		Tdap Vaccination No	PIII(M5)	37	37	100	90.5	100	531.8	373.0	758.1
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	645.5	386.5	1078.0
	Pedia group	Tdap Vaccination Yes	PIII(M5)	71	71	100	94.9	100	619.4	491.4	780.7
		Tdap Vaccination No	PIII(M5)	37	37	100	90.5	100	640.9	396.7	1035.6
		Tdap Vaccination Missing	PIII(M5)	26	26	100	86.8	100	518.8	321.3	837.8
	Penta group	Tdap Vaccination Yes	PIII(M5)	70	69	98.6	92.3	100	307.3	221.1	427.2
		Tdap Vaccination No	PIII(M5)	42	42	100	91.6	100	297.0	207.4	425.1
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	406.6	239.2	691.4
anti-Polio 2 antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	75	75	100	95.2	100	421.7	318.4	558.5
		Tdap Vaccination No	PIII(M5)	37	37	100	90.5	100	531.5	378.3	746.7
		Tdap Vaccination Missing	PIII(M5)	21	21	100	83.9	100	666.7	364.2	1220.5
	Pedia group	Tdap Vaccination Yes	PIII(M5)	68	68	100	94.7	100	522.6	379.3	719.9
		Tdap Vaccination No	PIII(M5)	36	36	100	90.3	100	853.2	567.2	1283.4
		Tdap Vaccination Missing	PIII(M5)	27	27	100	87.2	100	406.4	220.1	750.3
	Penta group	Tdap Vaccination Yes	PIII(M5)	69	69	100	94.8	100	278.8	210.0	370.1
		Tdap Vaccination No	PIII(M5)	41	41	100	91.4	100	247.1	165.5	368.9
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	372.9	214.4	648.6
anti-Polio 3 antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	71	71	100	94.9	100	731.2	542.9	984.7
		Tdap Vaccination No	PIII(M5)	34	34	100	89.7	100	674.3	438.6	1036.6
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	767.4	411.5	1431.1
	Pedia group	Tdap Vaccination Yes	PIII(M5)	69	69	100	94.8	100	1029.3	773.8	1369.1
		Tdap Vaccination No	PIII(M5)	36	36	100	90.3	100	1004.9	640.3	1577.0
		Tdap Vaccination Missing	PIII(M5)	27	27	100	87.2	100	637.2	349.8	1160.7
	Penta group	Tdap Vaccination Yes	PIII(M5)	65	63	96.9	89.3	99.6	244.0	158.8	374.9
		Tdap Vaccination No	PIII(M5)	38	38	100	90.7	100	301.8	187.6	485.6
		Tdap Vaccination Missing	PIII(M5)	23	23	100	85.2	100	482.4	253.6	917.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.10 Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination – by study lot (Primary ATP cohort for immunogenicity)

				≥ cut_off				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – qualified assay	Hexa_1 group	PIII(M5)	53	50	94.3	84.3	98.8	50	94.3	84.3	98.8	34	64.2	49.8	76.9	1.461	1.002	2.132
	Hexa_2 group	PIII(M5)	48	45	93.8	82.8	98.7	45	93.8	82.8	98.7	24	50.0	35.2	64.8	1.204	0.778	1.865
	Hexa_3 group	PIII(M5)	48	45	93.8	82.8	98.7	45	93.8	82.8	98.7	25	52.1	37.2	66.7	1.461	0.934	2.285
	Pedia group	PIII(M5)	153	151	98.7	95.4	99.8	151	98.7	95.4	99.8	144	94.1	89.1	97.3	10.327	8.127	13.122
	Penta group	PIII(M5)	153	151	98.7	95.4	99.8	151	98.7	95.4	99.8	126	82.4	75.4	88.0	6.485	4.922	8.544
anti-PRP – fully validated assay	Hexa_1 group	PIII(M5)	54	54	100	93.4	100	53	98.1	90.1	100	34	63.0	48.7	75.7	1.546	1.084	2.204
	Hexa_2 group	PIII(M5)	51	50	98.0	89.6	100	46	90.2	78.6	96.7	27	52.9	38.5	67.1	1.139	0.754	1.720
	Hexa_3 group	PIII(M5)	49	48	98.0	89.1	99.9	47	95.9	86.0	99.5	24	49.0	34.4	63.7	1.381	0.901	2.115
	Pedia group	PIII(M5)	154	153	99.4	96.4	100	151	98.1	94.4	99.6	145	94.2	89.2	97.3	9.258	7.362	11.642
	Penta group	PIII(M5)	156	154	98.7	95.4	99.8	154	98.7	95.4	99.8	130	83.3	76.5	88.8	5.717	4.363	7.492

Hexa_1 group = Subjects who received primary doses of Infanrix hexa from lot A and a booster dose of Infanrix and Hiberix vaccines
Hexa_2 group = Subjects who received primary doses of Infanrix hexa from lot B and a booster dose of Infanrix and Hiberix vaccines
Hexa_3 group = Subjects who received primary doses of Infanrix hexa from lot C and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note:Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

Table 7.11 Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination – by gender (Primary ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-PRP – qualified assay	Hexa group	Female	PIII(M5)	83	78	94.0	86.5	98.0	78	94.0	86.5	98.0	46	55.4	44.1	66.3	1.365	0.985	1.892
		Male	PIII(M5)	66	62	93.9	85.2	98.3	62	93.9	85.2	98.3	37	56.1	43.3	68.3	1.383	0.972	1.967
	Pedia group	Female	PIII(M5)	60	59	98.3	91.1	100	59	98.3	91.1	100	57	95.0	86.1	99.0	10.639	7.271	15.568
		Male	PIII(M5)	93	92	98.9	94.2	100	92	98.9	94.2	100	87	93.5	86.5	97.6	10.130	7.401	13.866
	Penta group	Female	PIII(M5)	74	73	98.6	92.7	100	73	98.6	92.7	100	63	85.1	75.0	92.3	7.881	5.403	11.496
		Male	PIII(M5)	79	78	98.7	93.1	100	78	98.7	93.1	100	63	79.7	69.2	88.0	5.402	3.606	8.091
anti-PRP – fully validated assay	Hexa group	Female	PIII(M5)	85	84	98.8	93.6	100	80	94.1	86.8	98.1	46	54.1	43.0	65.0	1.328	0.972	1.813
		Male	PIII(M5)	69	68	98.6	92.2	100	66	95.7	87.8	99.1	39	56.5	44.0	68.4	1.373	0.985	1.914
	Pedia group	Female	PIII(M5)	61	60	98.4	91.2	100	60	98.4	91.2	100	58	95.1	86.3	99.0	9.251	6.348	13.482
		Male	PIII(M5)	93	93	100	96.1	100	91	97.8	92.4	99.7	87	93.5	86.5	97.6	9.262	6.904	12.426
	Penta group	Female	PIII(M5)	74	74	100	95.1	100	74	100	95.1	100	64	86.5	76.5	93.3	6.995	4.903	9.980
		Male	PIII(M5)	82	80	97.6	91.5	99.7	80	97.6	91.5	99.7	66	80.5	70.3	88.4	4.766	3.179	7.146

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note:Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

Table 7.12 Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination – by geographical ancestry (Primary ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – qualified assay	Hexa group	White Caucasian	PIII(M5)	95	87	91.6	84.1	96.3	87	91.6	84.1	96.3	49	51.6	41.1	62.0	1.090	0.818	1.453
		other	PIII(M5)	54	53	98.1	90.1	100	53	98.1	90.1	100	34	63.0	48.7	75.7	2.061	1.377	3.085
	Pedia group	White Caucasian	PIII(M5)	103	101	98.1	93.2	99.8	101	98.1	93.2	99.8	95	92.2	85.3	96.6	7.778	5.747	10.529
		other	PIII(M5)	50	50	100	92.9	100	50	100	92.9	100	49	98.0	89.4	99.9	18.514	13.122	26.122
	Penta group	White Caucasian	PIII(M5)	88	88	100	95.9	100	88	100	95.9	100	72	81.8	72.2	89.2	6.058	4.218	8.699
		other	PIII(M5)	65	63	96.9	89.3	99.6	63	96.9	89.3	99.6	54	83.1	71.7	91.2	7.111	4.598	10.999
anti-PRP – fully validated assay	Hexa group	White Caucasian	PIII(M5)	98	97	99.0	94.4	100	92	93.9	87.1	97.7	50	51.0	40.7	61.3	1.151	0.880	1.507
		other	PIII(M5)	56	55	98.2	90.4	100	54	96.4	87.7	99.6	35	62.5	48.5	75.1	1.775	1.187	2.654
	Pedia group	White Caucasian	PIII(M5)	104	103	99.0	94.8	100	101	97.1	91.8	99.4	97	93.3	86.6	97.3	7.173	5.368	9.585
		other	PIII(M5)	50	50	100	92.9	100	50	100	92.9	100	48	96.0	86.3	99.5	15.739	11.279	21.963
	Penta group	White Caucasian	PIII(M5)	89	88	98.9	93.9	100	88	98.9	93.9	100	74	83.1	73.7	90.2	5.592	3.896	8.027
		other	PIII(M5)	67	66	98.5	92.0	100	66	98.5	92.0	100	56	83.6	72.5	91.5	5.887	3.876	8.942

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note:Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

Table 7.13 Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination – by Tdap vaccination of mother (Primary ATP cohort for immunogenicity)

					≥ cut_off L				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – qualified assay	Hexa group	Tdap Vaccination Yes	PIII(M5)	81	73	90.1	81.5	95.6	73	90.1	81.5	95.6	47	58.0	46.5	68.9	1.223	0.881	1.698
		Tdap Vaccination No	PIII(M5)	41	41	100	91.4	100	41	100	91.4	100	23	56.1	39.7	71.5	1.866	1.210	2.879
		Tdap Vaccination Missing	PIII(M5)	27	26	96.3	81.0	99.9	26	96.3	81.0	99.9	13	48.1	28.7	68.1	1.219	0.670	2.219
	Pedia group	Tdap Vaccination Yes	PIII(M5)	77	77	100	95.3	100	77	100	95.3	100	75	97.4	90.9	99.7	14.977	11.254	19.932
		Tdap Vaccination No	PIII(M5)	43	41	95.3	84.2	99.4	41	95.3	84.2	99.4	38	88.4	74.9	96.1	6.289	3.652	10.828
		Tdap Vaccination Missing	PIII(M5)	33	33	100	89.4	100	33	100	89.4	100	31	93.9	79.8	99.3	8.277	4.942	13.863
	Penta group	Tdap Vaccination Yes	PIII(M5)	80	80	100	95.5	100	80	100	95.5	100	70	87.5	78.2	93.8	9.628	6.653	13.934
		Tdap Vaccination No	PIII(M5)	49	47	95.9	86.0	99.5	47	95.9	86.0	99.5	37	75.5	61.1	86.7	3.469	2.134	5.637
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	24	100	85.8	100	19	79.2	57.8	92.9	6.230	3.045	12.748
anti-PRP – fully validated assay	Hexa group	Tdap Vaccination Yes	PIII(M5)	83	81	97.6	91.6	99.7	78	94.0	86.5	98.0	47	56.6	45.3	67.5	1.182	0.872	1.601
		Tdap Vaccination No	PIII(M5)	42	42	100	91.6	100	40	95.2	83.8	99.4	24	57.1	41.0	72.3	1.776	1.145	2.756
		Tdap Vaccination Missing	PIII(M5)	29	29	100	88.1	100	28	96.6	82.2	99.9	14	48.3	29.4	67.5	1.316	0.751	2.305
	Pedia group	Tdap Vaccination Yes	PIII(M5)	79	79	100	95.4	100	79	100	95.4	100	76	96.2	89.3	99.2	12.839	9.743	16.918
		Tdap Vaccination No	PIII(M5)	42	41	97.6	87.4	99.9	39	92.9	80.5	98.5	38	90.5	77.4	97.3	5.844	3.440	9.926
		Tdap Vaccination Missing	PIII(M5)	33	33	100	89.4	100	33	100	89.4	100	31	93.9	79.8	99.3	7.600	4.649	12.427
	Penta group	Tdap Vaccination Yes	PIII(M5)	81	80	98.8	93.3	100	80	98.8	93.3	100	72	88.9	80.0	94.8	8.584	5.963	12.358
		Tdap Vaccination No	PIII(M5)	51	50	98.0	89.6	100	50	98.0	89.6	100	37	72.5	58.3	84.1	3.003	1.882	4.791
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	24	100	85.8	100	21	87.5	67.6	97.3	5.699	2.833	11.463

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note:Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

Table 7.14 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination - by gender (Primary ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	Female	PIII(M5)	73	73	100	95.1	100	73	100	95.1	100	2283.9	1870.9	2788.1
		Male	PIII(M5)	61	61	100	94.1	100	61	100	94.1	100	2229.2	1674.2	2968.2
	Pedia group	Female	PIII(M5)	52	52	100	93.2	100	52	100	93.2	100	2266.7	1763.9	2912.8
		Male	PIII(M5)	86	86	100	95.8	100	86	100	95.8	100	1687.6	1303.4	2185.0
	Penta group	Female	PIII(M5)	68	67	98.5	92.1	100	67	98.5	92.1	100	1493.6	1014.0	2200.0
		Male	PIII(M5)	68	67	98.5	92.1	100	66	97.1	89.8	99.6	743.0	472.1	1169.3

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.15 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination – by geographical ancestry (Primary ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	White Caucasian	PIII(M5)	84	84	100	95.7	100	84	100	95.7	100	2277.1	1822.9	2844.5
		other	PIII(M5)	50	50	100	92.9	100	50	100	92.9	100	2228.5	1721.7	2884.5
	Pedia group	White Caucasian	PIII(M5)	91	91	100	96.0	100	91	100	96.0	100	1734.9	1351.0	2227.9
		other	PIII(M5)	47	47	100	92.5	100	47	100	92.5	100	2216.9	1710.4	2873.6
	Penta group	White Caucasian	PIII(M5)	78	77	98.7	93.1	100	76	97.4	91.0	99.7	889.0	587.5	1345.2
		other	PIII(M5)	58	57	98.3	90.8	100	57	98.3	90.8	100	1323.5	854.2	2050.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.16 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination – by Tdap vaccination of mother (Primary ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	Tdap Vaccination Yes	PIII(M5)	74	74	100	95.1	100	74	100	95.1	100	2014.5	1571.2	2582.8
		Tdap Vaccination No	PIII(M5)	38	38	100	90.7	100	38	100	90.7	100	2652.1	2030.0	3464.8
		Tdap Vaccination Missing	PIII(M5)	22	22	100	84.6	100	22	100	84.6	100	2516.2	1689.4	3747.8
	Pedia group	Tdap Vaccination Yes	PIII(M5)	71	71	100	94.9	100	71	100	94.9	100	2001.3	1536.4	2606.9
		Tdap Vaccination No	PIII(M5)	37	37	100	90.5	100	37	100	90.5	100	1651.9	1125.6	2424.3
		Tdap Vaccination Missing	PIII(M5)	30	30	100	88.4	100	30	100	88.4	100	1930.0	1306.3	2851.5
	Penta group	Tdap Vaccination Yes	PIII(M5)	71	70	98.6	92.4	100	69	97.2	90.2	99.7	1160.4	763.4	1763.8
		Tdap Vaccination No	PIII(M5)	41	40	97.6	87.1	99.9	40	97.6	87.1	99.9	893.7	488.4	1635.3
		Tdap Vaccination Missing	PIII(M5)	24	24	100	85.8	100	24	100	85.8	100	1048.1	542.9	2023.5

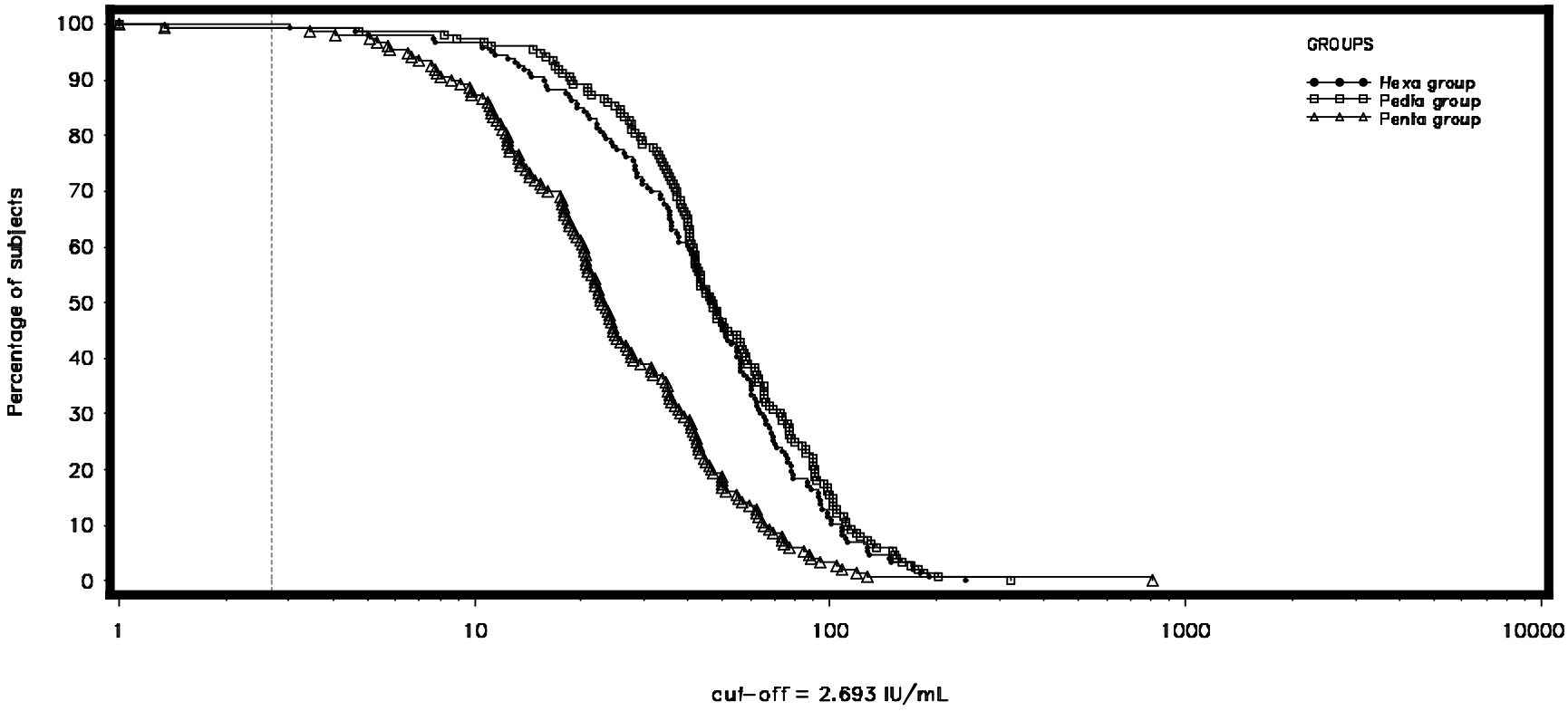
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.17 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination – by Hepatitis B vaccination of subject (Primary ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	HepB at birth Yes	PIII(M5)	124	124	100	97.1	100	124	100	97.1	100	2322.2	1951.3	2763.6
		HepB at birth No	PIII(M5)	10	10	100	69.2	100	10	100	69.2	100	1602.9	799.9	3212.1
	Pedia group	HepB at birth Yes	PIII(M5)	122	122	100	97.0	100	122	100	97.0	100	2026.9	1681.8	2442.9
		HepB at birth No	PIII(M5)	16	16	100	79.4	100	16	100	79.4	100	1088.7	506.6	2339.6
	Penta group	HepB at birth Yes	PIII(M5)	126	124	98.4	94.4	99.8	123	97.6	93.2	99.5	1043.4	755.4	1441.2
		HepB at birth No	PIII(M5)	10	10	100	69.2	100	10	100	69.2	100	1188.2	755.3	1869.1

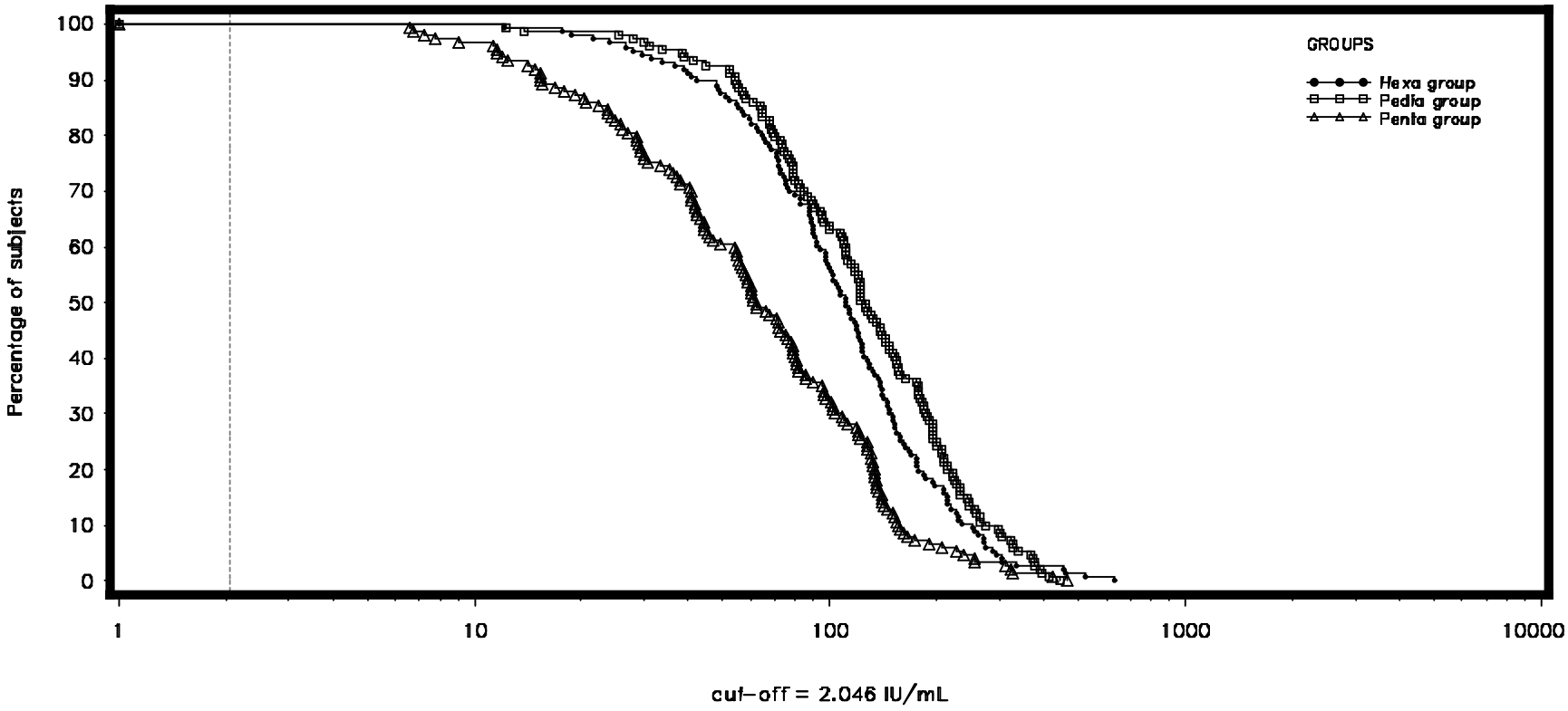
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Figure 7.1 Reverse cumulative distribution curves for anti-PT concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



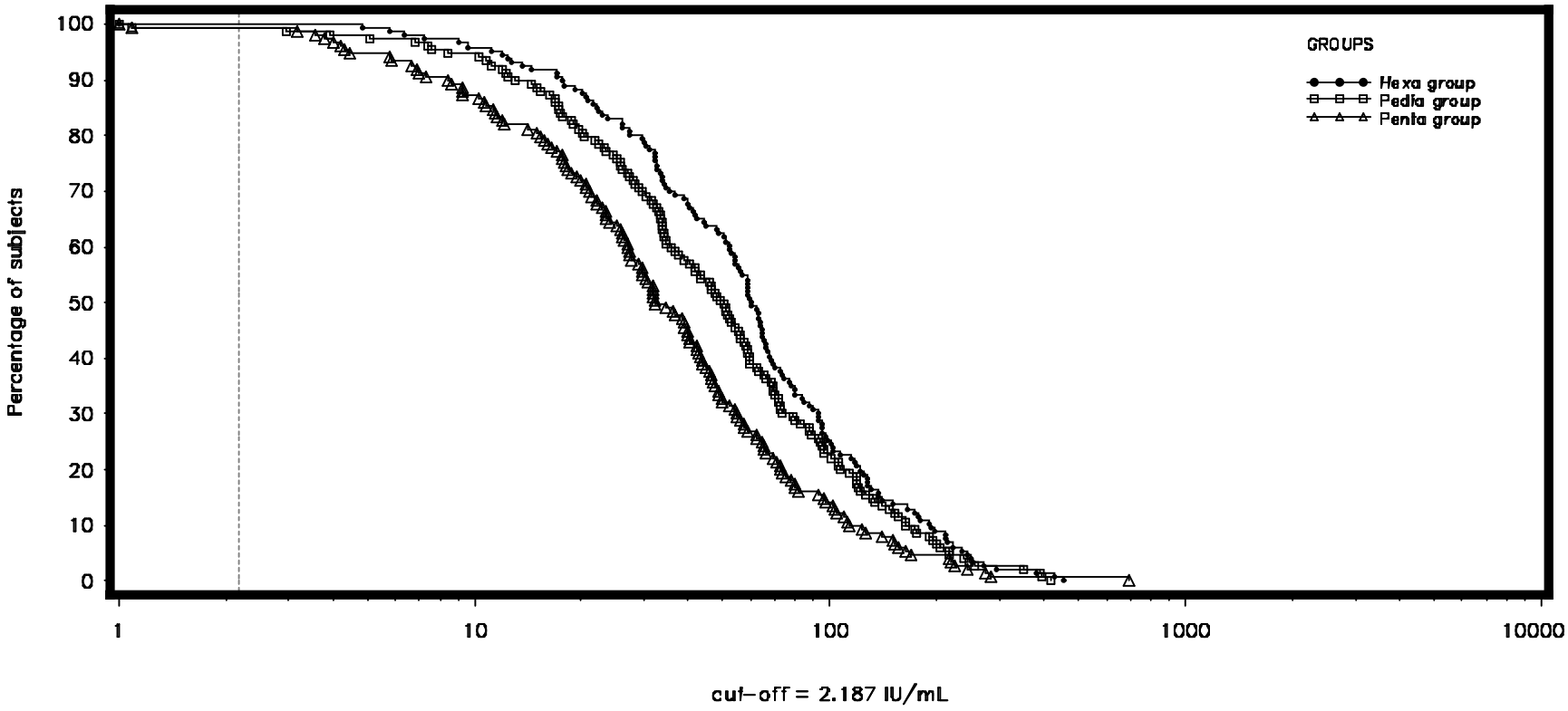
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.2 Reverse cumulative distribution curves for anti-FHA concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



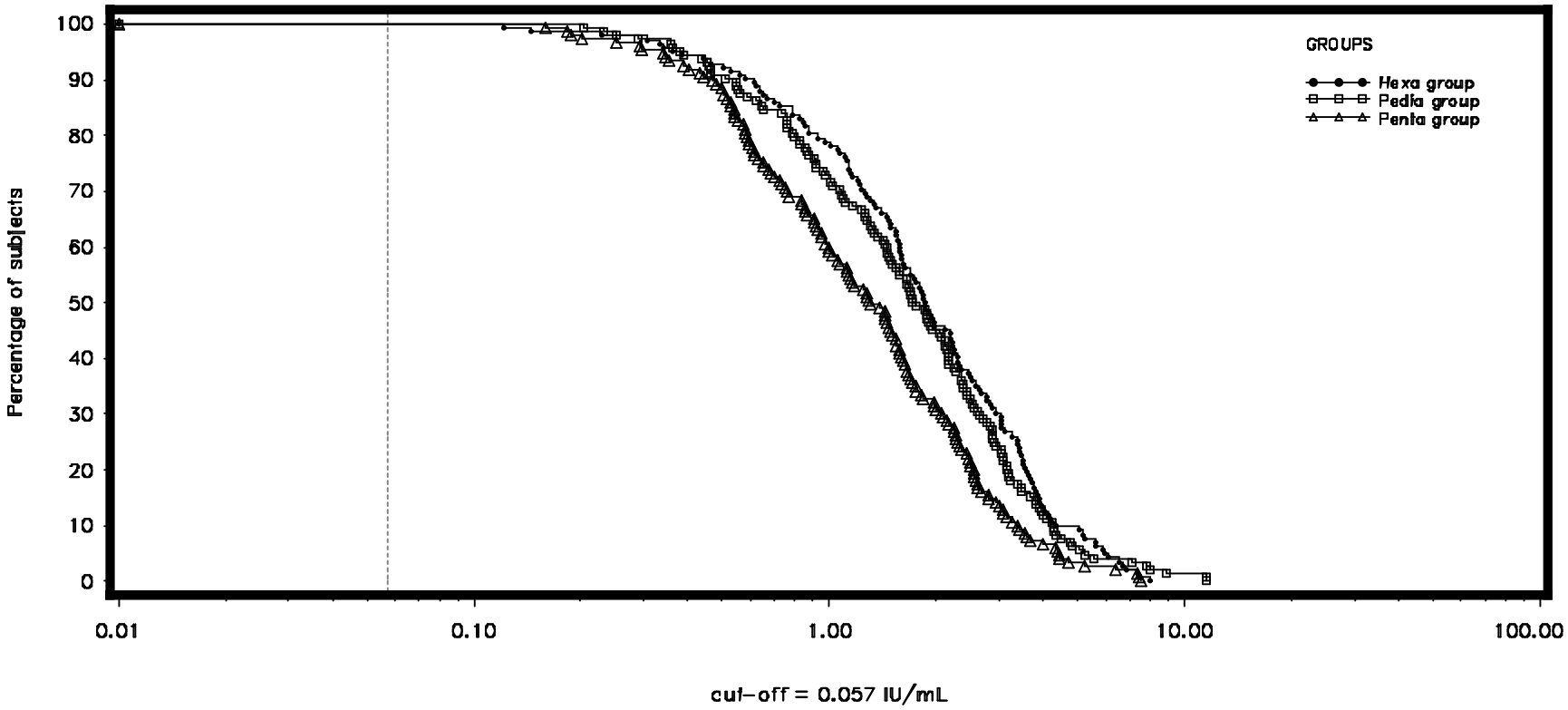
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.3 Reverse cumulative distribution curves for anti-PRN concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



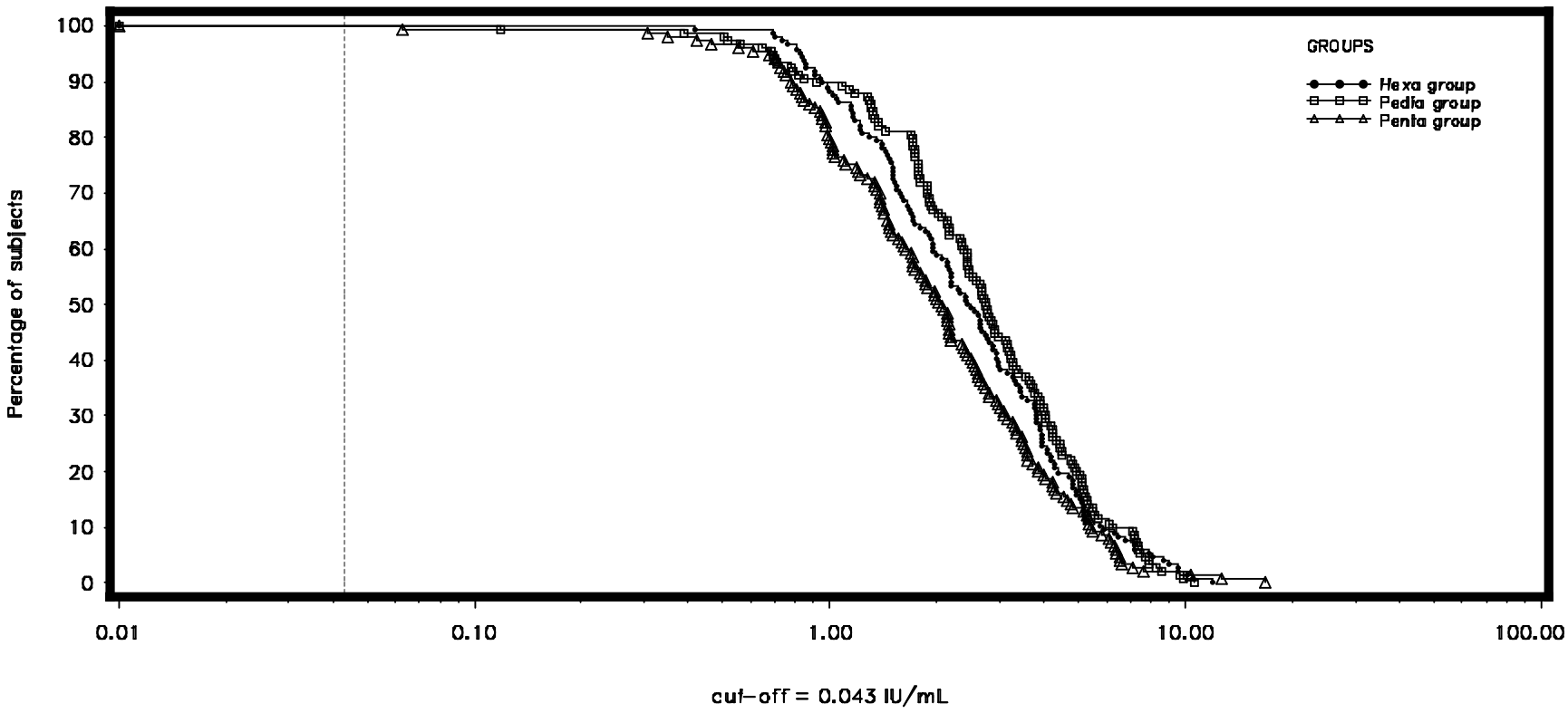
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.4 Reverse cumulative distribution curves for anti-D concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



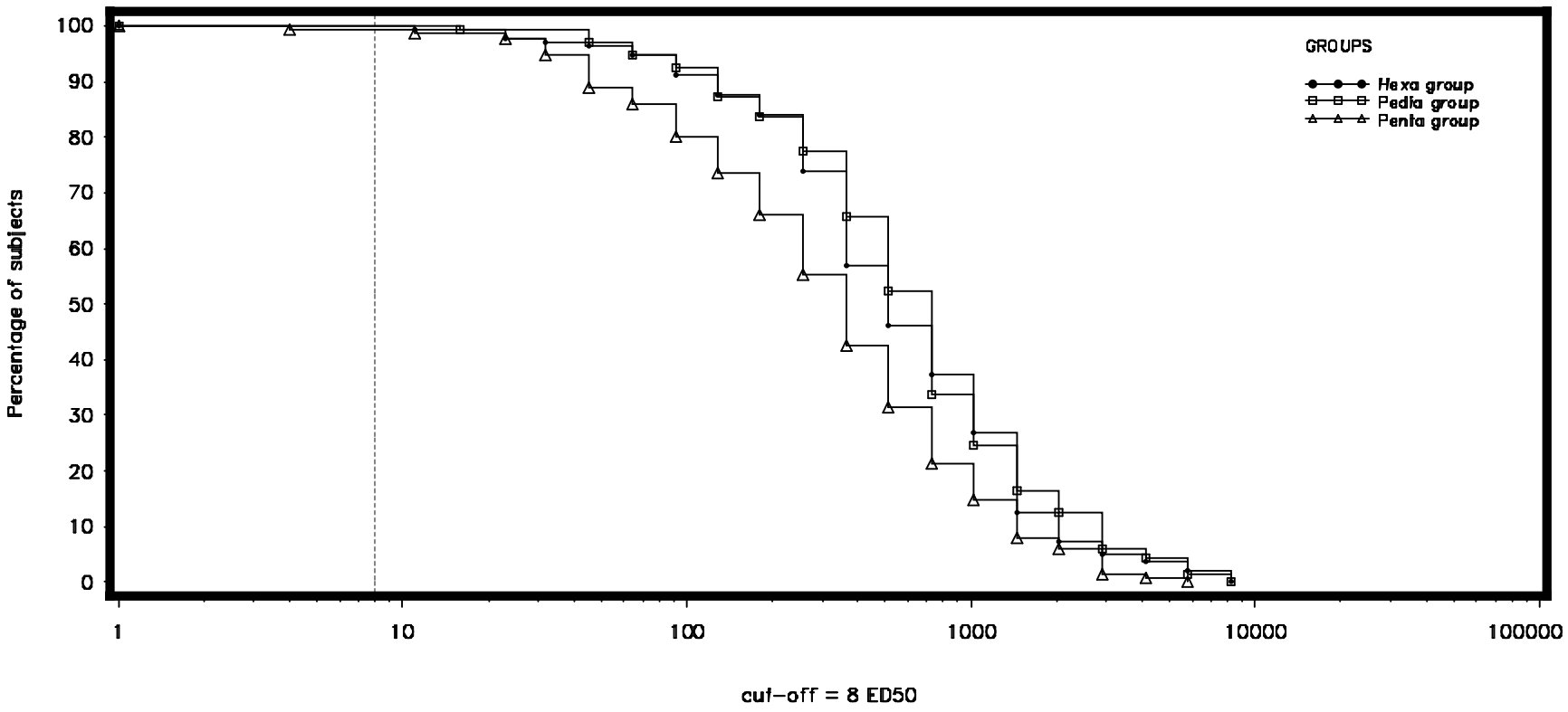
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.5 Reverse cumulative distribution curves for anti-T concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



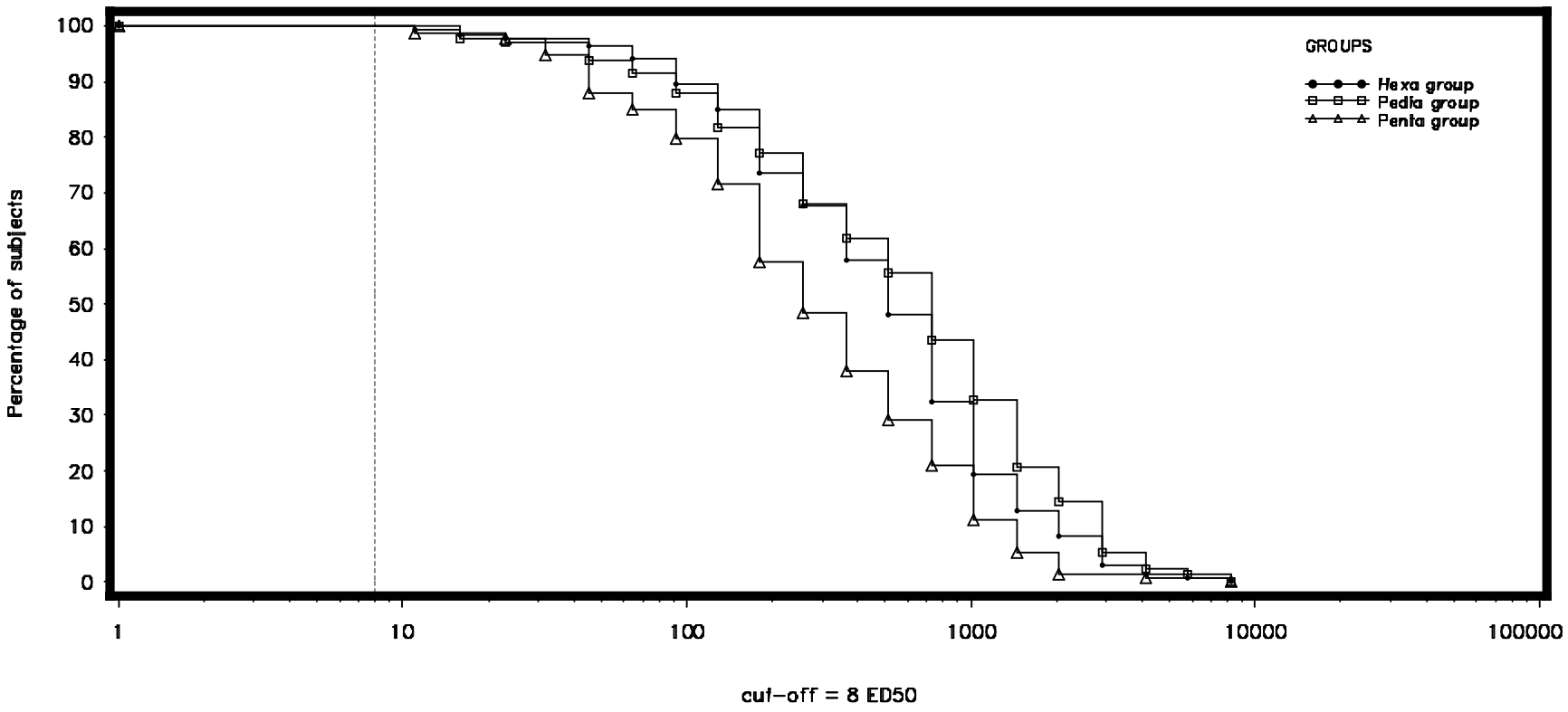
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.6 Reverse cumulative distribution curves for anti-Polio 1 titers one month post primary vaccination (Primary ATP cohort for immunogenicity)



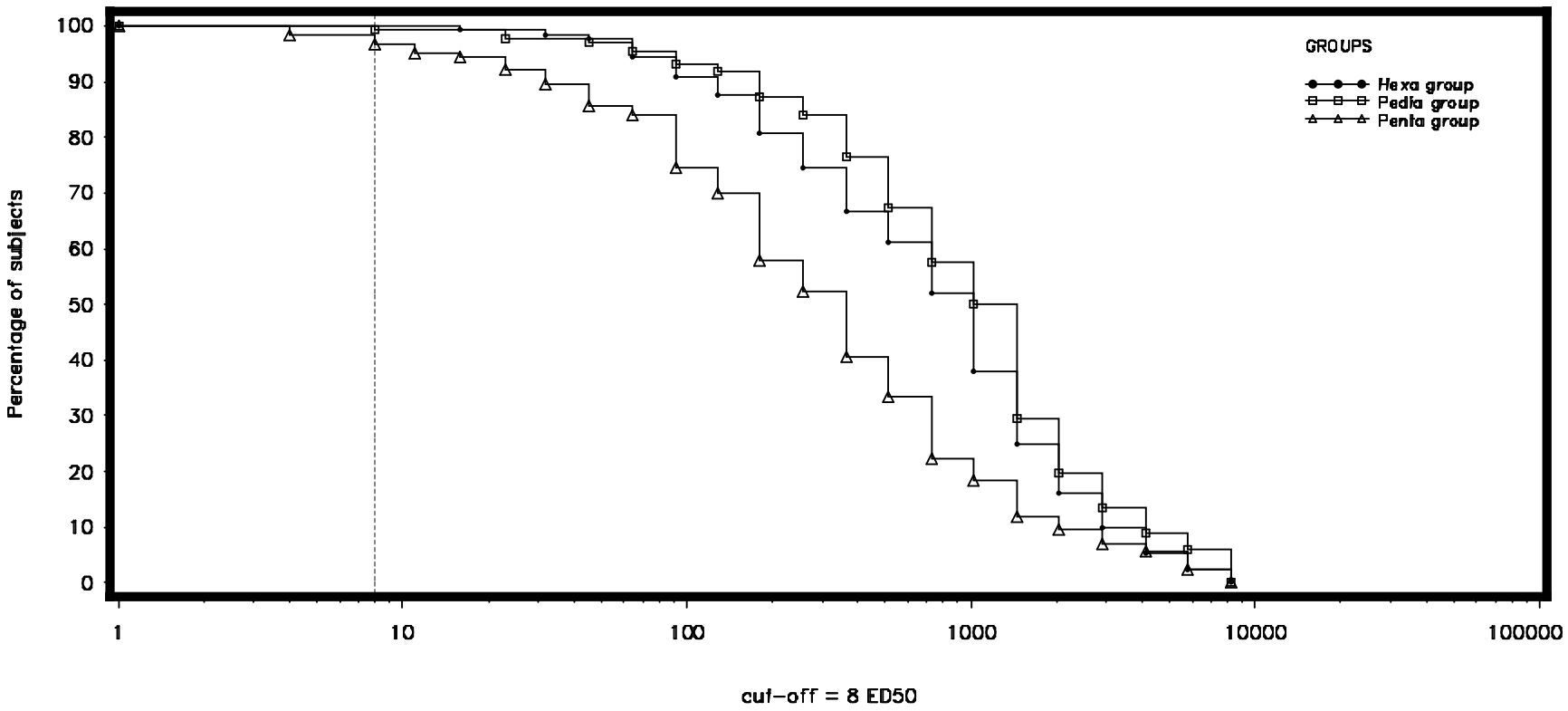
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.7 Reverse cumulative distribution curves for anti-Polio 2 titers one month post primary vaccination (Primary ATP cohort for immunogenicity)



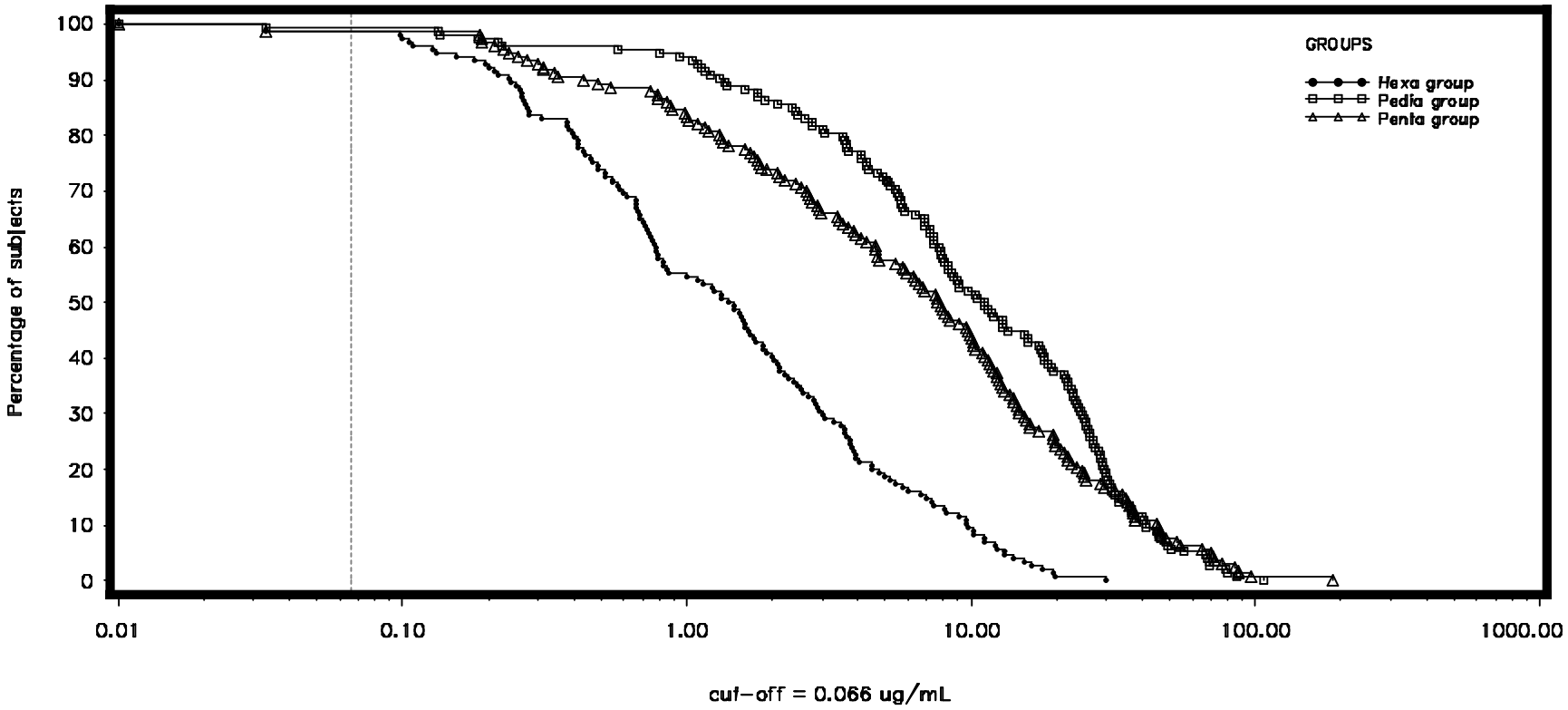
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.8 Reverse cumulative distribution curves for anti-Polio 3 titers one month post primary vaccination (Primary ATP cohort for immunogenicity)



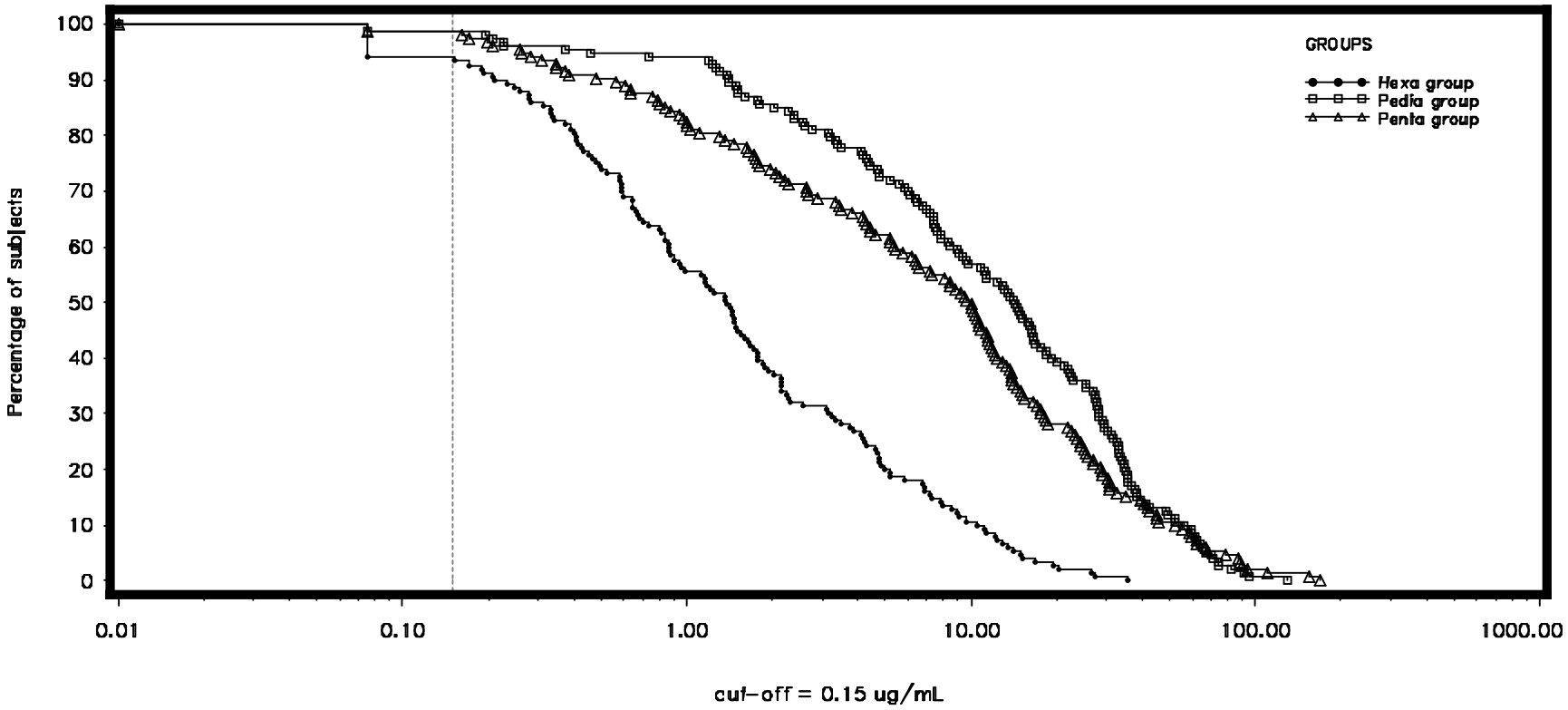
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.9 Reverse cumulative distribution curves for anti-PRP (fully validated assay) concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



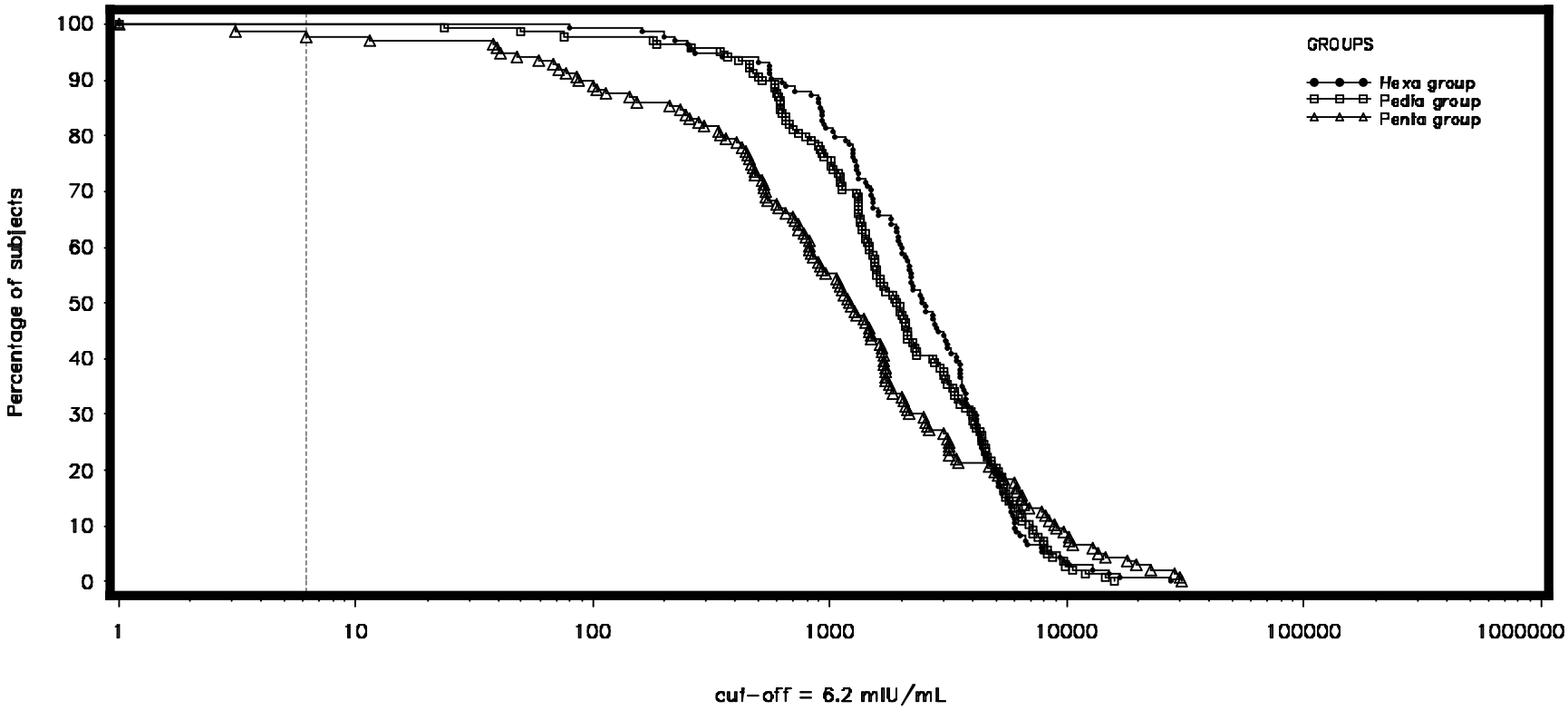
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.10 Reverse cumulative distribution curves for anti-PRP (qualified assay) concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.11 Reverse cumulative distribution curves for anti-HBs concentrations one month post primary vaccination (Primary ATP cohort for immunogenicity)



Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Table 7.18 Ratio of GMCs/GMTs for antibody concentrations/titers between groups (Pedia group divided by Hexa group), one month post primary vaccination (Primary ATP cohort for immunogenicity)

					Adjusted GMC/T ratio (Pedia group / Hexa group)		
	Pedia group		Hexa group			95% CI	
Antibody	N	Adjusted GMC/T	N	Adjusted GMC/T	Value	LL	UL
anti-D antibody (IU/mL)	144	1.629	142	1.795	0.91	0.75	1.09
anti-T antibody (IU/mL)	149	2.635	146	2.454	1.07	0.91	1.27
anti-Polio 1 antibody (ED50)	134	603.4	137	547.2	1.10	0.83	1.47
anti-Polio 2 antibody (ED50)	131	567.0	133	485.8	1.17	0.86	1.58
anti-Polio 3 antibody (ED50)	132	926.5	129	722.8	1.28	0.91	1.81
anti-PRP – qualified assay (µg/mL)	153	10.380	149	1.359	7.64	5.37	10.86
anti-PRP – fully validated assay (µg/mL)	154	9.249	154	1.337	6.92	4.93	9.71

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Table 7.19 Ratio of GMCs/GMTs for antibody concentrations/titers between groups (Penta group divided by Hexa group), one month post primary vaccination (Primary ATP cohort for immunogenicity)

					Adjusted GMC/T ratio (Penta group / Hexa group)		
	Penta group		Hexa group			95% CI	
Antibody	N	Adjusted GMC/T	N	Adjusted GMC/T	Value	LL	UL
anti-PT antibody (IU/mL)	149	24.2	146	43.6	0.55	0.47	0.66
anti-FHA antibody (IU/mL)	149	59.4	146	107.3	0.55	0.47	0.65
anti-PRN antibody (IU/mL)	149	33.2	146	58.2	0.57	0.46	0.71
anti-D antibody (IU/mL)	149	1.251	142	1.795	0.70	0.58	0.84
anti-T antibody (IU/mL)	149	2.014	146	2.454	0.82	0.69	0.97
anti-Polio 1 antibody (ED50)	136	319.6	137	547.2	0.58	0.44	0.78
anti-Polio 2 antibody (ED50)	134	282.1	133	485.8	0.58	0.43	0.79
anti-Polio 3 antibody (ED50)	126	294.5	129	722.8	0.41	0.29	0.58
anti-PRP – qualified assay (µg/mL)	153	6.514	149	1.359	4.79	3.37	6.81
anti-PRP – fully validated assay (µg/mL)	156	5.769	154	1.337	4.32	3.08	6.06

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Table 7.20 Ratio of GMC for anti-HBs antibody concentrations between groups (Pedia group divided by Hexa group), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				Adjusted GMC ratio (Pedia group / Hexa group)		
Pedia group		Hexa group			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
138	1899.9	134	2250.0	0.84	0.61	1.16

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother and Hepatitis B vaccination of the subject
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother and Hepatitis B vaccination history of the subject - pooled variance); LL = lower limit, UL = upper limit

Table 7.21 Ratio of GMC for anti-HBs antibody concentrations between groups (Penta group divided by Hexa group), one month post primary vaccination (Primary ATP cohort for immunogenicity)

				Adjusted GMC ratio (Penta group / Hexa group)		
Penta group		Hexa group			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
136	1049.7	134	2250.0	0.47	0.34	0.64

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother and Hepatitis B vaccination of the subject
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother and Hepatitis B vaccination history of the subject - pooled variance); LL = lower limit, UL = upper limit

Table 7.22 Difference between groups (Pedia group minus Hexa group) in percentage of subjects with antibody concentration/titer equal to or above the proposed cut-off, one month post primary vaccination (Primary ATP cohort for immunogenicity)

								Difference in percentage (Pedia group minus Hexa group)		
		Hexa group			Pedia group				95% CI	
Antibody	**Type**	**N**	**n**	**%**	**N**	**n**	**%**	**%**	**LL**	**UL**
anti-D antibody	0.1 IU/mL	142	142	100	144	144	100	0.00	-2.61	2.64
	1 IU/mL	142	112	78.9	144	105	72.9	-5.96	-15.85	4.01
anti-T antibody	0.1 IU/mL	146	146	100	149	149	100	0.00	-2.52	2.57
	1 IU/mL	146	130	89.0	149	134	89.9	0.89	-6.32	8.18
anti-Polio 1 antibody	8 ED50	137	137	100	134	134	100	0.00	-2.80	2.74
anti-Polio 2 antibody	8 ED50	133	133	100	131	131	100	0.00	-2.86	2.82
anti-Polio 3 antibody	8 ED50	129	129	100	132	132	100	0.00	-2.84	2.90
anti-PRP – qualified assay	0.15 µg/mL	149	140	94.0	153	151	98.7	4.73	0.59	9.95
	1 µg/mL	149	83	55.7	153	144	94.1	38.41	29.52	47.11
anti-PRP – fully validated assay	0.15 µg/mL	154	146	94.8	154	151	98.1	3.25	-1.06	8.23
	1 µg/mL	154	85	55.2	154	145	94.2	38.96	30.17	47.53
anti-HBs antibody	10 mIU/mL	141	141	100	147	147	100	0.00	-2.56	2.66

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines

Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines

N = number of subjects with available results

n/% = number/percentage of subjects with titer and concentration within the specified range

95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.23 Difference between groups (Penta group minus Hexa group) in percentage of subjects with antibody concentration/titer equal to or above the proposed cut-off, one month post primary vaccination (Primary ATP cohort for immunogenicity)

								Difference in percentage (Penta group minus Hexa group)		
		Hexa group			Penta group				95% CI	
Antibody	**Type**	**N**	**n**	**%**	**N**	**n**	**%**	**%**	**LL**	**UL**
anti-D antibody	0.1 IU/mL	142	142	100	149	149	100	0.00	-2.52	2.64
	1 IU/mL	142	112	78.9	149	88	59.1	-19.81	-29.98	-9.26
anti-T antibody	0.1 IU/mL	146	146	100	149	148	99.3	-0.67	-3.71	1.91
	1 IU/mL	146	130	89.0	149	119	79.9	-9.18	-17.57	-0.91
anti-Polio 1 antibody	8 ED50	137	137	100	136	135	99.3	-0.74	-4.06	2.01
anti-Polio 2 antibody	8 ED50	133	133	100	134	134	100	0.00	-2.80	2.82
anti-Polio 3 antibody	8 ED50	129	129	100	126	124	98.4	-1.59	-5.61	1.34
anti-PRP – qualified assay	0.15 µg/mL	149	140	94.0	153	151	98.7	4.73	0.59	9.95
	1 µg/mL	149	83	55.7	153	126	82.4	26.65	16.44	36.44
anti-PRP – fully validated assay	0.15 µg/mL	154	146	94.8	156	154	98.7	3.91	-0.03	8.80
	1 µg/mL	154	85	55.2	156	130	83.3	28.14	18.14	37.71
anti-HBs antibody	10 mIU/mL	141	141	100	146	143	97.9	-2.05	-5.88	0.63

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with available results
n/% = number/percentage of subjects with titer and concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.24 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), before and one month post booster vaccination - by gender (Booster ATP cohort for immunogenicity)

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	Female	PRE-BST	70	55	78.6	67.1	87.5	4.9	4.0	6.1
			POST-BST	72	72	100	95.0	100	73.7	62.4	87.0
		Male	PRE-BST	61	52	85.2	73.8	93.0	5.9	4.7	7.3
			POST-BST	66	66	100	94.6	100	69.0	55.7	85.4
	Pedia group	Female	PRE-BST	45	40	88.9	75.9	96.3	6.8	5.1	9.0
			POST-BST	47	47	100	92.5	100	86.5	66.6	112.5
		Male	PRE-BST	87	74	85.1	75.8	91.8	6.4	5.3	7.8
			POST-BST	89	89	100	95.9	100	88.2	75.4	103.1
	Penta group	Female	PRE-BST	53	29	54.7	40.4	68.4	3.0	2.4	3.8
			POST-BST	57	57	100	93.7	100	50.6	40.4	63.3
		Male	PRE-BST	68	34	50.0	37.6	62.4	3.1	2.4	4.0
			POST-BST	69	69	100	94.8	100	59.9	47.8	75.2
anti-FHA antibody	Hexa group	Female	PRE-BST	70	69	98.6	92.3	100	16.3	13.2	20.2
			POST-BST	72	72	100	95.0	100	190.3	162.4	222.9
		Male	PRE-BST	61	61	100	94.1	100	18.0	14.5	22.5
			POST-BST	66	66	100	94.6	100	183.2	150.3	223.3
	Pedia group	Female	PRE-BST	45	45	100	92.1	100	20.8	15.7	27.6
			POST-BST	47	47	100	92.5	100	255.0	200.3	324.6
		Male	PRE-BST	87	85	97.7	91.9	99.7	22.4	17.8	28.2
			POST-BST	89	89	100	95.9	100	248.0	213.1	288.7
	Penta group	Female	PRE-BST	53	50	94.3	84.3	98.8	8.0	6.1	10.6
			POST-BST	57	57	100	93.7	100	87.3	69.5	109.6
		Male	PRE-BST	68	63	92.6	83.7	97.6	8.1	6.0	10.9
			POST-BST	69	69	100	94.8	100	113.9	91.4	141.9
anti-PRN antibody	Hexa group	Female	PRE-BST	70	59	84.3	73.6	91.9	6.9	5.2	9.2
			POST-BST	71	71	100	94.9	100	221.0	171.5	285.0
		Male	PRE-BST	61	51	83.6	71.9	91.8	6.6	4.8	9.1
			POST-BST	66	65	98.5	91.8	100	194.9	146.4	259.4
	Pedia group	Female	PRE-BST	45	35	77.8	62.9	88.8	5.9	4.0	8.6
			POST-BST	47	47	100	92.5	100	203.6	144.0	287.9
		Male	PRE-BST	87	69	79.3	69.3	87.3	5.2	4.2	6.6
			POST-BST	89	89	100	95.9	100	222.1	172.4	286.3
	Penta group	Female	PRE-BST	53	42	79.2	65.9	89.2	6.2	4.4	8.6
			POST-BST	57	57	100	93.7	100	127.1	96.2	167.8
		Male	PRE-BST	67	49	73.1	60.9	83.2	5.9	4.3	8.0
			POST-BST	68	67	98.5	92.1	100	133.5	97.6	182.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.25 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), before and one month post booster vaccination – by geographical ancestry (Booster ATP cohort for immunogenicity)

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	White Caucasian	PRE-BST	80	67	83.8	73.8	91.1	5.3	4.4	6.4
			POST-BST	84	84	100	95.7	100	61.3	52.1	72.2
		other	PRE-BST	51	40	78.4	64.7	88.7	5.4	4.1	7.0
			POST-BST	54	54	100	93.4	100	90.5	73.1	112.0
	Pedia group	White Caucasian	PRE-BST	86	76	88.4	79.7	94.3	6.3	5.3	7.6
			POST-BST	88	88	100	95.9	100	74.4	62.6	88.5
		other	PRE-BST	46	38	82.6	68.6	92.2	6.9	5.1	9.5
			POST-BST	48	48	100	92.6	100	118.1	97.8	142.7
	Penta group	White Caucasian	PRE-BST	67	33	49.3	36.8	61.8	3.0	2.3	3.8
			POST-BST	70	70	100	94.9	100	47.2	37.8	58.9
		other	PRE-BST	54	30	55.6	41.4	69.1	3.2	2.5	4.1
			POST-BST	56	56	100	93.6	100	68.0	54.5	84.8
anti-FHA antibody	Hexa group	White Caucasian	PRE-BST	80	80	100	95.5	100	16.9	14.0	20.2
			POST-BST	84	84	100	95.7	100	163.1	140.6	189.2
		other	PRE-BST	51	50	98.0	89.6	100	17.5	13.4	22.9
			POST-BST	54	54	100	93.4	100	230.8	187.0	285.0
	Pedia group	White Caucasian	PRE-BST	86	84	97.7	91.9	99.7	20.7	16.5	25.9
			POST-BST	88	88	100	95.9	100	213.1	179.9	252.4
		other	PRE-BST	46	46	100	92.3	100	24.3	18.1	32.4
			POST-BST	48	48	100	92.6	100	336.7	286.0	396.4
	Penta group	White Caucasian	PRE-BST	67	63	94.0	85.4	98.3	7.0	5.5	9.1
			POST-BST	70	70	100	94.9	100	72.9	60.0	88.5
		other	PRE-BST	54	50	92.6	82.1	97.9	9.5	6.8	13.3
			POST-BST	56	56	100	93.6	100	151.8	121.6	189.6
anti-PRN antibody	Hexa group	White Caucasian	PRE-BST	80	66	82.5	72.4	90.1	6.1	4.7	7.9
			POST-BST	84	83	98.8	93.5	100	191.2	149.2	245.0
		other	PRE-BST	51	44	86.3	73.7	94.3	8.0	5.6	11.2
			POST-BST	53	53	100	93.3	100	237.7	177.1	319.1
	Pedia group	White Caucasian	PRE-BST	86	67	77.9	67.7	86.1	5.0	4.0	6.3
			POST-BST	88	88	100	95.9	100	183.6	142.4	236.8
		other	PRE-BST	46	37	80.4	66.1	90.6	6.4	4.5	9.2
			POST-BST	48	48	100	92.6	100	289.2	208.2	401.6
	Penta group	White Caucasian	PRE-BST	66	44	66.7	54.0	77.8	4.7	3.5	6.3
			POST-BST	69	68	98.6	92.2	100	131.5	98.6	175.5
		other	PRE-BST	54	47	87.0	75.1	94.6	8.1	5.9	11.3
			POST-BST	56	56	100	93.6	100	129.2	94.5	176.8

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.26 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), before and one month post booster vaccination – by Tdap vaccination of mother (Booster ATP cohort for immunogenicity)

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	77	58	75.3	64.2	84.4	4.5	3.7	5.5
			POST-BST	79	79	100	95.4	100	61.1	51.2	72.9
		Tdap Vaccination No	PRE-BST	31	29	93.5	78.6	99.2	7.2	5.4	9.5
			POST-BST	34	34	100	89.7	100	95.2	71.7	126.3
		Tdap Vaccination Missing	PRE-BST	23	20	87.0	66.4	97.2	6.2	4.2	9.1
			POST-BST	25	25	100	86.3	100	79.0	61.0	102.4
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	61	83.6	73.0	91.2	6.0	4.8	7.4
			POST-BST	73	73	100	95.1	100	76.6	63.8	91.9
		Tdap Vaccination No	PRE-BST	34	32	94.1	80.3	99.3	7.6	5.8	9.9
			POST-BST	34	34	100	89.7	100	126.8	102.0	157.7
		Tdap Vaccination Missing	PRE-BST	25	21	84.0	63.9	95.5	6.9	4.4	10.7
			POST-BST	29	29	100	88.1	100	79.6	56.8	111.5
	Penta group	Tdap Vaccination Yes	PRE-BST	69	34	49.3	37.0	61.6	2.7	2.2	3.4
			POST-BST	72	72	100	95.0	100	47.9	38.9	59.0
		Tdap Vaccination No	PRE-BST	39	25	64.1	47.2	78.8	4.2	2.9	6.0
			POST-BST	39	39	100	91.0	100	68.6	50.4	93.4
		Tdap Vaccination Missing	PRE-BST	13	4	30.8	9.1	61.4	2.3	1.3	4.0
			POST-BST	15	15	100	78.2	100	65.2	43.6	97.5
anti-FHA antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	77	77	100	95.3	100	14.9	12.4	17.9
			POST-BST	79	79	100	95.4	100	172.7	145.5	205.0
		Tdap Vaccination No	PRE-BST	31	31	100	88.8	100	23.8	18.2	31.1
			POST-BST	34	34	100	89.7	100	234.0	183.7	298.0
		Tdap Vaccination Missing	PRE-BST	23	22	95.7	78.1	99.9	17.3	10.7	28.1
			POST-BST	25	25	100	86.3	100	176.5	134.2	232.2
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	71	97.3	90.5	99.7	18.3	14.2	23.4
			POST-BST	73	73	100	95.1	100	211.2	178.4	250.0
		Tdap Vaccination No	PRE-BST	34	34	100	89.7	100	33.2	25.4	43.5
			POST-BST	34	34	100	89.7	100	349.2	290.7	419.5
		Tdap Vaccination Missing	PRE-BST	25	25	100	86.3	100	20.8	13.3	32.5
			POST-BST	29	29	100	88.1	100	260.5	183.0	370.7
	Penta group	Tdap Vaccination Yes	PRE-BST	69	63	91.3	82.0	96.7	7.2	5.4	9.5
			POST-BST	72	72	100	95.0	100	82.7	67.2	101.8
		Tdap Vaccination No	PRE-BST	39	39	100	91.0	100	10.6	7.8	14.6
			POST-BST	39	39	100	91.0	100	147.0	112.9	191.3
		Tdap Vaccination Missing	PRE-BST	13	11	84.6	54.6	98.1	6.5	3.3	13.1
			POST-BST	15	15	100	78.2	100	99.4	60.4	163.6
anti-PRN antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	77	62	80.5	69.9	88.7	5.6	4.3	7.3
			POST-BST	79	78	98.7	93.1	100	199.2	154.2	257.3
		Tdap Vaccination No	PRE-BST	31	30	96.8	83.3	99.9	11.7	7.6	17.8
			POST-BST	33	33	100	89.4	100	253.9	184.9	348.6
		Tdap Vaccination Missing	PRE-BST	23	18	78.3	56.3	92.5	6.2	3.7	10.4

					≥ cut_off				GMC		
							95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
			POST-BST	25	25	100	86.3	100	183.3	107.8	311.9
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	50	68.5	56.6	78.9	4.1	3.2	5.4
			POST-BST	73	73	100	95.1	100	192.4	142.5	259.6
		Tdap Vaccination No	PRE-BST	34	31	91.2	76.3	98.1	8.3	5.7	12.2
			POST-BST	34	34	100	89.7	100	258.4	184.0	362.9
		Tdap Vaccination Missing	PRE-BST	25	23	92.0	74.0	99.0	6.9	4.6	10.4
			POST-BST	29	29	100	88.1	100	232.1	147.8	364.5
	Penta group	Tdap Vaccination Yes	PRE-BST	69	49	71.0	58.8	81.3	5.3	3.9	7.2
			POST-BST	72	71	98.6	92.5	100	146.4	111.0	193.1
		Tdap Vaccination No	PRE-BST	38	31	81.6	65.7	92.3	6.0	4.1	8.9
			POST-BST	38	38	100	90.7	100	109.9	74.4	162.5
		Tdap Vaccination Missing	PRE-BST	13	11	84.6	54.6	98.1	11.0	5.3	22.8
			POST-BST	15	15	100	78.2	100	116.0	59.9	224.8

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.27 Booster response for anti-PT, anti-FHA and anti-PRN antibodies, one month post booster vaccination - by gender (Booster ATP cohort for immunogenicity)

					Booster response			
							95% CI	
Antibody	Group	Sub-group	Pre-vaccination status	N	n	%	LL	UL
anti-PT antibody (IU/mL)	Hexa group	Female	S-	15	15	100	78.2	100
			S+ (<4*cut_off IU/mL)	41	40	97.6	87.1	99.9
			S+ (≥4*cut_off IU/mL)	14	14	100	76.8	100
			Total	70	69	98.6	92.3	100
		Male	S-	9	7	77.8	40.0	97.2
			S+ (<4*cut_off IU/mL)	37	35	94.6	81.8	99.3
			S+ (≥4*cut_off IU/mL)	15	15	100	78.2	100
			Total	61	57	93.4	84.1	98.2
	Pedia group	Female	S-	5	5	100	47.8	100
			S+ (<4*cut_off IU/mL)	29	27	93.1	77.2	99.2
			S+ (≥4*cut_off IU/mL)	11	10	90.9	58.7	99.8
			Total	45	42	93.3	81.7	98.6
		Male	S-	13	13	100	75.3	100
			S+ (<4*cut_off IU/mL)	57	54	94.7	85.4	98.9
			S+ (≥4*cut_off IU/mL)	15	12	80.0	51.9	95.7
			Total	85	79	92.9	85.3	97.4
	Penta group	Female	S-	24	23	95.8	78.9	99.9
			S+ (<4*cut_off IU/mL)	22	22	100	84.6	100
			S+ (≥4*cut_off IU/mL)	6	6	100	54.1	100
			Total	52	51	98.1	89.7	100
		Male	S-	32	29	90.6	75.0	98.0
			S+ (<4*cut_off IU/mL)	24	23	95.8	78.9	99.9
			S+ (≥4*cut_off IU/mL)	8	8	100	63.1	100
			Total	64	60	93.8	84.8	98.3
anti-FHA antibody (IU/mL)	Hexa group	Female	S-	1	1	100	2.5	100
			S+ (<4*cut_off IU/mL)	15	15	100	78.2	100
			S+ (≥4*cut_off IU/mL)	54	54	100	93.4	100
			Total	70	70	100	94.9	100
		Male	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	12	12	100	73.5	100
			S+ (≥4*cut_off IU/mL)	49	48	98.0	89.1	99.9
			Total	61	60	98.4	91.2	100
	Pedia group	Female	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	5	5	100	47.8	100
			S+ (≥4*cut_off IU/mL)	40	39	97.5	86.8	99.9
			Total	45	44	97.8	88.2	99.9
		Male	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	12	12	100	73.5	100
			S+ (≥4*cut_off IU/mL)	71	69	97.2	90.2	99.7
			Total	85	83	97.6	91.8	99.7
	Penta group	Female	S-	3	3	100	29.2	100
			S+ (<4*cut_off IU/mL)	23	23	100	85.2	100
			S+ (≥4*cut_off IU/mL)	26	25	96.2	80.4	99.9
			Total	52	51	98.1	89.7	100
		Male	S-	5	5	100	47.8	100
			S+ (<4*cut_off IU/mL)	34	33	97.1	84.7	99.9
			S+ (≥4*cut_off IU/mL)	25	25	100	86.3	100
			Total	64	63	98.4	91.6	100

					Booster response			
							95% CI	
Antibody	Group	Sub-group	Pre-vaccination status	N	n	%	LL	UL
anti-PRN antibody (IU/mL)	Hexa group	Female	S-	11	11	100	71.5	100
			S+ (<4*cut_off IU/mL)	29	29	100	88.1	100
			S+ (≥4*cut_off IU/mL)	29	28	96.6	82.2	99.9
			Total	69	68	98.6	92.2	100
		Male	S-	10	9	90.0	55.5	99.7
			S+ (<4*cut_off IU/mL)	25	25	100	86.3	100
			S+ (≥4*cut_off IU/mL)	26	26	100	86.8	100
			Total	61	60	98.4	91.2	100
	Pedia group	Female	S-	10	10	100	69.2	100
			S+ (<4*cut_off IU/mL)	16	16	100	79.4	100
			S+ (≥4*cut_off IU/mL)	19	19	100	82.4	100
			Total	45	45	100	92.1	100
		Male	S-	18	17	94.4	72.7	99.9
			S+ (<4*cut_off IU/mL)	39	38	97.4	86.5	99.9
			S+ (≥4*cut_off IU/mL)	28	28	100	87.7	100
			Total	85	83	97.6	91.8	99.7
	Penta group	Female	S-	11	11	100	71.5	100
			S+ (<4*cut_off IU/mL)	21	21	100	83.9	100
			S+ (≥4*cut_off IU/mL)	20	20	100	83.2	100
			Total	52	52	100	93.2	100
		Male	S-	17	15	88.2	63.6	98.5
			S+ (<4*cut_off IU/mL)	19	18	94.7	74.0	99.9
			S+ (≥4*cut_off IU/mL)	27	27	100	87.2	100
			Total	63	60	95.2	86.7	99.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Booster response to PT, FHA and PRN antigens is defined as:
For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration = 4 times the assay cut-off,
For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration,
For subjects with pre-vaccination antibody concentration equal or above 4 times the assay cut off, post-vaccination antibody concentration equal or above 2 times the pre-vaccination antibody concentration
N = number of subjects with pre- and post-vaccination results available
n/% = number/percentage of subjects with booster response
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.28 Booster response for anti-PT, anti-FHA and anti-PRN antibodies, one month post booster vaccination – by geographical ancestry (Booster ATP cohort for immunogenicity)

					Booster response			
							95% CI	
Antibody	Group	Sub-group	Pre-vaccination status	N	n	%	LL	UL
anti-PT antibody (IU/mL)	Hexa group	White Caucasian	S-	13	12	92.3	64.0	99.8
			S+ (<4*cut_off IU/mL)	51	48	94.1	83.8	98.8
			S+ (≥4*cut_off IU/mL)	16	16	100	79.4	100
			Total	80	76	95.0	87.7	98.6
		other	S-	11	10	90.9	58.7	99.8
			S+ (<4*cut_off IU/mL)	27	27	100	87.2	100
			S+ (≥4*cut_off IU/mL)	13	13	100	75.3	100
			Total	51	50	98.0	89.6	100
	Pedia group	White Caucasian	S-	10	10	100	69.2	100
			S+ (<4*cut_off IU/mL)	62	57	91.9	82.2	97.3
			S+ (≥4*cut_off IU/mL)	12	9	75.0	42.8	94.5
			Total	84	76	90.5	82.1	95.8
		other	S-	8	8	100	63.1	100
			S+ (<4*cut_off IU/mL)	24	24	100	85.8	100
			S+ (≥4*cut_off IU/mL)	14	13	92.9	66.1	99.8
			Total	46	45	97.8	88.5	99.9
	Penta group	White Caucasian	S-	33	29	87.9	71.8	96.6
			S+ (<4*cut_off IU/mL)	24	23	95.8	78.9	99.9
			S+ (≥4*cut_off IU/mL)	8	8	100	63.1	100
			Total	65	60	92.3	83.0	97.5
		other	S-	23	23	100	85.2	100
			S+ (<4*cut_off IU/mL)	22	22	100	84.6	100
			S+ (≥4*cut_off IU/mL)	6	6	100	54.1	100
			Total	51	51	100	93.0	100
anti-FHA antibody (IU/mL)	Hexa group	White Caucasian	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	16	16	100	79.4	100
			S+ (≥4*cut_off IU/mL)	64	63	98.4	91.6	100
			Total	80	79	98.8	93.2	100
		other	S-	1	1	100	2.5	100
			S+ (<4*cut_off IU/mL)	11	11	100	71.5	100
			S+ (≥4*cut_off IU/mL)	39	39	100	91.0	100
			Total	51	51	100	93.0	100
	Pedia group	White Caucasian	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	12	12	100	73.5	100
			S+ (≥4*cut_off IU/mL)	70	68	97.1	90.1	99.7
			Total	84	82	97.6	91.7	99.7
		other	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	5	5	100	47.8	100
			S+ (≥4*cut_off IU/mL)	41	40	97.6	87.1	99.9
			Total	46	45	97.8	88.5	99.9
	Penta group	White Caucasian	S-	4	4	100	39.8	100
			S+ (<4*cut_off IU/mL)	33	32	97.0	84.2	99.9
			S+ (≥4*cut_off IU/mL)	28	27	96.4	81.7	99.9
			Total	65	63	96.9	89.3	99.6
		other	S-	4	4	100	39.8	100
			S+ (<4*cut_off IU/mL)	24	24	100	85.8	100
			S+ (≥4*cut_off IU/mL)	23	23	100	85.2	100
			Total	51	51	100	93.0	100

					Booster response			
							95% CI	
Antibody	**Group**	**Sub-group**	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
anti-PRN antibody (IU/mL)	Hexa group	White Caucasian	S-	14	13	92.9	66.1	99.8
			S+ (<4*cut_off IU/mL)	33	33	100	89.4	100
			S+ (≥4*cut_off IU/mL)	33	33	100	89.4	100
			Total	80	79	98.8	93.2	100
		other	S-	7	7	100	59.0	100
			S+ (<4*cut_off IU/mL)	21	21	100	83.9	100
			S+ (≥4*cut_off IU/mL)	22	21	95.5	77.2	99.9
			Total	50	49	98.0	89.4	99.9
	Pedia group	White Caucasian	S-	19	18	94.7	74.0	99.9
			S+ (<4*cut_off IU/mL)	38	37	97.4	86.2	99.9
			S+ (≥4*cut_off IU/mL)	27	27	100	87.2	100
			Total	84	82	97.6	91.7	99.7
		other	S-	9	9	100	66.4	100
			S+ (<4*cut_off IU/mL)	17	17	100	80.5	100
			S+ (≥4*cut_off IU/mL)	20	20	100	83.2	100
			Total	46	46	100	92.3	100
	Penta group	White Caucasian	S-	21	19	90.5	69.6	98.8
			S+ (<4*cut_off IU/mL)	20	19	95.0	75.1	99.9
			S+ (≥4*cut_off IU/mL)	23	23	100	85.2	100
			Total	64	61	95.3	86.9	99.0
		other	S-	7	7	100	59.0	100
			S+ (<4*cut_off IU/mL)	20	20	100	83.2	100
			S+ (≥4*cut_off IU/mL)	24	24	100	85.8	100
			Total	51	51	100	93.0	100

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Booster response to PT, FHA and PRN antigens is defined as:
For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration = 4 times the assay cut-off,
For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration,
For subjects with pre-vaccination antibody concentration equal or above 4 times the assay cut off, post-vaccination antibody concentration equal or above 2 times the pre-vaccination antibody concentration
N = number of subjects with pre- and post-vaccination results available
n/% = number/percentage of subjects with booster response
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.29 Booster response for anti-PT, anti-FHA and anti-PRN antibodies, one month post booster vaccination – by Tdap vaccination of mother (Booster ATP cohort for immunogenicity)

					Booster response			
							95% CI	
Antibody	Group	Sub-group	Pre-vaccination status	N	n	%	LL	UL
anti-PT antibody (IU/mL)	Hexa group	Tdap Vaccination Yes	S-	19	17	89.5	66.9	98.7
			S+ (<4*cut_off IU/mL)	44	43	97.7	88.0	99.9
			S+ (≥4*cut_off IU/mL)	14	14	100	76.8	100
			Total	77	74	96.1	89.0	99.2
		Tdap Vaccination No	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	20	19	95.0	75.1	99.9
			S+ (≥4*cut_off IU/mL)	9	9	100	66.4	100
			Total	31	30	96.8	83.3	99.9
		Tdap Vaccination Missing	S-	3	3	100	29.2	100
			S+ (<4*cut_off IU/mL)	14	13	92.9	66.1	99.8
			S+ (≥4*cut_off IU/mL)	6	6	100	54.1	100
			Total	23	22	95.7	78.1	99.9
	Pedia group	Tdap Vaccination Yes	S-	12	12	100	73.5	100
			S+ (<4*cut_off IU/mL)	45	40	88.9	75.9	96.3
			S+ (≥4*cut_off IU/mL)	15	13	86.7	59.5	98.3
			Total	72	65	90.3	81.0	96.0
		Tdap Vaccination No	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	26	26	100	86.8	100
			S+ (≥4*cut_off IU/mL)	5	5	100	47.8	100
			Total	33	33	100	89.4	100
		Tdap Vaccination Missing	S-	4	4	100	39.8	100
			S+ (<4*cut_off IU/mL)	15	15	100	78.2	100
			S+ (≥4*cut_off IU/mL)	6	4	66.7	22.3	95.7
			Total	25	23	92.0	74.0	99.0
	Penta group	Tdap Vaccination Yes	S-	34	31	91.2	76.3	98.1
			S+ (<4*cut_off IU/mL)	27	26	96.3	81.0	99.9
			S+ (≥4*cut_off IU/mL)	7	7	100	59.0	100
			Total	68	64	94.1	85.6	98.4
		Tdap Vaccination No	S-	13	12	92.3	64.0	99.8
			S+ (<4*cut_off IU/mL)	16	16	100	79.4	100
			S+ (≥4*cut_off IU/mL)	6	6	100	54.1	100
			Total	35	34	97.1	85.1	99.9
		Tdap Vaccination Missing	S-	9	9	100	66.4	100
			S+ (<4*cut_off IU/mL)	3	3	100	29.2	100
			S+ (≥4*cut_off IU/mL)	1	1	100	2.5	100
			Total	13	13	100	75.3	100
anti-FHA antibody (IU/mL)	Hexa group	Tdap Vaccination Yes	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	20	20	100	83.2	100
			S+ (≥4*cut_off IU/mL)	57	57	100	93.7	100
			Total	77	77	100	95.3	100
		Tdap Vaccination No	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	3	3	100	29.2	100
			S+ (≥4*cut_off IU/mL)	28	28	100	87.7	100
			Total	31	31	100	88.8	100
		Tdap Vaccination Missing	S-	1	1	100	2.5	100
			S+ (<4*cut_off IU/mL)	4	4	100	39.8	100
			S+ (≥4*cut_off IU/mL)	18	17	94.4	72.7	99.9
			Total	23	22	95.7	78.1	99.9

					Booster response			
							95% CI	
Antibody	**Group**	**Sub-group**	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
	Pedia group	Tdap Vaccination Yes	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	11	11	100	71.5	100
			S+ (≥4*cut_off IU/mL)	59	57	96.6	88.3	99.6
			Total	72	70	97.2	90.3	99.7
		Tdap Vaccination No	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	0	-	-	-	-
			S+ (≥4*cut_off IU/mL)	33	33	100	89.4	100
			Total	33	33	100	89.4	100
		Tdap Vaccination Missing	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	6	6	100	54.1	100
			S+ (≥4*cut_off IU/mL)	19	18	94.7	74.0	99.9
			Total	25	24	96.0	79.6	99.9
	Penta group	Tdap Vaccination Yes	S-	6	6	100	54.1	100
			S+ (<4*cut_off IU/mL)	36	35	97.2	85.5	99.9
			S+ (≥4*cut_off IU/mL)	26	25	96.2	80.4	99.9
			Total	68	66	97.1	89.8	99.6
		Tdap Vaccination No	S-	0	-	-	-	-
			S+ (<4*cut_off IU/mL)	15	15	100	78.2	100
			S+ (≥4*cut_off IU/mL)	20	20	100	83.2	100
			Total	35	35	100	90.0	100
		Tdap Vaccination Missing	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	6	6	100	54.1	100
			S+ (≥4*cut_off IU/mL)	5	5	100	47.8	100
			Total	13	13	100	75.3	100
anti-PRN antibody (IU/mL)	Hexa group	Tdap Vaccination Yes	S-	15	14	93.3	68.1	99.8
			S+ (<4*cut_off IU/mL)	33	33	100	89.4	100
			S+ (≥4*cut_off IU/mL)	29	29	100	88.1	100
			Total	77	76	98.7	93.0	100
		Tdap Vaccination No	S-	1	1	100	2.5	100
			S+ (<4*cut_off IU/mL)	11	11	100	71.5	100
			S+ (≥4*cut_off IU/mL)	18	17	94.4	72.7	99.9
			Total	30	29	96.7	82.8	99.9
		Tdap Vaccination Missing	S-	5	5	100	47.8	100
			S+ (<4*cut_off IU/mL)	10	10	100	69.2	100
			S+ (≥4*cut_off IU/mL)	8	8	100	63.1	100
			Total	23	23	100	85.2	100
	Pedia group	Tdap Vaccination Yes	S-	23	22	95.7	78.1	99.9
			S+ (<4*cut_off IU/mL)	32	31	96.9	83.8	99.9
			S+ (≥4*cut_off IU/mL)	17	17	100	80.5	100
			Total	72	70	97.2	90.3	99.7
		Tdap Vaccination No	S-	3	3	100	29.2	100
			S+ (<4*cut_off IU/mL)	12	12	100	73.5	100
			S+ (≥4*cut_off IU/mL)	18	18	100	81.5	100
			Total	33	33	100	89.4	100
		Tdap Vaccination Missing	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	11	11	100	71.5	100
			S+ (≥4*cut_off IU/mL)	12	12	100	73.5	100
			Total	25	25	100	86.3	100
	Penta group	Tdap Vaccination Yes	S-	20	19	95.0	75.1	99.9
			S+ (<4*cut_off IU/mL)	26	26	100	86.8	100
			S+ (≥4*cut_off IU/mL)	22	22	100	84.6	100
			Total	68	67	98.5	92.1	100

					Booster response			
							95% CI	
Antibody	**Group**	**Sub-group**	**Pre-vaccination status**	**N**	**n**	**%**	**LL**	**UL**
		Tdap Vaccination No	S-	6	5	83.3	35.9	99.6
			S+ (<4*cut_off IU/mL)	13	12	92.3	64.0	99.8
			S+ (≥4*cut_off IU/mL)	15	15	100	78.2	100
			Total	34	32	94.1	80.3	99.3
		Tdap Vaccination Missing	S-	2	2	100	15.8	100
			S+ (<4*cut_off IU/mL)	1	1	100	2.5	100
			S+ (≥4*cut_off IU/mL)	10	10	100	69.2	100
			Total	13	13	100	75.3	100

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Booster response to PT, FHA and PRN antigens is defined as:
For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration = 4 times the assay cut-off,
For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration,
For subjects with pre-vaccination antibody concentration equal or above 4 times the assay cut off, post-vaccination antibody concentration equal or above 2 times the pre-vaccination antibody concentration
N = number of subjects with pre- and post-vaccination results available
n/% = number/percentage of subjects with booster response
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.30 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), before and one month post booster vaccination - by gender (Booster ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	Female	PRE-BST	70	70	100	94.9	100	68	97.1	90.1	99.7	22	31.4	20.9	43.6	0.716	0.577	0.887
			POST-BST	72	72	100	95.0	100	72	100	95.0	100	72	100	95.0	100	8.447	7.344	9.715
		Male	PRE-BST	61	61	100	94.1	100	60	98.4	91.2	100	21	34.4	22.7	47.7	0.685	0.533	0.882
			POST-BST	66	66	100	94.6	100	66	100	94.6	100	66	100	94.6	100	8.212	6.922	9.742
	Pedia group	Female	PRE-BST	45	44	97.8	88.2	99.9	41	91.1	78.8	97.5	19	42.2	27.7	57.8	0.716	0.517	0.993
			POST-BST	47	47	100	92.5	100	47	100	92.5	100	47	100	92.5	100	8.905	7.226	10.974
		Male	PRE-BST	87	85	97.7	91.9	99.7	82	94.3	87.1	98.1	29	33.3	23.6	44.3	0.578	0.455	0.734
			POST-BST	89	89	100	95.9	100	89	100	95.9	100	89	100	95.9	100	7.395	6.341	8.625
	Penta group	Female	PRE-BST	53	52	98.1	89.9	100	52	98.1	89.9	100	26	49.1	35.1	63.2	0.939	0.711	1.240
			POST-BST	57	57	100	93.7	100	57	100	93.7	100	57	100	93.7	100	9.335	7.752	11.242
		Male	PRE-BST	68	66	97.1	89.8	99.6	63	92.6	83.7	97.6	25	36.8	25.4	49.3	0.650	0.496	0.852
			POST-BST	69	69	100	94.8	100	69	100	94.8	100	69	100	94.8	100	7.930	6.660	9.442
anti-T antibody	Hexa group	Female	PRE-BST	70	70	100	94.9	100	64	91.4	82.3	96.8	6	8.6	3.2	17.7	0.313	0.260	0.376
			POST-BST	72	72	100	95.0	100	72	100	95.0	100	72	100	95.0	100	9.240	7.500	11.383
		Male	PRE-BST	61	60	98.4	91.2	100	54	88.5	77.8	95.3	10	16.4	8.2	28.1	0.344	0.268	0.442
			POST-BST	66	66	100	94.6	100	66	100	94.6	100	66	100	94.6	100	9.182	7.177	11.747
	Pedia group	Female	PRE-BST	45	44	97.8	88.2	99.9	42	93.3	81.7	98.6	6	13.3	5.1	26.8	0.366	0.278	0.484
			POST-BST	47	47	100	92.5	100	47	100	92.5	100	45	95.7	85.5	99.5	8.289	6.318	10.876
		Male	PRE-BST	87	85	97.7	91.9	99.7	81	93.1	85.6	97.4	11	12.6	6.5	21.5	0.421	0.341	0.519
			POST-BST	89	89	100	95.9	100	89	100	95.9	100	88	98.9	93.9	100	9.193	7.727	10.939
	Penta group	Female	PRE-BST	53	52	98.1	89.9	100	48	90.6	79.3	96.9	8	15.1	6.7	27.6	0.348	0.263	0.461
			POST-BST	57	57	100	93.7	100	57	100	93.7	100	57	100	93.7	100	6.754	5.545	8.226

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
		Male	PRE-BST	68	67	98.5	92.1	100	59	86.8	76.4	93.8	11	16.2	8.4	27.1	0.333	0.256	0.433
			POST-BST	69	69	100	94.8	100	68	98.6	92.2	100	68	98.6	92.2	100	6.986	5.546	8.800

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.31 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), before and one month post booster vaccination – by geographical anc (Booster ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	White Caucasian	PRE-BST	80	80	100	95.5	100	77	96.3	89.4	99.2	21	26.3	17.0	37.3	0.589	0.472	0.735
			POST-BST	84	84	100	95.7	100	84	100	95.7	100	84	100	95.7	100	7.883	6.838	9.087
		other	PRE-BST	51	51	100	93.0	100	51	100	93.0	100	22	43.1	29.3	57.8	0.922	0.742	1.145
			POST-BST	54	54	100	93.4	100	54	100	93.4	100	54	100	93.4	100	9.087	7.674	10.760
	Pedia group	White Caucasian	PRE-BST	86	83	96.5	90.1	99.3	79	91.9	83.9	96.7	27	31.4	21.8	42.3	0.517	0.406	0.660
			POST-BST	88	88	100	95.9	100	88	100	95.9	100	88	100	95.9	100	6.736	5.785	7.845
		other	PRE-BST	46	46	100	92.3	100	44	95.7	85.2	99.5	21	45.7	30.9	61.0	0.876	0.655	1.172
			POST-BST	48	48	100	92.6	100	48	100	92.6	100	48	100	92.6	100	10.526	8.705	12.728
	Penta group	White Caucasian	PRE-BST	67	65	97.0	89.6	99.6	62	92.5	83.4	97.5	25	37.3	25.8	50.0	0.660	0.494	0.884
			POST-BST	70	70	100	94.9	100	70	100	94.9	100	70	100	94.9	100	7.672	6.432	9.151
		other	PRE-BST	54	53	98.1	90.1	100	53	98.1	90.1	100	26	48.1	34.3	62.2	0.915	0.715	1.171
			POST-BST	56	56	100	93.6	100	56	100	93.6	100	56	100	93.6	100	9.757	8.155	11.675

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-T antibody	Hexa group	White Caucasian	PRE-BST	80	79	98.8	93.2	100	70	87.5	78.2	93.8	7	8.8	3.6	17.2	0.279	0.230	0.340
			POST-BST	84	84	100	95.7	100	84	100	95.7	100	84	100	95.7	100	7.591	6.233	9.244
		other	PRE-BST	51	51	100	93.0	100	48	94.1	83.8	98.8	9	17.6	8.4	30.9	0.418	0.333	0.524
			POST-BST	54	54	100	93.4	100	54	100	93.4	100	54	100	93.4	100	12.449	9.687	16.000
	Pedia group	White Caucasian	PRE-BST	86	83	96.5	90.1	99.3	78	90.7	82.5	95.9	8	9.3	4.1	17.5	0.366	0.294	0.454
			POST-BST	88	88	100	95.9	100	88	100	95.9	100	85	96.6	90.4	99.3	7.723	6.389	9.337
		other	PRE-BST	46	46	100	92.3	100	45	97.8	88.5	99.9	9	19.6	9.4	33.9	0.478	0.372	0.614
			POST-BST	48	48	100	92.6	100	48	100	92.6	100	48	100	92.6	100	11.433	9.249	14.133
	Penta group	White Caucasian	PRE-BST	67	66	98.5	92.0	100	59	88.1	77.8	94.7	8	11.9	5.3	22.2	0.315	0.244	0.407
			POST-BST	70	70	100	94.9	100	69	98.6	92.3	100	69	98.6	92.3	100	6.226	4.961	7.813
		other	PRE-BST	54	53	98.1	90.1	100	48	88.9	77.4	95.8	11	20.4	10.6	33.5	0.372	0.279	0.496
			POST-BST	56	56	100	93.6	100	56	100	93.6	100	56	100	93.6	100	7.795	6.405	9.487

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.32 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), before and one month post booster vaccination – by Tdap vaccination (Booster ATP cohort for immunogenicity)

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	77	77	100	95.3	100	76	98.7	93.0	100	18	23.4	14.5	34.4	0.624	0.508	0.766
			POST-BST	79	79	100	95.4	100	79	100	95.4	100	79	100	95.4	100	7.308	6.319	8.453
		Tdap Vaccination No	PRE-BST	31	31	100	88.8	100	31	100	88.8	100	18	58.1	39.1	75.5	1.066	0.792	1.434
			POST-BST	34	34	100	89.7	100	34	100	89.7	100	34	100	89.7	100	10.761	8.954	12.932
		Tdap Vaccination Missing	PRE-BST	23	23	100	85.2	100	21	91.3	72.0	98.9	7	30.4	13.2	52.9	0.592	0.373	0.939
			POST-BST	25	25	100	86.3	100	25	100	86.3	100	25	100	86.3	100	8.915	6.755	11.764
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	72	98.6	92.6	100	69	94.5	86.6	98.5	28	38.4	27.2	50.5	0.654	0.508	0.843
			POST-BST	73	73	100	95.1	100	73	100	95.1	100	73	100	95.1	100	7.439	6.234	8.876
		Tdap Vaccination No	PRE-BST	34	33	97.1	84.7	99.9	32	94.1	80.3	99.3	13	38.2	22.2	56.4	0.609	0.423	0.877
			POST-BST	34	34	100	89.7	100	34	100	89.7	100	34	100	89.7	100	8.090	6.320	10.356
		Tdap Vaccination Missing	PRE-BST	25	24	96.0	79.6	99.9	22	88.0	68.8	97.5	7	28.0	12.1	49.4	0.551	0.325	0.935
			POST-BST	29	29	100	88.1	100	29	100	88.1	100	29	100	88.1	100	8.863	6.854	11.461
	Penta group	Tdap Vaccination Yes	PRE-BST	69	67	97.1	89.9	99.6	65	94.2	85.8	98.4	29	42.0	30.2	54.5	0.747	0.576	0.969
			POST-BST	72	72	100	95.0	100	72	100	95.0	100	72	100	95.0	100	9.004	7.603	10.662
		Tdap Vaccination No	PRE-BST	39	39	100	91.0	100	38	97.4	86.5	99.9	17	43.6	27.8	60.4	0.803	0.567	1.136
			POST-BST	39	39	100	91.0	100	39	100	91.0	100	39	100	91.0	100	9.054	7.283	11.255
		Tdap Vaccination Missing	PRE-BST	13	12	92.3	64.0	99.8	12	92.3	64.0	99.8	5	38.5	13.9	68.4	0.741	0.360	1.527
			POST-BST	15	15	100	78.2	100	15	100	78.2	100	15	100	78.2	100	5.676	3.786	8.512
anti-T antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	77	76	98.7	93.0	100	71	92.2	83.8	97.1	8	10.4	4.6	19.4	0.326	0.269	0.395
			POST-BST	79	79	100	95.4	100	79	100	95.4	100	79	100	95.4	100	10.346	8.547	12.523
		Tdap Vaccination No	PRE-BST	31	31	100	88.8	100	25	80.6	62.5	92.5	5	16.1	5.5	33.7	0.322	0.226	0.460
			POST-BST	34	34	100	89.7	100	34	100	89.7	100	34	100	89.7	100	9.035	6.603	12.362
		Tdap Vaccination Missing	PRE-BST	23	23	100	85.2	100	22	95.7	78.1	99.9	3	13.0	2.8	33.6	0.337	0.233	0.487
			POST-BST	25	25	100	86.3	100	25	100	86.3	100	25	100	86.3	100	6.554	4.013	10.705
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	72	98.6	92.6	100	69	94.5	86.6	98.5	12	16.4	8.8	27.0	0.435	0.348	0.544
			POST-BST	73	73	100	95.1	100	73	100	95.1	100	72	98.6	92.6	100	9.896	8.327	11.760
		Tdap Vaccination No	PRE-BST	34	32	94.1	80.3	99.3	31	91.2	76.3	98.1	3	8.8	1.9	23.7	0.346	0.242	0.493
			POST-BST	34	34	100	89.7	100	34	100	89.7	100	32	94.1	80.3	99.3	7.497	5.244	10.718
		Tdap Vaccination Missing	PRE-BST	25	25	100	86.3	100	23	92.0	74.0	99.0	2	8.0	1.0	26.0	0.391	0.269	0.566

					≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
			POST-BST	29	29	100	88.1	100	29	100	88.1	100	29	100	88.1	100	8.203	5.788	11.627
	Penta group	Tdap Vaccination Yes	PRE-BST	69	68	98.6	92.2	100	63	91.3	82.0	96.7	15	21.7	12.7	33.3	0.398	0.311	0.511
			POST-BST	72	72	100	95.0	100	71	98.6	92.5	100	71	98.6	92.5	100	8.169	6.563	10.169
		Tdap Vaccination No	PRE-BST	39	38	97.4	86.5	99.9	32	82.1	66.5	92.5	3	7.7	1.6	20.9	0.278	0.196	0.395
			POST-BST	39	39	100	91.0	100	39	100	91.0	100	39	100	91.0	100	5.878	4.576	7.550
		Tdap Vaccination Missing	PRE-BST	13	13	100	75.3	100	12	92.3	64.0	99.8	1	7.7	0.2	36.0	0.266	0.151	0.468
			POST-BST	15	15	100	78.2	100	15	100	78.2	100	15	100	78.2	100	4.541	3.402	6.062

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.33 Number and percentage of subjects with anti-PRP antibody concentration equal to or above 0.066 µg/mL and 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), before and one month post booster vaccination – by gender (Booster ATP cohort for immunogenicity)

					≥ 0.066 µg/mL				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – fully validated assay	Hexa group	Female	PRE-BST	70	66	94.3	86.0	98.4	48	68.6	56.4	79.1	14	20.0	11.4	31.3	0.319	0.238	0.428
			POST-BST	72	72	100	95.0	100	72	100	95.0	100	72	100	95.0	100	43.889	33.093	58.207
		Male	PRE-BST	61	52	85.2	73.8	93.0	43	70.5	57.4	81.5	9	14.8	7.0	26.2	0.280	0.203	0.388
			POST-BST	66	66	100	94.6	100	66	100	94.6	100	64	97.0	89.5	99.6	34.961	24.545	49.797
	Pedia group	Female	PRE-BST	45	43	95.6	84.9	99.5	40	88.9	75.9	96.3	26	57.8	42.2	72.3	0.994	0.640	1.546
			POST-BST	47	47	100	92.5	100	47	100	92.5	100	47	100	92.5	100	53.188	39.017	72.506
		Male	PRE-BST	87	86	98.9	93.8	100	82	94.3	87.1	98.1	45	51.7	40.8	62.6	0.983	0.734	1.316
			POST-BST	92	92	100	96.1	100	92	100	96.1	100	91	98.9	94.1	100	50.125	38.734	64.866
	Penta group	Female	PRE-BST	53	50	94.3	84.3	98.8	42	79.2	65.9	89.2	20	37.7	24.8	52.1	0.628	0.401	0.984
			POST-BST	58	58	100	93.8	100	58	100	93.8	100	57	98.3	90.8	100	29.112	20.128	42.106
		Male	PRE-BST	68	61	89.7	79.9	95.8	52	76.5	64.6	85.9	27	39.7	28.0	52.3	0.602	0.406	0.894
			POST-BST	73	72	98.6	92.6	100	71	97.3	90.5	99.7	71	97.3	90.5	99.7	25.971	18.083	37.301

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

Table 7.34 Number and percentage of subjects with anti-PRP antibody concentration equal to or above 0.066 µg/mL and 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), before and one month post booster vaccination – by geographical ancestry (Booster ATP cohort for immunogenicity)

					≥ 0.066 µg/mL				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – fully validated assay	Hexa group	White Caucasian	PRE-BST	80	71	88.8	79.7	94.7	52	65.0	53.5	75.3	11	13.8	7.1	23.3	0.267	0.204	0.351
			POST-BST	84	84	100	95.7	100	84	100	95.7	100	82	97.6	91.7	99.7	35.337	26.365	47.362
		other	PRE-BST	51	47	92.2	81.1	97.8	39	76.5	62.5	87.2	12	23.5	12.8	37.5	0.361	0.252	0.516
			POST-BST	54	54	100	93.4	100	54	100	93.4	100	54	100	93.4	100	46.564	32.943	65.815
	Pedia group	White Caucasian	PRE-BST	86	83	96.5	90.1	99.3	76	88.4	79.7	94.3	38	44.2	33.5	55.3	0.702	0.528	0.934
			POST-BST	90	90	100	96.0	100	90	100	96.0	100	90	100	96.0	100	42.570	33.277	54.458
		other	PRE-BST	46	46	100	92.3	100	46	100	92.3	100	33	71.7	56.5	84.0	1.864	1.262	2.754
			POST-BST	49	49	100	92.7	100	49	100	92.7	100	48	98.0	89.1	99.9	71.627	51.854	98.940
	Penta group	White Caucasian	PRE-BST	67	61	91.0	81.5	96.6	51	76.1	64.1	85.7	25	37.3	25.8	50.0	0.581	0.383	0.881
			POST-BST	72	71	98.6	92.5	100	71	98.6	92.5	100	71	98.6	92.5	100	27.853	19.598	39.584
		other	PRE-BST	54	50	92.6	82.1	97.9	43	79.6	66.5	89.4	22	40.7	27.6	55.0	0.657	0.433	0.995
			POST-BST	59	59	100	93.9	100	58	98.3	90.9	100	57	96.6	88.3	99.6	26.679	18.140	39.239

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

Table 7.35 Number and percentage of subjects with anti-PRP antibody concentration equal to or above 0.066 µg/mL and 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), before and one month post booster vaccination – by Tdap vaccination of the (Booster ATP cohort for immunogenicity)

					≥ 0.066 µg/mL				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
							95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-PRP – fully validated assay	Hexa group	Tdap Vaccination Yes	PRE-BST	77	67	87.0	77.4	93.6	51	66.2	54.6	76.6	12	15.6	8.3	25.6	0.265	0.199	0.352
			POST-BST	79	79	100	95.4	100	79	100	95.4	100	78	98.7	93.1	100	42.173	31.237	56.936
		Tdap Vaccination No	PRE-BST	31	31	100	88.8	100	24	77.4	58.9	90.4	9	29.0	14.2	48.0	0.425	0.287	0.629
			POST-BST	34	34	100	89.7	100	34	100	89.7	100	34	100	89.7	100	42.094	27.788	63.766
		Tdap Vaccination Missing	PRE-BST	23	20	87.0	66.4	97.2	16	69.6	47.1	86.8	2	8.7	1.1	28.0	0.289	0.159	0.524
			POST-BST	25	25	100	86.3	100	25	100	86.3	100	24	96.0	79.6	99.9	28.907	16.015	52.177
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	72	98.6	92.6	100	70	95.9	88.5	99.1	46	63.0	50.9	74.0	1.286	0.922	1.794
			POST-BST	75	75	100	95.2	100	75	100	95.2	100	74	98.7	92.8	100	59.334	45.893	76.712
		Tdap Vaccination No	PRE-BST	34	33	97.1	84.7	99.9	31	91.2	76.3	98.1	13	38.2	22.2	56.4	0.727	0.474	1.115
			POST-BST	35	35	100	90.0	100	35	100	90.0	100	35	100	90.0	100	44.301	30.348	64.669
		Tdap Vaccination Missing	PRE-BST	25	24	96.0	79.6	99.9	21	84.0	63.9	95.5	12	48.0	27.8	68.7	0.690	0.383	1.244
			POST-BST	29	29	100	88.1	100	29	100	88.1	100	29	100	88.1	100	41.409	24.272	70.646
	Penta group	Tdap Vaccination Yes	PRE-BST	69	64	92.8	83.9	97.6	57	82.6	71.6	90.7	33	47.8	35.6	60.2	0.892	0.595	1.339
			POST-BST	73	72	98.6	92.6	100	72	98.6	92.6	100	71	97.3	90.5	99.7	34.428	24.144	49.093
		Tdap Vaccination No	PRE-BST	39	36	92.3	79.1	98.4	28	71.8	55.1	85.0	9	23.1	11.1	39.3	0.360	0.241	0.539
			POST-BST	43	43	100	91.8	100	42	97.7	87.7	99.9	42	97.7	87.7	99.9	17.724	11.258	27.902
		Tdap Vaccination Missing	PRE-BST	13	11	84.6	54.6	98.1	9	69.2	38.6	90.9	5	38.5	13.9	68.4	0.417	0.137	1.265
			POST-BST	15	15	100	78.2	100	15	100	78.2	100	15	100	78.2	100	30.628	16.934	55.397

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

Table 7.36 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), before booster vaccination - by gender (Booster ATP cohort for immunogenicity)

					≥ 8 ED50				GMT		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	Female	PRE-BST	68	68	100	94.7	100	130.0	98.8	171.2
		Male	PRE-BST	60	56	93.3	83.8	98.2	73.5	51.2	105.5
	Pedia group	Female	PRE-BST	45	45	100	92.1	100	149.4	101.1	220.9
		Male	PRE-BST	83	76	91.6	83.4	96.5	89.9	65.3	123.7
	Penta group	Female	PRE-BST	50	45	90.0	78.2	96.7	59.3	40.3	87.1
		Male	PRE-BST	66	55	83.3	72.1	91.4	32.7	23.2	46.0
anti-Polio 2 antibody	Hexa group	Female	PRE-BST	67	63	94.0	85.4	98.3	133.3	93.3	190.5
		Male	PRE-BST	61	56	91.8	81.9	97.3	65.3	45.2	94.4
	Pedia group	Female	PRE-BST	45	43	95.6	84.9	99.5	133.1	86.4	205.2
		Male	PRE-BST	83	79	95.2	88.1	98.7	101.9	76.1	136.5
	Penta group	Female	PRE-BST	51	47	92.2	81.1	97.8	66.5	45.5	97.4
		Male	PRE-BST	66	62	93.9	85.2	98.3	41.8	31.8	55.1
anti-Polio 3 antibody	Hexa group	Female	PRE-BST	66	65	98.5	91.8	100	162.0	117.4	223.6
		Male	PRE-BST	61	58	95.1	86.3	99.0	89.9	61.3	131.9
	Pedia group	Female	PRE-BST	45	44	97.8	88.2	99.9	198.6	133.6	295.3
		Male	PRE-BST	84	82	97.6	91.7	99.7	143.1	104.9	195.2
	Penta group	Female	PRE-BST	51	37	72.5	58.3	84.1	39.5	23.5	66.5
		Male	PRE-BST	66	43	65.2	52.4	76.5	22.0	14.7	32.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.37 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), before booster vaccination – by geographical ancestry (Booster ATP cohort for immunogenicity)

					≥ 8 ED50				GMT		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	White Caucasian	PRE-BST	78	74	94.9	87.4	98.6	86.6	63.9	117.4
		other	PRE-BST	50	50	100	92.9	100	123.7	88.5	172.9
	Pedia group	White Caucasian	PRE-BST	82	76	92.7	84.8	97.3	99.9	72.2	138.1
		other	PRE-BST	46	45	97.8	88.5	99.9	122.4	82.3	182.0
	Penta group	White Caucasian	PRE-BST	63	50	79.4	67.3	88.5	34.8	24.3	49.8
		other	PRE-BST	53	50	94.3	84.3	98.8	53.2	36.7	77.2
anti-Polio 2 antibody	Hexa group	White Caucasian	PRE-BST	77	68	88.3	79.0	94.5	68.3	48.1	97.2
		other	PRE-BST	51	51	100	93.0	100	155.8	109.8	221.1
	Pedia group	White Caucasian	PRE-BST	82	76	92.7	84.8	97.3	96.2	69.8	132.4
		other	PRE-BST	46	46	100	92.3	100	146.8	103.3	208.6
	Penta group	White Caucasian	PRE-BST	64	57	89.1	78.8	95.5	44.2	31.3	62.5
		other	PRE-BST	53	52	98.1	89.9	100	61.1	46.0	81.3
anti-Polio 3 antibody	Hexa group	White Caucasian	PRE-BST	76	72	94.7	87.1	98.5	92.1	66.5	127.5
		other	PRE-BST	51	51	100	93.0	100	186.0	127.6	271.0
	Pedia group	White Caucasian	PRE-BST	83	80	96.4	89.8	99.2	142.7	103.5	196.8
		other	PRE-BST	46	46	100	92.3	100	198.1	137.2	286.1
	Penta group	White Caucasian	PRE-BST	64	42	65.6	52.7	77.1	24.3	15.9	37.0
		other	PRE-BST	53	38	71.7	57.7	83.2	34.3	20.8	56.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.38 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), before booster vaccination – by Tdap vaccination of mother (Booster ATP cohort for immunogenicity)

					≥ 8 ED50				GMT		
							95% CI			95% CI	
Antibody	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	75	72	96.0	88.8	99.2	92.6	69.0	124.3
		Tdap Vaccination No	PRE-BST	31	31	100	88.8	100	111.9	72.4	173.0
		Tdap Vaccination Missing	PRE-BST	22	21	95.5	77.2	99.9	107.9	55.2	210.6
	Pedia group	Tdap Vaccination Yes	PRE-BST	72	70	97.2	90.3	99.7	113.0	82.2	155.4
		Tdap Vaccination No	PRE-BST	34	30	88.2	72.5	96.7	121.7	69.9	212.0
		Tdap Vaccination Missing	PRE-BST	22	21	95.5	77.2	99.9	75.0	40.5	138.9
	Penta group	Tdap Vaccination Yes	PRE-BST	68	58	85.3	74.6	92.7	41.0	29.0	58.1
		Tdap Vaccination No	PRE-BST	36	31	86.1	70.5	95.3	43.5	27.3	69.2
		Tdap Vaccination Missing	PRE-BST	12	11	91.7	61.5	99.8	45.4	18.6	111.1
anti-Polio 2 antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	76	70	92.1	83.6	97.0	75.6	54.1	105.7
		Tdap Vaccination No	PRE-BST	30	29	96.7	82.8	99.9	120.9	75.7	193.1
		Tdap Vaccination Missing	PRE-BST	22	20	90.9	70.8	98.9	149.8	69.2	324.6
	Pedia group	Tdap Vaccination Yes	PRE-BST	72	70	97.2	90.3	99.7	110.4	81.9	148.7
		Tdap Vaccination No	PRE-BST	34	33	97.1	84.7	99.9	175.8	107.7	286.9
		Tdap Vaccination Missing	PRE-BST	22	19	86.4	65.1	97.1	58.4	30.6	111.3
	Penta group	Tdap Vaccination Yes	PRE-BST	68	62	91.2	81.8	96.7	47.1	34.6	64.1
		Tdap Vaccination No	PRE-BST	37	36	97.3	85.8	99.9	58.2	39.2	86.4
		Tdap Vaccination Missing	PRE-BST	12	11	91.7	61.5	99.8	55.3	23.9	127.9
anti-Polio 3 antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	75	73	97.3	90.7	99.7	120.4	88.3	164.2
		Tdap Vaccination No	PRE-BST	30	29	96.7	82.8	99.9	126.7	73.2	219.4
		Tdap Vaccination Missing	PRE-BST	22	21	95.5	77.2	99.9	122.0	57.9	256.9
	Pedia group	Tdap Vaccination Yes	PRE-BST	73	72	98.6	92.6	100	162.4	118.3	222.9
		Tdap Vaccination No	PRE-BST	34	34	100	89.7	100	275.0	181.8	415.9
		Tdap Vaccination Missing	PRE-BST	22	20	90.9	70.8	98.9	67.0	35.3	127.2
	Penta group	Tdap Vaccination Yes	PRE-BST	68	45	66.2	53.7	77.2	25.9	16.8	40.0
		Tdap Vaccination No	PRE-BST	37	27	73.0	55.9	86.2	37.2	20.9	66.1
		Tdap Vaccination Missing	PRE-BST	12	8	66.7	34.9	90.1	20.7	7.3	58.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.39 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), before booster vaccination - by gender (Booster ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	Female	PRE-BST	70	70	100	94.9	100	69	98.6	92.3	100	354.2	266.9	470.1
		Male	PRE-BST	63	62	98.4	91.5	100	62	98.4	91.5	100	302.5	208.1	439.7
	Pedia group	Female	PRE-BST	45	45	100	92.1	100	45	100	92.1	100	276.7	188.3	406.8
		Male	PRE-BST	86	85	98.8	93.7	100	83	96.5	90.1	99.3	216.9	163.6	287.5
	Penta group	Female	PRE-BST	53	50	94.3	84.3	98.8	48	90.6	79.3	96.9	173.5	102.4	294.2
		Male	PRE-BST	68	60	88.2	78.1	94.8	57	83.8	72.9	91.6	133.0	74.1	238.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.40 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), before booster vaccination – by geographical ancestry (Booster ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	White Caucasian	PRE-BST	81	81	100	95.5	100	81	100	95.5	100	363.7	277.1	477.5
		other	PRE-BST	52	51	98.1	89.7	100	50	96.2	86.8	99.5	280.8	186.0	423.8
	Pedia group	White Caucasian	PRE-BST	84	83	98.8	93.5	100	81	96.4	89.9	99.3	188.6	141.8	250.9
		other	PRE-BST	47	47	100	92.5	100	47	100	92.5	100	351.6	247.4	499.6
	Penta group	White Caucasian	PRE-BST	66	59	89.4	79.4	95.6	56	84.8	73.9	92.5	115.6	68.4	195.2
		other	PRE-BST	55	51	92.7	82.4	98.0	49	89.1	77.8	95.9	203.4	110.1	375.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.41 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), before booster vaccination – by Tdap vaccination of mother (Booster ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	Tdap Vaccination Yes	PRE-BST	78	77	98.7	93.1	100	76	97.4	91.0	99.7	290.9	209.4	404.0
		Tdap Vaccination No	PRE-BST	32	32	100	89.1	100	32	100	89.1	100	384.1	247.5	595.9
		Tdap Vaccination Missing	PRE-BST	23	23	100	85.2	100	23	100	85.2	100	400.8	259.0	620.2
	Pedia group	Tdap Vaccination Yes	PRE-BST	74	74	100	95.1	100	72	97.3	90.6	99.7	259.2	191.6	350.7
		Tdap Vaccination No	PRE-BST	34	33	97.1	84.7	99.9	33	97.1	84.7	99.9	156.2	96.4	252.9
		Tdap Vaccination Missing	PRE-BST	23	23	100	85.2	100	23	100	85.2	100	319.9	201.3	508.6
	Penta group	Tdap Vaccination Yes	PRE-BST	69	63	91.3	82.0	96.7	59	85.5	75.0	92.8	158.6	94.7	265.5
		Tdap Vaccination No	PRE-BST	40	36	90.0	76.3	97.2	35	87.5	73.2	95.8	149.5	67.4	331.6
		Tdap Vaccination Missing	PRE-BST	12	11	91.7	61.5	99.8	11	91.7	61.5	99.8	106.0	39.0	288.5

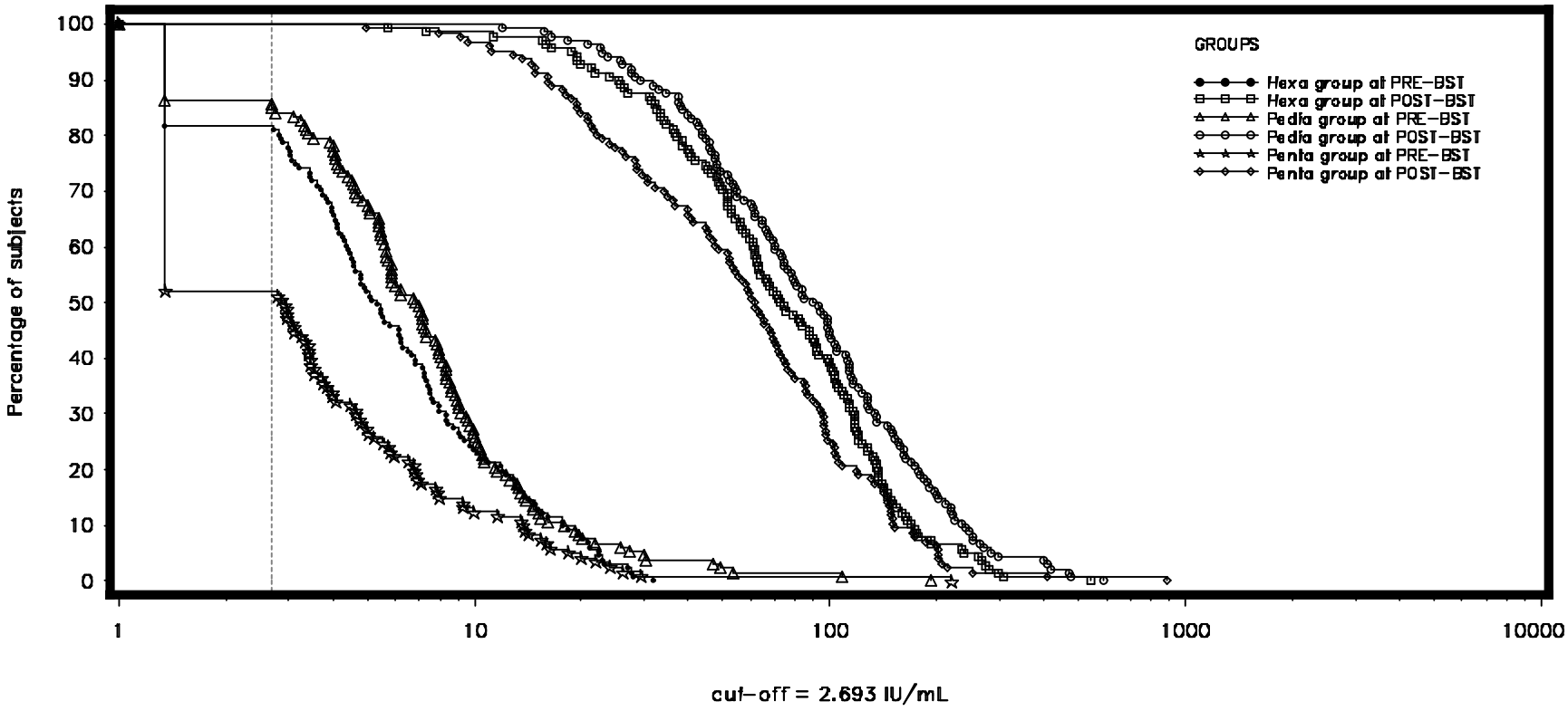
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.42 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), before booster vaccination – by Hepatitis B vaccination of subject (Booster ATP cohort for immunogenicity)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	HepB at birth Yes	PRE-BST	124	123	99.2	95.6	100	122	98.4	94.3	99.8	358.4	283.6	452.9
		HepB at birth No	PRE-BST	9	9	100	66.4	100	9	100	66.4	100	99.8	46.4	214.9
	Pedia group	HepB at birth Yes	PRE-BST	115	114	99.1	95.3	100	113	98.3	93.9	99.8	251.1	197.7	318.9
		HepB at birth No	PRE-BST	16	16	100	79.4	100	15	93.8	69.8	99.8	150.0	73.8	305.0
	Penta group	HepB at birth Yes	PRE-BST	111	100	90.1	83.0	94.9	95	85.6	77.6	91.5	152.4	99.6	233.1
		HepB at birth No	PRE-BST	10	10	100	69.2	100	10	100	69.2	100	119.9	39.1	367.3

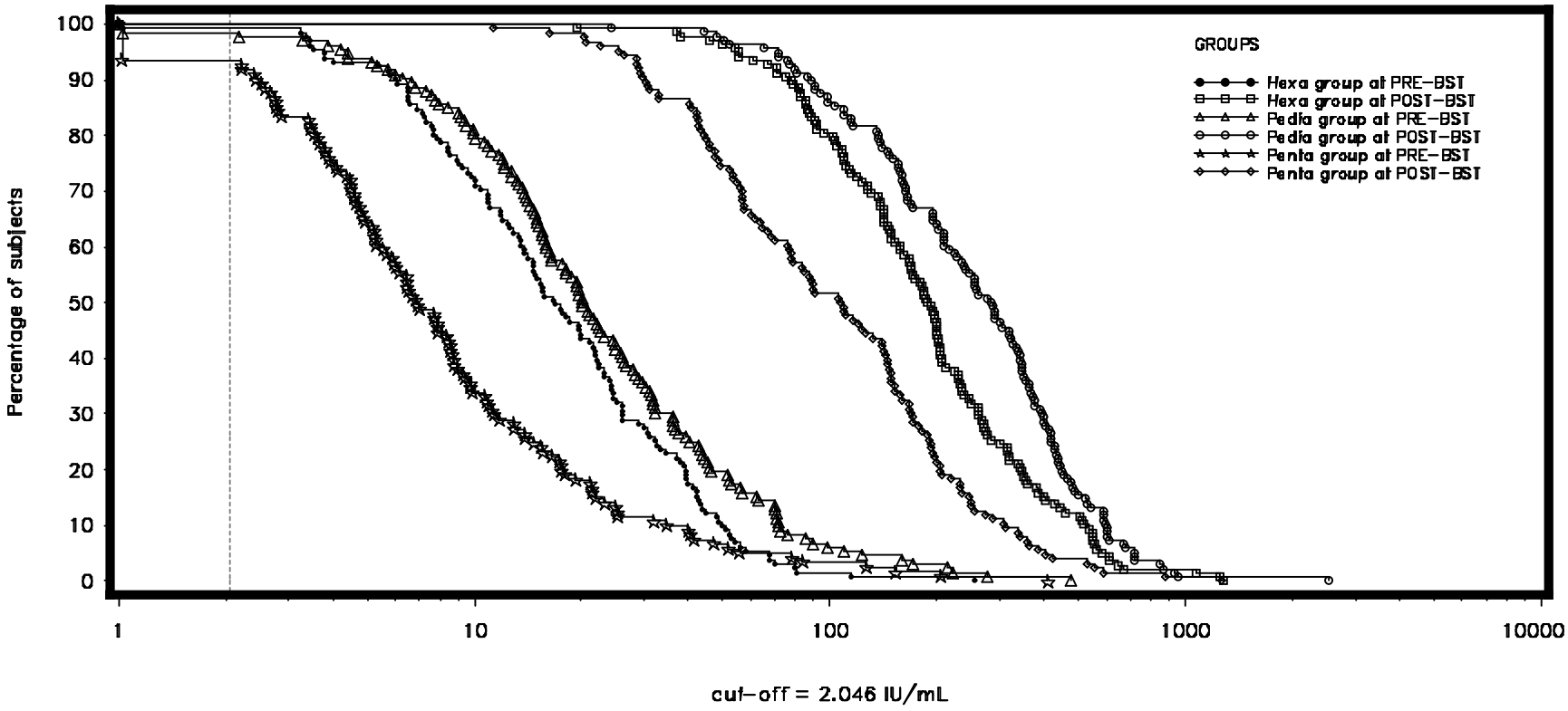
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Figure 7.12 Reverse cumulative distribution curves for anti-PT concentration, before and one month post booster vaccination (Booster ATP cohort for immunogenicity)



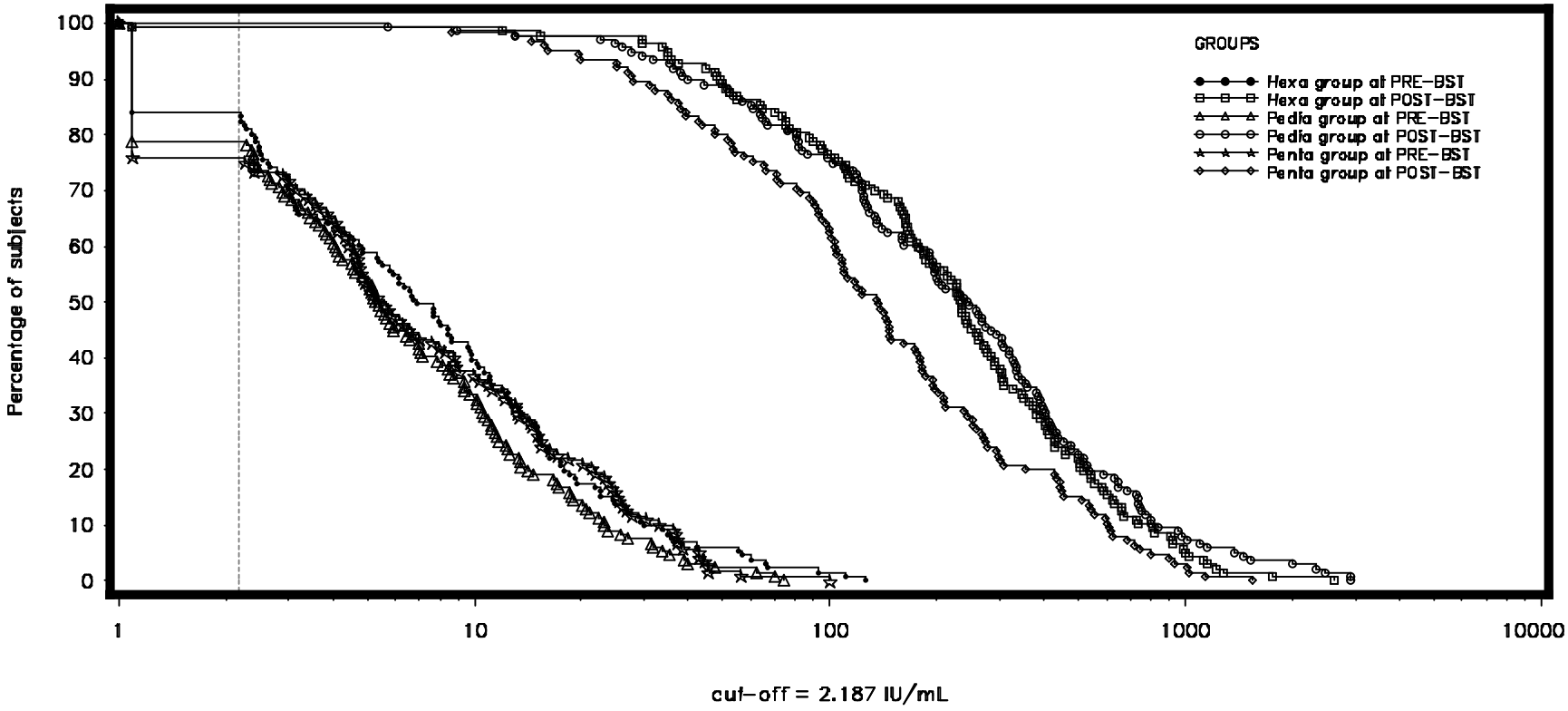
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.13 Reverse cumulative distribution curves for anti-FHA concentration, before and one month post booster vaccination (Booster ATP cohort for immunogenicity)



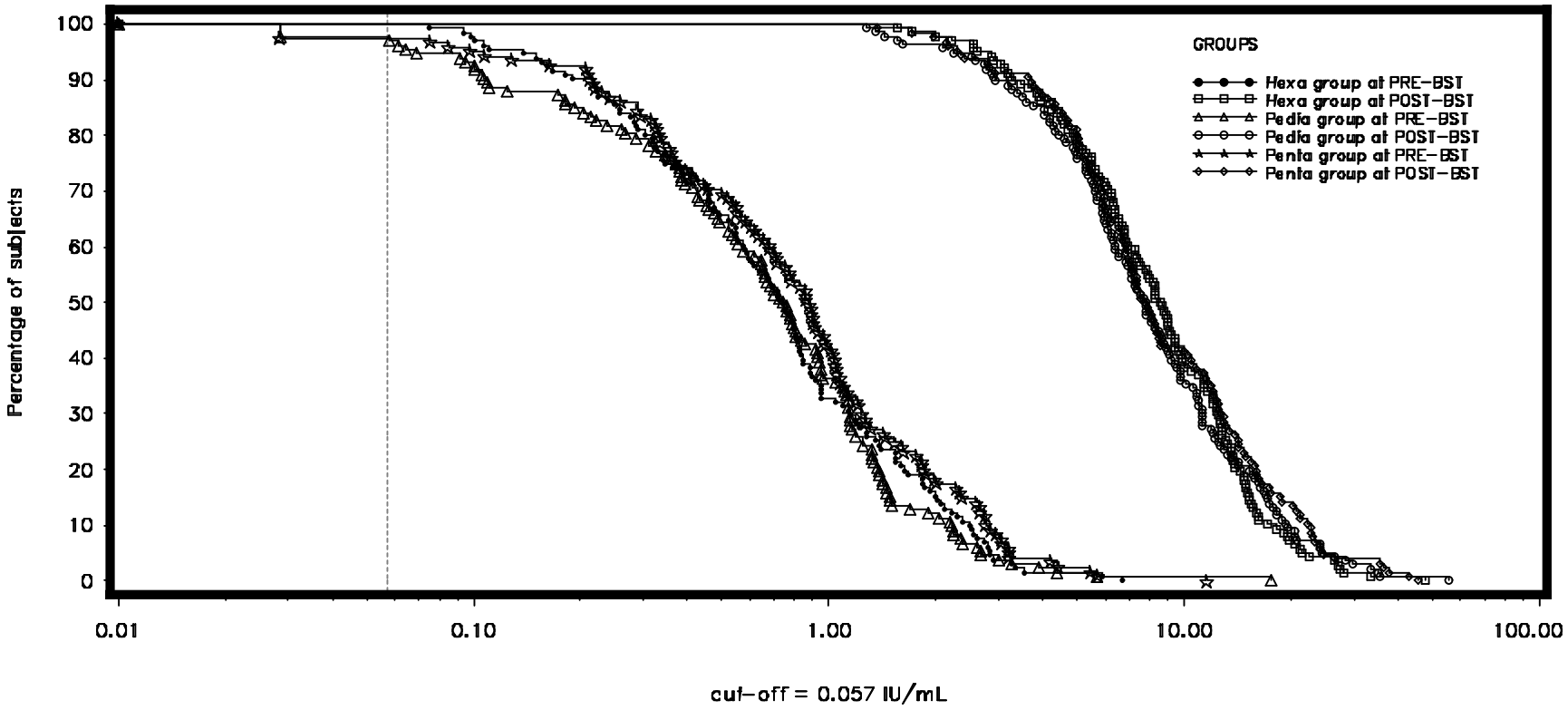
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.14 Reverse cumulative distribution curves for anti-PRN concentration, before and one month post booster vaccination (Booster ATP cohort for immunogenicity)



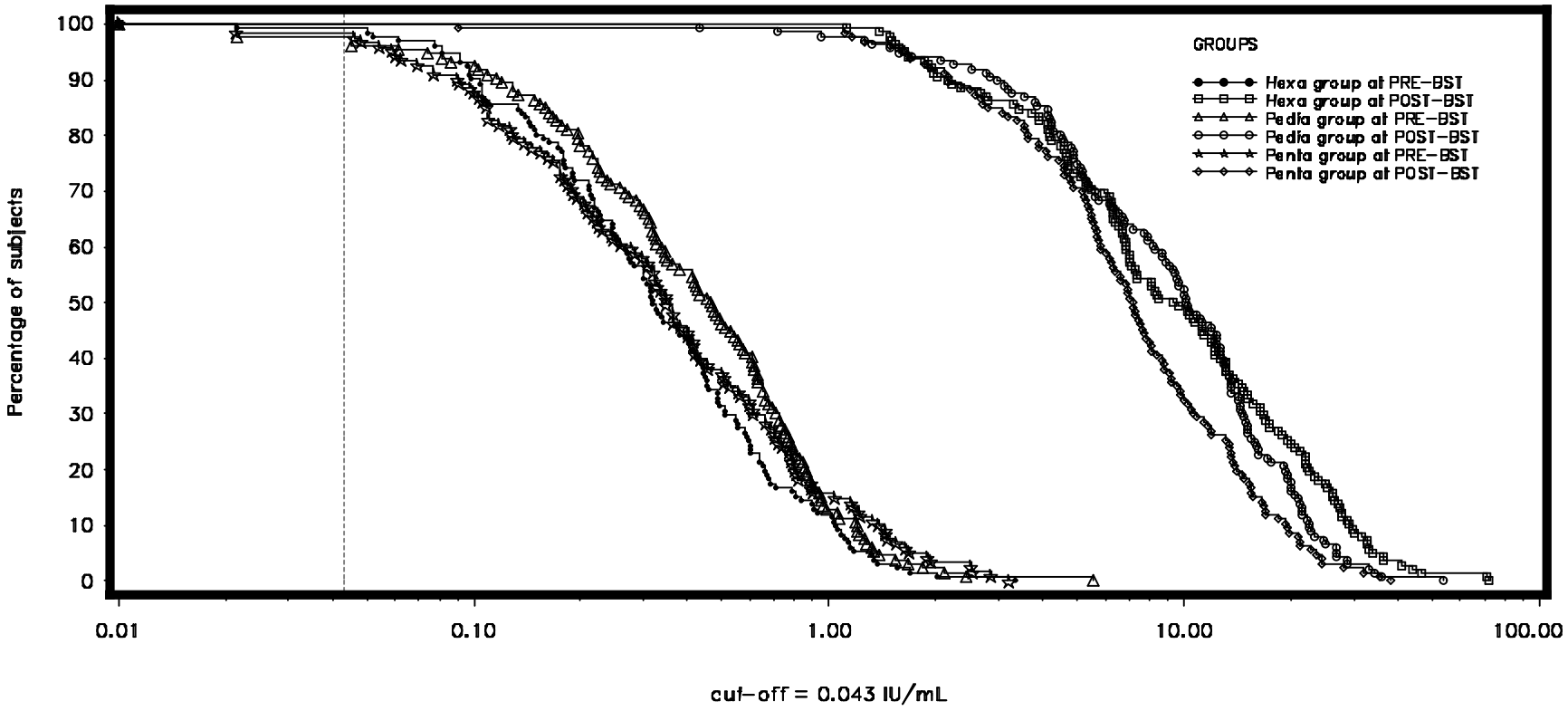
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.15 Reverse cumulative distribution curves for anti-D concentration, before and one month post booster vaccination (Booster ATP cohort for immunogenicity)



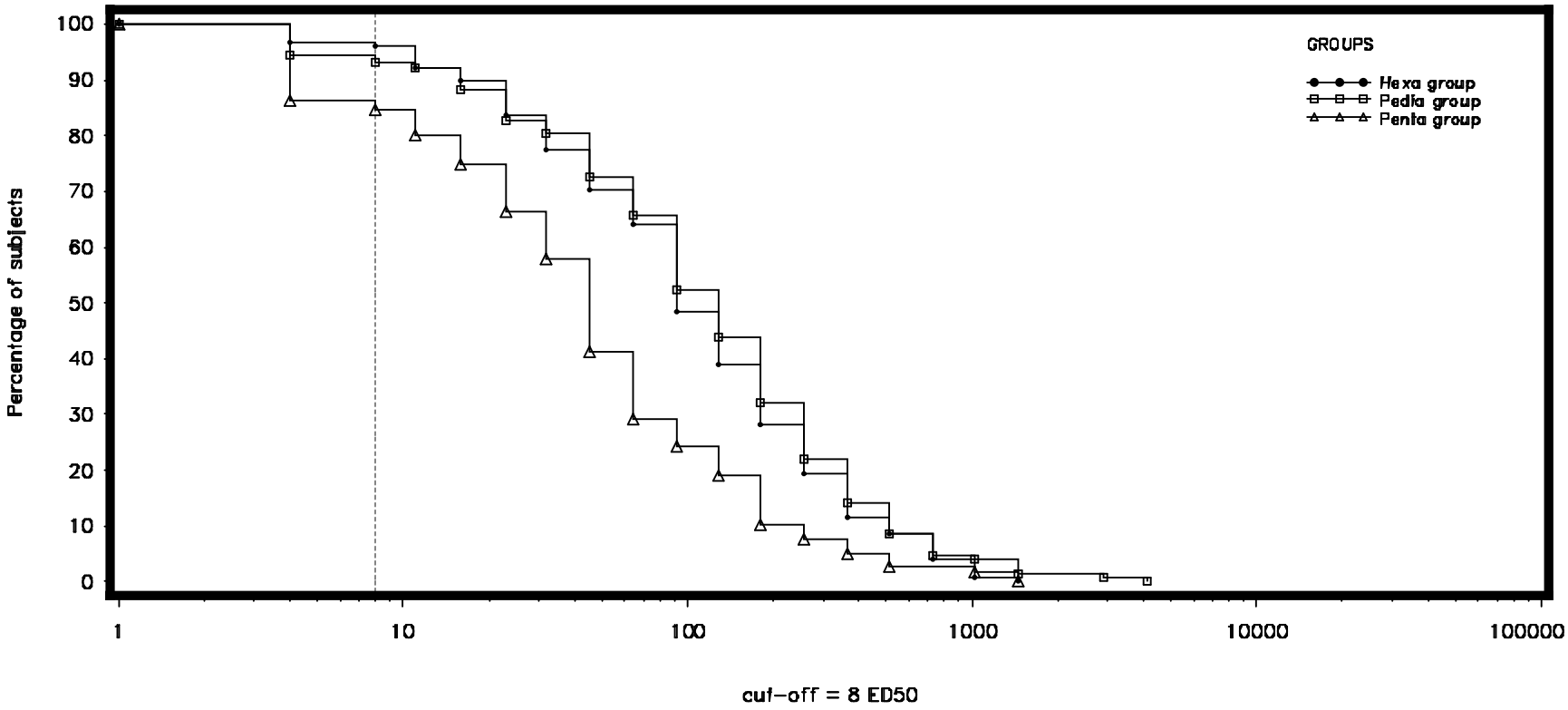
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.16 Reverse cumulative distribution curves for anti-T concentration, before and one month post booster vaccination (Booster ATP cohort for immunogenicity)



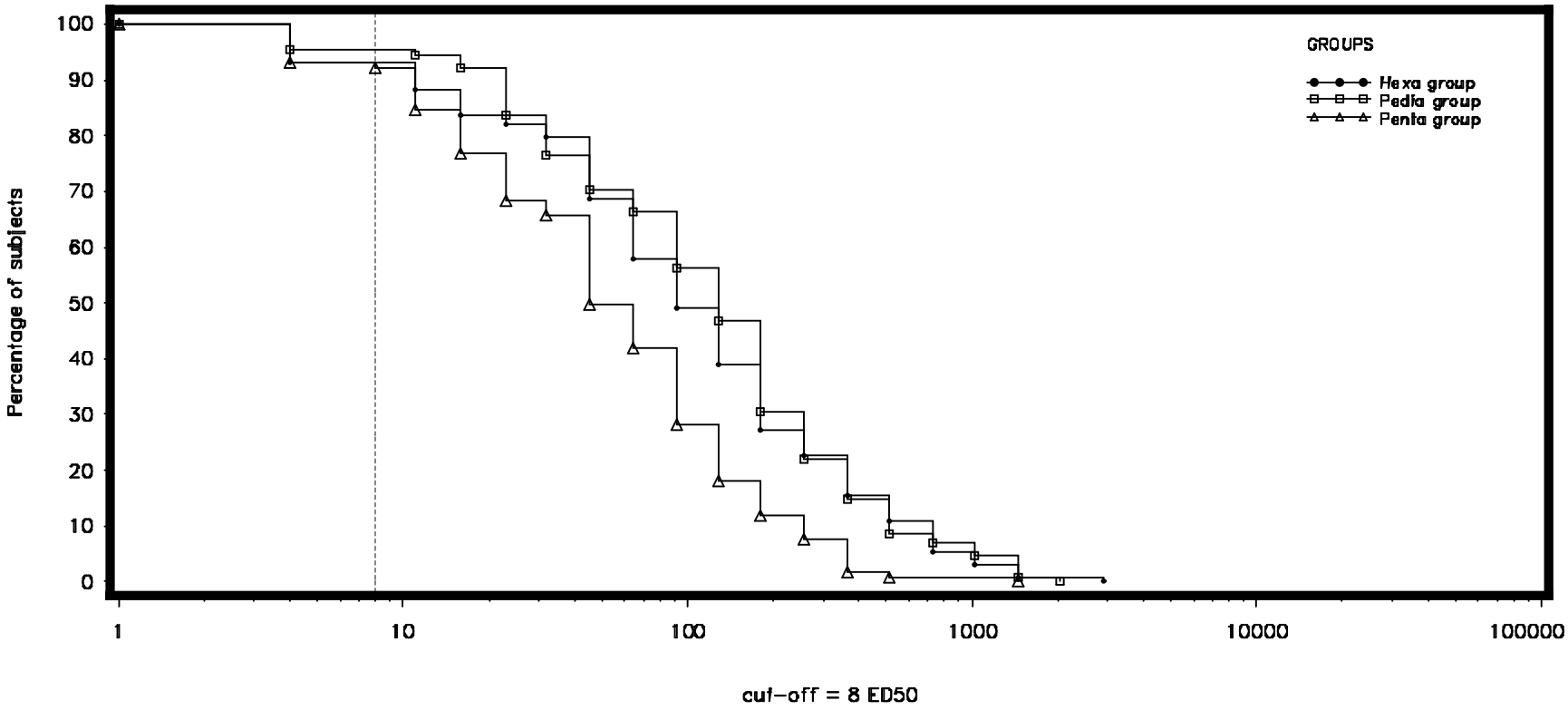
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.17 Reverse cumulative distribution curves for anti-Polio 1 antibody titer before booster vaccination (Booster ATP cohort for immunogenicity)



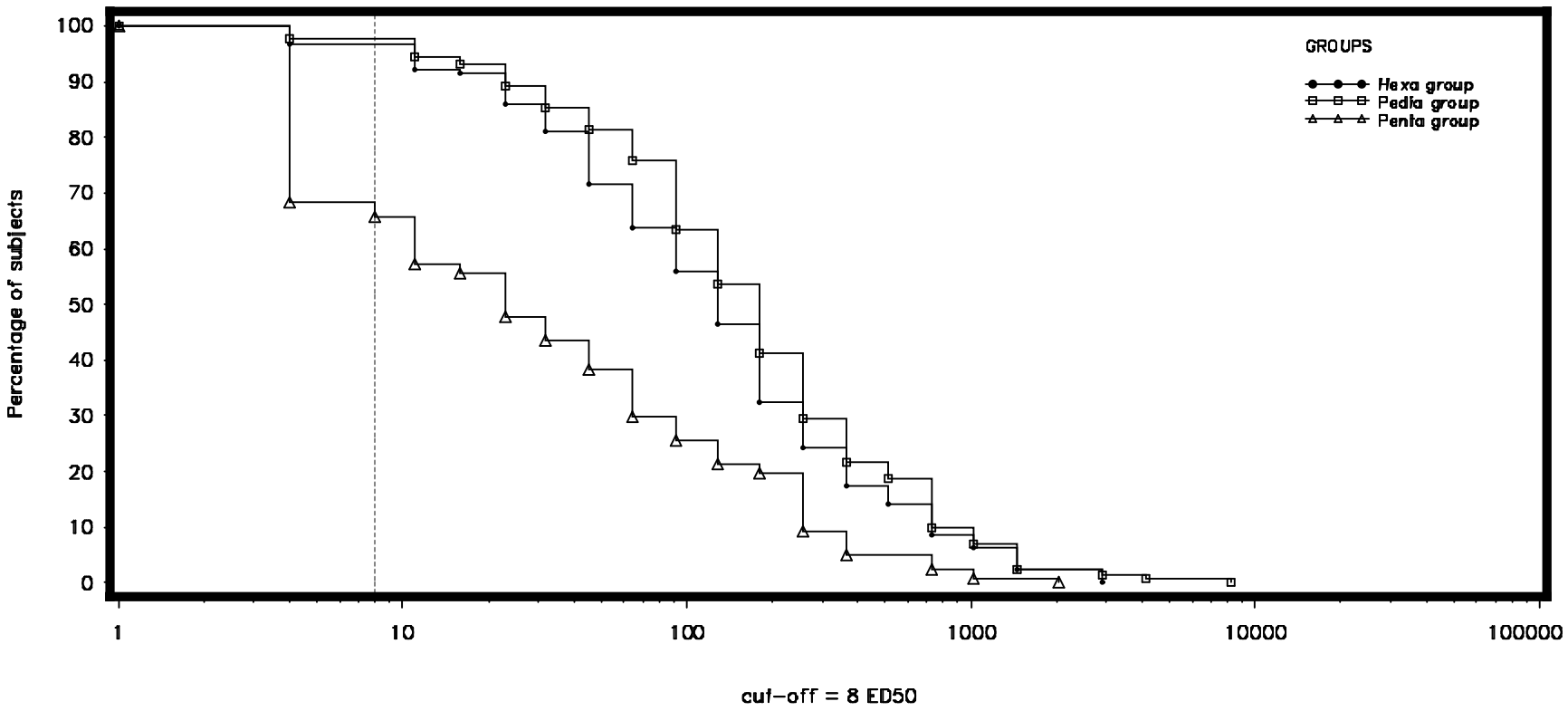
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.18 Reverse cumulative distribution curves for anti-Polio 2 antibody titer before booster vaccination (Booster ATP cohort for immunogenicity)



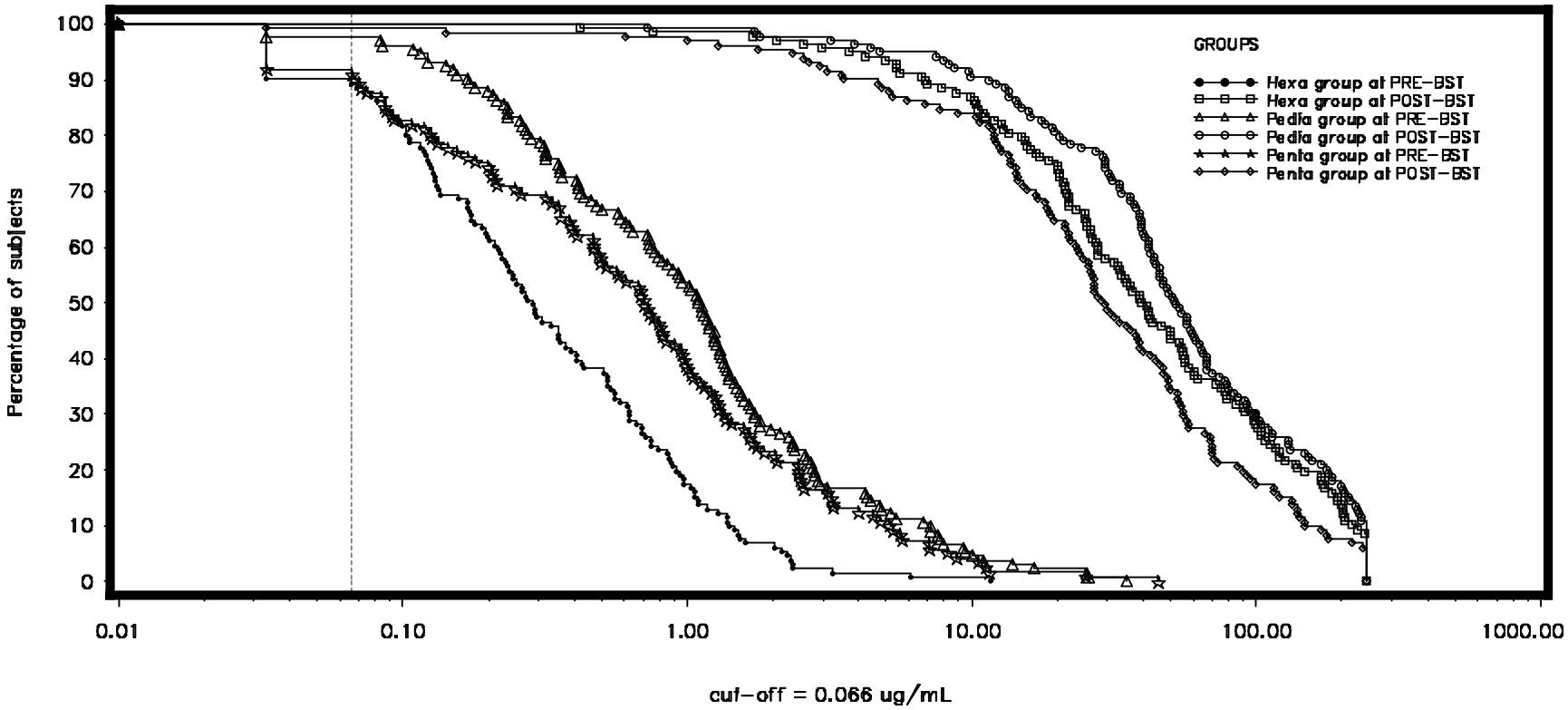
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.19 Reverse cumulative distribution curves for anti-Polio 3 antibody titer before booster vaccination (Booster ATP cohort for immunogenicity)



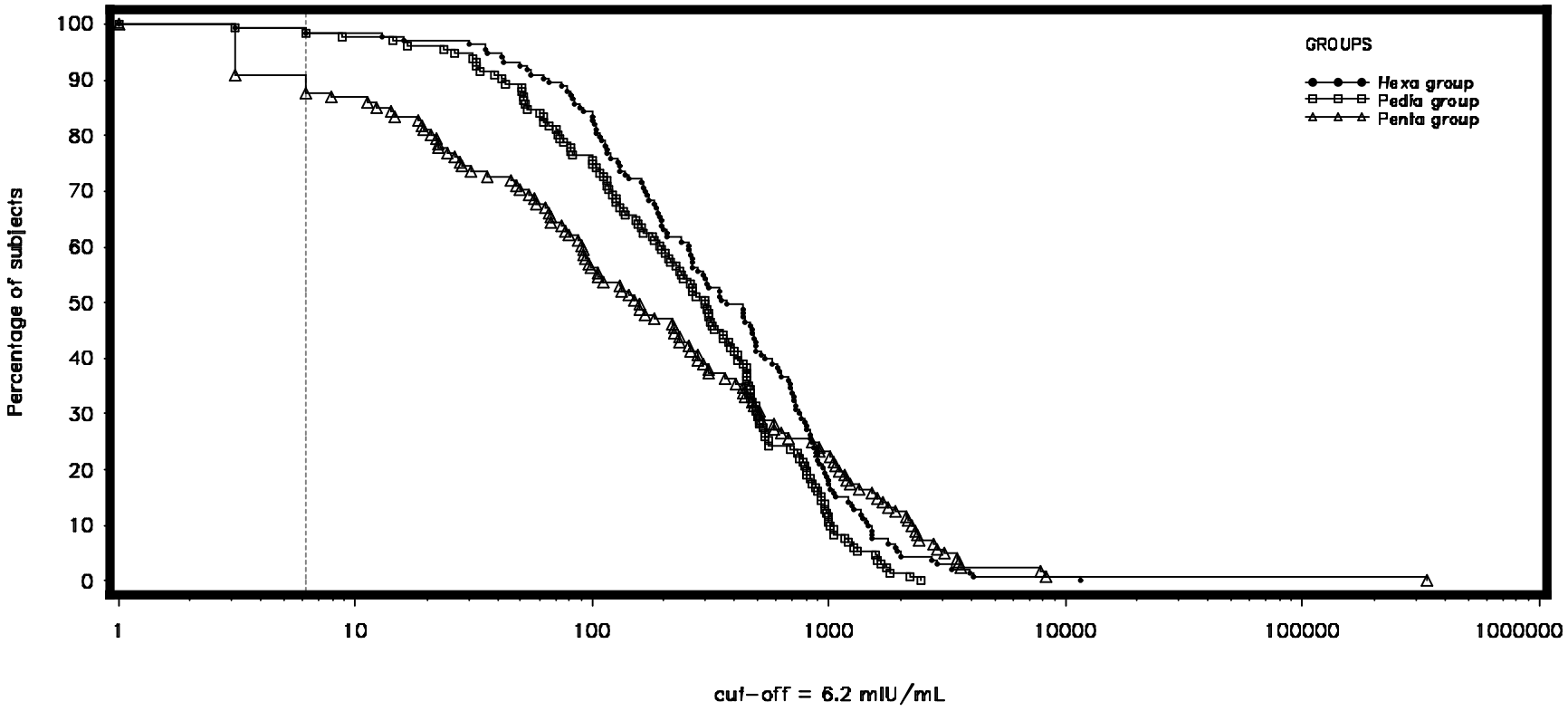
Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.20 Reverse cumulative distribution curves for anti-PRP concentration, before and one month post booster vaccination (Booster ATP cohort for immunogenicity)



Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Figure 7.21 Reverse cumulative distribution curve for anti-HBs antibody concentration, before booster vaccination (Booster ATP cohort for immunogenicity)



Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

Table 7.43 Ratio of GMCs/GMTs for antibody concentrations/titers between groups (Pedia group divided by Hexa group), before booster vaccination (Booster ATP cohort for immunogenicity)

					Adjusted GMC/T ratio (Pedia group / Hexa group)		
	Pedia group		Hexa group			95% CI	
Antibody	N	Adjusted GMC/T	N	Adjusted GMC/T	Value	LL	UL
anti-PT antibody (IU/mL)	132	6.5	131	5.4	1.21	0.97	1.51
anti-FHA antibody (IU/mL)	132	21.9	131	17.4	1.26	0.99	1.61
anti-PRN antibody (IU/mL)	132	5.4	131	6.8	0.79	0.60	1.06
anti-D antibody (IU/mL)	132	0.625	131	0.707	0.88	0.69	1.14
anti-T antibody (IU/mL)	132	0.402	131	0.325	1.24	0.98	1.56
anti-Polio 1 antibody (ED50)	128	107.7	128	100.0	1.08	0.77	1.51
anti-Polio 2 antibody (ED50)	128	112.0	128	96.1	1.17	0.83	1.63
anti-Polio 3 antibody (ED50)	129	162.1	127	124.6	1.30	0.90	1.89
anti-PRP – fully validated assay (µg/mL)	132	0.994	131	0.299	3.33	2.36	4.69

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Table 7.44 Ratio of GMCs/GMTs for antibody concentrations/titers between groups (Penta group divided by Hexa group), before booster vaccination (Booster ATP cohort for immunogenicity)

					Adjusted GMC/T ratio (Penta group / Hexa group)		
	Penta group		Hexa group			95% CI	
Antibody	N	Adjusted GMC/T	N	Adjusted GMC/T	Value	LL	UL
anti-PT antibody (IU/mL)	121	3.0	131	5.4	0.56	0.45	0.71
anti-FHA antibody (IU/mL)	121	7.9	131	17.4	0.45	0.35	0.58
anti-PRN antibody (IU/mL)	120	6.0	131	6.8	0.87	0.65	1.17
anti-D antibody (IU/mL)	121	0.754	131	0.707	1.07	0.82	1.38
anti-T antibody (IU/mL)	121	0.341	131	0.325	1.05	0.83	1.33
anti-Polio 1 antibody (ED50)	116	41.9	128	100.0	0.42	0.30	0.59
anti-Polio 2 antibody (ED50)	117	50.4	128	96.1	0.52	0.37	0.74
anti-Polio 3 antibody (ED50)	117	27.5	127	124.6	0.22	0.15	0.32
anti-PRP – fully validated assay (µg/mL)	121	0.612	131	0.299	2.05	1.44	2.91

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Table 7.45 Ratio of GMC for anti-HBs antibody concentrations between groups (Pedia group divided by Hexa group), before booster vaccination (Booster ATP cohort for immunogenicity)

				Adjusted GMC ratio (Pedia group / Hexa group)		
Pedia group		Hexa group			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
131	239.4	133	321.9	0.74	0.50	1.11

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother and Hepatitis B vaccination of the subject
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother and Hepatitis B vaccination history of the subject - pooled variance); LL = lower limit, UL = upper limit

Table 7.46 Ratio of GMC for anti-HBs antibody concentrations between groups (Penta group divided by Hexa group), before booster vaccination (Booster ATP cohort for immunogenicity)

				Adjusted GMC ratio (Penta group / Hexa group)		
Penta group		Hexa group			95% CI	
N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
121	150.4	133	321.9	0.47	0.31	0.70

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother and Hepatitis B vaccination of the subject
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother and Hepatitis B vaccination history of the subject - pooled variance); LL = lower limit, UL = upper limit

Table 7.47 Difference between groups (Pedia group minus Hexa group) in percentage of subjects with antibody concentration/titer equal to or above the proposed cut-off, before booster vaccination (Booster ATP cohort for immunogenicity)

								Difference in percentage (Pedia group minus Hexa group)		
		Hexa group			Pedia group				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-D antibody	0.1 IU/mL	131	128	97.7	132	123	93.2	-4.53	-10.47	0.61
	1 IU/mL	131	43	32.8	132	48	36.4	3.54	-7.97	14.96
anti-T antibody	0.1 IU/mL	131	118	90.1	132	123	93.2	3.11	-3.81	10.29
	1 IU/mL	131	16	12.2	132	17	12.9	0.67	-7.58	8.91
anti-Polio 1 antibody	8 ED50	128	124	96.9	128	121	94.5	-2.34	-8.16	3.02
anti-Polio 2 antibody	8 ED50	128	119	93.0	128	122	95.3	2.34	-3.76	8.76
anti-Polio 3 antibody	8 ED50	127	123	96.9	129	126	97.7	0.82	-3.88	5.80
anti-PRP – fully validated assay	0.15 µg/mL	131	91	69.5	132	122	92.4	22.96	13.89	32.20
	1 µg/mL	131	23	17.6	132	71	53.8	36.23	25.12	46.50
anti-HBs antibody	10 mIU/mL	133	131	98.5	131	128	97.7	-0.79	-5.20	3.30

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
N = number of subjects with available results
n/% = number/percentage of subjects with titer and concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.48 Difference between groups (Penta group minus Hexa group) in percentage of subjects with antibody concentration/titer equal to or above the proposed cut-off, before booster vaccination (Booster ATP cohort for immunogenicity)

								Difference in percentage (Penta group minus Hexa group)		
		Hexa group			Penta group				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-D antibody	0.1 IU/mL	131	128	97.7	121	115	95.0	-2.67	-8.41	2.25
	1 IU/mL	131	43	32.8	121	51	42.1	9.32	-2.64	21.10
anti-T antibody	0.1 IU/mL	131	118	90.1	121	107	88.4	-1.65	-9.74	6.19
	1 IU/mL	131	16	12.2	121	19	15.7	3.49	-5.16	12.40
anti-Polio 1 antibody	8 ED50	128	124	96.9	116	100	86.2	-10.67	-18.51	-4.02
anti-Polio 2 antibody	8 ED50	128	119	93.0	117	109	93.2	0.19	-6.77	6.95
anti-Polio 3 antibody	8 ED50	127	123	96.9	117	80	68.4	-28.47	-37.76	-19.83
anti-PRP – fully validated assay	0.15 µg/mL	131	91	69.5	121	94	77.7	8.22	-2.75	18.97
	1 µg/mL	131	23	17.6	121	47	38.8	21.29	10.30	32.02
anti-HBs antibody	10 mIU/mL	133	131	98.5	121	105	86.8	-11.72	-19.10	-5.90

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with available results
n/% = number/percentage of subjects with titer and concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.49 Ratio of GMCs/GMTs for antibody concentrations/titers between groups (Pedia group divided by Hexa group), one month post booster vaccination (Booster ATP cohort for immunogenicity)

					Adjusted GMC ratio (Pedia group / Hexa group)		
	Pedia group		Hexa group			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PT antibody (IU/mL)	136	87.6	138	72.0	1.22	1.01	1.48
anti-FHA antibody (IU/mL)	136	251.0	138	188.5	1.33	1.11	1.60
anti-PRN antibody (IU/mL)	136	216.0	137	208.4	1.04	0.79	1.37
anti-D antibody (IU/mL)	136	7.897	138	8.359	0.94	0.80	1.11
anti-T antibody (IU/mL)	136	8.970	138	9.194	0.98	0.79	1.20
anti-PRP – fully validated assay (µg/mL)	139	51.402	138	39.145	1.31	0.96	1.80

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Table 7.50 Ratio of GMCs/GMTs for antibody concentrations/titers between groups (Penta group divided by Hexa group), one month post booster vaccination (Booster ATP cohort for immunogenicity)

					Adjusted GMC ratio (Penta group / Hexa group)		
	Penta group		Hexa group			95% CI	
Antibody	N	Adjusted GMC	N	Adjusted GMC	Value	LL	UL
anti-PT antibody (IU/mL)	126	55.0	138	72.0	0.76	0.63	0.93
anti-FHA antibody (IU/mL)	126	99.8	138	188.5	0.53	0.44	0.64
anti-PRN antibody (IU/mL)	125	129.9	137	208.4	0.62	0.47	0.83
anti-D antibody (IU/mL)	126	8.495	138	8.359	1.02	0.86	1.20
anti-T antibody (IU/mL)	126	6.812	138	9.194	0.74	0.60	0.92
anti-PRP – fully validated assay (µg/mL)	131	27.332	138	39.145	0.70	0.51	0.96

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Adjusted GMC/T = geometric mean antibody concentration/titer adjusted for Tdap vaccination of the mother
N = Number of subjects with both pre- and post-primary vaccination results available
95% CI = 95% confidence interval for the adjusted GMC ratio (ANCOVA model: adjustment for Tdap vaccination of mother - pooled variance); LL = lower limit, UL = upper limit

Table 7.51 Difference between groups (Pedia group minus Hexa group) in percentage of subjects with antibody concentration/titer equal to or above the proposed cut-off, one month post booster vaccination (Booster ATP cohort for immunogenicity)

								Difference in percentage (Pedia group minus Hexa group)		
		Hexa group			Pedia group				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-D antibody	0.1 IU/mL	138	138	100	136	136	100	0.00	-2.76	2.72
	1 IU/mL	138	138	100	136	136	100	0.00	-2.76	2.72
anti-T antibody	0.1 IU/mL	138	138	100	136	136	100	0.00	-2.76	2.72
	1 IU/mL	138	138	100	136	133	97.8	-2.21	-6.30	0.54
anti-PRP – fully validated assay	0.15 µg/mL	138	138	100	139	139	100	0.00	-2.70	2.72
	1 µg/mL	138	136	98.6	139	138	99.3	0.73	-2.65	4.50

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
N = number of subjects with available results
n/% = number/percentage of subjects with titer and concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.52 Difference between groups (Penta group minus Hexa group) in percentage of subjects with antibody concentration/titer equal to or above the proposed cut-off, one month post booster vaccination (Booster ATP cohort for immunogenicity)

								Difference in percentage (Penta group minus Hexa group)		
		Hexa group			Penta group				95% CI	
Antibody	Type	N	n	%	N	n	%	%	LL	UL
anti-D antibody	0.1 IU/mL	138	138	100	126	126	100	0.00	-2.97	2.72
	1 IU/mL	138	138	100	126	126	100	0.00	-2.97	2.72
anti-T antibody	0.1 IU/mL	138	138	100	126	125	99.2	-0.79	-4.37	1.94
	1 IU/mL	138	138	100	126	125	99.2	-0.79	-4.37	1.94
anti-PRP – fully validated assay	0.15 µg/mL	138	138	100	131	129	98.5	-1.53	-5.41	1.21
	1 µg/mL	138	136	98.6	131	128	97.7	-0.84	-5.25	3.12

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with available results
n/% = number/percentage of subjects with titer and concentration within the specified range
95% CI = Standardized asymptotic 95% confidence interval; LL = lower limit, UL = upper limit

Table 7.53 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), one month post primary vaccination (Primary Total vaccinated cohort)

				≥ cut_off				GMC		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	PIII(M5)	152	152	100	97.6	100	42.8	37.8	48.5
	Pedia group	PIII(M5)	158	157	99.4	96.5	100	48.6	43.2	54.7
	Penta group	PIII(M5)	156	155	99.4	96.5	100	24.6	21.6	28.1
anti-FHA antibody	Hexa group	PIII(M5)	152	152	100	97.6	100	106.6	95.5	119.0
	Pedia group	PIII(M5)	158	158	100	97.7	100	126.3	113.3	140.7
	Penta group	PIII(M5)	156	156	100	97.7	100	60.6	52.4	70.2
anti-PRN antibody	Hexa group	PIII(M5)	152	152	100	97.6	100	54.7	47.0	63.5
	Pedia group	PIII(M5)	158	157	99.4	96.5	100	48.2	41.1	56.5
	Penta group	PIII(M5)	156	155	99.4	96.5	100	32.2	27.3	38.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.54 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary Total vaccinated cohort)

				≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-D antibody	Hexa group	PIII(M5)	148	148	100	97.5	100	148	100	97.5	100	116	78.4	70.9	84.7	1.733	1.511	1.987
	Pedia group	PIII(M5)	152	152	100	97.6	100	152	100	97.6	100	112	73.7	65.9	80.5	1.695	1.484	1.937
	Penta group	PIII(M5)	156	156	100	97.7	100	156	100	97.7	100	93	59.6	51.5	67.4	1.256	1.104	1.430
anti-T antibody	Hexa group	PIII(M5)	152	152	100	97.6	100	152	100	97.6	100	136	89.5	83.5	93.9	2.457	2.204	2.740
	Pedia group	PIII(M5)	158	158	100	97.7	100	158	100	97.7	100	143	90.5	84.8	94.6	2.667	2.378	2.990
	Penta group	PIII(M5)	156	156	100	97.7	100	155	99.4	96.5	100	126	80.8	73.7	86.6	2.026	1.788	2.295

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.55 Number and percentage of subjects with anti-Polio 1, 2, and 3 antibody titer equal to or above 8 and geometric mean titer (GMT), one month post primary vaccination (Primary Total vaccinated cohort)

				≥ 8 ED50				GMT		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	PIII(M5)	143	143	100	97.5	100	534.9	439.7	650.7
	Pedia group	PIII(M5)	143	143	100	97.5	100	626.0	517.1	757.9
	Penta group	PIII(M5)	142	141	99.3	96.1	100	311.9	251.4	387.0
anti-Polio 2 antibody	Hexa group	PIII(M5)	139	139	100	97.4	100	472.8	386.4	578.4
	Pedia group	PIII(M5)	140	140	100	97.4	100	564.0	446.4	712.4
	Penta group	PIII(M5)	141	141	100	97.4	100	287.3	234.3	352.2
anti-Polio 3 antibody	Hexa group	PIII(M5)	135	135	100	97.3	100	707.6	566.0	884.7
	Pedia group	PIII(M5)	141	141	100	97.4	100	958.5	773.0	1188.5
	Penta group	PIII(M5)	133	131	98.5	94.7	99.8	297.0	225.7	390.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.56 Number and percentage of subjects with anti-PRP antibody concentration equal to or above the assay cut-off, 0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary Total vaccinated cohort)

				≥ cut_off				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – qualified assay	Hexa group	PIII(M5)	155	146	94.2	89.3	97.3	146	94.2	89.3	97.3	87	56.1	47.9	64.1	1.372	1.091	1.727
	Pedia group	PIII(M5)	162	160	98.8	95.6	99.9	160	98.8	95.6	99.9	153	94.4	89.7	97.4	10.512	8.363	13.213
	Penta group	PIII(M5)	161	159	98.8	95.6	99.8	159	98.8	95.6	99.8	134	83.2	76.5	88.6	6.608	5.071	8.609
anti-PRP – fully validated assay	Hexa group	PIII(M5)	161	159	98.8	95.6	99.8	153	95.0	90.4	97.8	89	55.3	47.3	63.1	1.348	1.084	1.676
	Pedia group	PIII(M5)	165	164	99.4	96.7	100	162	98.2	94.8	99.6	156	94.5	89.9	97.5	9.518	7.664	11.822
	Penta group	PIII(M5)	164	162	98.8	95.7	99.9	162	98.8	95.7	99.9	138	84.1	77.6	89.4	5.803	4.478	7.521

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)
Note:Two assays were used for anti-PRP, for the fully validated assay, the assay cut off is 0.066 µg/mL while 0.15 µg/mL was used for the qualified assay.

Table 7.57 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination (Primary Total vaccinated cohort)

				≥ 6.2 mIU/mL				≥ 10 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-HBs antibody	Hexa group	PIII(M5)	146	146	100	97.5	100	146	100	97.5	100	2218.2	1888.7	2605.1
	Pedia group	PIII(M5)	156	156	100	97.7	100	156	100	97.7	100	1803.8	1511.3	2152.8
	Penta group	PIII(M5)	154	152	98.7	95.4	99.8	151	98.1	94.4	99.6	1058.1	805.6	1389.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.58 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10.0 mIU/mL and geometric mean concentration (GMC), one month post primary vaccination – by Hepatitis B vaccination at birth (Primary Total vaccinated cohort)

					≥ 6.2 mIU/mL				≥ 10 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-HBs antibody	Hexa group	HepB at birth Yes	PIII(M5)	135	135	100	97.3	100	135	100	97.3	100	2318.7	1970.0	2729.1
		HepB at birth No	PIII(M5)	11	11	100	71.5	100	11	100	71.5	100	1287.8	585.5	2832.6
	Pedia group	HepB at birth Yes	PIII(M5)	137	137	100	97.3	100	137	100	97.3	100	1922.2	1602.3	2306.0
		HepB at birth No	PIII(M5)	19	19	100	82.4	100	19	100	82.4	100	1140.4	603.1	2156.3
	Penta group	HepB at birth Yes	PIII(M5)	143	141	98.6	95.0	99.8	140	97.9	94.0	99.6	1041.7	777.7	1395.1
		HepB at birth No	PIII(M5)	11	11	100	71.5	100	11	100	71.5	100	1296.5	828.3	2029.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PIII(M5) = Post primary vaccine dose 3 at month 5 (Visit 4)

Table 7.59 Number and percentage of subjects with anti-PT, anti-FHA and anti-PRN antibody concentration equal to or above the assay cut-off and geometric mean concentration (GMC), before and one month post booster vaccination (Booster Total vaccinated cohort)

				≥ cut_off				GMC		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-PT antibody	Hexa group	PRE-BST	153	124	81.0	73.9	86.9	5.3	4.6	6.1
		POST-BST	147	147	100	97.5	100	74.2	65.1	84.5
	Pedia group	PRE-BST	147	123	83.7	76.7	89.3	6.2	5.3	7.2
		POST-BST	138	138	100	97.4	100	87.1	76.2	99.5
	Penta group	PRE-BST	144	79	54.9	46.4	63.2	3.2	2.7	3.7
		POST-BST	136	136	100	97.3	100	56.3	48.5	65.4
anti-FHA antibody	Hexa group	PRE-BST	153	151	98.7	95.4	99.8	16.8	14.5	19.3
		POST-BST	147	147	100	97.5	100	187.2	166.1	211.0
	Pedia group	PRE-BST	147	145	98.6	95.2	99.8	21.2	18.0	24.9
		POST-BST	138	138	100	97.4	100	247.7	218.1	281.2
	Penta group	PRE-BST	144	136	94.4	89.3	97.6	8.6	7.2	10.3
		POST-BST	136	136	100	97.3	100	102.6	88.5	119.0
anti-PRN antibody	Hexa group	PRE-BST	153	129	84.3	77.6	89.7	7.1	5.8	8.6
		POST-BST	146	145	99.3	96.2	100	202.0	167.7	243.2
	Pedia group	PRE-BST	147	116	78.9	71.4	85.2	5.5	4.6	6.7
		POST-BST	138	138	100	97.4	100	217.6	178.2	265.7
	Penta group	PRE-BST	143	112	78.3	70.7	84.8	6.3	5.1	7.7
		POST-BST	135	134	99.3	95.9	100	127.5	104.8	155.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.60 Booster response for anti-PT, anti-FHA and anti-PRN antibodies, one month post booster vaccination (Booster Total vaccinated cohort)

				Booster response			
						95% CI	
Antibody	Group	Pre-vaccination status	N	n	%	LL	UL
anti-PT antibody (IU/mL)	Hexa group	S-	26	24	92.3	74.9	99.1
		S+ (<4*cut_off IU/mL)	83	80	96.4	89.8	99.2
		S+ (≥4*cut_off IU/mL)	29	29	100	88.1	100
		Total	138	133	96.4	91.7	98.8
	Pedia group	S-	19	19	100	82.4	100
		S+ (<4*cut_off IU/mL)	87	82	94.3	87.1	98.1
		S+ (≥4*cut_off IU/mL)	26	22	84.6	65.1	95.6
		Total	132	123	93.2	87.5	96.8
	Penta group	S-	57	53	93.0	83.0	98.1
		S+ (<4*cut_off IU/mL)	53	52	98.1	89.9	100
		S+ (≥4*cut_off IU/mL)	15	14	93.3	68.1	99.8
		Total	125	119	95.2	89.8	98.2
anti-FHA antibody (IU/mL)	Hexa group	S-	1	1	100	2.5	100
		S+ (<4*cut_off IU/mL)	30	30	100	88.4	100
		S+ (≥4*cut_off IU/mL)	107	106	99.1	94.9	100
		Total	138	137	99.3	96.0	100
	Pedia group	S-	2	2	100	15.8	100
		S+ (<4*cut_off IU/mL)	18	18	100	81.5	100
		S+ (≥4*cut_off IU/mL)	112	109	97.3	92.4	99.4
		Total	132	129	97.7	93.5	99.5
	Penta group	S-	8	8	100	63.1	100
		S+ (<4*cut_off IU/mL)	59	58	98.3	90.9	100
		S+ (≥4*cut_off IU/mL)	58	57	98.3	90.8	100
		Total	125	123	98.4	94.3	99.8
anti-PRN antibody (IU/mL)	Hexa group	S-	22	21	95.5	77.2	99.9
		S+ (<4*cut_off IU/mL)	57	57	100	93.7	100
		S+ (≥4*cut_off IU/mL)	58	57	98.3	90.8	100
		Total	137	135	98.5	94.8	99.8
	Pedia group	S-	28	27	96.4	81.7	99.9
		S+ (<4*cut_off IU/mL)	56	55	98.2	90.4	100
		S+ (≥4*cut_off IU/mL)	48	48	100	92.6	100
		Total	132	130	98.5	94.6	99.8
	Penta group	S-	29	27	93.1	77.2	99.2
		S+ (<4*cut_off IU/mL)	44	43	97.7	88.0	99.9
		S+ (≥4*cut_off IU/mL)	51	51	100	93.0	100
		Total	124	121	97.6	93.1	99.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Booster response to PT, FHA and PRN antigens is defined as:
For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration = 4 times the assay cut-off,
For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration,
For subjects with pre-vaccination antibody concentration equal or above 4 times the assay cut off, post-vaccination antibody concentration equal or above 2 times the pre-vaccination antibody concentration
N = number of subjects with pre- and post-vaccination results available

n/% = number/percentage of subjects with booster response
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Note: The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

Table 7.61 Number and percentage of subjects with anti-D and anti-T antibody concentration equal to or above the assay cut-off, 0.1 IU/mL and 1.0 IU/mL and geometric mean concentration (GMC), before and one month post booster vaccination (Booster Total vaccinated cohort)

				≥ cut_off				≥ 0.1 IU/mL				≥ 1 IU/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-D antibody	Hexa group	PRE-BST	152	150	98.7	95.3	99.8	146	96.1	91.6	98.5	51	33.6	26.1	41.7	0.686	0.584	0.807
		POST-BST	147	147	100	97.5	100	147	100	97.5	100	146	99.3	96.3	100	8.136	7.282	9.090
	Pedia group	PRE-BST	147	144	98.0	94.2	99.6	137	93.2	87.8	96.7	53	36.1	28.3	44.4	0.629	0.527	0.752
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	138	100	97.4	100	7.806	6.908	8.821
	Penta group	PRE-BST	144	139	96.5	92.1	98.9	136	94.4	89.3	97.6	64	44.4	36.2	52.9	0.789	0.650	0.959
		POST-BST	136	136	100	97.3	100	136	100	97.3	100	136	100	97.3	100	8.370	7.403	9.464
anti-T antibody	Hexa group	PRE-BST	153	151	98.7	95.4	99.8	135	88.2	82.0	92.9	16	10.5	6.1	16.4	0.312	0.271	0.360
		POST-BST	147	147	100	97.5	100	147	100	97.5	100	147	100	97.5	100	9.041	7.738	10.563
	Pedia group	PRE-BST	147	144	98.0	94.2	99.6	138	93.9	88.7	97.2	20	13.6	8.5	20.2	0.402	0.344	0.469
		POST-BST	138	138	100	97.4	100	138	100	97.4	100	135	97.8	93.8	99.5	8.787	7.607	10.150
	Penta group	PRE-BST	144	142	98.6	95.1	99.8	128	88.9	82.6	93.5	23	16.0	10.4	23.0	0.340	0.287	0.404
		POST-BST	136	136	100	97.3	100	135	99.3	96.0	100	135	99.3	96.0	100	6.835	5.898	7.921

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)
Note: The assay cut off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T.

Table 7.62 Number and percentage of subjects with anti-PRP antibody concentration equal to or above 0.066 µg/mL,0.15 µg/mL and 1.0 µg/mL and geometric mean concentration (GMC), before and one month post booster vaccination (Booster Total vaccinated cohort)

				≥ 0.066 µg/mL				≥ 0.15 µg/mL				≥ 1 µg/mL				GMC		
						95% CI				95% CI				95% CI			95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-PRP – fully validated assay	Hexa group	PRE-BST	153	137	89.5	83.6	93.9	104	68.0	60.0	75.3	29	19.0	13.1	26.1	0.309	0.250	0.383
		POST-BST	147	147	100	97.5	100	147	100	97.5	100	145	98.6	95.2	99.8	38.049	30.626	47.270
	Pedia group	PRE-BST	147	142	96.6	92.2	98.9	135	91.8	86.2	95.7	80	54.4	46.0	62.6	0.989	0.783	1.250
		POST-BST	141	141	100	97.4	100	141	100	97.4	100	140	99.3	96.1	100	49.429	40.409	60.463
	Penta group	PRE-BST	144	134	93.1	87.6	96.6	117	81.3	73.9	87.3	53	36.8	28.9	45.2	0.607	0.472	0.781
		POST-BST	141	140	99.3	96.1	100	139	98.6	95.0	99.8	138	97.9	93.9	99.6	26.875	21.099	34.231

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)
POST-BST = Post booster vaccination at Month 14-17 (Visit 6)

Table 7.63 Number and percentage of subjects with anti-Polio 1, 2 and 3 antibody titers equal to or above 8 and geometric mean titers (GMT), before the booster vaccination (Booster Total vaccinated cohort)

				≥ 8 ED50				GMT		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
anti-Polio 1 antibody	Hexa group	PRE-BST	149	145	97.3	93.3	99.3	99.1	81.1	121.2
	Pedia group	PRE-BST	142	135	95.1	90.1	98.0	110.1	86.8	139.5
	Penta group	PRE-BST	137	119	86.9	80.0	92.0	45.5	36.0	57.4
anti-Polio 2 antibody	Hexa group	PRE-BST	149	139	93.3	88.0	96.7	90.8	71.8	114.9
	Pedia group	PRE-BST	141	134	95.0	90.0	98.0	113.9	90.3	143.5
	Penta group	PRE-BST	137	128	93.4	87.9	97.0	55.4	44.8	68.5
anti-Polio 3 antibody	Hexa group	PRE-BST	148	143	96.6	92.3	98.9	116.7	92.7	147.0
	Pedia group	PRE-BST	143	138	96.5	92.0	98.9	155.1	122.3	196.6
	Penta group	PRE-BST	136	97	71.3	62.9	78.7	32.1	23.8	43.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 7.64 Number and percentage of subjects with anti-HBs antibody concentration equal to or above 6.2 mIU/mL and 10 mIU/mL and geometric mean concentration (GMC), before the booster vaccination (Booster Total vaccinated cohort)

				≥ 6.2 mIU/mL				≥ 10 mIU/mL				GMC		
						95% CI				95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	n	%	LL	UL	value	LL	UL
anti-HBs antibody	Hexa group	PRE-BST	156	154	98.7	95.4	99.8	153	98.1	94.5	99.6	304.9	244.1	380.9
	Pedia group	PRE-BST	145	144	99.3	96.2	100	142	97.9	94.1	99.6	230.8	186.1	286.3
	Penta group	PRE-BST	143	131	91.6	85.8	95.6	126	88.1	81.6	92.9	150.5	105.8	214.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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
PRE-BST = Pre booster vaccination at Month 13-16 (Visit 5)

Table 8.1 Incidence and nature of symptoms (solicited and unsolicited) that are causally related to vaccination reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	159	81.5	75.4	86.7	195	144	73.8	67.1	79.9	195	111	56.9	49.7	64.0
	Pedia group	194	180	92.8	88.2	96.0	194	175	90.2	85.1	94.0	194	144	74.2	67.5	80.2
	Penta group	196	177	90.3	85.3	94.1	196	169	86.2	80.6	90.7	196	128	65.3	58.2	71.9
Dose 2	Hexa group	186	156	83.9	77.8	88.8	186	143	76.9	70.2	82.7	186	105	56.5	49.0	63.7
	Pedia group	188	165	87.8	82.2	92.1	188	155	82.4	76.2	87.6	188	135	71.8	64.8	78.1
	Penta group	189	161	85.2	79.3	89.9	189	154	81.5	75.2	86.7	189	117	61.9	54.6	68.9
Dose 3	Hexa group	183	150	82.0	75.6	87.2	183	134	73.2	66.2	79.5	183	103	56.3	48.8	63.6
	Pedia group	185	156	84.3	78.3	89.2	185	147	79.5	72.9	85.0	185	118	63.8	56.4	70.7
	Penta group	180	146	81.1	74.6	86.5	180	135	75.0	68.0	81.1	180	107	59.4	51.9	66.7
Overall/dose	Hexa group	564	465	82.4	79.1	85.5	564	421	74.6	70.8	78.2	564	319	56.6	52.4	60.7
	Pedia group	567	501	88.4	85.4	90.9	567	477	84.1	80.9	87.0	567	397	70.0	66.1	73.8
	Penta group	565	484	85.7	82.5	88.4	565	458	81.1	77.6	84.2	565	352	62.3	58.2	66.3
Overall/subject	Hexa group	195	181	92.8	88.2	96.0	195	173	88.7	83.4	92.8	195	151	77.4	70.9	83.1
	Pedia group	194	186	95.9	92.0	98.2	194	183	94.3	90.1	97.1	194	168	86.6	81.0	91.1
	Penta group	196	182	92.9	88.3	96.0	196	180	91.8	87.1	95.3	196	162	82.7	76.6	87.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.2 Incidence and nature of grade 3 symptoms (solicited and unsolicited) that are causally related to vaccination reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	17	8.7	5.2	13.6	195	10	5.1	2.5	9.2	195	12	6.2	3.2	10.5
	Pedia group	194	40	20.6	15.2	27.0	194	21	10.8	6.8	16.1	194	32	16.5	11.6	22.5
	Penta group	196	35	17.9	12.8	23.9	196	24	12.2	8.0	17.7	196	22	11.2	7.2	16.5
Dose 2	Hexa group	186	17	9.1	5.4	14.2	186	13	7.0	3.8	11.7	186	5	2.7	0.9	6.2
	Pedia group	188	26	13.8	9.2	19.6	188	18	9.6	5.8	14.7	188	13	6.9	3.7	11.5
	Penta group	189	16	8.5	4.9	13.4	189	12	6.3	3.3	10.8	189	10	5.3	2.6	9.5
Dose 3	Hexa group	183	9	4.9	2.3	9.1	183	8	4.4	1.9	8.4	183	1	0.5	0.0	3.0
	Pedia group	185	27	14.6	9.8	20.5	185	18	9.7	5.9	14.9	185	13	7.0	3.8	11.7
	Penta group	180	20	11.1	6.9	16.6	180	15	8.3	4.7	13.4	180	8	4.4	1.9	8.6
Overall/dose	Hexa group	564	43	7.6	5.6	10.1	564	31	5.5	3.8	7.7	564	18	3.2	1.9	5.0
	Pedia group	567	93	16.4	13.4	19.7	567	57	10.1	7.7	12.8	567	58	10.2	7.9	13.0
	Penta group	565	71	12.6	9.9	15.6	565	51	9.0	6.8	11.7	565	40	7.1	5.1	9.5
Overall/subject	Hexa group	195	34	17.4	12.4	23.5	195	24	12.3	8.0	17.8	195	16	8.2	4.8	13.0
	Pedia group	194	71	36.6	29.8	43.8	194	43	22.2	16.5	28.7	194	46	23.7	17.9	30.3
	Penta group	196	54	27.6	21.4	34.4	196	39	19.9	14.5	26.2	196	35	17.9	12.8	23.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.3 Incidence and nature of symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	169	86.7	81.1	91.1	195	158	81.0	74.8	86.3	195	111	56.9	49.7	64.0
	Pedia group	194	185	95.4	91.4	97.9	194	182	93.8	89.4	96.8	194	144	74.2	67.5	80.2
	Penta group	196	180	91.8	87.1	95.3	196	176	89.8	84.7	93.7	196	128	65.3	58.2	71.9
Dose 2	Hexa group	186	164	88.2	82.6	92.4	186	155	83.3	77.2	88.4	186	105	56.5	49.0	63.7
	Pedia group	188	173	92.0	87.2	95.5	188	166	88.3	82.8	92.5	188	135	71.8	64.8	78.1
	Penta group	189	165	87.3	81.7	91.7	189	161	85.2	79.3	89.9	189	117	61.9	54.6	68.9
Dose 3	Hexa group	183	160	87.4	81.7	91.9	183	153	83.6	77.4	88.7	183	104	56.8	49.3	64.1
	Pedia group	185	163	88.1	82.6	92.4	185	159	85.9	80.1	90.6	185	118	63.8	56.4	70.7
	Penta group	180	153	85.0	78.9	89.9	180	148	82.2	75.8	87.5	180	107	59.4	51.9	66.7
Overall/dose	Hexa group	564	493	87.4	84.4	90.0	564	466	82.6	79.2	85.7	564	320	56.7	52.5	60.9
	Pedia group	567	521	91.9	89.3	94.0	567	507	89.4	86.6	91.8	567	397	70.0	66.1	73.8
	Penta group	565	498	88.1	85.2	90.7	565	485	85.8	82.7	88.6	565	352	62.3	58.2	66.3
Overall/subject	Hexa group	195	186	95.4	91.4	97.9	195	185	94.9	90.8	97.5	195	152	77.9	71.5	83.6
	Pedia group	194	189	97.4	94.1	99.2	194	188	96.9	93.4	98.9	194	168	86.6	81.0	91.1
	Penta group	196	186	94.9	90.8	97.5	196	186	94.9	90.8	97.5	196	162	82.7	76.6	87.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.4 Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	17	8.7	5.2	13.6	195	10	5.1	2.5	9.2	195	12	6.2	3.2	10.5
	Pedia group	194	41	21.1	15.6	27.6	194	22	11.3	7.2	16.7	194	32	16.5	11.6	22.5
	Penta group	196	35	17.9	12.8	23.9	196	24	12.2	8.0	17.7	196	22	11.2	7.2	16.5
Dose 2	Hexa group	186	17	9.1	5.4	14.2	186	13	7.0	3.8	11.7	186	5	2.7	0.9	6.2
	Pedia group	188	26	13.8	9.2	19.6	188	19	10.1	6.2	15.3	188	13	6.9	3.7	11.5
	Penta group	189	16	8.5	4.9	13.4	189	12	6.3	3.3	10.8	189	10	5.3	2.6	9.5
Dose 3	Hexa group	183	9	4.9	2.3	9.1	183	8	4.4	1.9	8.4	183	1	0.5	0.0	3.0
	Pedia group	185	27	14.6	9.8	20.5	185	20	10.8	6.7	16.2	185	13	7.0	3.8	11.7
	Penta group	180	20	11.1	6.9	16.6	180	15	8.3	4.7	13.4	180	8	4.4	1.9	8.6
Overall/dose	Hexa group	564	43	7.6	5.6	10.1	564	31	5.5	3.8	7.7	564	18	3.2	1.9	5.0
	Pedia group	567	94	16.6	13.6	19.9	567	61	10.8	8.3	13.6	567	58	10.2	7.9	13.0
	Penta group	565	71	12.6	9.9	15.6	565	51	9.0	6.8	11.7	565	40	7.1	5.1	9.5
Overall/subject	Hexa group	195	34	17.4	12.4	23.5	195	24	12.3	8.0	17.8	195	16	8.2	4.8	13.0
	Pedia group	194	72	37.1	30.3	44.3	194	45	23.2	17.5	29.8	194	46	23.7	17.9	30.3
	Penta group	196	54	27.6	21.4	34.4	196	39	19.9	14.5	26.2	196	35	17.9	12.8	23.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.5 Incidence and nature of symptoms (solicited and unsolicited) that are causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	159	81.5	75.4	86.7	195	144	73.8	67.1	79.9	195	111	56.9	49.7	64.0
	Pedia group	194	180	92.8	88.2	96.0	194	175	90.2	85.1	94.0	194	144	74.2	67.5	80.2
	Penta group	196	177	90.3	85.3	94.1	196	169	86.2	80.6	90.7	196	128	65.3	58.2	71.9
Dose 2	Hexa group	186	156	83.9	77.8	88.8	186	143	76.9	70.2	82.7	186	105	56.5	49.0	63.7
	Pedia group	188	165	87.8	82.2	92.1	188	155	82.4	76.2	87.6	188	135	71.8	64.8	78.1
	Penta group	189	162	85.7	79.9	90.4	189	155	82.0	75.8	87.2	189	117	61.9	54.6	68.9
Dose 3	Hexa group	183	150	82.0	75.6	87.2	183	135	73.8	66.8	80.0	183	104	56.8	49.3	64.1
	Pedia group	185	156	84.3	78.3	89.2	185	147	79.5	72.9	85.0	185	118	63.8	56.4	70.7
	Penta group	180	146	81.1	74.6	86.5	180	135	75.0	68.0	81.1	180	107	59.4	51.9	66.7
Overall/dose	Hexa group	564	465	82.4	79.1	85.5	564	422	74.8	71.0	78.4	564	320	56.7	52.5	60.9
	Pedia group	567	501	88.4	85.4	90.9	567	477	84.1	80.9	87.0	567	397	70.0	66.1	73.8
	Penta group	565	485	85.8	82.7	88.6	565	459	81.2	77.8	84.4	565	352	62.3	58.2	66.3
Overall/subject	Hexa group	195	181	92.8	88.2	96.0	195	173	88.7	83.4	92.8	195	152	77.9	71.5	83.6
	Pedia group	194	186	95.9	92.0	98.2	194	183	94.3	90.1	97.1	194	168	86.6	81.0	91.1
	Penta group	196	182	92.9	88.3	96.0	196	180	91.8	87.1	95.3	196	162	82.7	76.6	87.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.6 Incidence and nature of grade 3 symptoms (solicited and unsolicited) that are causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall (Primary 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
Dose 1	Hexa group	195	17	8.7	5.2	13.6	195	10	5.1	2.5	9.2	195	12	6.2	3.2	10.5
	Pedia group	194	40	20.6	15.2	27.0	194	21	10.8	6.8	16.1	194	32	16.5	11.6	22.5
	Penta group	196	35	17.9	12.8	23.9	196	24	12.2	8.0	17.7	196	22	11.2	7.2	16.5
Dose 2	Hexa group	186	17	9.1	5.4	14.2	186	13	7.0	3.8	11.7	186	5	2.7	0.9	6.2
	Pedia group	188	26	13.8	9.2	19.6	188	18	9.6	5.8	14.7	188	13	6.9	3.7	11.5
	Penta group	189	16	8.5	4.9	13.4	189	12	6.3	3.3	10.8	189	10	5.3	2.6	9.5
Dose 3	Hexa group	183	9	4.9	2.3	9.1	183	8	4.4	1.9	8.4	183	1	0.5	0.0	3.0
	Pedia group	185	27	14.6	9.8	20.5	185	18	9.7	5.9	14.9	185	13	7.0	3.8	11.7
	Penta group	180	20	11.1	6.9	16.6	180	15	8.3	4.7	13.4	180	8	4.4	1.9	8.6
Overall/dose	Hexa group	564	43	7.6	5.6	10.1	564	31	5.5	3.8	7.7	564	18	3.2	1.9	5.0
	Pedia group	567	93	16.4	13.4	19.7	567	57	10.1	7.7	12.8	567	58	10.2	7.9	13.0
	Penta group	565	71	12.6	9.9	15.6	565	51	9.0	6.8	11.7	565	40	7.1	5.1	9.5
Overall/subject	Hexa group	195	34	17.4	12.4	23.5	195	24	12.3	8.0	17.8	195	16	8.2	4.8	13.0
	Pedia group	194	71	36.6	29.8	43.8	194	43	22.2	16.5	28.7	194	46	23.7	17.9	30.3
	Penta group	196	54	27.6	21.4	34.4	196	39	19.9	14.5	26.2	196	35	17.9	12.8	23.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom whatever the study vaccine administered
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom whatever the study vaccine administered
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.7 Incidence of local symptoms (solicited and unsolicited) that are causally related to vaccination reported for Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B vaccines during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

		INFANRIXHEXA					PEDIARIX					ACTHIB					PENTACEL					ENGERIX-B				
					95% CI					95% CI					95% CI					95% CI					95% CI	
	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Hexa group	195	111	56.9	49.7	64.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	131	67.5	60.4	74.1	194	139	71.6	64.8	77.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	123	62.8	55.6	69.5	196	118	60.2	53.0	67.1
Dose 2	Hexa group	186	104	55.9	48.5	63.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	188	127	67.6	60.4	74.2	188	122	64.9	57.6	71.7	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	187	116	62.0	54.7	69.0	13	7	53.8	25.1	80.8
Dose 3	Hexa group	183	101	55.2	47.7	62.5	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	185	108	58.4	50.9	65.6	185	113	61.1	53.7	68.1	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	180	98	54.4	46.9	61.9	180	95	52.8	45.2	60.2
Overall/dose	Hexa group	564	316	56.0	51.8	60.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	567	366	64.6	60.5	68.5	567	374	66.0	61.9	69.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	563	337	59.9	55.7	63.9	389	220	56.6	51.5	61.5
Overall/subject	Hexa group	195	149	76.4	69.8	82.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	159	82.0	75.8	87.1	194	164	84.5	78.7	89.3	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	156	79.6	73.3	85.0	196	145	74.0	67.2	80.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.8 Incidence of grade 3 local symptoms (solicited and unsolicited) that are causally related to vaccination reported for Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B vaccines during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

		INFANRIXHEXA					PEDIARIX					ACTHIB					PENTACEL					ENGERIX-B				
					95% CI					95% CI					95% CI					95% CI					95% CI	
	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Hexa group	195	12	6.2	3.2	10.5	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	21	10.8	6.8	16.1	194	28	14.4	9.8	20.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	22	11.2	7.2	16.5	196	13	6.6	3.6	11.1
Dose 2	Hexa group	186	5	2.7	0.9	6.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	188	11	5.9	3.0	10.2	188	10	5.3	2.6	9.6	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	187	10	5.3	2.6	9.6	13	0	0.0	0.0	24.7
Dose 3	Hexa group	183	1	0.5	0.0	3.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	185	11	5.9	3.0	10.4	185	9	4.9	2.2	9.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	180	7	3.9	1.6	7.8	180	7	3.9	1.6	7.8
Overall/dose	Hexa group	564	18	3.2	1.9	5.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	567	43	7.6	5.5	10.1	567	47	8.3	6.2	10.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	563	39	6.9	5.0	9.3	389	20	5.1	3.2	7.8
Overall/subject	Hexa group	195	16	8.2	4.8	13.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Pedia group	0	0	0.0	0.0	0.0	194	36	18.6	13.3	24.8	194	38	19.6	14.2	25.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0
	Penta group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	196	34	17.3	12.3	23.4	196	19	9.7	5.9	14.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
For overall/dose:
N = number of administered doses
n/% = number/percentage of doses followed by at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.9 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall – by gender (Primary Total vaccinated cohort)

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																																
Pain	Total	All	96	45	46.9	36.6	57.3	89	49	55.1	44.1	65.6	76	51	67.1	55.4	77.5	113	77	68.1	58.7	76.6	90	51	56.7	45.8	67.1	98	68	69.4	59.3	78.3
		Grade 2 or 3	96	22	22.9	15.0	32.6	89	18	20.2	12.4	30.1	76	33	43.4	32.1	55.3	113	42	37.2	28.3	46.8	90	28	31.1	21.8	41.7	98	28	28.6	19.9	38.6
		Grade 3	96	4	4.2	1.1	10.3	89	4	4.5	1.2	11.1	76	11	14.5	7.5	24.4	113	13	11.5	6.3	18.9	90	5	5.6	1.8	12.5	98	7	7.1	2.9	14.2
		Medical advice	96	1	1.0	0.0	5.7	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											76	49	64.5	52.7	75.1	113	74	65.5	56.0	74.2	90	44	48.9	38.2	59.7	98	56	57.1	46.7	67.1
		Grade 2 or 3											76	30	39.5	28.4	51.4	113	36	31.9	23.4	41.3	90	23	25.6	16.9	35.8	98	22	22.4	14.6	32.0
		Grade 3											76	10	13.2	6.5	22.9	113	12	10.6	5.6	17.8	90	3	3.3	0.7	9.4	98	7	7.1	2.9	14.2
		Medical advice											76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Hexa/Pediarix/Pentacel	All	96	45	46.9	36.6	57.3	89	49	55.1	44.1	65.6	76	47	61.8	50.0	72.8	113	66	58.4	48.8	67.6	90	49	54.4	43.6	65.0	98	66	67.3	57.1	76.5
		Grade 2 or 3	96	22	22.9	15.0	32.6	89	18	20.2	12.4	30.1	76	31	40.8	29.6	52.7	113	34	30.1	21.8	39.4	90	26	28.9	19.8	39.4	98	25	25.5	17.2	35.3
		Grade 3	96	4	4.2	1.1	10.3	89	4	4.5	1.2	11.1	76	8	10.5	4.7	19.7	113	9	8.0	3.7	14.6	90	5	5.6	1.8	12.5	98	7	7.1	2.9	14.2
		Medical advice	96	1	1.0	0.0	5.7	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Redness (mm)	Total	All	96	25	26.0	17.6	36.0	89	22	24.7	16.2	35.0	76	29	38.2	27.2	50.0	113	44	38.9	29.9	48.6	90	31	34.4	24.7	45.2	98	36	36.7	27.2	47.1
		>5	96	8	8.3	3.7	15.8	89	7	7.9	3.2	15.5	76	9	11.8	5.6	21.3	113	18	15.9	9.7	24.0	90	14	15.6	8.8	24.7	98	13	13.3	7.3	21.6
		>20	96	2	2.1	0.3	7.3	89	1	1.1	0.0	6.1	76	1	1.3	0.0	7.1	113	9	8.0	3.7	14.6	90	1	1.1	0.0	6.0	98	3	3.1	0.6	8.7
		Medical advice	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											76	24	31.6	21.4	43.3	113	39	34.5	25.8	44.0	90	28	31.1	21.8	41.7	98	27	27.6	19.0	37.5
		>5											76	6	7.9	3.0	16.4	113	13	11.5	6.3	18.9	90	9	10.0	4.7	18.1	98	3	3.1	0.6	8.7
		>20											76	1	1.3	0.0	7.1	113	7	6.2	2.5	12.3	90	1	1.1	0.0	6.0	98	0	0.0	0.0	3.7

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI					95 % CI			
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		Medical advice											76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Hexa/Pediarix/Pentacel	All	96	25	26.0	17.6	36.0	89	22	24.7	16.2	35.0	76	22	28.9	19.1	40.5	113	34	30.1	21.8	39.4	90	25	27.8	18.9	38.2	98	32	32.7	23.5	42.9
		>5	96	8	8.3	3.7	15.8	89	7	7.9	3.2	15.5	76	6	7.9	3.0	16.4	113	9	8.0	3.7	14.6	90	9	10.0	4.7	18.1	98	11	11.2	5.7	19.2
		>20	96	2	2.1	0.3	7.3	89	1	1.1	0.0	6.1	76	1	1.3	0.0	7.1	113	3	2.7	0.6	7.6	90	0	0.0	0.0	4.0	98	3	3.1	0.6	8.7
		Medical advice	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Swelling (mm)	Total	All	96	14	14.6	8.2	23.3	89	17	19.1	11.5	28.8	76	23	30.3	20.2	41.9	113	23	20.4	13.4	29.0	90	20	22.2	14.1	32.2	98	33	33.7	24.4	43.9
		>5	96	4	4.2	1.1	10.3	89	6	6.7	2.5	14.1	76	8	10.5	4.7	19.7	113	10	8.8	4.3	15.7	90	10	11.1	5.5	19.5	98	14	14.3	8.0	22.8
		>20	96	1	1.0	0.0	5.7	89	1	1.1	0.0	6.1	76	2	2.6	0.3	9.2	113	5	4.4	1.5	10.0	90	3	3.3	0.7	9.4	98	8	8.2	3.6	15.5
		Medical advice	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											76	19	25.0	15.8	36.3	113	22	19.5	12.6	28.0	90	17	18.9	11.4	28.5	98	22	22.4	14.6	32.0
		>5											76	4	5.3	1.5	12.9	113	10	8.8	4.3	15.7	90	6	6.7	2.5	13.9	98	8	8.2	3.6	15.5
		>20											76	2	2.6	0.3	9.2	113	4	3.5	1.0	8.8	90	1	1.1	0.0	6.0	98	2	2.0	0.2	7.2
		Medical advice											76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Hexa/Pediarix/Pentacel	All	96	14	14.6	8.2	23.3	89	17	19.1	11.5	28.8	76	17	22.4	13.6	33.4	113	18	15.9	9.7	24.0	90	18	20.0	12.3	29.8	98	27	27.6	19.0	37.5
		>5	96	4	4.2	1.1	10.3	89	6	6.7	2.5	14.1	76	7	9.2	3.8	18.1	113	7	6.2	2.5	12.3	90	10	11.1	5.5	19.5	98	14	14.3	8.0	22.8
		>20	96	1	1.0	0.0	5.7	89	1	1.1	0.0	6.1	76	1	1.3	0.0	7.1	113	2	1.8	0.2	6.2	90	3	3.3	0.7	9.4	98	8	8.2	3.6	15.5
		Medical advice	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Dose 2																																
Pain	Total	All	94	43	45.7	35.4	56.3	88	41	46.6	35.9	57.5	75	47	62.7	50.7	73.6	109	65	59.6	49.8	68.9	83	37	44.6	33.7	55.9	97	56	57.7	47.3	67.7
		Grade 2 or 3	94	12	12.8	6.8	21.2	88	13	14.8	8.1	23.9	75	20	26.7	17.1	38.1	109	34	31.2	22.7	40.8	83	11	13.3	6.8	22.5	97	21	21.6	13.9	31.2
		Grade 3	94	0	0.0	0.0	3.8	88	1	1.1	0.0	6.2	75	4	5.3	1.5	13.1	109	6	5.5	2.0	11.6	83	2	2.4	0.3	8.4	97	4	4.1	1.1	10.2
		Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	83	0	0.0	0.0	4.3	97	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											75	41	54.7	42.7	66.2	109	63	57.8	48.0	67.2	5	4	80.0	28.4	99.5	8	2	25.0	3.2	65.1
		Grade 2 or 3											75	18	24.0	14.9	35.3	109	29	26.6	18.6	35.9	5	1	20.0	0.5	71.6	8	1	12.5	0.3	52.7

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI					95 % CI			
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		Grade 3											75	3	4.0	0.8	11.2	109	6	5.5	2.0	11.6	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9
		Medical advice											75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9
	Hexa/Pediarix/Pentacel	All	94	43	45.7	35.4	56.3	88	41	46.6	35.9	57.5	75	45	60.0	48.0	71.1	109	63	57.8	48.0	67.2	83	37	44.6	33.7	55.9	97	56	57.7	47.3	67.7
		Grade 2 or 3	94	12	12.8	6.8	21.2	88	13	14.8	8.1	23.9	75	16	21.3	12.7	32.3	109	28	25.7	17.8	34.9	83	10	12.0	5.9	21.0	97	21	21.6	13.9	31.2
		Grade 3	94	0	0.0	0.0	3.8	88	1	1.1	0.0	6.2	75	3	4.0	0.8	11.2	109	4	3.7	1.0	9.1	83	2	2.4	0.3	8.4	97	4	4.1	1.1	10.2
		Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	83	0	0.0	0.0	4.3	97	0	0.0	0.0	3.7
Redness (mm)	Total	All	94	26	27.7	18.9	37.8	88	33	37.5	27.4	48.5	75	33	44.0	32.5	55.9	109	44	40.4	31.1	50.2	83	32	38.6	28.1	49.9	97	32	33.0	23.8	43.3
		>5	94	9	9.6	4.5	17.4	88	6	6.8	2.5	14.3	75	11	14.7	7.6	24.7	109	11	10.1	5.1	17.3	83	8	9.6	4.3	18.1	97	8	8.2	3.6	15.6
		>20	94	2	2.1	0.3	7.5	88	1	1.1	0.0	6.2	75	1	1.3	0.0	7.2	109	2	1.8	0.2	6.5	83	1	1.2	0.0	6.5	97	1	1.0	0.0	5.6
		Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	83	0	0.0	0.0	4.3	97	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											75	28	37.3	26.4	49.3	109	38	34.9	26.0	44.6	5	3	60.0	14.7	94.7	8	2	25.0	3.2	65.1
		>5											75	10	13.3	6.6	23.2	109	7	6.4	2.6	12.8	5	1	20.0	0.5	71.6	8	0	0.0	0.0	36.9
		>20											75	1	1.3	0.0	7.2	109	0	0.0	0.0	3.3	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9
		Medical advice											75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9
	Hexa/Pediarix/Pentacel	All	94	26	27.7	18.9	37.8	88	33	37.5	27.4	48.5	75	27	36.0	25.2	47.9	109	34	31.2	22.7	40.8	83	32	38.6	28.1	49.9	97	32	33.0	23.8	43.3
		>5	94	9	9.6	4.5	17.4	88	6	6.8	2.5	14.3	75	5	6.7	2.2	14.9	109	7	6.4	2.6	12.8	83	7	8.4	3.5	16.6	97	8	8.2	3.6	15.6
		>20	94	2	2.1	0.3	7.5	88	1	1.1	0.0	6.2	75	1	1.3	0.0	7.2	109	2	1.8	0.2	6.5	83	1	1.2	0.0	6.5	97	1	1.0	0.0	5.6
		Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	83	0	0.0	0.0	4.3	97	0	0.0	0.0	3.7
Swelling (mm)	Total	All	94	21	22.3	14.4	32.1	88	20	22.7	14.5	32.9	75	21	28.0	18.2	39.6	109	30	27.5	19.4	36.9	83	24	28.9	19.5	39.9	97	20	20.6	13.1	30.0
		>5	94	5	5.3	1.7	12.0	88	5	5.7	1.9	12.8	75	7	9.3	3.8	18.3	109	9	8.3	3.8	15.1	83	5	6.0	2.0	13.5	97	2	2.1	0.3	7.3
		>20	94	2	2.1	0.3	7.5	88	0	0.0	0.0	4.1	75	2	2.7	0.3	9.3	109	0	0.0	0.0	3.3	83	2	2.4	0.3	8.4	97	1	1.0	0.0	5.6
		Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	83	0	0.0	0.0	4.3	97	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											75	15	20.0	11.6	30.8	109	25	22.9	15.4	32.0	5	2	40.0	5.3	85.3	8	1	12.5	0.3	52.7
		>5											75	6	8.0	3.0	16.6	109	5	4.6	1.5	10.4	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI					95 % CI			
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		>20											75	1	1.3	0.0	7.2	109	0	0.0	0.0	3.3	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9
		Medical advice											75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	5	0	0.0	0.0	52.2	8	0	0.0	0.0	36.9
	Hexa/Pediarix/Pentacel	All	94	21	22.3	14.4	32.1	88	20	22.7	14.5	32.9	75	17	22.7	13.8	33.8	109	23	21.1	13.9	30.0	83	22	26.5	17.4	37.3	97	20	20.6	13.1	30.0
		>5	94	5	5.3	1.7	12.0	88	5	5.7	1.9	12.8	75	5	6.7	2.2	14.9	109	7	6.4	2.6	12.8	83	5	6.0	2.0	13.5	97	2	2.1	0.3	7.3
		>20	94	2	2.1	0.3	7.5	88	0	0.0	0.0	4.1	75	2	2.7	0.3	9.3	109	0	0.0	0.0	3.3	83	2	2.4	0.3	8.4	97	1	1.0	0.0	5.6
		Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	83	0	0.0	0.0	4.3	97	0	0.0	0.0	3.7
Dose 3																																
Pain	Total	All	88	32	36.4	26.4	47.3	84	35	41.7	31.0	52.9	68	42	61.8	49.2	73.3	107	56	52.3	42.5	62.1	78	35	44.9	33.6	56.6	93	48	51.6	41.0	62.1
		Grade 2 or 3	88	6	6.8	2.5	14.3	84	12	14.3	7.6	23.6	68	16	23.5	14.1	35.4	107	29	27.1	19.0	36.6	78	14	17.9	10.2	28.3	93	14	15.1	8.5	24.0
		Grade 3	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	3	4.4	0.9	12.4	107	5	4.7	1.5	10.6	78	4	5.1	1.4	12.6	93	3	3.2	0.7	9.1
		Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	93	0	0.0	0.0	3.9
	ActHIB/Engerix B	All											68	39	57.4	44.8	69.3	107	54	50.5	40.6	60.3	78	32	41.0	30.0	52.7	91	43	47.3	36.7	58.0
		Grade 2 or 3											68	13	19.1	10.6	30.5	107	28	26.2	18.1	35.6	78	13	16.7	9.2	26.8	91	12	13.2	7.0	21.9
		Grade 3											68	2	2.9	0.4	10.2	107	5	4.7	1.5	10.6	78	3	3.8	0.8	10.8	91	2	2.2	0.3	7.7
		Medical advice											68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	91	0	0.0	0.0	4.0
	Hexa/Pediarix/Pentacel	All	88	32	36.4	26.4	47.3	84	35	41.7	31.0	52.9	68	38	55.9	43.3	67.9	107	52	48.6	38.8	58.5	78	34	43.6	32.4	55.3	92	42	45.7	35.2	56.4
		Grade 2 or 3	88	6	6.8	2.5	14.3	84	12	14.3	7.6	23.6	68	15	22.1	12.9	33.8	107	24	22.4	14.9	31.5	78	12	15.4	8.2	25.3	92	8	8.7	3.8	16.4
		Grade 3	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	3	4.4	0.9	12.4	107	4	3.7	1.0	9.3	78	4	5.1	1.4	12.6	92	3	3.3	0.7	9.2
		Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
Redness (mm)	Total	All	88	35	39.8	29.5	50.8	84	28	33.3	23.4	44.5	68	32	47.1	34.8	59.6	107	49	45.8	36.1	55.7	78	28	35.9	25.3	47.6	93	37	39.8	29.8	50.5
		>5	88	7	8.0	3.3	15.7	84	0	0.0	0.0	4.3	68	5	7.4	2.4	16.3	107	9	8.4	3.9	15.4	78	11	14.1	7.3	23.8	93	5	5.4	1.8	12.1
		>20	88	1	1.1	0.0	6.2	84	0	0.0	0.0	4.3	68	2	2.9	0.4	10.2	107	2	1.9	0.2	6.6	78	2	2.6	0.3	9.0	93	0	0.0	0.0	3.9
		Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	93	0	0.0	0.0	3.9

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI				95 % CI						95 % CI					95 % CI								95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	ActHIB/Engerix B	All											68	29	42.6	30.7	55.2	107	40	37.4	28.2	47.3	78	23	29.5	19.7	40.9	91	28	30.8	21.5	41.3
		>5											68	3	4.4	0.9	12.4	107	4	3.7	1.0	9.3	78	7	9.0	3.7	17.6	91	2	2.2	0.3	7.7
		>20											68	1	1.5	0.0	7.9	107	0	0.0	0.0	3.4	78	2	2.6	0.3	9.0	91	0	0.0	0.0	4.0
		Medical advice											68	0	0.0	0.0	5.3	107	0	0.0	0.0	3.4	78	0	0.0	0.0	4.6	91	0	0.0	0.0	4.0
	Hexa/Pediarix/Pentacel	All	88	35	39.8	29.5	50.8	84	28	33.3	23.4	44.5	68	24	35.3	24.1	47.8	107	42	39.3	30.0	49.2	78	23	29.5	19.7	40.9	92	33	35.9	26.1	46.5
		>5	88	7	8.0	3.3	15.7	84	0	0.0	0.0	4.3	68	3	4.4	0.9	12.4	107	9	8.4	3.9	15.4	78	6	7.7	2.9	16.0	92	5	5.4	1.8	12.2
		>20	88	1	1.1	0.0	6.2	84	0	0.0	0.0	4.3	68	1	1.5	0.0	7.9	107	2	1.9	0.2	6.6	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
		Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
Swelling (mm)	Total	All	88	25	28.4	19.3	39.0	84	18	21.4	13.2	31.7	68	20	29.4	19.0	41.7	107	33	30.8	22.3	40.5	78	18	23.1	14.3	34.0	93	26	28.0	19.1	38.2
		>5	88	6	6.8	2.5	14.3	84	1	1.2	0.0	6.5	68	3	4.4	0.9	12.4	107	9	8.4	3.9	15.4	78	5	6.4	2.1	14.3	93	3	3.2	0.7	9.1
		>20	88	1	1.1	0.0	6.2	84	0	0.0	0.0	4.3	68	2	2.9	0.4	10.2	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	93	0	0.0	0.0	3.9
		Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	93	0	0.0	0.0	3.9
	ActHIB/Engerix B	All											68	16	23.5	14.1	35.4	107	26	24.3	16.5	33.5	78	14	17.9	10.2	28.3	91	23	25.3	16.7	35.5
		>5											68	2	2.9	0.4	10.2	107	5	4.7	1.5	10.6	78	4	5.1	1.4	12.6	91	3	3.3	0.7	9.3
		>20											68	1	1.5	0.0	7.9	107	0	0.0	0.0	3.4	78	0	0.0	0.0	4.6	91	0	0.0	0.0	4.0
		Medical advice											68	0	0.0	0.0	5.3	107	0	0.0	0.0	3.4	78	0	0.0	0.0	4.6	91	0	0.0	0.0	4.0
	Hexa/Pediarix/Pentacel	All	88	25	28.4	19.3	39.0	84	18	21.4	13.2	31.7	68	16	23.5	14.1	35.4	107	28	26.2	18.1	35.6	78	13	16.7	9.2	26.8	92	22	23.9	15.6	33.9
		>5	88	6	6.8	2.5	14.3	84	1	1.2	0.0	6.5	68	3	4.4	0.9	12.4	107	7	6.5	2.7	13.0	78	1	1.3	0.0	6.9	92	3	3.3	0.7	9.2
		>20	88	1	1.1	0.0	6.2	84	0	0.0	0.0	4.3	68	2	2.9	0.4	10.2	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
		Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Overall/dose																																
Pain	Total	All	278	120	43.2	37.3	49.2	261	125	47.9	41.7	54.1	219	140	63.9	57.2	70.3	329	198	60.2	54.7	65.5	251	123	49.0	42.7	55.4	288	172	59.7	53.8	65.4
		Grade 2 or 3	278	40	14.4	10.5	19.1	261	43	16.5	12.2	21.5	219	69	31.5	25.4	38.1	329	105	31.9	26.9	37.3	251	53	21.1	16.2	26.7	288	63	21.9	17.2	27.1
		Grade 3	278	4	1.4	0.4	3.6	261	5	1.9	0.6	4.4	219	18	8.2	4.9	12.7	329	24	7.3	4.7	10.7	251	11	4.4	2.2	7.7	288	14	4.9	2.7	8.0
		Medical advice	278	1	0.4	0.0	2.0	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	251	0	0.0	0.0	1.5	288	0	0.0	0.0	1.3
	ActHIB/Engerix B	All											219	129	58.9	52.1	65.5	329	191	58.1	52.5	63.4	173	80	46.2	38.6	54.0	197	101	51.3	44.1	58.4
		Grade 2 or 3											219	61	27.9	22.0	34.3	329	93	28.3	23.5	33.5	173	37	21.4	15.5	28.3	197	35	17.8	12.7	23.8
		Grade 3											219	15	6.8	3.9	11.0	329	23	7.0	4.5	10.3	173	6	3.5	1.3	7.4	197	9	4.6	2.1	8.5
		Medical advice											219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	173	0	0.0	0.0	2.1	197	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	278	120	43.2	37.3	49.2	261	125	47.9	41.7	54.1	219	130	59.4	52.5	65.9	329	181	55.0	49.5	60.5	251	120	47.8	41.5	54.2	287	164	57.1	51.2	62.9
		Grade 2 or 3	278	40	14.4	10.5	19.1	261	43	16.5	12.2	21.5	219	62	28.3	22.4	34.8	329	86	26.1	21.5	31.2	251	48	19.1	14.4	24.5	287	54	18.8	14.5	23.8
		Grade 3	278	4	1.4	0.4	3.6	261	5	1.9	0.6	4.4	219	14	6.4	3.5	10.5	329	17	5.2	3.0	8.1	251	11	4.4	2.2	7.7	287	14	4.9	2.7	8.0
		Medical advice	278	1	0.4	0.0	2.0	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	1	0.3	0.0	1.7	251	0	0.0	0.0	1.5	287	0	0.0	0.0	1.3
Redness (mm)	Total	All	278	86	30.9	25.6	36.7	261	83	31.8	26.2	37.8	219	94	42.9	36.3	49.8	329	137	41.6	36.3	47.2	251	91	36.3	30.3	42.5	288	105	36.5	30.9	42.3
		>5	278	24	8.6	5.6	12.6	261	13	5.0	2.7	8.4	219	25	11.4	7.5	16.4	329	38	11.6	8.3	15.5	251	33	13.1	9.2	18.0	288	26	9.0	6.0	12.9
		>20	278	5	1.8	0.6	4.1	261	2	0.8	0.1	2.7	219	4	1.8	0.5	4.6	329	13	4.0	2.1	6.7	251	4	1.6	0.4	4.0	288	4	1.4	0.4	3.5
		Medical advice	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	251	0	0.0	0.0	1.5	288	0	0.0	0.0	1.3
	ActHIB/Engerix B	All											219	81	37.0	30.6	43.8	329	117	35.6	30.4	41.0	173	54	31.2	24.4	38.7	197	57	28.9	22.7	35.8
		>5											219	19	8.7	5.3	13.2	329	24	7.3	4.7	10.7	173	17	9.8	5.8	15.3	197	5	2.5	0.8	5.8
		>20											219	3	1.4	0.3	4.0	329	7	2.1	0.9	4.3	173	3	1.7	0.4	5.0	197	0	0.0	0.0	1.9
		Medical advice											219	0	0.0	0.0	1.7	329	1	0.3	0.0	1.7	173	0	0.0	0.0	2.1	197	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	278	86	30.9	25.6	36.7	261	83	31.8	26.2	37.8	219	73	33.3	27.1	40.0	329	110	33.4	28.4	38.8	251	80	31.9	26.2	38.0	287	97	33.8	28.3	39.6
		>5	278	24	8.6	5.6	12.6	261	13	5.0	2.7	8.4	219	14	6.4	3.5	10.5	329	25	7.6	5.0	11.0	251	22	8.8	5.6	13.0	287	24	8.4	5.4	12.2
		>20	278	5	1.8	0.6	4.1	261	2	0.8	0.1	2.7	219	3	1.4	0.3	4.0	329	7	2.1	0.9	4.3	251	1	0.4	0.0	2.2	287	4	1.4	0.4	3.5

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI					95 % CI		
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
		Medical advice	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	1	0.3	0.0	1.7	251	0	0.0	0.0	1.5	287	0	0.0	0.0	1.3
Swelling (mm)	Total	All	278	60	21.6	16.9	26.9	261	55	21.1	16.3	26.5	219	64	29.2	23.3	35.7	329	86	26.1	21.5	31.2	251	62	24.7	19.5	30.5	288	79	27.4	22.4	33.0
		>5	278	15	5.4	3.1	8.7	261	12	4.6	2.4	7.9	219	18	8.2	4.9	12.7	329	28	8.5	5.7	12.1	251	20	8.0	4.9	12.0	288	19	6.6	4.0	10.1
		>20	278	4	1.4	0.4	3.6	261	1	0.4	0.0	2.1	219	6	2.7	1.0	5.9	329	6	1.8	0.7	3.9	251	5	2.0	0.6	4.6	288	9	3.1	1.4	5.8
		Medical advice	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	251	0	0.0	0.0	1.5	288	0	0.0	0.0	1.3
	ActHIB/Engerix B	All											219	50	22.8	17.4	29.0	329	73	22.2	17.8	27.1	173	33	19.1	13.5	25.7	197	46	23.4	17.6	29.9
		>5											219	12	5.5	2.9	9.4	329	20	6.1	3.8	9.2	173	10	5.8	2.8	10.4	197	11	5.6	2.8	9.8
		>20											219	4	1.8	0.5	4.6	329	4	1.2	0.3	3.1	173	1	0.6	0.0	3.2	197	2	1.0	0.1	3.6
		Medical advice											219	0	0.0	0.0	1.7	329	1	0.3	0.0	1.7	173	0	0.0	0.0	2.1	197	0	0.0	0.0	1.9
	Hexa/Pediarix/Pentacel	All	278	60	21.6	16.9	26.9	261	55	21.1	16.3	26.5	219	50	22.8	17.4	29.0	329	69	21.0	16.7	25.8	251	53	21.1	16.2	26.7	287	69	24.0	19.2	29.4
		>5	278	15	5.4	3.1	8.7	261	12	4.6	2.4	7.9	219	15	6.8	3.9	11.0	329	21	6.4	4.0	9.6	251	16	6.4	3.7	10.1	287	19	6.6	4.0	10.1
		>20	278	4	1.4	0.4	3.6	261	1	0.4	0.0	2.1	219	5	2.3	0.7	5.2	329	3	0.9	0.2	2.6	251	5	2.0	0.6	4.6	287	9	3.1	1.4	5.9
		Medical advice	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	1	0.3	0.0	1.7	251	0	0.0	0.0	1.5	287	0	0.0	0.0	1.3
Overall/subject																																
Pain	Total	All	97	64	66.0	55.7	75.3	90	63	70.0	59.4	79.2	76	64	84.2	74.0	91.6	113	91	80.5	72.0	87.4	90	68	75.6	65.4	84.0	98	82	83.7	74.8	90.4
		Grade 2 or 3	97	29	29.9	21.0	40.0	90	29	32.2	22.8	42.9	76	43	56.6	44.7	67.9	113	61	54.0	44.4	63.4	90	41	45.6	35.0	56.4	98	47	48.0	37.8	58.3
		Grade 3	97	4	4.1	1.1	10.2	90	4	4.4	1.2	11.0	76	15	19.7	11.5	30.5	113	19	16.8	10.4	25.0	90	11	12.2	6.3	20.8	98	11	11.2	5.7	19.2
		Medical advice	97	1	1.0	0.0	5.6	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											76	61	80.3	69.5	88.5	113	87	77.0	68.1	84.4	90	58	64.4	53.7	74.3	98	69	70.4	60.3	79.2
		Grade 2 or 3											76	38	50.0	38.3	61.7	113	58	51.3	41.7	60.8	90	32	35.6	25.7	46.3	98	30	30.6	21.7	40.7
		Grade 3											76	12	15.8	8.4	26.0	113	18	15.9	9.7	24.0	90	6	6.7	2.5	13.9	98	8	8.2	3.6	15.5
		Medical advice											76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Hexa/Pediarix/Pentacel	All	97	64	66.0	55.7	75.3	90	63	70.0	59.4	79.2	76	63	82.9	72.5	90.6	113	88	77.9	69.1	85.1	90	65	72.2	61.8	81.1	98	82	83.7	74.8	90.4
		Grade 2 or	97	29	29.9	21.0	40.0	90	29	32.2	22.8	42.9	76	38	50.0	38.3	61.7	113	55	48.7	39.2	58.3	90	38	42.2	31.9	53.1	98	42	42.9	32.9	53.3

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI				95 % CI						95 % CI					95 % CI								95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		3																														
		Grade 3	97	4	4.1	1.1	10.2	90	4	4.4	1.2	11.0	76	12	15.8	8.4	26.0	113	15	13.3	7.6	20.9	90	11	12.2	6.3	20.8	98	11	11.2	5.7	19.2
		Medical advice	97	1	1.0	0.0	5.6	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Redness (mm)	Total	All	97	48	49.5	39.2	59.8	90	46	51.1	40.3	61.8	76	51	67.1	55.4	77.5	113	69	61.1	51.4	70.1	90	48	53.3	42.5	63.9	98	58	59.2	48.8	69.0
		>5	97	17	17.5	10.6	26.6	90	10	11.1	5.5	19.5	76	20	26.3	16.9	37.7	113	29	25.7	17.9	34.7	90	26	28.9	19.8	39.4	98	19	19.4	12.1	28.6
		>20	97	5	5.2	1.7	11.6	90	2	2.2	0.3	7.8	76	4	5.3	1.5	12.9	113	11	9.7	5.0	16.8	90	4	4.4	1.2	11.0	98	4	4.1	1.1	10.1
		Medical advice	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											76	46	60.5	48.6	71.6	113	62	54.9	45.2	64.2	90	36	40.0	29.8	50.9	98	41	41.8	31.9	52.2
		>5											76	17	22.4	13.6	33.4	113	21	18.6	11.9	27.0	90	16	17.8	10.5	27.3	98	4	4.1	1.1	10.1
		>20											76	3	3.9	0.8	11.1	113	7	6.2	2.5	12.3	90	3	3.3	0.7	9.4	98	0	0.0	0.0	3.7
		Medical advice											76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Hexa/Pediarix/Pentacel	All	97	48	49.5	39.2	59.8	90	46	51.1	40.3	61.8	76	36	47.4	35.8	59.2	113	62	54.9	45.2	64.2	90	42	46.7	36.1	57.5	98	55	56.1	45.7	66.1
		>5	97	17	17.5	10.6	26.6	90	10	11.1	5.5	19.5	76	11	14.5	7.5	24.4	113	21	18.6	11.9	27.0	90	19	21.1	13.2	31.0	98	18	18.4	11.3	27.5
		>20	97	5	5.2	1.7	11.6	90	2	2.2	0.3	7.8	76	3	3.9	0.8	11.1	113	6	5.3	2.0	11.2	90	1	1.1	0.0	6.0	98	4	4.1	1.1	10.1
		Medical advice	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Swelling (mm)	Total	All	97	38	39.2	29.4	49.6	90	35	38.9	28.8	49.7	76	40	52.6	40.8	64.2	113	48	42.5	33.2	52.1	90	33	36.7	26.8	47.5	98	48	49.0	38.7	59.3
		>5	97	10	10.3	5.1	18.1	90	10	11.1	5.5	19.5	76	14	18.4	10.5	29.0	113	20	17.7	11.2	26.0	90	15	16.7	9.6	26.0	98	14	14.3	8.0	22.8
		>20	97	3	3.1	0.6	8.8	90	1	1.1	0.0	6.0	76	5	6.6	2.2	14.7	113	6	5.3	2.0	11.2	90	4	4.4	1.2	11.0	98	8	8.2	3.6	15.5
		Medical advice	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	ActHIB/Engerix B	All											76	33	43.4	32.1	55.3	113	45	39.8	30.7	49.5	90	27	30.0	20.8	40.6	98	37	37.8	28.2	48.1
		>5											76	10	13.2	6.5	22.9	113	15	13.3	7.6	20.9	90	9	10.0	4.7	18.1	98	9	9.2	4.3	16.7
		>20											76	3	3.9	0.8	11.1	113	4	3.5	1.0	8.8	90	1	1.1	0.0	6.0	98	2	2.0	0.2	7.2

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		Medical advice											76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Hexa/Pediarix/Pentacel	All	97	38	39.2	29.4	49.6	90	35	38.9	28.8	49.7	76	30	39.5	28.4	51.4	113	40	35.4	26.6	45.0	90	29	32.2	22.8	42.9	98	43	43.9	33.9	54.3
		>5	97	10	10.3	5.1	18.1	90	10	11.1	5.5	19.5	76	11	14.5	7.5	24.4	113	15	13.3	7.6	20.9	90	12	13.3	7.1	22.1	98	14	14.3	8.0	22.8
		>20	97	3	3.1	0.6	8.8	90	1	1.1	0.0	6.0	76	4	5.3	1.5	12.9	113	3	2.7	0.6	7.6	90	4	4.4	1.2	11.0	98	8	8.2	3.6	15.5
		Medical advice	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.10 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall – by geographical ancestry (Primary Total vaccinated cohort)

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																																
Pain	Total	All	112	60	53.6	43.9	63.0	73	34	46.6	34.8	58.6	123	85	69.1	60.1	77.1	66	43	65.2	52.4	76.5	112	74	66.1	56.5	74.7	76	45	59.2	47.3	70.4
		Grade 2 or 3	112	25	22.3	15.0	31.2	73	15	20.5	12.0	31.6	123	46	37.4	28.8	46.6	66	29	43.9	31.7	56.7	112	41	36.6	27.7	46.2	76	15	19.7	11.5	30.5
		Grade 3	112	6	5.4	2.0	11.3	73	2	2.7	0.3	9.5	123	14	11.4	6.4	18.4	66	10	15.2	7.5	26.1	112	10	8.9	4.4	15.8	76	2	2.6	0.3	9.2
		Medical advice	112	1	0.9	0.0	4.9	73	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	ActHIB/Engerix B	All											123	82	66.7	57.6	74.9	66	41	62.1	49.3	73.8	112	61	54.5	44.8	63.9	76	39	51.3	39.6	63.0
		Grade 2 or 3											123	39	31.7	23.6	40.7	66	27	40.9	29.0	53.7	112	32	28.6	20.4	37.9	76	13	17.1	9.4	27.5
		Grade 3											123	13	10.6	5.7	17.4	66	9	13.6	6.4	24.3	112	9	8.0	3.7	14.7	76	1	1.3	0.0	7.1
		Medical advice											123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Hexa/Pediarix/Pentacel	All	112	60	53.6	43.9	63.0	73	34	46.6	34.8	58.6	123	77	62.6	53.4	71.2	66	36	54.5	41.8	66.9	112	71	63.4	53.8	72.3	76	44	57.9	46.0	69.1
		Grade 2 or 3	112	25	22.3	15.0	31.2	73	15	20.5	12.0	31.6	123	42	34.1	25.8	43.2	66	23	34.8	23.5	47.6	112	36	32.1	23.6	41.6	76	15	19.7	11.5	30.5
		Grade 3	112	6	5.4	2.0	11.3	73	2	2.7	0.3	9.5	123	11	8.9	4.5	15.4	66	6	9.1	3.4	18.7	112	10	8.9	4.4	15.8	76	2	2.6	0.3	9.2
		Medical advice	112	1	0.9	0.0	4.9	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Redness (mm)	Total	All	112	35	31.3	22.8	40.7	73	12	16.4	8.8	27.0	123	56	45.5	36.5	54.8	66	17	25.8	15.8	38.0	112	44	39.3	30.2	49.0	76	23	30.3	20.2	41.9
		>5	112	13	11.6	6.3	19.0	73	2	2.7	0.3	9.5	123	20	16.3	10.2	24.0	66	7	10.6	4.4	20.6	112	20	17.9	11.3	26.2	76	7	9.2	3.8	18.1
		>20	112	3	2.7	0.6	7.6	73	0	0.0	0.0	4.9	123	7	5.7	2.3	11.4	66	3	4.5	0.9	12.7	112	2	1.8	0.2	6.3	76	2	2.6	0.3	9.2
		Medical advice	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	ActHIB/Engerix B	All											123	48	39.0	30.4	48.2	66	15	22.7	13.3	34.7	112	35	31.3	22.8	40.7	76	20	26.3	16.9	37.7
		>5											123	13	10.6	5.7	17.4	66	6	9.1	3.4	18.7	112	8	7.1	3.1	13.6	76	4	5.3	1.5	12.9
		>20											123	5	4.1	1.3	9.2	66	3	4.5	0.9	12.7	112	1	0.9	0.0	4.9	76	0	0.0	0.0	4.7

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		Medical advice											123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Hexa/Pediarix/Pentacel	All	112	35	31.3	22.8	40.7	73	12	16.4	8.8	27.0	123	47	38.2	29.6	47.4	66	9	13.6	6.4	24.3	112	39	34.8	26.1	44.4	76	18	23.7	14.7	34.8
		>5	112	13	11.6	6.3	19.0	73	2	2.7	0.3	9.5	123	12	9.8	5.1	16.4	66	3	4.5	0.9	12.7	112	15	13.4	7.7	21.1	76	5	6.6	2.2	14.7
		>20	112	3	2.7	0.6	7.6	73	0	0.0	0.0	4.9	123	3	2.4	0.5	7.0	66	1	1.5	0.0	8.2	112	1	0.9	0.0	4.9	76	2	2.6	0.3	9.2
		Medical advice	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Swelling (mm)	Total	All	112	20	17.9	11.3	26.2	73	11	15.1	7.8	25.4	123	32	26.0	18.5	34.7	66	14	21.2	12.1	33.0	112	34	30.4	22.0	39.8	76	19	25.0	15.8	36.3
		>5	112	8	7.1	3.1	13.6	73	2	2.7	0.3	9.5	123	14	11.4	6.4	18.4	66	4	6.1	1.7	14.8	112	16	14.3	8.4	22.2	76	8	10.5	4.7	19.7
		>20	112	2	1.8	0.2	6.3	73	0	0.0	0.0	4.9	123	6	4.9	1.8	10.3	66	1	1.5	0.0	8.2	112	8	7.1	3.1	13.6	76	3	3.9	0.8	11.1
		Medical advice	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	ActHIB/Engerix B	All											123	29	23.6	16.4	32.1	66	12	18.2	9.8	29.6	112	24	21.4	14.2	30.2	76	15	19.7	11.5	30.5
		>5											123	13	10.6	5.7	17.4	66	1	1.5	0.0	8.2	112	8	7.1	3.1	13.6	76	6	7.9	3.0	16.4
		>20											123	5	4.1	1.3	9.2	66	1	1.5	0.0	8.2	112	3	2.7	0.6	7.6	76	0	0.0	0.0	4.7
		Medical advice											123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Hexa/Pediarix/Pentacel	All	112	20	17.9	11.3	26.2	73	11	15.1	7.8	25.4	123	26	21.1	14.3	29.4	66	9	13.6	6.4	24.3	112	28	25.0	17.3	34.1	76	17	22.4	13.6	33.4
		>5	112	8	7.1	3.1	13.6	73	2	2.7	0.3	9.5	123	10	8.1	4.0	14.4	66	4	6.1	1.7	14.8	112	16	14.3	8.4	22.2	76	8	10.5	4.7	19.7
		>20	112	2	1.8	0.2	6.3	73	0	0.0	0.0	4.9	123	2	1.6	0.2	5.8	66	1	1.5	0.0	8.2	112	8	7.1	3.1	13.6	76	3	3.9	0.8	11.1
		Medical advice	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Dose 2																																
Pain	Total	All	110	54	49.1	39.4	58.8	72	30	41.7	30.2	53.9	119	70	58.8	49.4	67.8	65	42	64.6	51.8	76.1	107	60	56.1	46.1	65.7	73	33	45.2	33.5	57.3
		Grade 2 or 3	110	15	13.6	7.8	21.5	72	10	13.9	6.9	24.1	119	28	23.5	16.2	32.2	65	26	40.0	28.0	52.9	107	20	18.7	11.8	27.4	73	12	16.4	8.8	27.0
		Grade 3	110	1	0.9	0.0	5.0	72	0	0.0	0.0	5.0	119	4	3.4	0.9	8.4	65	6	9.2	3.5	19.0	107	3	2.8	0.6	8.0	73	3	4.1	0.9	11.5
		Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	73	0	0.0	0.0	4.9
	ActHIB/Engerix B	All											119	67	56.3	46.9	65.4	65	37	56.9	44.0	69.2	9	5	55.6	21.2	86.3	4	1	25.0	0.6	80.6
		Grade 2 or 3											119	24	20.2	13.4	28.5	65	23	35.4	23.9	48.2	9	1	11.1	0.3	48.2	4	1	25.0	0.6	80.6

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		Grade 3											119	3	2.5	0.5	7.2	65	6	9.2	3.5	19.0	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2
		Medical advice											119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2
	Hexa/Pediarix/Pentacel	All	110	54	49.1	39.4	58.8	72	30	41.7	30.2	53.9	119	66	55.5	46.1	64.6	65	42	64.6	51.8	76.1	107	60	56.1	46.1	65.7	73	33	45.2	33.5	57.3
		Grade 2 or 3	110	15	13.6	7.8	21.5	72	10	13.9	6.9	24.1	119	24	20.2	13.4	28.5	65	20	30.8	19.9	43.4	107	20	18.7	11.8	27.4	73	11	15.1	7.8	25.4
		Grade 3	110	1	0.9	0.0	5.0	72	0	0.0	0.0	5.0	119	2	1.7	0.2	5.9	65	5	7.7	2.5	17.0	107	3	2.8	0.6	8.0	73	3	4.1	0.9	11.5
		Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	73	0	0.0	0.0	4.9
Redness (mm)	Total	All	110	40	36.4	27.4	46.1	72	19	26.4	16.7	38.1	119	56	47.1	37.8	56.4	65	21	32.3	21.2	45.1	107	41	38.3	29.1	48.2	73	23	31.5	21.1	43.4
		>5	110	9	8.2	3.8	15.0	72	6	8.3	3.1	17.3	119	18	15.1	9.2	22.8	65	4	6.2	1.7	15.0	107	9	8.4	3.9	15.4	73	7	9.6	3.9	18.8
		>20	110	1	0.9	0.0	5.0	72	2	2.8	0.3	9.7	119	1	0.8	0.0	4.6	65	2	3.1	0.4	10.7	107	1	0.9	0.0	5.1	73	1	1.4	0.0	7.4
		Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	73	0	0.0	0.0	4.9
	ActHIB/Engerix B	All											119	49	41.2	32.2	50.6	65	17	26.2	16.0	38.5	9	3	33.3	7.5	70.1	4	2	50.0	6.8	93.2
		>5											119	14	11.8	6.6	19.0	65	3	4.6	1.0	12.9	9	0	0.0	0.0	33.6	4	1	25.0	0.6	80.6
		>20											119	0	0.0	0.0	3.1	65	1	1.5	0.0	8.3	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2
		Medical advice											119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2
	Hexa/Pediarix/Pentacel	All	110	40	36.4	27.4	46.1	72	19	26.4	16.7	38.1	119	46	38.7	29.9	48.0	65	15	23.1	13.5	35.2	107	41	38.3	29.1	48.2	73	23	31.5	21.1	43.4
		>5	110	9	8.2	3.8	15.0	72	6	8.3	3.1	17.3	119	10	8.4	4.1	14.9	65	2	3.1	0.4	10.7	107	9	8.4	3.9	15.4	73	6	8.2	3.1	17.0
		>20	110	1	0.9	0.0	5.0	72	2	2.8	0.3	9.7	119	1	0.8	0.0	4.6	65	2	3.1	0.4	10.7	107	1	0.9	0.0	5.1	73	1	1.4	0.0	7.4
		Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	73	0	0.0	0.0	4.9
Swelling (mm)	Total	All	110	21	19.1	12.2	27.7	72	20	27.8	17.9	39.6	119	36	30.3	22.2	39.3	65	15	23.1	13.5	35.2	107	29	27.1	19.0	36.6	73	15	20.5	12.0	31.6
		>5	110	4	3.6	1.0	9.0	72	6	8.3	3.1	17.3	119	13	10.9	5.9	18.0	65	3	4.6	1.0	12.9	107	5	4.7	1.5	10.6	73	2	2.7	0.3	9.5
		>20	110	0	0.0	0.0	3.3	72	2	2.8	0.3	9.7	119	0	0.0	0.0	3.1	65	2	3.1	0.4	10.7	107	3	2.8	0.6	8.0	73	0	0.0	0.0	4.9
		Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	73	0	0.0	0.0	4.9
	ActHIB/Engerix B	All											119	29	24.4	17.0	33.1	65	11	16.9	8.8	28.3	9	2	22.2	2.8	60.0	4	1	25.0	0.6	80.6
		>5											119	8	6.7	2.9	12.8	65	3	4.6	1.0	12.9	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		>20											119	0	0.0	0.0	3.1	65	1	1.5	0.0	8.3	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2
		Medical advice											119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	9	0	0.0	0.0	33.6	4	0	0.0	0.0	60.2
	Hexa/Pediarix/Pentacel	All	110	21	19.1	12.2	27.7	72	20	27.8	17.9	39.6	119	27	22.7	15.5	31.3	65	13	20.0	11.1	31.8	107	27	25.2	17.3	34.6	73	15	20.5	12.0	31.6
		>5	110	4	3.6	1.0	9.0	72	6	8.3	3.1	17.3	119	9	7.6	3.5	13.9	65	3	4.6	1.0	12.9	107	5	4.7	1.5	10.6	73	2	2.7	0.3	9.5
		>20	110	0	0.0	0.0	3.3	72	2	2.8	0.3	9.7	119	0	0.0	0.0	3.1	65	2	3.1	0.4	10.7	107	3	2.8	0.6	8.0	73	0	0.0	0.0	4.9
		Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	73	0	0.0	0.0	4.9
Dose 3																																
Pain	Total	All	106	43	40.6	31.1	50.5	66	24	36.4	24.9	49.1	116	64	55.2	45.7	64.4	59	34	57.6	44.1	70.4	106	51	48.1	38.3	58.0	65	32	49.2	36.6	61.9
		Grade 2 or 3	106	10	9.4	4.6	16.7	66	8	12.1	5.4	22.5	116	31	26.7	18.9	35.7	59	14	23.7	13.6	36.6	106	16	15.1	8.9	23.4	65	12	18.5	9.9	30.0
		Grade 3	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	6	5.2	1.9	10.9	59	2	3.4	0.4	11.7	106	6	5.7	2.1	11.9	65	1	1.5	0.0	8.3
		Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	65	0	0.0	0.0	5.5
	ActHIB/Engerix B	All											116	59	50.9	41.4	60.3	59	34	57.6	44.1	70.4	104	45	43.3	33.6	53.3	65	30	46.2	33.7	59.0
		Grade 2 or 3											116	28	24.1	16.7	33.0	59	13	22.0	12.3	34.7	104	14	13.5	7.6	21.6	65	11	16.9	8.8	28.3
		Grade 3											116	5	4.3	1.4	9.8	59	2	3.4	0.4	11.7	104	4	3.8	1.1	9.6	65	1	1.5	0.0	8.3
		Medical advice											116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	104	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
	Hexa/Pediarix/Pentacel	All	106	43	40.6	31.1	50.5	66	24	36.4	24.9	49.1	116	59	50.9	41.4	60.3	59	31	52.5	39.1	65.7	106	46	43.4	33.8	53.4	64	30	46.9	34.3	59.8
		Grade 2 or 3	106	10	9.4	4.6	16.7	66	8	12.1	5.4	22.5	116	27	23.3	15.9	32.0	59	12	20.3	11.0	32.8	106	11	10.4	5.3	17.8	64	9	14.1	6.6	25.0
		Grade 3	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	5	4.3	1.4	9.8	59	2	3.4	0.4	11.7	106	6	5.7	2.1	11.9	64	1	1.6	0.0	8.4
		Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	64	0	0.0	0.0	5.6
Redness (mm)	Total	All	106	47	44.3	34.7	54.3	66	16	24.2	14.5	36.4	116	60	51.7	42.3	61.1	59	21	35.6	23.6	49.1	106	43	40.6	31.1	50.5	65	22	33.8	22.6	46.6
		>5	106	6	5.7	2.1	11.9	66	1	1.5	0.0	8.2	116	11	9.5	4.8	16.3	59	3	5.1	1.1	14.1	106	10	9.4	4.6	16.7	65	6	9.2	3.5	19.0
		>20	106	0	0.0	0.0	3.4	66	1	1.5	0.0	8.2	116	3	2.6	0.5	7.4	59	1	1.7	0.0	9.1	106	2	1.9	0.2	6.6	65	0	0.0	0.0	5.5
		Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	65	0	0.0	0.0	5.5

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	ActHIB/Engerix B	All											116	52	44.8	35.6	54.3	59	17	28.8	17.8	42.1	104	34	32.7	23.8	42.6	65	17	26.2	16.0	38.5
		>5											116	5	4.3	1.4	9.8	59	2	3.4	0.4	11.7	104	7	6.7	2.7	13.4	65	2	3.1	0.4	10.7
		>20											116	1	0.9	0.0	4.7	59	0	0.0	0.0	6.1	104	2	1.9	0.2	6.8	65	0	0.0	0.0	5.5
		Medical advice											116	0	0.0	0.0	3.1	59	0	0.0	0.0	6.1	104	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
	Hexa/Pediarix/Pentacel	All	106	47	44.3	34.7	54.3	66	16	24.2	14.5	36.4	116	49	42.2	33.1	51.8	59	17	28.8	17.8	42.1	106	35	33.0	24.2	42.8	64	21	32.8	21.6	45.7
		>5	106	6	5.7	2.1	11.9	66	1	1.5	0.0	8.2	116	9	7.8	3.6	14.2	59	3	5.1	1.1	14.1	106	5	4.7	1.5	10.7	64	6	9.4	3.5	19.3
		>20	106	0	0.0	0.0	3.4	66	1	1.5	0.0	8.2	116	2	1.7	0.2	6.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	64	0	0.0	0.0	5.6
		Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	64	0	0.0	0.0	5.6
Swelling (mm)	Total	All	106	26	24.5	16.7	33.8	66	17	25.8	15.8	38.0	116	37	31.9	23.6	41.2	59	16	27.1	16.4	40.3	106	24	22.6	15.1	31.8	65	20	30.8	19.9	43.4
		>5	106	4	3.8	1.0	9.4	66	3	4.5	0.9	12.7	116	9	7.8	3.6	14.2	59	3	5.1	1.1	14.1	106	6	5.7	2.1	11.9	65	2	3.1	0.4	10.7
		>20	106	0	0.0	0.0	3.4	66	1	1.5	0.0	8.2	116	1	0.9	0.0	4.7	59	2	3.4	0.4	11.7	106	0	0.0	0.0	3.4	65	0	0.0	0.0	5.5
		Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	65	0	0.0	0.0	5.5
	ActHIB/Engerix B	All											116	29	25.0	17.4	33.9	59	13	22.0	12.3	34.7	104	19	18.3	11.4	27.1	65	18	27.7	17.3	40.2
		>5											116	4	3.4	0.9	8.6	59	3	5.1	1.1	14.1	104	5	4.8	1.6	10.9	65	2	3.1	0.4	10.7
		>20											116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	104	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
		Medical advice											116	0	0.0	0.0	3.1	59	0	0.0	0.0	6.1	104	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
	Hexa/Pediarix/Pentacel	All	106	26	24.5	16.7	33.8	66	17	25.8	15.8	38.0	116	30	25.9	18.2	34.8	59	14	23.7	13.6	36.6	106	20	18.9	11.9	27.6	64	15	23.4	13.8	35.7
		>5	106	4	3.8	1.0	9.4	66	3	4.5	0.9	12.7	116	7	6.0	2.5	12.0	59	3	5.1	1.1	14.1	106	3	2.8	0.6	8.0	64	1	1.6	0.0	8.4
		>20	106	0	0.0	0.0	3.4	66	1	1.5	0.0	8.2	116	1	0.9	0.0	4.7	59	2	3.4	0.4	11.7	106	0	0.0	0.0	3.4	64	0	0.0	0.0	5.6
		Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	106	0	0.0	0.0	3.4	64	0	0.0	0.0	5.6
Overall/dose																																
Pain	Total	All	328	157	47.9	42.3	53.4	211	88	41.7	35.0	48.7	358	219	61.2	55.9	66.3	190	119	62.6	55.3	69.5	325	185	56.9	51.3	62.4	214	110	51.4	44.5	58.3
		Grade 2 or 3	328	50	15.2	11.5	19.6	211	33	15.6	11.0	21.3	358	105	29.3	24.7	34.3	190	69	36.3	29.5	43.6	325	77	23.7	19.2	28.7	214	39	18.2	13.3	24.1
		Grade 3	328	7	2.1	0.9	4.3	211	2	0.9	0.1	3.4	358	24	6.7	4.3	9.8	190	18	9.5	5.7	14.6	325	19	5.8	3.6	9.0	214	6	2.8	1.0	6.0

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		Medical advice	328	1	0.3	0.0	1.7	211	0	0.0	0.0	1.7	358	1	0.3	0.0	1.5	190	1	0.5	0.0	2.9	325	0	0.0	0.0	1.1	214	0	0.0	0.0	1.7
	ActHIB/Engerix B	All											358	208	58.1	52.8	63.3	190	112	58.9	51.6	66.0	225	111	49.3	42.6	56.1	145	70	48.3	39.9	56.7
		Grade 2 or 3											358	91	25.4	21.0	30.3	190	63	33.2	26.5	40.3	225	47	20.9	15.8	26.8	145	25	17.2	11.5	24.4
		Grade 3											358	21	5.9	3.7	8.8	190	17	8.9	5.3	13.9	225	13	5.8	3.1	9.7	145	2	1.4	0.2	4.9
		Medical advice											358	1	0.3	0.0	1.5	190	1	0.5	0.0	2.9	225	0	0.0	0.0	1.6	145	0	0.0	0.0	2.5
	Hexa/Pediarix/Pentacel	All	328	157	47.9	42.3	53.4	211	88	41.7	35.0	48.7	358	202	56.4	51.1	61.6	190	109	57.4	50.0	64.5	325	177	54.5	48.9	60.0	213	107	50.2	43.3	57.1
		Grade 2 or 3	328	50	15.2	11.5	19.6	211	33	15.6	11.0	21.3	358	93	26.0	21.5	30.8	190	55	28.9	22.6	36.0	325	67	20.6	16.3	25.4	213	35	16.4	11.7	22.1
		Grade 3	328	7	2.1	0.9	4.3	211	2	0.9	0.1	3.4	358	18	5.0	3.0	7.8	190	13	6.8	3.7	11.4	325	19	5.8	3.6	9.0	213	6	2.8	1.0	6.0
		Medical advice	328	1	0.3	0.0	1.7	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	1	0.5	0.0	2.9	325	0	0.0	0.0	1.1	213	0	0.0	0.0	1.7
Redness (mm)	Total	All	328	122	37.2	31.9	42.7	211	47	22.3	16.8	28.5	358	172	48.0	42.8	53.4	190	59	31.1	24.6	38.2	325	128	39.4	34.0	44.9	214	68	31.8	25.6	38.5
		>5	328	28	8.5	5.7	12.1	211	9	4.3	2.0	7.9	358	49	13.7	10.3	17.7	190	14	7.4	4.1	12.1	325	39	12.0	8.7	16.0	214	20	9.3	5.8	14.1
		>20	328	4	1.2	0.3	3.1	211	3	1.4	0.3	4.1	358	11	3.1	1.5	5.4	190	6	3.2	1.2	6.7	325	5	1.5	0.5	3.6	214	3	1.4	0.3	4.0
		Medical advice	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	1	0.3	0.0	1.5	190	1	0.5	0.0	2.9	325	0	0.0	0.0	1.1	214	0	0.0	0.0	1.7
	ActHIB/Engerix B	All											358	149	41.6	36.5	46.9	190	49	25.8	19.7	32.6	225	72	32.0	26.0	38.5	145	39	26.9	19.9	34.9
		>5											358	32	8.9	6.2	12.4	190	11	5.8	2.9	10.1	225	15	6.7	3.8	10.8	145	7	4.8	2.0	9.7
		>20											358	6	1.7	0.6	3.6	190	4	2.1	0.6	5.3	225	3	1.3	0.3	3.8	145	0	0.0	0.0	2.5
		Medical advice											358	1	0.3	0.0	1.5	190	0	0.0	0.0	1.9	225	0	0.0	0.0	1.6	145	0	0.0	0.0	2.5
	Hexa/Pediarix/Pentacel	All	328	122	37.2	31.9	42.7	211	47	22.3	16.8	28.5	358	142	39.7	34.6	44.9	190	41	21.6	16.0	28.1	325	115	35.4	30.2	40.9	213	62	29.1	23.1	35.7
		>5	328	28	8.5	5.7	12.1	211	9	4.3	2.0	7.9	358	31	8.7	6.0	12.1	190	8	4.2	1.8	8.1	325	29	8.9	6.1	12.6	213	17	8.0	4.7	12.5
		>20	328	4	1.2	0.3	3.1	211	3	1.4	0.3	4.1	358	6	1.7	0.6	3.6	190	4	2.1	0.6	5.3	325	2	0.6	0.1	2.2	213	3	1.4	0.3	4.1
		Medical advice	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	1	0.5	0.0	2.9	325	0	0.0	0.0	1.1	213	0	0.0	0.0	1.7
Swelling (mm)	Total	All	328	67	20.4	16.2	25.2	211	48	22.7	17.3	29.0	358	105	29.3	24.7	34.3	190	45	23.7	17.8	30.4	325	87	26.8	22.0	31.9	214	54	25.2	19.6	31.6
		>5	328	16	4.9	2.8	7.8	211	11	5.2	2.6	9.1	358	36	10.1	7.1	13.6	190	10	5.3	2.6	9.5	325	27	8.3	5.5	11.9	214	12	5.6	2.9	9.6

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
		>20	328	2	0.6	0.1	2.2	211	3	1.4	0.3	4.1	358	7	2.0	0.8	4.0	190	5	2.6	0.9	6.0	325	11	3.4	1.7	6.0	214	3	1.4	0.3	4.0
		Medical advice	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	1	0.3	0.0	1.5	190	1	0.5	0.0	2.9	325	0	0.0	0.0	1.1	214	0	0.0	0.0	1.7
	ActHIB/Engerix B	All											358	87	24.3	19.9	29.1	190	36	18.9	13.6	25.3	225	45	20.0	15.0	25.8	145	34	23.4	16.8	31.2
		>5											358	25	7.0	4.6	10.1	190	7	3.7	1.5	7.4	225	13	5.8	3.1	9.7	145	8	5.5	2.4	10.6
		>20											358	5	1.4	0.5	3.2	190	3	1.6	0.3	4.5	225	3	1.3	0.3	3.8	145	0	0.0	0.0	2.5
		Medical advice											358	1	0.3	0.0	1.5	190	0	0.0	0.0	1.9	225	0	0.0	0.0	1.6	145	0	0.0	0.0	2.5
	Hexa/Pediarix/Pentacel	All	328	67	20.4	16.2	25.2	211	48	22.7	17.3	29.0	358	83	23.2	18.9	27.9	190	36	18.9	13.6	25.3	325	75	23.1	18.6	28.0	213	47	22.1	16.7	28.2
		>5	328	16	4.9	2.8	7.8	211	11	5.2	2.6	9.1	358	26	7.3	4.8	10.5	190	10	5.3	2.6	9.5	325	24	7.4	4.8	10.8	213	11	5.2	2.6	9.1
		>20	328	2	0.6	0.1	2.2	211	3	1.4	0.3	4.1	358	3	0.8	0.2	2.4	190	5	2.6	0.9	6.0	325	11	3.4	1.7	6.0	213	3	1.4	0.3	4.1
		Medical advice	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	1	0.5	0.0	2.9	325	0	0.0	0.0	1.1	213	0	0.0	0.0	1.7
Overall/subject																																
Pain	Total	All	113	80	70.8	61.5	79.0	74	47	63.5	51.5	74.4	123	100	81.3	73.3	87.8	66	55	83.3	72.1	91.4	112	92	82.1	73.8	88.7	76	58	76.3	65.2	85.3
		Grade 2 or 3	113	38	33.6	25.0	43.1	74	20	27.0	17.4	38.6	123	64	52.0	42.8	61.1	66	40	60.6	47.8	72.4	112	57	50.9	41.3	60.5	76	31	40.8	29.6	52.7
		Grade 3	113	6	5.3	2.0	11.2	74	2	2.7	0.3	9.4	123	20	16.3	10.2	24.0	66	14	21.2	12.1	33.0	112	16	14.3	8.4	22.2	76	6	7.9	3.0	16.4
		Medical advice	113	1	0.9	0.0	4.8	74	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	ActHIB/Engerix B	All											123	97	78.9	70.6	85.7	66	51	77.3	65.3	86.7	112	77	68.8	59.3	77.2	76	50	65.8	54.0	76.3
		Grade 2 or 3											123	58	47.2	38.1	56.4	66	38	57.6	44.8	69.7	112	40	35.7	26.9	45.3	76	22	28.9	19.1	40.5
		Grade 3											123	17	13.8	8.3	21.2	66	13	19.7	10.9	31.3	112	12	10.7	5.7	18.0	76	2	2.6	0.3	9.2
		Medical advice											123	1	0.8	0.0	4.4	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Hexa/Pediarix/Pentacel	All	113	80	70.8	61.5	79.0	74	47	63.5	51.5	74.4	123	98	79.7	71.5	86.4	66	53	80.3	68.7	89.1	112	90	80.4	71.8	87.3	76	57	75.0	63.7	84.2
		Grade 2 or 3	113	38	33.6	25.0	43.1	74	20	27.0	17.4	38.6	123	58	47.2	38.1	56.4	66	35	53.0	40.3	65.4	112	51	45.5	36.1	55.2	76	29	38.2	27.2	50.0
		Grade 3	113	6	5.3	2.0	11.2	74	2	2.7	0.3	9.4	123	16	13.0	7.6	20.3	66	11	16.7	8.6	27.9	112	16	14.3	8.4	22.2	76	6	7.9	3.0	16.4
		Medical advice	113	1	0.9	0.0	4.8	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Redness (mm)	Total	All	113	65	57.5	47.9	66.8	74	29	39.2	28.0	51.2	123	86	69.9	61.0	77.9	66	34	51.5	38.9	64.0	112	65	58.0	48.3	67.3	76	41	53.9	42.1	65.5
		>5	113	19	16.8	10.4	25.0	74	8	10.8	4.8	20.2	123	38	30.9	22.9	39.9	66	11	16.7	8.6	27.9	112	29	25.9	18.1	35.0	76	16	21.1	12.5	31.9
		>20	113	4	3.5	1.0	8.8	74	3	4.1	0.8	11.4	123	10	8.1	4.0	14.4	66	5	7.6	2.5	16.8	112	5	4.5	1.5	10.1	76	3	3.9	0.8	11.1
		Medical advice	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	ActHIB/Engerix B	All											123	78	63.4	54.3	71.9	66	30	45.5	33.1	58.2	112	50	44.6	35.2	54.3	76	27	35.5	24.9	47.3
		>5											123	28	22.8	15.7	31.2	66	10	15.2	7.5	26.1	112	14	12.5	7.0	20.1	76	6	7.9	3.0	16.4
		>20											123	6	4.9	1.8	10.3	66	4	6.1	1.7	14.8	112	3	2.7	0.6	7.6	76	0	0.0	0.0	4.7
		Medical advice											123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Hexa/Pediarix/Pentacel	All	113	65	57.5	47.9	66.8	74	29	39.2	28.0	51.2	123	70	56.9	47.7	65.8	66	28	42.4	30.3	55.2	112	61	54.5	44.8	63.9	76	36	47.4	35.8	59.2
		>5	113	19	16.8	10.4	25.0	74	8	10.8	4.8	20.2	123	25	20.3	13.6	28.5	66	7	10.6	4.4	20.6	112	23	20.5	13.5	29.2	76	14	18.4	10.5	29.0
		>20	113	4	3.5	1.0	8.8	74	3	4.1	0.8	11.4	123	5	4.1	1.3	9.2	66	4	6.1	1.7	14.8	112	2	1.8	0.2	6.3	76	3	3.9	0.8	11.1
		Medical advice	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Swelling (mm)	Total	All	113	43	38.1	29.1	47.7	74	30	40.5	29.3	52.6	123	62	50.4	41.2	59.5	66	26	39.4	27.6	52.2	112	49	43.8	34.4	53.4	76	32	42.1	30.9	54.0
		>5	113	12	10.6	5.6	17.8	74	8	10.8	4.8	20.2	123	27	22.0	15.0	30.3	66	7	10.6	4.4	20.6	112	20	17.9	11.3	26.2	76	9	11.8	5.6	21.3
		>20	113	2	1.8	0.2	6.2	74	2	2.7	0.3	9.4	123	7	5.7	2.3	11.4	66	4	6.1	1.7	14.8	112	9	8.0	3.7	14.7	76	3	3.9	0.8	11.1
		Medical advice	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	ActHIB/Engerix B	All											123	55	44.7	35.7	53.9	66	23	34.8	23.5	47.6	112	37	33.0	24.4	42.6	76	27	35.5	24.9	47.3
		>5											123	19	15.4	9.6	23.1	66	6	9.1	3.4	18.7	112	11	9.8	5.0	16.9	76	7	9.2	3.8	18.1
		>20											123	5	4.1	1.3	9.2	66	2	3.0	0.4	10.5	112	3	2.7	0.6	7.6	76	0	0.0	0.0	4.7
		Medical advice											123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Hexa/Pediarix/Pentacel	All	113	43	38.1	29.1	47.7	74	30	40.5	29.3	52.6	123	49	39.8	31.1	49.1	66	21	31.8	20.9	44.4	112	44	39.3	30.2	49.0	76	28	36.8	26.1	48.7
		>5	113	12	10.6	5.6	17.8	74	8	10.8	4.8	20.2	123	19	15.4	9.6	23.1	66	7	10.6	4.4	20.6	112	18	16.1	9.8	24.2	76	8	10.5	4.7	19.7
		>20	113	2	1.8	0.2	6.2	74	2	2.7	0.3	9.4	123	3	2.4	0.5	7.0	66	4	6.1	1.7	14.8	112	9	8.0	3.7	14.7	76	3	3.9	0.8	11.1
		Medical advice	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	1	1.5	0.0	8.2	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.11 Incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall- by gender (Primary Total vaccinated cohort)

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI					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	N	n	%	LL	UL
Dose 1																															
Drowsiness	All	96	58	60.4	49.9	70.3	89	56	62.9	52.0	72.9	76	57	75.0	63.7	84.2	113	86	76.1	67.2	83.6	90	74	82.2	72.7	89.5	98	75	76.5	66.9	84.5
	Grade 2 or 3	96	19	19.8	12.4	29.2	89	17	19.1	11.5	28.8	76	26	34.2	23.7	46.0	113	30	26.5	18.7	35.7	90	29	32.2	22.8	42.9	98	24	24.5	16.4	34.2
	Grade 3	96	2	2.1	0.3	7.3	89	1	1.1	0.0	6.1	76	5	6.6	2.2	14.7	113	3	2.7	0.6	7.6	90	6	6.7	2.5	13.9	98	6	6.1	2.3	12.9
	Related	96	58	60.4	49.9	70.3	89	54	60.7	49.7	70.9	76	53	69.7	58.1	79.8	113	83	73.5	64.3	81.3	90	70	77.8	67.8	85.9	98	71	72.4	62.5	81.0
	Grade 3 Related	96	2	2.1	0.3	7.3	89	1	1.1	0.0	6.1	76	4	5.3	1.5	12.9	113	3	2.7	0.6	7.6	90	6	6.7	2.5	13.9	98	6	6.1	2.3	12.9
	Medical advice	96	1	1.0	0.0	5.7	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Irritability / Fussiness	All	96	63	65.6	55.2	75.0	89	52	58.4	47.5	68.8	76	64	84.2	74.0	91.6	113	101	89.4	82.2	94.4	90	73	81.1	71.5	88.6	98	80	81.6	72.5	88.7
	Grade 2 or 3	96	25	26.0	17.6	36.0	89	17	19.1	11.5	28.8	76	34	44.7	33.3	56.6	113	45	39.8	30.7	49.5	90	32	35.6	25.7	46.3	98	36	36.7	27.2	47.1
	Grade 3	96	4	4.2	1.1	10.3	89	5	5.6	1.8	12.6	76	7	9.2	3.8	18.1	113	10	8.8	4.3	15.7	90	6	6.7	2.5	13.9	98	9	9.2	4.3	16.7
	Related	96	62	64.6	54.2	74.1	89	51	57.3	46.4	67.7	76	64	84.2	74.0	91.6	113	99	87.6	80.1	93.1	90	70	77.8	67.8	85.9	98	77	78.6	69.1	86.2
	Grade 3 Related	96	4	4.2	1.1	10.3	89	5	5.6	1.8	12.6	76	7	9.2	3.8	18.1	113	10	8.8	4.3	15.7	90	6	6.7	2.5	13.9	98	9	9.2	4.3	16.7
	Medical advice	96	1	1.0	0.0	5.7	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Loss Of Appetite	All	96	27	28.1	19.4	38.2	89	26	29.2	20.1	39.8	76	30	39.5	28.4	51.4	113	46	40.7	31.6	50.4	90	38	42.2	31.9	53.1	98	42	42.9	32.9	53.3
	Grade 2 or 3	96	4	4.2	1.1	10.3	89	4	4.5	1.2	11.1	76	5	6.6	2.2	14.7	113	8	7.1	3.1	13.5	90	13	14.4	7.9	23.4	98	13	13.3	7.3	21.6
	Grade 3	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	1	1.1	0.0	6.0	98	3	3.1	0.6	8.7
	Related	96	25	26.0	17.6	36.0	89	23	25.8	17.1	36.2	76	29	38.2	27.2	50.0	113	44	38.9	29.9	48.6	90	36	40.0	29.8	50.9	98	41	41.8	31.9	52.2
	Grade 3 Related	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	1	1.1	0.0	6.0	98	3	3.1	0.6	8.7
	Medical advice	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI				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**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Rectally) (°C)	All	96	14	14.6	8.2	23.3	89	8	9.0	4.0	16.9	76	14	18.4	10.5	29.0	113	20	17.7	11.2	26.0	90	15	16.7	9.6	26.0	98	14	14.3	8.0	22.8
	>38.5	96	2	2.1	0.3	7.3	89	0	0.0	0.0	4.1	76	2	2.6	0.3	9.2	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	5	5.1	1.7	11.5
	>39.0	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	2	2.0	0.2	7.2
	>39.5	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	>40.0	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Related	96	11	11.5	5.9	19.6	89	4	4.5	1.2	11.1	76	12	15.8	8.4	26.0	113	19	16.8	10.4	25.0	90	14	15.6	8.8	24.7	98	13	13.3	7.3	21.6
	>40.0 Related	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Medical advice	96	0	0.0	0.0	3.8	89	0	0.0	0.0	4.1	76	0	0.0	0.0	4.7	113	0	0.0	0.0	3.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
Dose 2																															
Drowsiness	All	94	45	47.9	37.5	58.4	88	52	59.1	48.1	69.5	75	52	69.3	57.6	79.5	109	80	73.4	64.1	81.4	82	52	63.4	52.0	73.8	97	57	58.8	48.3	68.7
	Grade 2 or 3	94	15	16.0	9.2	25.0	88	16	18.2	10.8	27.8	75	19	25.3	16.0	36.7	109	24	22.0	14.6	31.0	82	19	23.2	14.6	33.8	97	20	20.6	13.1	30.0
	Grade 3	94	5	5.3	1.7	12.0	88	3	3.4	0.7	9.6	75	3	4.0	0.8	11.2	109	4	3.7	1.0	9.1	82	1	1.2	0.0	6.6	97	3	3.1	0.6	8.8
	Related	94	43	45.7	35.4	56.3	88	51	58.0	47.0	68.4	75	48	64.0	52.1	74.8	109	78	71.6	62.1	79.8	82	52	63.4	52.0	73.8	97	56	57.7	47.3	67.7
	Grade 3 Related	94	5	5.3	1.7	12.0	88	2	2.3	0.3	8.0	75	3	4.0	0.8	11.2	109	4	3.7	1.0	9.1	82	1	1.2	0.0	6.6	97	2	2.1	0.3	7.3
	Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	0	0.0	0.0	4.4	97	0	0.0	0.0	3.7
Irritability / Fussiness	All	94	61	64.9	54.4	74.5	88	67	76.1	65.9	84.6	75	57	76.0	64.7	85.1	109	90	82.6	74.1	89.2	82	57	69.5	58.4	79.2	97	79	81.4	72.3	88.6
	Grade 2 or 3	94	26	27.7	18.9	37.8	88	27	30.7	21.3	41.4	75	28	37.3	26.4	49.3	109	42	38.5	29.4	48.3	82	26	31.7	21.9	42.9	97	35	36.1	26.6	46.5
	Grade 3	94	3	3.2	0.7	9.0	88	3	3.4	0.7	9.6	75	4	5.3	1.5	13.1	109	10	9.2	4.5	16.2	82	2	2.4	0.3	8.5	97	9	9.3	4.3	16.9
	Related	94	60	63.8	53.3	73.5	88	65	73.9	63.4	82.7	75	54	72.0	60.4	81.8	109	89	81.7	73.1	88.4	82	55	67.1	55.8	77.1	97	78	80.4	71.1	87.8
	Grade 3 Related	94	3	3.2	0.7	9.0	88	3	3.4	0.7	9.6	75	3	4.0	0.8	11.2	109	10	9.2	4.5	16.2	82	2	2.4	0.3	8.5	97	9	9.3	4.3	16.9
	Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	2	2.4	0.3	8.5	97	0	0.0	0.0	3.7
Loss Of Appetite	All	94	26	27.7	18.9	37.8	88	30	34.1	24.3	45.0	75	21	28.0	18.2	39.6	109	34	31.2	22.7	40.8	82	26	31.7	21.9	42.9	97	30	30.9	21.9	41.1
	Grade 2 or 3	94	8	8.5	3.7	16.1	88	9	10.2	4.8	18.5	75	7	9.3	3.8	18.3	109	8	7.3	3.2	14.0	82	6	7.3	2.7	15.2	97	9	9.3	4.3	16.9

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI				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	N	n	%	LL	UL
	Grade 3	94	1	1.1	0.0	5.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	1	0.9	0.0	5.0	82	0	0.0	0.0	4.4	97	2	2.1	0.3	7.3
	Related	94	24	25.5	17.1	35.6	88	28	31.8	22.3	42.6	75	19	25.3	16.0	36.7	109	32	29.4	21.0	38.8	82	25	30.5	20.8	41.6	97	30	30.9	21.9	41.1
	Grade 3 Related	94	1	1.1	0.0	5.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	1	0.9	0.0	5.0	82	0	0.0	0.0	4.4	97	2	2.1	0.3	7.3
	Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	1	1.2	0.0	6.6	97	0	0.0	0.0	3.7
Temperature/(Rectally) (°C)	All	94	26	27.7	18.9	37.8	88	21	23.9	15.4	34.1	75	15	20.0	11.6	30.8	109	21	19.3	12.3	27.9	82	15	18.3	10.6	28.4	97	20	20.6	13.1	30.0
	>38.5	94	9	9.6	4.5	17.4	88	6	6.8	2.5	14.3	75	6	8.0	3.0	16.6	109	7	6.4	2.6	12.8	82	2	2.4	0.3	8.5	97	7	7.2	3.0	14.3
	>39.0	94	2	2.1	0.3	7.5	88	0	0.0	0.0	4.1	75	2	2.7	0.3	9.3	109	1	0.9	0.0	5.0	82	0	0.0	0.0	4.4	97	2	2.1	0.3	7.3
	>39.5	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	0	0.0	0.0	4.4	97	1	1.0	0.0	5.6
	>40.0	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	0	0.0	0.0	4.4	97	0	0.0	0.0	3.7
	Related	94	19	20.2	12.6	29.8	88	18	20.5	12.6	30.4	75	14	18.7	10.6	29.3	109	18	16.5	10.1	24.8	82	14	17.1	9.7	27.0	97	19	19.6	12.2	28.9
	>40.0 Related	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	0	0.0	0.0	4.4	97	0	0.0	0.0	3.7
	Medical advice	94	0	0.0	0.0	3.8	88	0	0.0	0.0	4.1	75	0	0.0	0.0	4.8	109	0	0.0	0.0	3.3	82	0	0.0	0.0	4.4	97	0	0.0	0.0	3.7
Dose 3																															
Drowsiness	All	88	41	46.6	35.9	57.5	84	44	52.4	41.2	63.4	68	43	63.2	50.7	74.6	107	65	60.7	50.8	70.0	78	42	53.8	42.2	65.2	92	46	50.0	39.4	60.6
	Grade 2 or 3	88	9	10.2	4.8	18.5	84	14	16.7	9.4	26.4	68	16	23.5	14.1	35.4	107	21	19.6	12.6	28.4	78	15	19.2	11.2	29.7	92	10	10.9	5.3	19.1
	Grade 3	88	1	1.1	0.0	6.2	84	2	2.4	0.3	8.3	68	3	4.4	0.9	12.4	107	2	1.9	0.2	6.6	78	7	9.0	3.7	17.6	92	2	2.2	0.3	7.6
	Related	88	39	44.3	33.7	55.3	84	42	50.0	38.9	61.1	68	42	61.8	49.2	73.3	107	63	58.9	49.0	68.3	78	40	51.3	39.7	62.8	92	46	50.0	39.4	60.6
	Grade 3 Related	88	1	1.1	0.0	6.2	84	2	2.4	0.3	8.3	68	3	4.4	0.9	12.4	107	2	1.9	0.2	6.6	78	7	9.0	3.7	17.6	92	2	2.2	0.3	7.6
	Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	2	1.9	0.2	6.6	78	0	0.0	0.0	4.6	92	1	1.1	0.0	5.9
Irritability / Fussiness	All	88	59	67.0	56.2	76.7	84	67	79.8	69.6	87.7	68	52	76.5	64.6	85.9	107	83	77.6	68.5	85.1	78	55	70.5	59.1	80.3	92	67	72.8	62.6	81.6
	Grade 2 or 3	88	18	20.5	12.6	30.4	84	28	33.3	23.4	44.5	68	23	33.8	22.8	46.3	107	35	32.7	24.0	42.5	78	34	43.6	32.4	55.3	92	24	26.1	17.5	36.3
	Grade 3	88	3	3.4	0.7	9.6	84	3	3.6	0.7	10.1	68	5	7.4	2.4	16.3	107	10	9.3	4.6	16.5	78	7	9.0	3.7	17.6	92	4	4.3	1.2	10.8
	Related	88	56	63.6	52.7	73.6	84	65	77.4	67.0	85.8	68	48	70.6	58.3	81.0	107	81	75.7	66.5	83.5	78	54	69.2	57.8	79.2	92	66	71.7	61.4	80.6
	Grade 3	88	3	3.4	0.7	9.6	84	3	3.6	0.7	10.1	68	4	5.9	1.6	14.4	107	9	8.4	3.9	15.4	78	7	9.0	3.7	17.6	92	4	4.3	1.2	10.8

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
	Related																														
	Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	1	1.5	0.0	7.9	107	2	1.9	0.2	6.6	78	0	0.0	0.0	4.6	92	1	1.1	0.0	5.9
Loss Of Appetite	All	88	19	21.6	13.5	31.6	84	26	31.0	21.3	42.0	68	27	39.7	28.0	52.3	107	31	29.0	20.6	38.5	78	22	28.2	18.6	39.5	92	31	33.7	24.2	44.3
	Grade 2 or 3	88	5	5.7	1.9	12.8	84	6	7.1	2.7	14.9	68	4	5.9	1.6	14.4	107	9	8.4	3.9	15.4	78	6	7.7	2.9	16.0	92	9	9.8	4.6	17.8
	Grade 3	88	0	0.0	0.0	4.1	84	1	1.2	0.0	6.5	68	1	1.5	0.0	7.9	107	1	0.9	0.0	5.1	78	1	1.3	0.0	6.9	92	1	1.1	0.0	5.9
	Related	88	18	20.5	12.6	30.4	84	26	31.0	21.3	42.0	68	25	36.8	25.4	49.3	107	31	29.0	20.6	38.5	78	21	26.9	17.5	38.2	92	31	33.7	24.2	44.3
	Grade 3 Related	88	0	0.0	0.0	4.1	84	1	1.2	0.0	6.5	68	1	1.5	0.0	7.9	107	1	0.9	0.0	5.1	78	1	1.3	0.0	6.9	92	1	1.1	0.0	5.9
	Medical advice	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	1	0.9	0.0	5.1	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
Temperature/(Rectally) (°C)	All	88	24	27.3	18.3	37.8	84	16	19.0	11.3	29.1	68	21	30.9	20.2	43.3	107	24	22.4	14.9	31.5	78	20	25.6	16.4	36.8	92	17	18.5	11.1	27.9
	>38.5	88	5	5.7	1.9	12.8	84	7	8.3	3.4	16.4	68	7	10.3	4.2	20.1	107	14	13.1	7.3	21.0	78	8	10.3	4.5	19.2	92	7	7.6	3.1	15.1
	>39.0	88	1	1.1	0.0	6.2	84	3	3.6	0.7	10.1	68	4	5.9	1.6	14.4	107	7	6.5	2.7	13.0	78	2	2.6	0.3	9.0	92	5	5.4	1.8	12.2
	>39.5	88	0	0.0	0.0	4.1	84	1	1.2	0.0	6.5	68	0	0.0	0.0	5.3	107	3	2.8	0.6	8.0	78	0	0.0	0.0	4.6	92	1	1.1	0.0	5.9
	>40.0	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	2	1.9	0.2	6.6	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
	Related	88	21	23.9	15.4	34.1	84	14	16.7	9.4	26.4	68	18	26.5	16.5	38.6	107	21	19.6	12.6	28.4	78	19	24.4	15.3	35.4	92	16	17.4	10.3	26.7
	>40.0 Related	88	0	0.0	0.0	4.1	84	0	0.0	0.0	4.3	68	0	0.0	0.0	5.3	107	2	1.9	0.2	6.6	78	0	0.0	0.0	4.6	92	0	0.0	0.0	3.9
	Medical advice	88	0	0.0	0.0	4.1	84	1	1.2	0.0	6.5	68	0	0.0	0.0	5.3	107	2	1.9	0.2	6.6	78	0	0.0	0.0	4.6	92	1	1.1	0.0	5.9
Overall/dose																															
Drowsiness	All	278	144	51.8	45.8	57.8	261	152	58.2	52.0	64.3	219	152	69.4	62.8	75.4	329	231	70.2	65.0	75.1	250	168	67.2	61.0	73.0	287	178	62.0	56.1	67.7
	Grade 2 or 3	278	43	15.5	11.4	20.3	261	47	18.0	13.5	23.2	219	61	27.9	22.0	34.3	329	75	22.8	18.4	27.7	250	63	25.2	19.9	31.1	287	54	18.8	14.5	23.8
	Grade 3	278	8	2.9	1.3	5.6	261	6	2.3	0.8	4.9	219	11	5.0	2.5	8.8	329	9	2.7	1.3	5.1	250	14	5.6	3.1	9.2	287	11	3.8	1.9	6.8
	Related	278	140	50.4	44.3	56.4	261	147	56.3	50.1	62.4	219	143	65.3	58.6	71.6	329	224	68.1	62.7	73.1	250	162	64.8	58.5	70.7	287	173	60.3	54.4	66.0
	Grade 3 Related	278	8	2.9	1.3	5.6	261	5	1.9	0.6	4.4	219	10	4.6	2.2	8.2	329	9	2.7	1.3	5.1	250	14	5.6	3.1	9.2	287	10	3.5	1.7	6.3
	Medical advice	278	1	0.4	0.0	2.0	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	250	0	0.0	0.0	1.5	287	1	0.3	0.0	1.9

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
Irritability / Fussiness	All	278	183	65.8	59.9	71.4	261	186	71.3	65.4	76.7	219	173	79.0	73.0	84.2	329	274	83.3	78.8	87.2	250	185	74.0	68.1	79.3	287	226	78.7	73.6	83.3
	Grade 2 or 3	278	69	24.8	19.9	30.3	261	72	27.6	22.3	33.4	219	85	38.8	32.3	45.6	329	122	37.1	31.8	42.6	250	92	36.8	30.8	43.1	287	95	33.1	27.7	38.9
	Grade 3	278	10	3.6	1.7	6.5	261	11	4.2	2.1	7.4	219	16	7.3	4.2	11.6	329	30	9.1	6.2	12.8	250	15	6.0	3.4	9.7	287	22	7.7	4.9	11.4
	Related	278	178	64.0	58.1	69.7	261	181	69.3	63.4	74.9	219	166	75.8	69.6	81.3	329	269	81.8	77.2	85.8	250	179	71.6	65.6	77.1	287	221	77.0	71.7	81.7
	Grade 3 Related	278	10	3.6	1.7	6.5	261	11	4.2	2.1	7.4	219	14	6.4	3.5	10.5	329	29	8.8	6.0	12.4	250	15	6.0	3.4	9.7	287	22	7.7	4.9	11.4
	Medical advice	278	1	0.4	0.0	2.0	261	0	0.0	0.0	1.4	219	1	0.5	0.0	2.5	329	2	0.6	0.1	2.2	250	2	0.8	0.1	2.9	287	1	0.3	0.0	1.9
Loss Of Appetite	All	278	72	25.9	20.9	31.5	261	82	31.4	25.8	37.4	219	78	35.6	29.3	42.3	329	111	33.7	28.6	39.1	250	86	34.4	28.5	40.6	287	103	35.9	30.3	41.7
	Grade 2 or 3	278	17	6.1	3.6	9.6	261	19	7.3	4.4	11.1	219	16	7.3	4.2	11.6	329	25	7.6	5.0	11.0	250	25	10.0	6.6	14.4	287	31	10.8	7.5	15.0
	Grade 3	278	1	0.4	0.0	2.0	261	1	0.4	0.0	2.1	219	1	0.5	0.0	2.5	329	3	0.9	0.2	2.6	250	2	0.8	0.1	2.9	287	6	2.1	0.8	4.5
	Related	278	67	24.1	19.2	29.6	261	77	29.5	24.0	35.4	219	73	33.3	27.1	40.0	329	107	32.5	27.5	37.9	250	82	32.8	27.0	39.0	287	102	35.5	30.0	41.4
	Grade 3 Related	278	1	0.4	0.0	2.0	261	1	0.4	0.0	2.1	219	1	0.5	0.0	2.5	329	3	0.9	0.2	2.6	250	2	0.8	0.1	2.9	287	6	2.1	0.8	4.5
	Medical advice	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	1	0.3	0.0	1.7	250	1	0.4	0.0	2.2	287	0	0.0	0.0	1.3
Temperature/(Rectally) (°C)	All	278	64	23.0	18.2	28.4	261	45	17.2	12.9	22.4	219	50	22.8	17.4	29.0	329	65	19.8	15.6	24.5	250	50	20.0	15.2	25.5	287	51	17.8	13.5	22.7
	>38.5	278	16	5.8	3.3	9.2	261	13	5.0	2.7	8.4	219	15	6.8	3.9	11.0	329	23	7.0	4.5	10.3	250	10	4.0	1.9	7.2	287	19	6.6	4.0	10.1
	>39.0	278	3	1.1	0.2	3.1	261	3	1.1	0.2	3.3	219	6	2.7	1.0	5.9	329	8	2.4	1.1	4.7	250	2	0.8	0.1	2.9	287	9	3.1	1.4	5.9
	>39.5	278	0	0.0	0.0	1.3	261	1	0.4	0.0	2.1	219	0	0.0	0.0	1.7	329	3	0.9	0.2	2.6	250	0	0.0	0.0	1.5	287	2	0.7	0.1	2.5
	>40.0	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	250	0	0.0	0.0	1.5	287	0	0.0	0.0	1.3
	Related	278	51	18.3	14.0	23.4	261	36	13.8	9.9	18.6	219	44	20.1	15.0	26.0	329	58	17.6	13.7	22.2	250	47	18.8	14.2	24.2	287	48	16.7	12.6	21.6
	>40.0 Related	278	0	0.0	0.0	1.3	261	0	0.0	0.0	1.4	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	250	0	0.0	0.0	1.5	287	0	0.0	0.0	1.3
	Medical advice	278	0	0.0	0.0	1.3	261	1	0.4	0.0	2.1	219	0	0.0	0.0	1.7	329	2	0.6	0.1	2.2	250	0	0.0	0.0	1.5	287	1	0.3	0.0	1.9
Overall/subject																															
Drowsiness	All	97	74	76.3	66.6	84.3	90	73	81.1	71.5	88.6	76	71	93.4	85.3	97.8	113	101	89.4	82.2	94.4	90	80	88.9	80.5	94.5	98	88	89.8	82.0	95.0
	Grade 2 or 3	97	35	36.1	26.6	46.5	90	31	34.4	24.7	45.2	76	39	51.3	39.6	63.0	113	49	43.4	34.1	53.0	90	42	46.7	36.1	57.5	98	39	39.8	30.0	50.2

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI				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	N	n	%	LL	UL
	Grade 3	97	7	7.2	3.0	14.3	90	4	4.4	1.2	11.0	76	11	14.5	7.5	24.4	113	8	7.1	3.1	13.5	90	13	14.4	7.9	23.4	98	9	9.2	4.3	16.7
	Related	97	72	74.2	64.3	82.6	90	72	80.0	70.2	87.7	76	69	90.8	81.9	96.2	113	100	88.5	81.1	93.7	90	79	87.8	79.2	93.7	98	87	88.8	80.8	94.3
	Grade 3 Related	97	7	7.2	3.0	14.3	90	4	4.4	1.2	11.0	76	10	13.2	6.5	22.9	113	8	7.1	3.1	13.5	90	13	14.4	7.9	23.4	98	8	8.2	3.6	15.5
	Medical advice	97	1	1.0	0.0	5.6	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	1	1.0	0.0	5.6
Irritability / Fussiness	All	97	83	85.6	77.0	91.9	90	81	90.0	81.9	95.3	76	72	94.7	87.1	98.5	113	110	97.3	92.4	99.4	90	82	91.1	83.2	96.1	98	95	96.9	91.3	99.4
	Grade 2 or 3	97	48	49.5	39.2	59.8	90	48	53.3	42.5	63.9	76	50	65.8	54.0	76.3	113	78	69.0	59.6	77.4	90	58	64.4	53.7	74.3	98	62	63.3	52.9	72.8
	Grade 3	97	8	8.2	3.6	15.6	90	10	11.1	5.5	19.5	76	12	15.8	8.4	26.0	113	23	20.4	13.4	29.0	90	13	14.4	7.9	23.4	98	17	17.3	10.4	26.3
	Related	97	81	83.5	74.6	90.3	90	80	88.9	80.5	94.5	76	71	93.4	85.3	97.8	113	109	96.5	91.2	99.0	90	81	90.0	81.9	95.3	98	94	95.9	89.9	98.9
	Grade 3 Related	97	8	8.2	3.6	15.6	90	10	11.1	5.5	19.5	76	11	14.5	7.5	24.4	113	23	20.4	13.4	29.0	90	13	14.4	7.9	23.4	98	17	17.3	10.4	26.3
	Medical advice	97	1	1.0	0.0	5.6	90	0	0.0	0.0	4.0	76	1	1.3	0.0	7.1	113	2	1.8	0.2	6.2	90	2	2.2	0.3	7.8	98	1	1.0	0.0	5.6
Loss Of Appetite	All	97	47	48.5	38.2	58.8	90	48	53.3	42.5	63.9	76	46	60.5	48.6	71.6	113	65	57.5	47.9	66.8	90	53	58.9	48.0	69.2	98	64	65.3	55.0	74.6
	Grade 2 or 3	97	13	13.4	7.3	21.8	90	15	16.7	9.6	26.0	76	15	19.7	11.5	30.5	113	17	15.0	9.0	23.0	90	18	20.0	12.3	29.8	98	21	21.4	13.8	30.9
	Grade 3	97	1	1.0	0.0	5.6	90	1	1.1	0.0	6.0	76	1	1.3	0.0	7.1	113	2	1.8	0.2	6.2	90	2	2.2	0.3	7.8	98	4	4.1	1.1	10.1
	Related	97	45	46.4	36.2	56.8	90	46	51.1	40.3	61.8	76	44	57.9	46.0	69.1	113	64	56.6	47.0	65.9	90	52	57.8	46.9	68.1	98	64	65.3	55.0	74.6
	Grade 3 Related	97	1	1.0	0.0	5.6	90	1	1.1	0.0	6.0	76	1	1.3	0.0	7.1	113	2	1.8	0.2	6.2	90	2	2.2	0.3	7.8	98	4	4.1	1.1	10.1
	Medical advice	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	1	0.9	0.0	4.8	90	1	1.1	0.0	6.0	98	0	0.0	0.0	3.7
Temperature/(Rectally) (°C)	All	97	42	43.3	33.3	53.7	90	30	33.3	23.7	44.1	76	33	43.4	32.1	55.3	113	45	39.8	30.7	49.5	90	34	37.8	27.8	48.6	98	38	38.8	29.1	49.2
	>38.5	97	15	15.5	8.9	24.2	90	9	10.0	4.7	18.1	76	13	17.1	9.4	27.5	113	21	18.6	11.9	27.0	90	10	11.1	5.5	19.5	98	16	16.3	9.6	25.2
	>39.0	97	3	3.1	0.6	8.8	90	3	3.3	0.7	9.4	76	6	7.9	3.0	16.4	113	8	7.1	3.1	13.5	90	2	2.2	0.3	7.8	98	8	8.2	3.6	15.5
	>39.5	97	0	0.0	0.0	3.7	90	1	1.1	0.0	6.0	76	0	0.0	0.0	4.7	113	3	2.7	0.6	7.6	90	0	0.0	0.0	4.0	98	2	2.0	0.2	7.2
	>40.0	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7
	Related	97	34	35.1	25.6	45.4	90	27	30.0	20.8	40.6	76	31	40.8	29.6	52.7	113	43	38.1	29.1	47.7	90	33	36.7	26.8	47.5	98	36	36.7	27.2	47.1
	>40.0 Related	97	0	0.0	0.0	3.7	90	0	0.0	0.0	4.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	0	0.0	0.0	3.7

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI				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**	**N**	**n**	**%**	**LL**	**UL**
	Medical advice	97	0	0.0	0.0	3.7	90	1	1.1	0.0	6.0	76	0	0.0	0.0	4.7	113	2	1.8	0.2	6.2	90	0	0.0	0.0	4.0	98	1	1.0	0.0	5.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.12 Incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following each priming dose and overall- by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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	N	n	%	LL	UL
Dose 1																															
Drowsiness	All	112	78	69.6	60.2	78.0	73	36	49.3	37.4	61.3	123	93	75.6	67.0	82.9	66	50	75.8	63.6	85.5	112	92	82.1	73.8	88.7	76	57	75.0	63.7	84.2
	Grade 2 or 3	112	26	23.2	15.8	32.1	73	10	13.7	6.8	23.8	123	39	31.7	23.6	40.7	66	17	25.8	15.8	38.0	112	36	32.1	23.6	41.6	76	17	22.4	13.6	33.4
	Grade 3	112	3	2.7	0.6	7.6	73	0	0.0	0.0	4.9	123	7	5.7	2.3	11.4	66	1	1.5	0.0	8.2	112	9	8.0	3.7	14.7	76	3	3.9	0.8	11.1
	Related	112	76	67.9	58.4	76.4	73	36	49.3	37.4	61.3	123	89	72.4	63.6	80.0	66	47	71.2	58.7	81.7	112	86	76.8	67.9	84.2	76	55	72.4	60.9	82.0
	Grade 3 Related	112	3	2.7	0.6	7.6	73	0	0.0	0.0	4.9	123	6	4.9	1.8	10.3	66	1	1.5	0.0	8.2	112	9	8.0	3.7	14.7	76	3	3.9	0.8	11.1
	Medical advice	112	1	0.9	0.0	4.9	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Irritability / Fussiness	All	112	73	65.2	55.6	73.9	73	42	57.5	45.4	69.0	123	108	87.8	80.7	93.0	66	57	86.4	75.7	93.6	112	94	83.9	75.8	90.2	76	59	77.6	66.6	86.4
	Grade 2 or 3	112	28	25.0	17.3	34.1	73	14	19.2	10.9	30.1	123	55	44.7	35.7	53.9	66	24	36.4	24.9	49.1	112	43	38.4	29.4	48.1	76	25	32.9	22.5	44.6
	Grade 3	112	6	5.4	2.0	11.3	73	3	4.1	0.9	11.5	123	14	11.4	6.4	18.4	66	3	4.5	0.9	12.7	112	13	11.6	6.3	19.0	76	2	2.6	0.3	9.2
	Related	112	71	63.4	53.8	72.3	73	42	57.5	45.4	69.0	123	108	87.8	80.7	93.0	66	55	83.3	72.1	91.4	112	89	79.5	70.8	86.5	76	58	76.3	65.2	85.3
	Grade 3 Related	112	6	5.4	2.0	11.3	73	3	4.1	0.9	11.5	123	14	11.4	6.4	18.4	66	3	4.5	0.9	12.7	112	13	11.6	6.3	19.0	76	2	2.6	0.3	9.2
	Medical advice	112	1	0.9	0.0	4.9	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Loss Of Appetite	All	112	38	33.9	25.3	43.5	73	15	20.5	12.0	31.6	123	51	41.5	32.7	50.7	66	25	37.9	26.2	50.7	112	55	49.1	39.5	58.7	76	25	32.9	22.5	44.6
	Grade 2 or 3	112	7	6.3	2.5	12.5	73	1	1.4	0.0	7.4	123	9	7.3	3.4	13.4	66	4	6.1	1.7	14.8	112	14	12.5	7.0	20.1	76	12	15.8	8.4	26.0
	Grade 3	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	3	2.7	0.6	7.6	76	1	1.3	0.0	7.1
	Related	112	35	31.3	22.8	40.7	73	13	17.8	9.8	28.5	123	49	39.8	31.1	49.1	66	24	36.4	24.9	49.1	112	52	46.4	37.0	56.1	76	25	32.9	22.5	44.6
	Grade 3 Related	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	0	0.0	0.0	5.4	112	3	2.7	0.6	7.6	76	1	1.3	0.0	7.1
	Medical advice	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Rectally) (°C)	All	112	9	8.0	3.7	14.7	73	13	17.8	9.8	28.5	123	17	13.8	8.3	21.2	66	17	25.8	15.8	38.0	112	15	13.4	7.7	21.1	76	14	18.4	10.5	29.0
	>38.5	112	1	0.9	0.0	4.9	73	1	1.4	0.0	7.4	123	2	1.6	0.2	5.8	66	2	3.0	0.4	10.5	112	3	2.7	0.6	7.6	76	2	2.6	0.3	9.2
	>39.0	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	1	0.9	0.0	4.9	76	1	1.3	0.0	7.1
	>39.5	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	>40.0	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Related	112	7	6.3	2.5	12.5	73	8	11.0	4.9	20.5	123	15	12.2	7.0	19.3	66	16	24.2	14.5	36.4	112	15	13.4	7.7	21.1	76	12	15.8	8.4	26.0
	>40.0 Related	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Medical advice	112	0	0.0	0.0	3.2	73	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	0	0.0	0.0	5.4	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
Dose 2																															
Drowsiness	All	110	60	54.5	44.8	64.1	72	37	51.4	39.3	63.3	119	88	73.9	65.1	81.6	65	44	67.7	54.9	78.8	107	73	68.2	58.5	76.9	72	36	50.0	38.0	62.0
	Grade 2 or 3	110	20	18.2	11.5	26.7	72	11	15.3	7.9	25.7	119	32	26.9	19.2	35.8	65	11	16.9	8.8	28.3	107	24	22.4	14.9	31.5	72	15	20.8	12.2	32.0
	Grade 3	110	5	4.5	1.5	10.3	72	3	4.2	0.9	11.7	119	5	4.2	1.4	9.5	65	2	3.1	0.4	10.7	107	2	1.9	0.2	6.6	72	2	2.8	0.3	9.7
	Related	110	58	52.7	43.0	62.3	72	36	50.0	38.0	62.0	119	84	70.6	61.5	78.6	65	42	64.6	51.8	76.1	107	72	67.3	57.5	76.0	72	36	50.0	38.0	62.0
	Grade 3 Related	110	4	3.6	1.0	9.0	72	3	4.2	0.9	11.7	119	5	4.2	1.4	9.5	65	2	3.1	0.4	10.7	107	1	0.9	0.0	5.1	72	2	2.8	0.3	9.7
	Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	72	0	0.0	0.0	5.0
Irritability / Fussiness	All	110	86	78.2	69.3	85.5	72	42	58.3	46.1	69.8	119	96	80.7	72.4	87.3	65	51	78.5	66.5	87.7	107	82	76.6	67.5	84.3	72	54	75.0	63.4	84.5
	Grade 2 or 3	110	37	33.6	24.9	43.3	72	16	22.2	13.3	33.6	119	45	37.8	29.1	47.2	65	25	38.5	26.7	51.4	107	41	38.3	29.1	48.2	72	20	27.8	17.9	39.6
	Grade 3	110	4	3.6	1.0	9.0	72	2	2.8	0.3	9.7	119	11	9.2	4.7	15.9	65	3	4.6	1.0	12.9	107	6	5.6	2.1	11.8	72	5	6.9	2.3	15.5
	Related	110	83	75.5	66.3	83.2	72	42	58.3	46.1	69.8	119	93	78.2	69.6	85.2	65	50	76.9	64.8	86.5	107	80	74.8	65.4	82.7	72	53	73.6	61.9	83.3
	Grade 3 Related	110	4	3.6	1.0	9.0	72	2	2.8	0.3	9.7	119	10	8.4	4.1	14.9	65	3	4.6	1.0	12.9	107	6	5.6	2.1	11.8	72	5	6.9	2.3	15.5
	Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	1	0.9	0.0	5.1	72	1	1.4	0.0	7.5
Loss Of Appetite	All	110	37	33.6	24.9	43.3	72	19	26.4	16.7	38.1	119	37	31.1	22.9	40.2	65	18	27.7	17.3	40.2	107	37	34.6	25.6	44.4	72	19	26.4	16.7	38.1
	Grade 2 or 3	110	11	10.0	5.1	17.2	72	6	8.3	3.1	17.3	119	10	8.4	4.1	14.9	65	5	7.7	2.5	17.0	107	9	8.4	3.9	15.4	72	6	8.3	3.1	17.3

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
	Grade 3	110	0	0.0	0.0	3.3	72	1	1.4	0.0	7.5	119	1	0.8	0.0	4.6	65	0	0.0	0.0	5.5	107	1	0.9	0.0	5.1	72	1	1.4	0.0	7.5
	Related	110	34	30.9	22.4	40.4	72	18	25.0	15.5	36.6	119	34	28.6	20.7	37.6	65	17	26.2	16.0	38.5	107	36	33.6	24.8	43.4	72	19	26.4	16.7	38.1
	Grade 3 Related	110	0	0.0	0.0	3.3	72	1	1.4	0.0	7.5	119	1	0.8	0.0	4.6	65	0	0.0	0.0	5.5	107	1	0.9	0.0	5.1	72	1	1.4	0.0	7.5
	Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	1	0.9	0.0	5.1	72	0	0.0	0.0	5.0
Temperature/(Rectally) (°C)	All	110	26	23.6	16.1	32.7	72	21	29.2	19.0	41.1	119	23	19.3	12.7	27.6	65	13	20.0	11.1	31.8	107	24	22.4	14.9	31.5	72	11	15.3	7.9	25.7
	>38.5	110	7	6.4	2.6	12.7	72	8	11.1	4.9	20.7	119	7	5.9	2.4	11.7	65	6	9.2	3.5	19.0	107	6	5.6	2.1	11.8	72	3	4.2	0.9	11.7
	>39.0	110	2	1.8	0.2	6.4	72	0	0.0	0.0	5.0	119	1	0.8	0.0	4.6	65	2	3.1	0.4	10.7	107	1	0.9	0.0	5.1	72	1	1.4	0.0	7.5
	>39.5	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	1	0.9	0.0	5.1	72	0	0.0	0.0	5.0
	>40.0	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	72	0	0.0	0.0	5.0
	Related	110	21	19.1	12.2	27.7	72	16	22.2	13.3	33.6	119	20	16.8	10.6	24.8	65	12	18.5	9.9	30.0	107	23	21.5	14.1	30.5	72	10	13.9	6.9	24.1
	>40.0 Related	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	72	0	0.0	0.0	5.0
	Medical advice	110	0	0.0	0.0	3.3	72	0	0.0	0.0	5.0	119	0	0.0	0.0	3.1	65	0	0.0	0.0	5.5	107	0	0.0	0.0	3.4	72	0	0.0	0.0	5.0
Dose 3																															
Drowsiness	All	106	55	51.9	42.0	61.7	66	30	45.5	33.1	58.2	116	71	61.2	51.7	70.1	59	37	62.7	49.1	75.0	105	58	55.2	45.2	65.0	65	30	46.2	33.7	59.0
	Grade 2 or 3	106	13	12.3	6.7	20.1	66	10	15.2	7.5	26.1	116	28	24.1	16.7	33.0	59	9	15.3	7.2	27.0	105	15	14.3	8.2	22.5	65	10	15.4	7.6	26.5
	Grade 3	106	2	1.9	0.2	6.6	66	1	1.5	0.0	8.2	116	3	2.6	0.5	7.4	59	2	3.4	0.4	11.7	105	5	4.8	1.6	10.8	65	4	6.2	1.7	15.0
	Related	106	51	48.1	38.3	58.0	66	30	45.5	33.1	58.2	116	71	61.2	51.7	70.1	59	34	57.6	44.1	70.4	105	56	53.3	43.3	63.1	65	30	46.2	33.7	59.0
	Grade 3 Related	106	2	1.9	0.2	6.6	66	1	1.5	0.0	8.2	116	3	2.6	0.5	7.4	59	2	3.4	0.4	11.7	105	5	4.8	1.6	10.8	65	4	6.2	1.7	15.0
	Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	2	3.4	0.4	11.7	105	0	0.0	0.0	3.5	65	1	1.5	0.0	8.3
Irritability / Fussiness	All	106	78	73.6	64.1	81.7	66	48	72.7	60.4	83.0	116	93	80.2	71.7	87.0	59	42	71.2	57.9	82.2	105	79	75.2	65.9	83.1	65	43	66.2	53.4	77.4
	Grade 2 or 3	106	28	26.4	18.3	35.9	66	18	27.3	17.0	39.6	116	38	32.8	24.3	42.1	59	20	33.9	22.1	47.4	105	38	36.2	27.0	46.1	65	20	30.8	19.9	43.4
	Grade 3	106	4	3.8	1.0	9.4	66	2	3.0	0.4	10.5	116	11	9.5	4.8	16.3	59	4	6.8	1.9	16.5	105	7	6.7	2.7	13.3	65	4	6.2	1.7	15.0
	Related	106	73	68.9	59.1	77.5	66	48	72.7	60.4	83.0	116	89	76.7	68.0	84.1	59	40	67.8	54.4	79.4	105	77	73.3	63.8	81.5	65	43	66.2	53.4	77.4
	Grade 3	106	4	3.8	1.0	9.4	66	2	3.0	0.4	10.5	116	9	7.8	3.6	14.2	59	4	6.8	1.9	16.5	105	7	6.7	2.7	13.3	65	4	6.2	1.7	15.0

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
	Related																														
	Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	1	0.9	0.0	4.7	59	2	3.4	0.4	11.7	105	0	0.0	0.0	3.5	65	1	1.5	0.0	8.3
Loss Of Appetite	All	106	32	30.2	21.7	39.9	66	13	19.7	10.9	31.3	116	40	34.5	25.9	43.9	59	18	30.5	19.2	43.9	105	35	33.3	24.4	43.2	65	18	27.7	17.3	40.2
	Grade 2 or 3	106	4	3.8	1.0	9.4	66	7	10.6	4.4	20.6	116	10	8.6	4.2	15.3	59	3	5.1	1.1	14.1	105	8	7.6	3.3	14.5	65	7	10.8	4.4	20.9
	Grade 3	106	1	0.9	0.0	5.1	66	0	0.0	0.0	5.4	116	2	1.7	0.2	6.1	59	0	0.0	0.0	6.1	105	1	1.0	0.0	5.2	65	1	1.5	0.0	8.3
	Related	106	31	29.2	20.8	38.9	66	13	19.7	10.9	31.3	116	39	33.6	25.1	43.0	59	17	28.8	17.8	42.1	105	34	32.4	23.6	42.2	65	18	27.7	17.3	40.2
	Grade 3 Related	106	1	0.9	0.0	5.1	66	0	0.0	0.0	5.4	116	2	1.7	0.2	6.1	59	0	0.0	0.0	6.1	105	1	1.0	0.0	5.2	65	1	1.5	0.0	8.3
	Medical advice	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	1	1.7	0.0	9.1	105	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
Temperature/(Rectally) (°C)	All	106	21	19.8	12.7	28.7	66	19	28.8	18.3	41.3	116	25	21.6	14.5	30.1	59	20	33.9	22.1	47.4	105	20	19.0	12.0	27.9	65	17	26.2	16.0	38.5
	>38.5	106	7	6.6	2.7	13.1	66	5	7.6	2.5	16.8	116	12	10.3	5.5	17.4	59	9	15.3	7.2	27.0	105	8	7.6	3.3	14.5	65	7	10.8	4.4	20.9
	>39.0	106	0	0.0	0.0	3.4	66	4	6.1	1.7	14.8	116	5	4.3	1.4	9.8	59	6	10.2	3.8	20.8	105	3	2.9	0.6	8.1	65	4	6.2	1.7	15.0
	>39.5	106	0	0.0	0.0	3.4	66	1	1.5	0.0	8.2	116	1	0.9	0.0	4.7	59	2	3.4	0.4	11.7	105	0	0.0	0.0	3.5	65	1	1.5	0.0	8.3
	>40.0	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	2	3.4	0.4	11.7	105	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
	Related	106	18	17.0	10.4	25.5	66	17	25.8	15.8	38.0	116	22	19.0	12.3	27.3	59	17	28.8	17.8	42.1	105	20	19.0	12.0	27.9	65	15	23.1	13.5	35.2
	>40.0 Related	106	0	0.0	0.0	3.4	66	0	0.0	0.0	5.4	116	0	0.0	0.0	3.1	59	2	3.4	0.4	11.7	105	0	0.0	0.0	3.5	65	0	0.0	0.0	5.5
	Medical advice	106	0	0.0	0.0	3.4	66	1	1.5	0.0	8.2	116	0	0.0	0.0	3.1	59	2	3.4	0.4	11.7	105	0	0.0	0.0	3.5	65	1	1.5	0.0	8.3
Overall/dose																															
Drowsiness	All	328	193	58.8	53.3	64.2	211	103	48.8	41.9	55.8	358	252	70.4	65.4	75.1	190	131	68.9	61.8	75.4	324	223	68.8	63.5	73.8	213	123	57.7	50.8	64.5
	Grade 2 or 3	328	59	18.0	14.0	22.6	211	31	14.7	10.2	20.2	358	99	27.7	23.1	32.6	190	37	19.5	14.1	25.8	324	75	23.1	18.7	28.1	213	42	19.7	14.6	25.7
	Grade 3	328	10	3.0	1.5	5.5	211	4	1.9	0.5	4.8	358	15	4.2	2.4	6.8	190	5	2.6	0.9	6.0	324	16	4.9	2.8	7.9	213	9	4.2	2.0	7.9
	Related	328	185	56.4	50.8	61.8	211	102	48.3	41.4	55.3	358	244	68.2	63.1	73.0	190	123	64.7	57.5	71.5	324	214	66.0	60.6	71.2	213	121	56.8	49.9	63.6
	Grade 3 Related	328	9	2.7	1.3	5.1	211	4	1.9	0.5	4.8	358	14	3.9	2.2	6.5	190	5	2.6	0.9	6.0	324	15	4.6	2.6	7.5	213	9	4.2	2.0	7.9
	Medical advice	328	1	0.3	0.0	1.7	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	2	1.1	0.1	3.8	324	0	0.0	0.0	1.1	213	1	0.5	0.0	2.6

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
Irritability / Fussiness	All	328	237	72.3	67.1	77.0	211	132	62.6	55.7	69.1	358	297	83.0	78.7	86.7	190	150	78.9	72.5	84.5	324	255	78.7	73.8	83.0	213	156	73.2	66.8	79.1
	Grade 2 or 3	328	93	28.4	23.5	33.6	211	48	22.7	17.3	29.0	358	138	38.5	33.5	43.8	190	69	36.3	29.5	43.6	324	122	37.7	32.4	43.2	213	65	30.5	24.4	37.2
	Grade 3	328	14	4.3	2.4	7.1	211	7	3.3	1.3	6.7	358	36	10.1	7.1	13.6	190	10	5.3	2.6	9.5	324	26	8.0	5.3	11.5	213	11	5.2	2.6	9.1
	Related	328	227	69.2	63.9	74.2	211	132	62.6	55.7	69.1	358	290	81.0	76.6	84.9	190	145	76.3	69.6	82.2	324	246	75.9	70.9	80.5	213	154	72.3	65.8	78.2
	Grade 3 Related	328	14	4.3	2.4	7.1	211	7	3.3	1.3	6.7	358	33	9.2	6.4	12.7	190	10	5.3	2.6	9.5	324	26	8.0	5.3	11.5	213	11	5.2	2.6	9.1
	Medical advice	328	1	0.3	0.0	1.7	211	0	0.0	0.0	1.7	358	1	0.3	0.0	1.5	190	2	1.1	0.1	3.8	324	1	0.3	0.0	1.7	213	2	0.9	0.1	3.4
Loss Of Appetite	All	328	107	32.6	27.6	38.0	211	47	22.3	16.8	28.5	358	128	35.8	30.8	41.0	190	61	32.1	25.5	39.2	324	127	39.2	33.8	44.7	213	62	29.1	23.1	35.7
	Grade 2 or 3	328	22	6.7	4.3	10.0	211	14	6.6	3.7	10.9	358	29	8.1	5.5	11.4	190	12	6.3	3.3	10.8	324	31	9.6	6.6	13.3	213	25	11.7	7.7	16.8
	Grade 3	328	1	0.3	0.0	1.7	211	1	0.5	0.0	2.6	358	4	1.1	0.3	2.8	190	0	0.0	0.0	1.9	324	5	1.5	0.5	3.6	213	3	1.4	0.3	4.1
	Related	328	100	30.5	25.5	35.8	211	44	20.9	15.6	27.0	358	122	34.1	29.2	39.2	190	58	30.5	24.1	37.6	324	122	37.7	32.4	43.2	213	62	29.1	23.1	35.7
	Grade 3 Related	328	1	0.3	0.0	1.7	211	1	0.5	0.0	2.6	358	4	1.1	0.3	2.8	190	0	0.0	0.0	1.9	324	5	1.5	0.5	3.6	213	3	1.4	0.3	4.1
	Medical advice	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	1	0.5	0.0	2.9	324	1	0.3	0.0	1.7	213	0	0.0	0.0	1.7
Temperature/(Rectally) (°C)	All	328	56	17.1	13.2	21.6	211	53	25.1	19.4	31.5	358	65	18.2	14.3	22.5	190	50	26.3	20.2	33.2	324	59	18.2	14.2	22.9	213	42	19.7	14.6	25.7
	>38.5	328	15	4.6	2.6	7.4	211	14	6.6	3.7	10.9	358	21	5.9	3.7	8.8	190	17	8.9	5.3	13.9	324	17	5.2	3.1	8.3	213	12	5.6	2.9	9.6
	>39.0	328	2	0.6	0.1	2.2	211	4	1.9	0.5	4.8	358	6	1.7	0.6	3.6	190	8	4.2	1.8	8.1	324	5	1.5	0.5	3.6	213	6	2.8	1.0	6.0
	>39.5	328	0	0.0	0.0	1.1	211	1	0.5	0.0	2.6	358	1	0.3	0.0	1.5	190	2	1.1	0.1	3.8	324	1	0.3	0.0	1.7	213	1	0.5	0.0	2.6
	>40.0	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	2	1.1	0.1	3.8	324	0	0.0	0.0	1.1	213	0	0.0	0.0	1.7
	Related	328	46	14.0	10.5	18.3	211	41	19.4	14.3	25.4	358	57	15.9	12.3	20.1	190	45	23.7	17.8	30.4	324	58	17.9	13.9	22.5	213	37	17.4	12.5	23.1
	>40.0 Related	328	0	0.0	0.0	1.1	211	0	0.0	0.0	1.7	358	0	0.0	0.0	1.0	190	2	1.1	0.1	3.8	324	0	0.0	0.0	1.1	213	0	0.0	0.0	1.7
	Medical advice	328	0	0.0	0.0	1.1	211	1	0.5	0.0	2.6	358	0	0.0	0.0	1.0	190	2	1.1	0.1	3.8	324	0	0.0	0.0	1.1	213	1	0.5	0.0	2.6
Overall/subject																															
Drowsiness	All	113	94	83.2	75.0	89.6	74	53	71.6	59.9	81.5	123	110	89.4	82.6	94.3	66	62	93.9	85.2	98.3	112	104	92.9	86.4	96.9	76	64	84.2	74.0	91.6
	Grade 2 or 3	113	43	38.1	29.1	47.7	74	23	31.1	20.8	42.9	123	60	48.8	39.7	58.0	66	28	42.4	30.3	55.2	112	54	48.2	38.7	57.9	76	27	35.5	24.9	47.3

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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	N	n	%	LL	UL
	Grade 3	113	8	7.1	3.1	13.5	74	3	4.1	0.8	11.4	123	14	11.4	6.4	18.4	66	5	7.6	2.5	16.8	112	14	12.5	7.0	20.1	76	8	10.5	4.7	19.7
	Related	113	91	80.5	72.0	87.4	74	53	71.6	59.9	81.5	123	109	88.6	81.6	93.6	66	60	90.9	81.3	96.6	112	102	91.1	84.2	95.6	76	64	84.2	74.0	91.6
	Grade 3 Related	113	8	7.1	3.1	13.5	74	3	4.1	0.8	11.4	123	13	10.6	5.7	17.4	66	5	7.6	2.5	16.8	112	13	11.6	6.3	19.0	76	8	10.5	4.7	19.7
	Medical advice	113	1	0.9	0.0	4.8	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	2	3.0	0.4	10.5	112	0	0.0	0.0	3.2	76	1	1.3	0.0	7.1
Irritability / Fussiness	All	113	102	90.3	83.2	95.0	74	62	83.8	73.4	91.3	123	120	97.6	93.0	99.5	66	62	93.9	85.2	98.3	112	107	95.5	89.9	98.5	76	70	92.1	83.6	97.0
	Grade 2 or 3	113	64	56.6	47.0	65.9	74	32	43.2	31.8	55.3	123	85	69.1	60.1	77.1	66	43	65.2	52.4	76.5	112	72	64.3	54.7	73.1	76	48	63.2	51.3	73.9
	Grade 3	113	11	9.7	5.0	16.8	74	7	9.5	3.9	18.5	123	28	22.8	15.7	31.2	66	7	10.6	4.4	20.6	112	20	17.9	11.3	26.2	76	10	13.2	6.5	22.9
	Related	113	99	87.6	80.1	93.1	74	62	83.8	73.4	91.3	123	119	96.7	91.9	99.1	66	61	92.4	83.2	97.5	112	105	93.8	87.5	97.5	76	70	92.1	83.6	97.0
	Grade 3 Related	113	11	9.7	5.0	16.8	74	7	9.5	3.9	18.5	123	27	22.0	15.0	30.3	66	7	10.6	4.4	20.6	112	20	17.9	11.3	26.2	76	10	13.2	6.5	22.9
	Medical advice	113	1	0.9	0.0	4.8	74	0	0.0	0.0	4.9	123	1	0.8	0.0	4.4	66	2	3.0	0.4	10.5	112	1	0.9	0.0	4.9	76	2	2.6	0.3	9.2
Loss Of Appetite	All	113	65	57.5	47.9	66.8	74	30	40.5	29.3	52.6	123	77	62.6	53.4	71.2	66	34	51.5	38.9	64.0	112	76	67.9	58.4	76.4	76	41	53.9	42.1	65.5
	Grade 2 or 3	113	16	14.2	8.3	22.0	74	12	16.2	8.7	26.6	123	23	18.7	12.2	26.7	66	9	13.6	6.4	24.3	112	23	20.5	13.5	29.2	76	16	21.1	12.5	31.9
	Grade 3	113	1	0.9	0.0	4.8	74	1	1.4	0.0	7.3	123	3	2.4	0.5	7.0	66	0	0.0	0.0	5.4	112	3	2.7	0.6	7.6	76	3	3.9	0.8	11.1
	Related	113	62	54.9	45.2	64.2	74	29	39.2	28.0	51.2	123	75	61.0	51.8	69.6	66	33	50.0	37.4	62.6	112	75	67.0	57.4	75.6	76	41	53.9	42.1	65.5
	Grade 3 Related	113	1	0.9	0.0	4.8	74	1	1.4	0.0	7.3	123	3	2.4	0.5	7.0	66	0	0.0	0.0	5.4	112	3	2.7	0.6	7.6	76	3	3.9	0.8	11.1
	Medical advice	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	1	1.5	0.0	8.2	112	1	0.9	0.0	4.9	76	0	0.0	0.0	4.7
Temperature/(Rectally) (°C)	All	113	38	33.6	25.0	43.1	74	34	45.9	34.3	57.9	123	47	38.2	29.6	47.4	66	31	47.0	34.6	59.7	112	44	39.3	30.2	49.0	76	28	36.8	26.1	48.7
	>38.5	113	12	10.6	5.6	17.8	74	12	16.2	8.7	26.6	123	19	15.4	9.6	23.1	66	15	22.7	13.3	34.7	112	16	14.3	8.4	22.2	76	10	13.2	6.5	22.9
	>39.0	113	2	1.8	0.2	6.2	74	4	5.4	1.5	13.3	123	6	4.9	1.8	10.3	66	8	12.1	5.4	22.5	112	5	4.5	1.5	10.1	76	5	6.6	2.2	14.7
	>39.5	113	0	0.0	0.0	3.2	74	1	1.4	0.0	7.3	123	1	0.8	0.0	4.4	66	2	3.0	0.4	10.5	112	1	0.9	0.0	4.9	76	1	1.3	0.0	7.1
	>40.0	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	2	3.0	0.4	10.5	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7
	Related	113	33	29.2	21.0	38.5	74	28	37.8	26.8	49.9	123	44	35.8	27.3	44.9	66	30	45.5	33.1	58.2	112	43	38.4	29.4	48.1	76	26	34.2	23.7	46.0
	>40.0 Related	113	0	0.0	0.0	3.2	74	0	0.0	0.0	4.9	123	0	0.0	0.0	3.0	66	2	3.0	0.4	10.5	112	0	0.0	0.0	3.2	76	0	0.0	0.0	4.7

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
	Medical advice	113	0	0.0	0.0	3.2	74	1	1.4	0.0	7.3	123	0	0.0	0.0	3.0	66	2	3.0	0.4	10.5	112	0	0.0	0.0	3.2	76	1	1.3	0.0	7.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
For each dose and overall/subject:
N = number of subjects with at least one documented dose
n/% = number/percentage of subjects reporting the symptom at least once
For Overall/dose:
N = number of documented doses
n/% = number/percentage of doses followed by at least one type of symptom
95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 8.13 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		159	28.2	24.5	32.1	149	26.3	22.7	30.1	143	25.3	21.8	29.1
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Leukocytosis (10024378)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Lymphadenopathy (10025197)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	2	0.4	0.0	1.3
Congenital, familial and genetic disorders (10010331)	Congenital skin dimples (10072978)	0	0.0	0.0	0.7	3	0.5	0.1	1.5	1	0.2	0.0	1.0
	Dermoid cyst (10012522)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Hydrocele (10020488)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Hypospadias (10021093)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Macrocephaly (10050183)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Plagiocephaly (10048586)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	2	0.4	0.0	1.3
	Ear disorder (10014004)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Ear pain (10014020)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Anal fistula (10002156)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Constipation (10010774)	1	0.2	0.0	1.0	3	0.5	0.1	1.5	5	0.9	0.3	2.1
	Diarrhoea (10012735)	7	1.2	0.5	2.5	5	0.9	0.3	2.0	11	1.9	1.0	3.5
	Flatulence (10016766)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Frequent bowel movements (10017367)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.7	8	1.4	0.6	2.8	1	0.2	0.0	1.0
	Inguinal hernia (10022016)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Teething (10043183)	6	1.1	0.4	2.3	8	1.4	0.6	2.8	9	1.6	0.7	3.0
	Vomiting (10047700)	9	1.6	0.7	3.0	8	1.4	0.6	2.8	10	1.8	0.9	3.2
	Vomiting projectile (10047708)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Crying (10011469)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	0	0.0	0.0	0.7

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Ill-defined disorder (10061520)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site bruising (10022052)	2	0.4	0.0	1.3	2	0.4	0.0	1.3	5	0.9	0.3	2.1
	Injection site erythema (10022061)	4	0.7	0.2	1.8	2	0.4	0.0	1.3	5	0.9	0.3	2.1
	Injection site induration (10022075)	3	0.5	0.1	1.5	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Injection site mass (10022081)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Injection site pain (10022086)	5	0.9	0.3	2.1	8	1.4	0.6	2.8	7	1.2	0.5	2.5
	Injection site pruritus (10022093)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site rash (10022094)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	2	0.4	0.0	1.3
	Injection site swelling (10053425)	4	0.7	0.2	1.8	1	0.2	0.0	1.0	4	0.7	0.2	1.8
	Injection site warmth (10022112)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Oedema peripheral (10030124)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Peripheral swelling (10048959)	0	0.0	0.0	0.7	3	0.5	0.1	1.5	0	0.0	0.0	0.7
	Pyrexia (10037660)	13	2.3	1.2	3.9	6	1.1	0.4	2.3	16	2.8	1.6	4.6
	Swelling (10042674)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Vaccination site bruising (10069484)	0	0.0	0.0	0.7	3	0.5	0.1	1.5	1	0.2	0.0	1.0
	Vaccination site erythema (10059079)	2	0.4	0.0	1.3	4	0.7	0.2	1.8	3	0.5	0.1	1.5
	Vaccination site induration (10065117)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Vaccination site pain (10068879)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	3	0.5	0.1	1.5
	Vaccination site swelling (10069620)	3	0.5	0.1	1.5	1	0.2	0.0	1.0	2	0.4	0.0	1.3
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Milk allergy (10027633)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Infections and infestations (10021881)	Acute sinusitis (10001076)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Anal abscess (10048946)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Bronchiolitis (10006448)	3	0.5	0.1	1.5	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Bronchitis (10006451)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Candida infection (10074170)	2	0.4	0.0	1.3	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Candida nappy rash (10007135)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Cellulitis (10007882)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Conjunctivitis (10010741)	10	1.8	0.9	3.2	8	1.4	0.6	2.8	1	0.2	0.0	1.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Conjunctivitis viral (10010755)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Croup infectious (10011416)	2	0.4	0.0	1.3	2	0.4	0.0	1.3	0	0.0	0.0	0.7

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ear infection (10014011)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Eczema herpeticum (10014197)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Exanthema subitum (10015586)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Fungal infection (10017533)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Fungal skin infection (10017543)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Gastric infection (10056663)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Gastroenteritis (10017888)	1	0.2	0.0	1.0	2	0.4	0.0	1.3	1	0.2	0.0	1.0
	Hand-foot-and-mouth disease (10019113)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Herpangina (10019936)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Impetigo (10021531)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	3	0.5	0.1	1.5
	Influenza (10022000)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Nasopharyngitis (10028810)	3	0.5	0.1	1.5	1	0.2	0.0	1.0	3	0.5	0.1	1.5
	Oral candidiasis (10030963)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Otitis externa (10033072)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Otitis media (10033078)	9	1.6	0.7	3.0	7	1.2	0.5	2.5	9	1.6	0.7	3.0
	Otitis media acute (10033079)	1	0.2	0.0	1.0	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Otitis media chronic (10033081)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Pertussis (10034738)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Pharyngitis (10034835)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Pneumonia (10035664)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Respiratory syncytial virus infection (10061603)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Respiratory tract infection (10062352)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Rhinitis (10039083)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Roseola (10039222)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Sinusitis (10040753)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Skin candida (10054152)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Upper respiratory tract infection (10046306)	32	5.7	3.9	7.9	26	4.6	3.0	6.6	27	4.8	3.2	6.9
	Urinary tract infection (10046571)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	1	0.2	0.0	1.0
	Viraemia (10058874)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Viral infection (10047461)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	3	0.5	0.1	1.5
	Viral rash (10047476)	3	0.5	0.1	1.5	0	0.0	0.0	0.6	3	0.5	0.1	1.5
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	2	0.4	0.0	1.3
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Arthropod sting (10003402)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Clavicle fracture (10009245)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Concussion (10010254)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Corneal abrasion (10010984)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Craniocerebral injury (10070976)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Fall (10016173)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Foreign body (10070245)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Head injury (10019196)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	2	0.4	0.0	1.3
	Nasal injury (10078651)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Thermal burn (10053615)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Investigations (10022891)	Body temperature increased (10005911)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Cardiac murmur (10007586)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Weight decreased (10047895)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Musculoskeletal and connective tissue disorders (10028395)	Asymmetric gluteal fold (10072189)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Pain in extremity (10033425)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Positional plagiocephaly (10068711)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma (10018814)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Lethargy (10024264)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Poor quality sleep (10062519)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Tremor (10044565)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Psychiatric disorders (10037175)	Irritability (10022998)	5	0.9	0.3	2.1	3	0.5	0.1	1.5	1	0.2	0.0	1.0
	Screaming (10039740)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Renal and urinary disorders (10038359)	Urethral meatus stenosis (10058463)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Genital labial adhesions (10064162)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Penile adhesion (10059636)	3	0.5	0.1	1.5	3	0.5	0.1	1.5	0	0.0	0.0	0.7

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Penile erythema (10070655)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Bronchial hyperreactivity (10066091)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Cough (10011224)	16	2.8	1.6	4.6	7	1.2	0.5	2.5	7	1.2	0.5	2.5
	Dysphonia (10013952)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Epistaxis (10015090)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Nasal congestion (10028735)	2	0.4	0.0	1.3	6	1.1	0.4	2.3	2	0.4	0.0	1.3
	Respiratory arrest (10038669)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Respiratory disorder (10038683)	1	0.2	0.0	1.0	2	0.4	0.0	1.3	1	0.2	0.0	1.0
	Rhinitis allergic (10039085)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Rhinorrhoea (10039101)	3	0.5	0.1	1.5	2	0.4	0.0	1.3	4	0.7	0.2	1.8
	Sinus congestion (10040742)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Sneezing (10041232)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Upper respiratory tract congestion (10052252)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Wheezing (10047924)	3	0.5	0.1	1.5	0	0.0	0.0	0.6	2	0.4	0.0	1.3
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	3	0.5	0.1	1.5	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Dermatitis atopic (10012438)	2	0.4	0.0	1.3	3	0.5	0.1	1.5	5	0.9	0.3	2.1
	Dermatitis contact (10012442)	1	0.2	0.0	1.0	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Dermatitis diaper (10012444)	2	0.4	0.0	1.3	3	0.5	0.1	1.5	10	1.8	0.9	3.2
	Dry skin (10013786)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Eczema (10014184)	4	0.7	0.2	1.8	5	0.9	0.3	2.0	4	0.7	0.2	1.8
	Erythema (10015150)	0	0.0	0.0	0.7	3	0.5	0.1	1.5	0	0.0	0.0	0.7
	Hair growth abnormal (10019044)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Hypertrichosis (10020864)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Intertrigo (10022622)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Post inflammatory pigmentation change (10036229)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Rash (10037844)	4	0.7	0.2	1.8	4	0.7	0.2	1.8	6	1.1	0.4	2.3
	Rash macular (10037867)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Seborrhoea (10039792)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Seborrhoeic dermatitis (10039793)	3	0.5	0.1	1.5	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Urticaria (10046735)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.14 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		14	2.5	1.4	4.1	12	2.1	1.1	3.7	8	1.4	0.6	2.8
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Diarrhoea (10012735)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Teething (10043183)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Vomiting (10047700)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	0	0.0	0.0	0.7
General disorders and administration site conditions (10018065)	Crying (10011469)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Ill-defined disorder (10061520)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site erythema (10022061)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site pain (10022086)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Injection site swelling (10053425)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site warmth (10022112)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Pyrexia (10037660)	2	0.4	0.0	1.3	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Infections and infestations (10021881)	Bronchiolitis (10006448)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Conjunctivitis (10010741)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Croup infectious (10011416)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Gastroenteritis (10017888)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Hand-foot-and-mouth disease (10019113)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Nasopharyngitis (10028810)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Otitis media (10033078)	3	0.5	0.1	1.5	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Pharyngitis (10034835)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Respiratory syncytial virus infection (10061603)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Rhinitis (10039083)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Sinusitis (10040753)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Upper respiratory tract infection (10046306)	3	0.5	0.1	1.5	2	0.4	0.0	1.3	2	0.4	0.0	1.3
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Cough (10011224)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Respiratory arrest (10038669)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Wheezing (10047924)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines

Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines

Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

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

Table 8.15 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 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		24	12.3	8.0	17.8	28	14.4	9.8	20.2	34	17.3	12.3	23.4
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Diarrhoea (10012735)	1	0.5	0.0	2.8	2	1.0	0.1	3.7	3	1.5	0.3	4.4
	Flatulence (10016766)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Vomiting (10047700)	3	1.5	0.3	4.4	3	1.5	0.3	4.5	3	1.5	0.3	4.4
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site bruising (10022052)	2	1.0	0.1	3.7	2	1.0	0.1	3.7	4	2.0	0.6	5.1
	Injection site erythema (10022061)	4	2.1	0.6	5.2	2	1.0	0.1	3.7	5	2.6	0.8	5.9
	Injection site induration (10022075)	3	1.5	0.3	4.4	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Injection site mass (10022081)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Injection site pain (10022086)	4	2.1	0.6	5.2	6	3.1	1.1	6.6	7	3.6	1.4	7.2
	Injection site pruritus (10022093)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site rash (10022094)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	2	1.0	0.1	3.6
	Injection site swelling (10053425)	4	2.1	0.6	5.2	1	0.5	0.0	2.8	4	2.0	0.6	5.1
	Injection site warmth (10022112)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	0	0.0	0.0	1.9
	Oedema peripheral (10030124)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Peripheral swelling (10048959)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Pyrexia (10037660)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	3	1.5	0.3	4.4
	Swelling (10042674)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Vaccination site bruising (10069484)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	1	0.5	0.0	2.8
	Vaccination site erythema (10059079)	1	0.5	0.0	2.8	4	2.1	0.6	5.2	3	1.5	0.3	4.4
	Vaccination site induration (10065117)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Vaccination site pain (10068879)	2	1.0	0.1	3.7	1	0.5	0.0	2.8	3	1.5	0.3	4.4
	Vaccination site swelling (10069620)	3	1.5	0.3	4.4	1	0.5	0.0	2.8	2	1.0	0.1	3.6
Infections and infestations (10021881)	Nasopharyngitis (10028810)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Upper respiratory tract infection (10046306)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
	Viral rash (10047476)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	1	0.5	0.0	2.8
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Lethargy (10024264)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Poor quality sleep (10062519)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
	Cough (10011224)	1	0.5	0.0	2.8	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Nasal congestion (10028735)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Respiratory arrest (10038669)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Rhinorrhoea (10039101)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	1	0.5	0.0	2.8
Skin and subcutaneous tissue disorders (10040785)	Erythema (10015150)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Rash (10037844)	0	0.0	0.0	1.9	2	1.0	0.1	3.7	2	1.0	0.1	3.6

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.16 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		28	5.0	3.3	7.1	35	6.2	4.3	8.5	37	6.5	4.7	8.9
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Diarrhoea (10012735)	2	0.4	0.0	1.3	2	0.4	0.0	1.3	3	0.5	0.1	1.5
	Flatulence (10016766)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Vomiting (10047700)	3	0.5	0.1	1.5	3	0.5	0.1	1.5	3	0.5	0.1	1.5
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site bruising (10022052)	2	0.4	0.0	1.3	2	0.4	0.0	1.3	4	0.7	0.2	1.8
	Injection site erythema (10022061)	4	0.7	0.2	1.8	2	0.4	0.0	1.3	5	0.9	0.3	2.1
	Injection site induration (10022075)	3	0.5	0.1	1.5	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Injection site mass (10022081)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Injection site pain (10022086)	5	0.9	0.3	2.1	8	1.4	0.6	2.8	7	1.2	0.5	2.5
	Injection site pruritus (10022093)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site rash (10022094)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	2	0.4	0.0	1.3
	Injection site swelling (10053425)	4	0.7	0.2	1.8	1	0.2	0.0	1.0	4	0.7	0.2	1.8
	Injection site warmth (10022112)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	0	0.0	0.0	0.7
	Oedema peripheral (10030124)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Peripheral swelling (10048959)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Pyrexia (10037660)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	3	0.5	0.1	1.5
	Swelling (10042674)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Vaccination site bruising (10069484)	0	0.0	0.0	0.7	3	0.5	0.1	1.5	1	0.2	0.0	1.0
	Vaccination site erythema (10059079)	1	0.2	0.0	1.0	4	0.7	0.2	1.8	3	0.5	0.1	1.5
	Vaccination site induration (10065117)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Vaccination site pain (10068879)	2	0.4	0.0	1.3	1	0.2	0.0	1.0	3	0.5	0.1	1.5
	Vaccination site swelling (10069620)	3	0.5	0.1	1.5	1	0.2	0.0	1.0	2	0.4	0.0	1.3
Infections and infestations (10021881)	Nasopharyngitis (10028810)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Upper respiratory tract infection (10046306)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0
	Viral rash (10047476)	0	0.0	0.0	0.7	0	0.0	0.0	0.6	1	0.2	0.0	1.0

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Lethargy (10024264)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Poor quality sleep (10062519)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
	Cough (10011224)	1	0.2	0.0	1.0	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Nasal congestion (10028735)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Respiratory arrest (10038669)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Rhinorrhoea (10039101)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	1	0.2	0.0	1.0
Skin and subcutaneous tissue disorders (10040785)	Erythema (10015150)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Rash (10037844)	0	0.0	0.0	0.7	2	0.4	0.0	1.3	2	0.4	0.0	1.3

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.17 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	0.5	0.0	2.8	4	2.1	0.6	5.2	1	0.5	0.0	2.8
Gastrointestinal disorders (10017947)	Vomiting (10047700)	1	0.5	0.0	2.8	0	0.0	0.0	1.9	0	0.0	0.0	1.9
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site erythema (10022061)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site pain (10022086)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	1	0.5	0.0	2.8
	Injection site swelling (10053425)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
	Injection site warmth (10022112)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9
Respiratory, thoracic and mediastinal disorders (10038738)	Respiratory arrest (10038669)	0	0.0	0.0	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.18 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 564				Pedia group N = 567				Penta group N = 565			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	0.2	0.0	1.0	4	0.7	0.2	1.8	1	0.2	0.0	1.0
Gastrointestinal disorders (10017947)	Vomiting (10047700)	1	0.2	0.0	1.0	0	0.0	0.0	0.6	0	0.0	0.0	0.7
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site erythema (10022061)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site pain (10022086)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	1	0.2	0.0	1.0
	Injection site swelling (10053425)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
	Injection site warmth (10022112)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7
Respiratory, thoracic and mediastinal disorders (10038738)	Respiratory arrest (10038669)	0	0.0	0.0	0.7	1	0.2	0.0	1.0	0	0.0	0.0	0.7

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.19 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term, within the 31-day (Days 0-30) post-vaccination period following priming doses – by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		57	56.4	46.2	66.3	56	59.6	49.0	69.6	44	55.0	43.5	66.2	64	56.1	46.5	65.4	44	46.3	36.0	56.8	52	51.5	41.3	61.6
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Leukocytosis (10024378)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Lymphadenopathy (10025197)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	2	2.1	0.3	7.4	0	0.0	0.0	3.6
Congenital, familial and genetic disorders (10010331)	Congenital skin dimples (10072978)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	3	2.6	0.5	7.5	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Dermoid cyst (10012522)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Hydrocele (10020488)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Hypospadias (10021093)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Macrocephaly (10050183)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Plagiocephaly (10048586)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4
	Ear disorder (10014004)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Ear pain (10014020)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Anal fistula (10002156)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Constipation (10010774)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	2	2.5	0.3	8.7	0	0.0	0.0	3.2	1	1.1	0.0	5.7	4	4.0	1.1	9.8
	Diarrhoea (10012735)	3	3.0	0.6	8.4	3	3.2	0.7	9.0	1	1.3	0.0	6.8	4	3.5	1.0	8.7	6	6.3	2.4	13.2	4	4.0	1.1	9.8
	Flatulence (10016766)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Frequent bowel movements (10017367)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	3	3.8	0.8	10.6	5	4.4	1.4	9.9	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Inguinal hernia (10022016)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Teething (10043183)	3	3.0	0.6	8.4	3	3.2	0.7	9.0	2	2.5	0.3	8.7	6	5.3	2.0	11.1	4	4.2	1.2	10.4	5	5.0	1.6	11.2
	Vomiting (10047700)	4	4.0	1.1	9.8	5	5.3	1.7	12.0	4	5.0	1.4	12.3	4	3.5	1.0	8.7	4	4.2	1.2	10.4	6	5.9	2.2	12.5
	Vomiting projectile (10047708)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Crying (10011469)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Ill-defined disorder (10061520)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site bruising (10022052)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	5	5.0	1.6	11.2
	Injection site erythema (10022061)	2	2.0	0.2	7.0	2	2.1	0.3	7.5	1	1.3	0.0	6.8	1	0.9	0.0	4.8	4	4.2	1.2	10.4	1	1.0	0.0	5.4
	Injection site induration (10022075)	2	2.0	0.2	7.0	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site mass (10022081)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site pain (10022086)	3	3.0	0.6	8.4	1	1.1	0.0	5.8	4	5.0	1.4	12.3	2	1.8	0.2	6.2	2	2.1	0.3	7.4	5	5.0	1.6	11.2
	Injection site pruritus (10022093)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site rash (10022094)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4
	Injection site swelling (10053425)	3	3.0	0.6	8.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	3	3.2	0.7	9.0	1	1.0	0.0	5.4
	Injection site warmth (10022112)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Oedema peripheral (10030124)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Peripheral swelling (10048959)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	3	3.8	0.8	10.6	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pyrexia (10037660)	3	3.0	0.6	8.4	9	9.6	4.5	17.4	1	1.3	0.0	6.8	4	3.5	1.0	8.7	7	7.4	3.0	14.6	8	7.9	3.5	15.0
	Swelling (10042674)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Vaccination site bruising (10069484)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Vaccination site erythema (10059079)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	2	2.5	0.3	8.7	2	1.8	0.2	6.2	3	3.2	0.7	9.0	0	0.0	0.0	3.6
	Vaccination site induration (10065117)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Vaccination site pain (10068879)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	2	2.1	0.3	7.4	1	1.0	0.0	5.4
	Vaccination site swelling (10069620)	1	1.0	0.0	5.4	2	2.1	0.3	7.5	0	0.0	0.0	4.5	1	0.9	0.0	4.8	1	1.1	0.0	5.7	1	1.0	0.0	5.4
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Milk allergy (10027633)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
Infections and infestations (10021881)	Acute sinusitis (10001076)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Anal abscess (10048946)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Bronchiolitis (10006448)	2	2.0	0.2	7.0	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Bronchitis (10006451)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Candida infection (10074170)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Candida nappy rash (10007135)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Cellulitis (10007882)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Conjunctivitis (10010741)	1	1.0	0.0	5.4	9	9.6	4.5	17.4	2	2.5	0.3	8.7	6	5.3	2.0	11.1	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Conjunctivitis viral (10010755)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Croup infectious (10011416)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Ear infection (10014011)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Eczema herpeticum (10014197)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Exanthema subitum (10015586)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Fungal infection (10017533)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Fungal skin infection (10017543)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Gastric infection (10056663)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Gastroenteritis (10017888)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Herpangina (10019936)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Impetigo (10021531)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4
	Influenza (10022000)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Nasopharyngitis (10028810)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	3	3.2	0.7	9.0	0	0.0	0.0	3.6
	Oral candidiasis (10030963)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Otitis externa (10033072)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Otitis media (10033078)	4	4.0	1.1	9.8	5	5.3	1.7	12.0	2	2.5	0.3	8.7	5	4.4	1.4	9.9	2	2.1	0.3	7.4	7	6.9	2.8	13.8
	Otitis media acute (10033079)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Otitis media chronic (10033081)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Pertussis (10034738)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Pharyngitis (10034835)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Pneumonia (10035664)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Respiratory syncytial virus bronchiolitis (10038718)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Respiratory tract infection (10062352)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Rhinitis (10039083)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Roseola (10039222)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Sinusitis (10040753)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Skin candida (10054152)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Upper respiratory tract infection (10046306)	12	11.9	6.3	19.8	18	19.1	11.8	28.6	7	8.8	3.6	17.2	16	14.0	8.2	21.8	11	11.6	5.9	19.8	15	14.9	8.6	23.3
	Urinary tract infection (10046571)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Viraemia (10058874)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Viral infection (10047461)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	1	1.1	0.0	5.7	2	2.0	0.2	7.0
	Viral rash (10047476)	1	1.0	0.0	5.4	2	2.1	0.3	7.5	0	0.0	0.0	4.5	0	0.0	0.0	3.2	2	2.1	0.3	7.4	1	1.0	0.0	5.4
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	2	2.0	0.2	7.0
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Arthropod sting (10003402)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Clavicle fracture (10009245)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Concussion (10010254)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Corneal abrasion (10010984)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Craniocerebral injury (10070976)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Fall (10016173)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Foreign body (10070245)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Head injury (10019196)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	2	2.0	0.2	7.0
	Nasal injury (10078651)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Thermal burn (10053615)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Investigations (10022891)	Body temperature increased (10005911)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Cardiac murmur (10007586)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Weight decreased (10047895)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
Musculoskeletal and connective tissue disorders (10028395)	Asymmetric gluteal fold (10072189)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6

		Hexa group								Pedia group								Penta group							
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				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pain in extremity (10033425)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Positional plagiocephaly (10068711)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma (10018814)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Lethargy (10024264)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Poor quality sleep (10062519)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Tremor (10044565)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.6	4	4.3	1.2	10.5	2	2.5	0.3	8.7	1	0.9	0.0	4.8	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Screaming (10039740)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Renal and urinary disorders (10038359)	Urethral meatus stenosis (10058463)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Genital labial adhesions (10064162)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Penile adhesion (10059636)	0	0.0	0.0	3.6	3	3.2	0.7	9.0	0	0.0	0.0	4.5	3	2.6	0.5	7.5	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Penile erythema (10070655)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Cough (10011224)	6	5.9	2.2	12.5	9	9.6	4.5	17.4	0	0.0	0.0	4.5	7	6.1	2.5	12.2	2	2.1	0.3	7.4	5	5.0	1.6	11.2
	Dysphonia (10013952)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Epistaxis (10015090)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Nasal congestion (10028735)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	3	3.8	0.8	10.6	3	2.6	0.5	7.5	0	0.0	0.0	3.8	2	2.0	0.2	7.0
	Respiratory arrest (10038669)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Respiratory disorder (10038683)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	0	0.0	0.0	3.8	1	1.0	0.0	5.4

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis allergic (10039085)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Rhinorrhoea (10039101)	2	2.0	0.2	7.0	1	1.1	0.0	5.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	2	2.1	0.3	7.4	2	2.0	0.2	7.0
	Sinus congestion (10040742)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Sneezing (10041232)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Upper respiratory tract congestion (10052252)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Wheezing (10047924)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	3.6	3	3.2	0.7	9.0	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Dermatitis atopic (10012438)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	1	1.3	0.0	6.8	2	1.8	0.2	6.2	1	1.1	0.0	5.7	4	4.0	1.1	9.8
	Dermatitis contact (10012442)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Dermatitis diaper (10012444)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	2	2.5	0.3	8.7	1	0.9	0.0	4.8	6	6.3	2.4	13.2	3	3.0	0.6	8.4
	Dry skin (10013786)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Eczema (10014184)	3	3.0	0.6	8.4	1	1.1	0.0	5.8	2	2.5	0.3	8.7	3	2.6	0.5	7.5	2	2.1	0.3	7.4	2	2.0	0.2	7.0
	Erythema (10015150)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	3	3.8	0.8	10.6	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Hair growth abnormal (10019044)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Hypertrichosis (10020864)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Intertrigo (10022622)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Post inflammatory pigmentation change (10036229)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Rash (10037844)	1	1.0	0.0	5.4	3	3.2	0.7	9.0	2	2.5	0.3	8.7	2	1.8	0.2	6.2	1	1.1	0.0	5.7	5	5.0	1.6	11.2
	Rash macular (10037867)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Seborrhoea (10039792)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Seborrhoeic dermatitis (10039793)	0	0.0	0.0	3.6	3	3.2	0.7	9.0	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Urticaria (10046735)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.20 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses– by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		71	60.2	50.7	69.1	42	54.5	42.8	65.9	71	55.5	46.4	64.3	37	56.1	43.3	68.3	61	53.0	43.5	62.4	35	43.2	32.2	54.7
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Leukocytosis (10024378)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Lymphadenopathy (10025197)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	0	0.0	0.0	4.5
Congenital, familial and genetic disorders (10010331)	Congenital skin dimples (10072978)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	1	1.5	0.0	8.2	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Dermoid cyst (10012522)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Hydrocele (10020488)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Hypospadias (10021093)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Macrocephaly (10050183)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Plagiocephaly (10048586)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Ear disorder (10014004)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Ear pain (10014020)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Anal fistula (10002156)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Constipation (10010774)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	2	1.7	0.2	6.1	3	3.7	0.8	10.4
	Diarrhoea (10012735)	4	3.4	0.9	8.5	2	2.6	0.3	9.1	1	0.8	0.0	4.3	4	6.1	1.7	14.8	5	4.3	1.4	9.9	5	6.2	2.0	13.8
	Flatulence (10016766)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Frequent bowel movements (10017367)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	5	3.9	1.3	8.9	3	4.5	0.9	12.7	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Inguinal hernia (10022016)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Teething (10043183)	5	4.2	1.4	9.6	1	1.3	0.0	7.0	5	3.9	1.3	8.9	3	4.5	0.9	12.7	5	4.3	1.4	9.9	4	4.9	1.4	12.2
	Vomiting (10047700)	3	2.5	0.5	7.3	6	7.8	2.9	16.2	5	3.9	1.3	8.9	3	4.5	0.9	12.7	3	2.6	0.5	7.4	7	8.6	3.5	17.0
	Vomiting projectile (10047708)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Crying (10011469)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Ill-defined disorder (10061520)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site bruising (10022052)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	3	2.6	0.5	7.4	2	2.5	0.3	8.6
	Injection site erythema (10022061)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	2	1.6	0.2	5.5	0	0.0	0.0	5.4	3	2.6	0.5	7.4	2	2.5	0.3	8.6
	Injection site induration (10022075)	1	0.8	0.0	4.6	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site mass (10022081)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site pain (10022086)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	5	3.9	1.3	8.9	1	1.5	0.0	8.2	6	5.2	1.9	11.0	1	1.2	0.0	6.7
	Injection site pruritus (10022093)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site rash (10022094)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Injection site swelling (10053425)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	3	3.7	0.8	10.4
	Injection site warmth	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	(10022112)																								
	Oedema peripheral (10030124)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Peripheral swelling (10048959)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Pyrexia (10037660)	11	9.3	4.7	16.1	1	1.3	0.0	7.0	4	3.1	0.9	7.8	1	1.5	0.0	8.2	8	7.0	3.1	13.2	7	8.6	3.5	17.0
	Swelling (10042674)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Vaccination site bruising (10069484)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Vaccination site erythema (10059079)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	4	3.1	0.9	7.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	1	1.2	0.0	6.7
	Vaccination site induration (10065117)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Vaccination site pain (10068879)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	2	1.7	0.2	6.1	1	1.2	0.0	6.7
	Vaccination site swelling (10069620)	3	2.5	0.5	7.3	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Milk allergy (10027633)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Infections and infestations (10021881)	Acute sinusitis (10001076)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Anal abscess (10048946)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Bronchiolitis (10006448)	1	0.8	0.0	4.6	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Bronchitis (10006451)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Candida infection (10074170)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Candida nappy rash (10007135)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Cellulitis (10007882)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Conjunctivitis (10010741)	5	4.2	1.4	9.6	5	6.5	2.1	14.5	5	3.9	1.3	8.9	3	4.5	0.9	12.7	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Conjunctivitis viral (10010755)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Croup infectious (10011416)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Ear infection (10014011)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Eczema herpeticum (10014197)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Exanthema subitum (10015586)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Fungal infection (10017533)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Fungal skin infection (10017543)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Gastric infection (10056663)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Gastroenteritis (10017888)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	2	3.0	0.4	10.5	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Hand-foot-and-mouth disease (10019113)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Herpangina (10019936)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Impetigo (10021531)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Influenza (10022000)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Nasopharyngitis (10028810)	0	0.0	0.0	3.1	2	2.6	0.3	9.1	1	0.8	0.0	4.3	0	0.0	0.0	5.4	2	1.7	0.2	6.1	1	1.2	0.0	6.7
	Oral candidiasis (10030963)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Otitis externa (10033072)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Otitis media (10033078)	6	5.1	1.9	10.7	3	3.9	0.8	11.0	7	5.5	2.2	10.9	0	0.0	0.0	5.4	6	5.2	1.9	11.0	3	3.7	0.8	10.4
	Otitis media acute (10033079)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	2	3.0	0.4	10.5	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Otitis media chronic (10033081)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Pertussis (10034738)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Pharyngitis (10034835)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Pneumonia (10035664)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Respiratory syncytial virus	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	bronchiolitis (10038718)																								
	Respiratory syncytial virus infection (10061603)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Respiratory tract infection (10062352)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Rhinitis (10039083)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Roseola (10039222)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Sinusitis (10040753)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Skin candida (10054152)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Upper respiratory tract infection (10046306)	16	13.6	8.0	21.1	14	18.2	10.3	28.6	15	11.7	6.7	18.6	8	12.1	5.4	22.5	20	17.4	11.0	25.6	6	7.4	2.8	15.4
	Urinary tract infection (10046571)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	1	1.5	0.0	8.2	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Viraemia (10058874)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Viral infection (10047461)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	3	2.6	0.5	7.4	0	0.0	0.0	4.5
	Viral rash (10047476)	1	0.8	0.0	4.6	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	3	3.7	0.8	10.4
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	2	2.5	0.3	8.6
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Arthropod sting (10003402)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Clavicle fracture (10009245)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Concussion (10010254)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Corneal abrasion (10010984)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Craniocerebral injury (10070976)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Fall (10016173)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Foreign body (10070245)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Head injury (10019196)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Nasal injury (10078651)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Thermal burn (10053615)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Investigations (10022891)	Body temperature increased (10005911)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Cardiac murmur (10007586)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Weight decreased (10047895)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Musculoskeletal and connective tissue disorders (10028395)	Asymmetric gluteal fold (10072189)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Pain in extremity (10033425)	0	0.0	0.0	3.1	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Positional plagiocephaly (10068711)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma (10018814)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Lethargy (10024264)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Poor quality sleep (10062519)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Tremor (10044565)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Psychiatric disorders (10037175)	Irritability (10022998)	3	2.5	0.5	7.3	1	1.3	0.0	7.0	3	2.3	0.5	6.7	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Screaming (10039740)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Renal and urinary disorders (10038359)	Urethral meatus stenosis (10058463)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Genital labial adhesions (10064162)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Penile adhesion (10059636)	3	2.5	0.5	7.3	0	0.0	0.0	4.7	2	1.6	0.2	5.5	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Penile erythema (10070655)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.1	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Cough (10011224)	10	8.5	4.1	15.0	5	6.5	2.1	14.5	4	3.1	0.9	7.8	3	4.5	0.9	12.7	5	4.3	1.4	9.9	2	2.5	0.3	8.6
	Dysphonia (10013952)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Epistaxis (10015090)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Nasal congestion (10028735)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	3	2.3	0.5	6.7	3	4.5	0.9	12.7	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Respiratory arrest (10038669)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Respiratory disorder (10038683)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Rhinitis allergic (10039085)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Rhinorrhoea (10039101)	2	1.7	0.2	6.0	1	1.3	0.0	7.0	2	1.6	0.2	5.5	0	0.0	0.0	5.4	3	2.6	0.5	7.4	1	1.2	0.0	6.7
	Sinus congestion (10040742)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Sneezing (10041232)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Upper respiratory tract congestion (10052252)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Wheezing (10047924)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	0	0.0	0.0	4.5
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	1.7	0.2	6.0	1	1.3	0.0	7.0	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Dermatitis atopic (10012438)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	1	0.8	0.0	4.3	2	3.0	0.4	10.5	0	0.0	0.0	3.2	5	6.2	2.0	13.8
	Dermatitis contact (10012442)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Dermatitis diaper (10012444)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	2	1.6	0.2	5.5	1	1.5	0.0	8.2	3	2.6	0.5	7.4	6	7.4	2.8	15.4
	Dry skin (10013786)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Eczema (10014184)	3	2.5	0.5	7.3	1	1.3	0.0	7.0	2	1.6	0.2	5.5	3	4.5	0.9	12.7	2	1.7	0.2	6.1	2	2.5	0.3	8.6
	Erythema (10015150)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	2	3.0	0.4	10.5	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Hair growth abnormal (10019044)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Hypertrichosis (10020864)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Intertrigo (10022622)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Post inflammatory pigmentation change	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	(10036229)																								
	Rash (10037844)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	4	3.1	0.9	7.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	4	4.9	1.4	12.2
	Rash macular (10037867)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Seborrhoea (10039792)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Seborrhoeic dermatitis (10039793)	2	1.7	0.2	6.0	1	1.3	0.0	7.0	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Urticaria (10046735)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.21 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses- by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		5	5.0	1.6	11.2	8	8.5	3.7	16.1	3	3.8	0.8	10.6	9	7.9	3.7	14.5	4	4.2	1.2	10.4	3	3.0	0.6	8.4
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Diarrhoea (10012735)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Teething (10043183)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Vomiting (10047700)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Ill-defined disorder (10061520)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site erythema (10022061)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site pain (10022086)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Injection site swelling (10053425)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site warmth (10022112)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Pyrexia (10037660)	1	1.0	0.0	5.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Conjunctivitis (10010741)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Croup infectious (10011416)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Gastroenteritis (10017888)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Nasopharyngitis (10028810)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Otitis media (10033078)	1	1.0	0.0	5.4	2	2.1	0.3	7.5	0	0.0	0.0	4.5	1	0.9	0.0	4.8	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Pharyngitis (10034835)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Respiratory syncytial virus bronchiolitis (10038718)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis (10039083)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Sinusitis (10040753)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.6	3	3.2	0.7	9.0	0	0.0	0.0	4.5	2	1.8	0.2	6.2	2	2.1	0.3	7.4	0	0.0	0.0	3.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Cough (10011224)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Respiratory arrest (10038669)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Wheezing (10047924)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.22 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses- by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		8	6.8	3.0	12.9	5	6.5	2.1	14.5	8	6.3	2.7	11.9	4	6.1	1.7	14.8	4	3.5	1.0	8.7	3	3.7	0.8	10.4
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Diarrhoea (10012735)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Teething (10043183)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Vomiting (10047700)	0	0.0	0.0	3.1	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
General disorders and administration site conditions (10018065)	Crying (10011469)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Ill-defined disorder (10061520)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site erythema (10022061)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site pain (10022086)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Injection site swelling (10053425)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site warmth (10022112)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Pyrexia (10037660)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Infections and infestations (10021881)	Bronchiolitis (10006448)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Conjunctivitis (10010741)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	2	3.0	0.4	10.5	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Croup infectious (10011416)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Gastroenteritis (10017888)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Hand-foot-and-mouth disease (10019113)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Nasopharyngitis (10028810)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Otitis media (10033078)	3	2.5	0.5	7.3	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Pharyngitis (10034835)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Respiratory syncytial virus infection (10061603)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis (10039083)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Sinusitis (10040753)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Upper respiratory tract infection (10046306)	3	2.5	0.5	7.3	0	0.0	0.0	4.7	0	0.0	0.0	2.8	2	3.0	0.4	10.5	1	0.9	0.0	4.7	1	1.2	0.0	6.7
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Cough (10011224)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Respiratory arrest (10038669)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Wheezing (10047924)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.23 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses – by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		13	12.9	7.0	21.0	11	11.7	6.0	20.0	12	15.0	8.0	24.7	16	14.0	8.2	21.8	16	16.8	9.9	25.9	18	17.8	10.9	26.7
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Diarrhoea (10012735)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	2	2.1	0.3	7.4	1	1.0	0.0	5.4
	Flatulence (10016766)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Vomiting (10047700)	1	1.0	0.0	5.4	2	2.1	0.3	7.5	2	2.5	0.3	8.7	1	0.9	0.0	4.8	0	0.0	0.0	3.8	3	3.0	0.6	8.4
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site bruising (10022052)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	4	4.0	1.1	9.8
	Injection site erythema (10022061)	2	2.0	0.2	7.0	2	2.1	0.3	7.5	1	1.3	0.0	6.8	1	0.9	0.0	4.8	4	4.2	1.2	10.4	1	1.0	0.0	5.4
	Injection site induration (10022075)	2	2.0	0.2	7.0	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site mass (10022081)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site pain (10022086)	3	3.0	0.6	8.4	1	1.1	0.0	5.8	4	5.0	1.4	12.3	2	1.8	0.2	6.2	2	2.1	0.3	7.4	5	5.0	1.6	11.2
	Injection site pruritus (10022093)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site rash (10022094)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4
	Injection site swelling (10053425)	3	3.0	0.6	8.4	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	3	3.2	0.7	9.0	1	1.0	0.0	5.4
	Injection site warmth (10022112)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Oedema peripheral (10030124)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Peripheral swelling (10048959)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Pyrexia (10037660)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	2	2.0	0.2	7.0

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Swelling (10042674)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Vaccination site bruising (10069484)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Vaccination site erythema (10059079)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	2	2.5	0.3	8.7	2	1.8	0.2	6.2	3	3.2	0.7	9.0	0	0.0	0.0	3.6
	Vaccination site induration (10065117)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Vaccination site pain (10068879)	2	2.0	0.2	7.0	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	2	2.1	0.3	7.4	1	1.0	0.0	5.4
	Vaccination site swelling (10069620)	1	1.0	0.0	5.4	2	2.1	0.3	7.5	0	0.0	0.0	4.5	1	0.9	0.0	4.8	1	1.1	0.0	5.7	1	1.0	0.0	5.4
Infections and infestations (10021881)	Nasopharyngitis (10028810)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
	Viral rash (10047476)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Lethargy (10024264)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Poor quality sleep (10062519)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	1.0	0.0	5.4	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Cough (10011224)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Nasal congestion (10028735)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Respiratory arrest (10038669)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Rhinorrhoea (10039101)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
Skin and subcutaneous tissue disorders (10040785)	Erythema (10015150)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Rash (10037844)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	2	1.8	0.2	6.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.24 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses– by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		15	12.7	7.3	20.1	9	11.7	5.5	21.0	20	15.6	9.8	23.1	8	12.1	5.4	22.5	18	15.7	9.5	23.6	16	19.8	11.7	30.1
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Diarrhoea (10012735)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	2	3.0	0.4	10.5	1	0.9	0.0	4.7	2	2.5	0.3	8.6
	Flatulence (10016766)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Vomiting (10047700)	1	0.8	0.0	4.6	2	2.6	0.3	9.1	1	0.8	0.0	4.3	2	3.0	0.4	10.5	1	0.9	0.0	4.7	2	2.5	0.3	8.6
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site bruising (10022052)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	2	1.7	0.2	6.1	2	2.5	0.3	8.6
	Injection site erythema (10022061)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	2	1.6	0.2	5.5	0	0.0	0.0	5.4	3	2.6	0.5	7.4	2	2.5	0.3	8.6
	Injection site induration (10022075)	1	0.8	0.0	4.6	2	2.6	0.3	9.1	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site mass (10022081)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site pain (10022086)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	5	3.9	1.3	8.9	1	1.5	0.0	8.2	6	5.2	1.9	11.0	1	1.2	0.0	6.7
	Injection site pruritus (10022093)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Injection site rash (10022094)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Injection site swelling (10053425)	2	1.7	0.2	6.0	2	2.6	0.3	9.1	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	3	3.7	0.8	10.4
	Injection site warmth (10022112)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Oedema peripheral (10030124)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Peripheral swelling (10048959)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Pyrexia (10037660)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	3	3.7	0.8	10.4
	Swelling (10042674)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Vaccination site bruising (10069484)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Vaccination site erythema (10059079)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	4	3.1	0.9	7.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	1	1.2	0.0	6.7
	Vaccination site induration (10065117)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Vaccination site pain (10068879)	2	1.7	0.2	6.0	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	2	1.7	0.2	6.1	1	1.2	0.0	6.7
	Vaccination site swelling (10069620)	3	2.5	0.5	7.3	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
Infections and infestations (10021881)	Nasopharyngitis (10028810)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Viral rash (10047476)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Lethargy (10024264)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Poor quality sleep (10062519)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cough (10011224)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Nasal congestion (10028735)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	1	1.2	0.0	6.7
	Respiratory arrest (10038669)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Rhinorrhoea (10039101)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
Skin and subcutaneous tissue disorders (10040785)	Erythema (10015150)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Rash (10037844)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	2	1.6	0.2	5.5	0	0.0	0.0	5.4	0	0.0	0.0	3.2	2	2.5	0.3	8.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.25 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses- by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	3.6	1	1.1	0.0	5.8	1	1.3	0.0	6.8	3	2.6	0.5	7.5	0	0.0	0.0	3.8	1	1.0	0.0	5.4
Gastrointestinal disorders (10017947)	Vomiting (10047700)	0	0.0	0.0	3.6	1	1.1	0.0	5.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	0	0.0	0.0	3.8	0	0.0	0.0	3.6
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site erythema (10022061)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site pain (10022086)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	1	1.3	0.0	6.8	0	0.0	0.0	3.2	0	0.0	0.0	3.8	1	1.0	0.0	5.4
	Injection site swelling (10053425)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Injection site warmth (10022112)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
Respiratory, thoracic and mediastinal disorders (10038738)	Respiratory arrest (10038669)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.26 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses- by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	3.1	1	1.3	0.0	7.0	4	3.1	0.9	7.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Gastrointestinal disorders (10017947)	Vomiting (10047700)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site erythema (10022061)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site pain (10022086)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Injection site swelling (10053425)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Injection site warmth (10022112)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Respiratory, thoracic and mediastinal disorders (10038738)	Respiratory arrest (10038669)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.27 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term, within the 31-day (Days 0-30) post-vaccination period following priming doses – by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		72	24.7	19.8	30.0	87	32.0	26.5	37.9	56	24.3	18.9	30.4	93	27.6	22.9	32.7	66	24.6	19.6	30.2	77	25.9	21.0	31.3
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Leukocytosis (10024378)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Lymphadenopathy (10025197)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	2	0.7	0.1	2.7	0	0.0	0.0	1.2
Congenital, familial and genetic disorders (10010331)	Congenital skin dimples (10072978)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	3	0.9	0.2	2.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Dermoid cyst (10012522)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Hydrocele (10020488)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Hypospadias (10021093)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Macrocephaly (10050183)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Plagiocephaly (10048586)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	1	0.4	0.0	2.1	1	0.3	0.0	1.9
	Ear disorder (10014004)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Ear pain (10014020)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Anal fistula (10002156)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Constipation (10010774)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	3	1.3	0.3	3.8	0	0.0	0.0	1.1	1	0.4	0.0	2.1	4	1.3	0.4	3.4
	Diarrhoea (10012735)	4	1.4	0.4	3.5	3	1.1	0.2	3.2	1	0.4	0.0	2.4	4	1.2	0.3	3.0	6	2.2	0.8	4.8	5	1.7	0.5	3.9
	Flatulence (10016766)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Frequent bowel movements (10017367)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	3	1.3	0.3	3.8	5	1.5	0.5	3.4	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Inguinal hernia (10022016)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Teething (10043183)	3	1.0	0.2	3.0	3	1.1	0.2	3.2	2	0.9	0.1	3.1	6	1.8	0.7	3.8	4	1.5	0.4	3.8	5	1.7	0.5	3.9
	Vomiting (10047700)	4	1.4	0.4	3.5	5	1.8	0.6	4.2	4	1.7	0.5	4.4	4	1.2	0.3	3.0	4	1.5	0.4	3.8	6	2.0	0.7	4.3
	Vomiting projectile (10047708)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Crying (10011469)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Ill-defined disorder (10061520)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site bruising (10022052)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	5	1.7	0.5	3.9
	Injection site erythema (10022061)	2	0.7	0.1	2.5	2	0.7	0.1	2.6	1	0.4	0.0	2.4	1	0.3	0.0	1.6	4	1.5	0.4	3.8	1	0.3	0.0	1.9
	Injection site induration (10022075)	2	0.7	0.1	2.5	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site mass (10022081)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site pain (10022086)	4	1.4	0.4	3.5	1	0.4	0.0	2.0	4	1.7	0.5	4.4	4	1.2	0.3	3.0	2	0.7	0.1	2.7	5	1.7	0.5	3.9
	Injection site pruritus (10022093)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site rash (10022094)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	1	0.3	0.0	1.9
	Injection site swelling (10053425)	3	1.0	0.2	3.0	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	3	1.1	0.2	3.2	1	0.3	0.0	1.9
	Injection site warmth (10022112)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Oedema peripheral (10030124)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Peripheral swelling (10048959)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	3	1.3	0.3	3.8	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pyrexia (10037660)	3	1.0	0.2	3.0	10	3.7	1.8	6.7	1	0.4	0.0	2.4	5	1.5	0.5	3.4	7	2.6	1.1	5.3	9	3.0	1.4	5.7
	Swelling (10042674)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Vaccination site bruising (10069484)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	3	0.9	0.2	2.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Vaccination site erythema (10059079)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	2	0.9	0.1	3.1	2	0.6	0.1	2.1	3	1.1	0.2	3.2	0	0.0	0.0	1.2
	Vaccination site induration (10065117)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Vaccination site pain (10068879)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	2	0.7	0.1	2.7	1	0.3	0.0	1.9
	Vaccination site swelling (10069620)	1	0.3	0.0	1.9	2	0.7	0.1	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.6	1	0.4	0.0	2.1	1	0.3	0.0	1.9
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Milk allergy (10027633)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
Infections and infestations (10021881)	Acute sinusitis (10001076)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Anal abscess (10048946)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Bronchiolitis (10006448)	2	0.7	0.1	2.5	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Bronchitis (10006451)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Candida infection (10074170)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	1	0.4	0.0	2.4	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Candida nappy rash (10007135)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Cellulitis (10007882)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Conjunctivitis (10010741)	1	0.3	0.0	1.9	9	3.3	1.5	6.2	2	0.9	0.1	3.1	6	1.8	0.7	3.8	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Conjunctivitis viral (10010755)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Croup infectious (10011416)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Ear infection (10014011)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Eczema herpeticum (10014197)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
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				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Exanthema subitum (10015586)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Fungal infection (10017533)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Fungal skin infection (10017543)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Gastric infection (10056663)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Gastroenteritis (10017888)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	1	0.4	0.0	2.4	1	0.3	0.0	1.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Herpangina (10019936)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Impetigo (10021531)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	2	0.7	0.1	2.4
	Influenza (10022000)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Nasopharyngitis (10028810)	2	0.7	0.1	2.5	1	0.4	0.0	2.0	1	0.4	0.0	2.4	0	0.0	0.0	1.1	3	1.1	0.2	3.2	0	0.0	0.0	1.2
	Oral candidiasis (10030963)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Otitis externa (10033072)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Otitis media (10033078)	4	1.4	0.4	3.5	5	1.8	0.6	4.2	2	0.9	0.1	3.1	5	1.5	0.5	3.4	2	0.7	0.1	2.7	7	2.4	1.0	4.8
	Otitis media acute (10033079)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	1	0.4	0.0	2.4	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Otitis media chronic (10033081)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Pertussis (10034738)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Pharyngitis (10034835)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Pneumonia (10035664)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory tract infection (10062352)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Rhinitis (10039083)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Roseola (10039222)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Sinusitis (10040753)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Skin candida (10054152)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Upper respiratory tract infection (10046306)	13	4.5	2.4	7.5	19	7.0	4.3	10.7	9	3.9	1.8	7.3	17	5.0	3.0	8.0	11	4.1	2.1	7.2	16	5.4	3.1	8.6
	Urinary tract infection (10046571)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Viraemia (10058874)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Viral infection (10047461)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	1	0.4	0.0	2.1	2	0.7	0.1	2.4
	Viral rash (10047476)	1	0.3	0.0	1.9	2	0.7	0.1	2.6	0	0.0	0.0	1.6	0	0.0	0.0	1.1	2	0.7	0.1	2.7	1	0.3	0.0	1.9
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	2	0.7	0.1	2.4
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Arthropod sting (10003402)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Clavicle fracture (10009245)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Concussion (10010254)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Corneal abrasion (10010984)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Craniocerebral injury (10070976)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Fall (10016173)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Foreign body (10070245)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Head injury (10019196)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	2	0.7	0.1	2.4
	Nasal injury (10078651)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Thermal burn (10053615)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Investigations (10022891)	Body temperature increased (10005911)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Cardiac murmur (10007586)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Weight decreased (10047895)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
Musculoskeletal and connective tissue disorders (10028395)	Asymmetric gluteal fold (10072189)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Pain in extremity (10033425)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Positional plagiocephaly (10068711)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma (10018814)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Lethargy (10024264)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Poor quality sleep (10062519)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Tremor (10044565)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.3	5	1.8	0.6	4.2	2	0.9	0.1	3.1	1	0.3	0.0	1.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Screaming (10039740)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Renal and urinary disorders (10038359)	Urethral meatus stenosis (10058463)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Genital labial adhesions (10064162)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Penile adhesion (10059636)	0	0.0	0.0	1.3	3	1.1	0.2	3.2	0	0.0	0.0	1.6	3	0.9	0.2	2.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Penile erythema (10070655)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Cough (10011224)	7	2.4	1.0	4.9	9	3.3	1.5	6.2	0	0.0	0.0	1.6	7	2.1	0.8	4.2	2	0.7	0.1	2.7	5	1.7	0.5	3.9
	Dysphonia (10013952)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Epistaxis (10015090)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Nasal congestion (10028735)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	3	1.3	0.3	3.8	3	0.9	0.2	2.6	0	0.0	0.0	1.4	2	0.7	0.1	2.4
	Respiratory arrest (10038669)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory disorder (10038683)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	1	0.4	0.0	2.4	1	0.3	0.0	1.6	0	0.0	0.0	1.4	1	0.3	0.0	1.9

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rhinitis allergic (10039085)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Rhinorrhoea (10039101)	2	0.7	0.1	2.5	1	0.4	0.0	2.0	1	0.4	0.0	2.4	1	0.3	0.0	1.6	2	0.7	0.1	2.7	2	0.7	0.1	2.4
	Sinus congestion (10040742)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Sneezing (10041232)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Upper respiratory tract congestion (10052252)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Wheezing (10047924)	0	0.0	0.0	1.3	3	1.1	0.2	3.2	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	1	0.3	0.0	1.9
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	1.3	3	1.1	0.2	3.2	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Dermatitis atopic (10012438)	0	0.0	0.0	1.3	2	0.7	0.1	2.6	1	0.4	0.0	2.4	2	0.6	0.1	2.1	1	0.4	0.0	2.1	4	1.3	0.4	3.4
	Dermatitis contact (10012442)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Dermatitis diaper (10012444)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	2	0.9	0.1	3.1	1	0.3	0.0	1.6	6	2.2	0.8	4.8	4	1.3	0.4	3.4
	Dry skin (10013786)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Eczema (10014184)	3	1.0	0.2	3.0	1	0.4	0.0	2.0	2	0.9	0.1	3.1	3	0.9	0.2	2.6	2	0.7	0.1	2.7	2	0.7	0.1	2.4
	Erythema (10015150)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	3	1.3	0.3	3.8	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Hair growth abnormal (10019044)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Hypertrichosis (10020864)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Intertrigo (10022622)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Post inflammatory pigmentation change (10036229)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Rash (10037844)	1	0.3	0.0	1.9	3	1.1	0.2	3.2	2	0.9	0.1	3.1	2	0.6	0.1	2.1	1	0.4	0.0	2.1	5	1.7	0.5	3.9
	Rash macular (10037867)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Seborrhoea (10039792)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Seborrhoeic dermatitis (10039793)	0	0.0	0.0	1.3	3	1.1	0.2	3.2	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Urticaria (10046735)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.28 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses– by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		99	29.2	24.4	34.4	60	26.7	21.0	33.0	103	27.8	23.3	32.7	46	23.4	17.6	29.9	86	25.7	21.1	30.7	57	24.8	19.3	30.9
Blood and lymphatic system disorders (10005329)	Anaemia (10002034)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Leukocytosis (10024378)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Lymphadenopathy (10025197)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	2	0.6	0.1	2.1	0	0.0	0.0	1.6
Congenital, familial and genetic disorders (10010331)	Congenital skin dimples (10072978)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Dermoid cyst (10012522)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Hydrocele (10020488)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Hypospadias (10021093)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Macrocephaly (10050183)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Plagiocephaly (10048586)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Ear and labyrinth disorders (10013993)	Cerumen impaction (10050337)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	1	0.3	0.0	1.7	1	0.4	0.0	2.4
	Ear disorder (10014004)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Ear pain (10014020)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6

		Hexa group								Pedia group								Penta group							
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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**	**n**	**%**	**LL**	**UL**
Eye disorders (10015919)	Dacryostenosis acquired (10053990)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Anal fistula (10002156)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Constipation (10010774)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	3	0.8	0.2	2.4	0	0.0	0.0	1.9	2	0.6	0.1	2.1	3	1.3	0.3	3.8
	Diarrhoea (10012735)	5	1.5	0.5	3.4	2	0.9	0.1	3.2	1	0.3	0.0	1.5	4	2.0	0.6	5.1	5	1.5	0.5	3.4	6	2.6	1.0	5.6
	Flatulence (10016766)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Frequent bowel movements (10017367)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	5	1.4	0.4	3.1	3	1.5	0.3	4.4	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Inguinal hernia (10022016)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Teething (10043183)	5	1.5	0.5	3.4	1	0.4	0.0	2.5	5	1.4	0.4	3.1	3	1.5	0.3	4.4	5	1.5	0.5	3.4	4	1.7	0.5	4.4
	Vomiting (10047700)	3	0.9	0.2	2.6	6	2.7	1.0	5.7	5	1.4	0.4	3.1	3	1.5	0.3	4.4	3	0.9	0.2	2.6	7	3.0	1.2	6.2
	Vomiting projectile (10047708)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
General disorders and administration site conditions (10018065)	Adverse drug reaction (10061623)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Crying (10011469)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Ill-defined disorder (10061520)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site bruising (10022052)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	3	0.9	0.2	2.6	2	0.9	0.1	3.1
	Injection site erythema (10022061)	2	0.6	0.1	2.1	2	0.9	0.1	3.2	2	0.5	0.1	1.9	0	0.0	0.0	1.9	3	0.9	0.2	2.6	2	0.9	0.1	3.1
	Injection site induration (10022075)	1	0.3	0.0	1.6	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site mass (10022081)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site pain (10022086)	2	0.6	0.1	2.1	3	1.3	0.3	3.8	7	1.9	0.8	3.9	1	0.5	0.0	2.8	6	1.8	0.7	3.9	1	0.4	0.0	2.4

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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**	**n**	**%**	**LL**	**UL**
	Injection site pruritus (10022093)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site rash (10022094)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	1	0.4	0.0	2.4
	Injection site swelling (10053425)	2	0.6	0.1	2.1	2	0.9	0.1	3.2	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	3	1.3	0.3	3.8
	Injection site warmth (10022112)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Oedema peripheral (10030124)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Peripheral swelling (10048959)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Pyrexia (10037660)	12	3.5	1.8	6.1	1	0.4	0.0	2.5	5	1.4	0.4	3.1	1	0.5	0.0	2.8	9	2.7	1.2	5.0	7	3.0	1.2	6.2
	Swelling (10042674)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Vaccination site bruising (10069484)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	3	0.8	0.2	2.4	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Vaccination site erythema (10059079)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	4	1.1	0.3	2.7	0	0.0	0.0	1.9	2	0.6	0.1	2.1	1	0.4	0.0	2.4
	Vaccination site induration (10065117)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Vaccination site pain (10068879)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	2	0.6	0.1	2.1	1	0.4	0.0	2.4
	Vaccination site swelling (10069620)	3	0.9	0.2	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	1	0.4	0.0	2.4
Immune system disorders (10021428)	Food allergy (10016946)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Milk allergy (10027633)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
Infections and infestations (10021881)	Acute sinusitis (10001076)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Anal abscess (10048946)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Bronchiolitis (10006448)	1	0.3	0.0	1.6	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Bronchitis (10006451)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6

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				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Candida infection (10074170)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Candida nappy rash (10007135)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Cellulitis (10007882)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Conjunctivitis (10010741)	5	1.5	0.5	3.4	5	2.2	0.7	5.1	5	1.4	0.4	3.1	3	1.5	0.3	4.4	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Conjunctivitis viral (10010755)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Croup infectious (10011416)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Ear infection (10014011)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Eczema herpeticum (10014197)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Exanthema subitum (10015586)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Fungal infection (10017533)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Fungal skin infection (10017543)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Gastric infection (10056663)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Gastroenteritis (10017888)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	2	1.0	0.1	3.6	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Hand-foot-and-mouth disease (10019113)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Herpangina (10019936)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Impetigo (10021531)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	2	0.6	0.1	2.1	1	0.4	0.0	2.4
	Influenza (10022000)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Nasopharyngitis (10028810)	0	0.0	0.0	1.1	3	1.3	0.3	3.8	1	0.3	0.0	1.5	0	0.0	0.0	1.9	2	0.6	0.1	2.1	1	0.4	0.0	2.4
	Oral candidiasis (10030963)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Otitis externa (10033072)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Otitis media (10033078)	6	1.8	0.7	3.8	3	1.3	0.3	3.8	7	1.9	0.8	3.9	0	0.0	0.0	1.9	6	1.8	0.7	3.9	3	1.3	0.3	3.8
	Otitis media acute (10033079)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	2	1.0	0.1	3.6	0	0.0	0.0	1.1	0	0.0	0.0	1.6

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Otitis media chronic (10033081)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Pertussis (10034738)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Pharyngitis (10034835)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Pneumonia (10035664)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Respiratory syncytial virus infection (10061603)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Respiratory tract infection (10062352)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Rhinitis (10039083)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Roseola (10039222)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Sinusitis (10040753)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Skin candida (10054152)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Upper respiratory tract infection (10046306)	17	5.0	2.9	7.9	15	6.7	3.8	10.8	18	4.9	2.9	7.6	8	4.1	1.8	7.8	21	6.3	3.9	9.4	6	2.6	1.0	5.6
	Urinary tract infection (10046571)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	1	0.5	0.0	2.8	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Viraemia (10058874)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Viral infection (10047461)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	3	0.9	0.2	2.6	0	0.0	0.0	1.6
	Viral rash (10047476)	1	0.3	0.0	1.6	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	3	1.3	0.3	3.8
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	2	0.9	0.1	3.1
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Arthropod sting (10003402)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Clavicle fracture (10009245)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6

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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**	**n**	**%**	**LL**	**UL**
	Concussion (10010254)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Corneal abrasion (10010984)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Craniocerebral injury (10070976)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Fall (10016173)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Foreign body (10070245)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Head injury (10019196)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	1	0.4	0.0	2.4
	Nasal injury (10078651)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Thermal burn (10053615)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Investigations (10022891)	Body temperature increased (10005911)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Cardiac murmur (10007586)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Weight decreased (10047895)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
Musculoskeletal and connective tissue disorders (10028395)	Asymmetric gluteal fold (10072189)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Pain in extremity (10033425)	0	0.0	0.0	1.1	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Positional plagiocephaly (10068711)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Haemangioma (10018814)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Lethargy (10024264)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Poor quality sleep (10062519)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Tremor (10044565)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Psychiatric disorders (10037175)	Irritability (10022998)	4	1.2	0.3	3.0	1	0.4	0.0	2.5	3	0.8	0.2	2.4	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Screaming (10039740)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Renal and urinary disorders (10038359)	Urethral meatus stenosis (10058463)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	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**	**n**	**%**	**LL**	**UL**
Reproductive system and breast disorders (10038604)	Balanoposthitis (10004078)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Genital labial adhesions (10064162)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Penile adhesion (10059636)	3	0.9	0.2	2.6	0	0.0	0.0	1.6	2	0.5	0.1	1.9	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Penile erythema (10070655)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	1.1	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Cough (10011224)	11	3.2	1.6	5.7	5	2.2	0.7	5.1	4	1.1	0.3	2.7	3	1.5	0.3	4.4	5	1.5	0.5	3.4	2	0.9	0.1	3.1
	Dysphonia (10013952)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Epistaxis (10015090)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Nasal congestion (10028735)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	3	0.8	0.2	2.4	3	1.5	0.3	4.4	1	0.3	0.0	1.7	1	0.4	0.0	2.4
	Respiratory arrest (10038669)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Respiratory disorder (10038683)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Rhinitis allergic (10039085)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Rhinorrhoea (10039101)	2	0.6	0.1	2.1	1	0.4	0.0	2.5	2	0.5	0.1	1.9	0	0.0	0.0	1.9	3	0.9	0.2	2.6	1	0.4	0.0	2.4
	Sinus congestion (10040742)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Sneezing (10041232)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Upper respiratory tract congestion (10052252)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Wheezing (10047924)	1	0.3	0.0	1.6	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	2	0.6	0.1	2.1	0	0.0	0.0	1.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	2	0.6	0.1	2.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Dermatitis atopic (10012438)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	1	0.3	0.0	1.5	2	1.0	0.1	3.6	0	0.0	0.0	1.1	5	2.2	0.7	5.0
	Dermatitis contact (10012442)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Dermatitis diaper (10012444)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	2	0.5	0.1	1.9	1	0.5	0.0	2.8	3	0.9	0.2	2.6	7	3.0	1.2	6.2
	Dry skin (10013786)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	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**	**n**	**%**	**LL**	**UL**
	Eczema (10014184)	3	0.9	0.2	2.6	1	0.4	0.0	2.5	2	0.5	0.1	1.9	3	1.5	0.3	4.4	2	0.6	0.1	2.1	2	0.9	0.1	3.1
	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	2	1.0	0.1	3.6	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Hair growth abnormal (10019044)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Hypertrichosis (10020864)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Intertrigo (10022622)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Post inflammatory pigmentation change (10036229)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Rash (10037844)	2	0.6	0.1	2.1	2	0.9	0.1	3.2	4	1.1	0.3	2.7	0	0.0	0.0	1.9	2	0.6	0.1	2.1	4	1.7	0.5	4.4
	Rash macular (10037867)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Seborrhoea (10039792)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Seborrhoeic dermatitis (10039793)	2	0.6	0.1	2.1	1	0.4	0.0	2.5	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Urticaria (10046735)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.29 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses- by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		5	1.7	0.6	4.0	9	3.3	1.5	6.2	3	1.3	0.3	3.8	9	2.7	1.2	5.0	5	1.9	0.6	4.3	3	1.0	0.2	2.9
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Diarrhoea (10012735)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Teething (10043183)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Vomiting (10047700)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
General disorders and administration site conditions (10018065)	Crying (10011469)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Ill-defined disorder (10061520)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site erythema (10022061)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site pain (10022086)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Injection site swelling (10053425)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site warmth (10022112)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Pyrexia (10037660)	1	0.3	0.0	1.9	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
Infections and infestations (10021881)	Bronchiolitis (10006448)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Conjunctivitis (10010741)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Croup infectious (10011416)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Gastroenteritis (10017888)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Nasopharyngitis (10028810)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Otitis media (10033078)	1	0.3	0.0	1.9	2	0.7	0.1	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Pharyngitis (10034835)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Rhinitis (10039083)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Sinusitis (10040753)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Upper respiratory tract infection (10046306)	0	0.0	0.0	1.3	3	1.1	0.2	3.2	0	0.0	0.0	1.6	2	0.6	0.1	2.1	2	0.7	0.1	2.7	0	0.0	0.0	1.2
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Cough (10011224)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Respiratory arrest (10038669)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Wheezing (10047924)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.30 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following priming doses- by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI			95% CI					95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		9	2.7	1.2	5.0	5	2.2	0.7	5.1	8	2.2	0.9	4.2	4	2.0	0.6	5.1	5	1.5	0.5	3.4	3	1.3	0.3	3.8
Gastrointestinal disorders (10017947)	Abdominal pain upper (10000087)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Diarrhoea (10012735)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Teething (10043183)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Vomiting (10047700)	0	0.0	0.0	1.1	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
General disorders and administration site conditions (10018065)	Crying (10011469)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Ill-defined disorder (10061520)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site erythema (10022061)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site pain (10022086)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Injection site swelling (10053425)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site warmth (10022112)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Pyrexia (10037660)	1	0.3	0.0	1.6	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
Infections and infestations (10021881)	Bronchiolitis (10006448)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Conjunctivitis (10010741)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	2	1.0	0.1	3.6	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Croup infectious (10011416)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Gastroenteritis (10017888)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Hand-foot-and-mouth disease (10019113)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Nasopharyngitis (10028810)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Otitis media (10033078)	3	0.9	0.2	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Pharyngitis (10034835)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Respiratory syncytial virus infection (10061603)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Rhinitis (10039083)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Sinusitis (10040753)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Upper respiratory tract infection (10046306)	3	0.9	0.2	2.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	2	1.0	0.1	3.6	1	0.3	0.0	1.7	1	0.4	0.0	2.4
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Bronchial hyperreactivity (10066091)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Cough (10011224)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Respiratory arrest (10038669)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Wheezing (10047924)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.31 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses – by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		15	5.1	2.9	8.3	13	4.8	2.6	8.0	13	5.7	3.0	9.5	22	6.5	4.1	9.7	17	6.3	3.7	10.0	20	6.7	4.2	10.2
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Diarrhoea (10012735)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	2	0.7	0.1	2.7	1	0.3	0.0	1.9
	Flatulence (10016766)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Vomiting (10047700)	1	0.3	0.0	1.9	2	0.7	0.1	2.6	2	0.9	0.1	3.1	1	0.3	0.0	1.6	0	0.0	0.0	1.4	3	1.0	0.2	2.9
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site bruising (10022052)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	4	1.3	0.4	3.4
	Injection site erythema (10022061)	2	0.7	0.1	2.5	2	0.7	0.1	2.6	1	0.4	0.0	2.4	1	0.3	0.0	1.6	4	1.5	0.4	3.8	1	0.3	0.0	1.9
	Injection site induration (10022075)	2	0.7	0.1	2.5	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site mass (10022081)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site pain (10022086)	4	1.4	0.4	3.5	1	0.4	0.0	2.0	4	1.7	0.5	4.4	4	1.2	0.3	3.0	2	0.7	0.1	2.7	5	1.7	0.5	3.9
	Injection site pruritus (10022093)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site rash (10022094)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	1	0.3	0.0	1.9
	Injection site swelling (10053425)	3	1.0	0.2	3.0	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	3	1.1	0.2	3.2	1	0.3	0.0	1.9
	Injection site warmth (10022112)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Oedema peripheral (10030124)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Peripheral swelling (10048959)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Pyrexia (10037660)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	2	0.7	0.1	2.4
	Swelling (10042674)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Vaccination site bruising (10069484)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	3	0.9	0.2	2.6	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Vaccination site erythema (10059079)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	2	0.9	0.1	3.1	2	0.6	0.1	2.1	3	1.1	0.2	3.2	0	0.0	0.0	1.2
	Vaccination site induration (10065117)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Vaccination site pain (10068879)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	2	0.7	0.1	2.7	1	0.3	0.0	1.9
	Vaccination site swelling (10069620)	1	0.3	0.0	1.9	2	0.7	0.1	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.6	1	0.4	0.0	2.1	1	0.3	0.0	1.9
Infections and infestations (10021881)	Nasopharyngitis (10028810)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Upper respiratory tract infection (10046306)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Viral rash (10047476)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Lethargy (10024264)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Poor quality sleep (10062519)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Cough (10011224)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Nasal congestion (10028735)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Respiratory arrest (10038669)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Rhinorrhoea (10039101)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
Skin and subcutaneous tissue disorders (10040785)	Erythema (10015150)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Rash (10037844)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	2	0.6	0.1	2.1	1	0.4	0.0	2.1	1	0.3	0.0	1.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.32 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses– by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		17	5.0	2.9	7.9	11	4.9	2.5	8.6	27	7.3	4.9	10.4	8	4.1	1.8	7.8	18	5.4	3.2	8.4	19	8.3	5.0	12.6
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Gastrointestinal disorders (10017947)	Constipation (10010774)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Diarrhoea (10012735)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	2	1.0	0.1	3.6	1	0.3	0.0	1.7	2	0.9	0.1	3.1
	Flatulence (10016766)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Vomiting (10047700)	1	0.3	0.0	1.6	2	0.9	0.1	3.2	1	0.3	0.0	1.5	2	1.0	0.1	3.6	1	0.3	0.0	1.7	2	0.9	0.1	3.1
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site bruising (10022052)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	2	0.6	0.1	2.1	2	0.9	0.1	3.1
	Injection site erythema (10022061)	2	0.6	0.1	2.1	2	0.9	0.1	3.2	2	0.5	0.1	1.9	0	0.0	0.0	1.9	3	0.9	0.2	2.6	2	0.9	0.1	3.1
	Injection site induration (10022075)	1	0.3	0.0	1.6	2	0.9	0.1	3.2	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site mass (10022081)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site pain (10022086)	2	0.6	0.1	2.1	3	1.3	0.3	3.8	7	1.9	0.8	3.9	1	0.5	0.0	2.8	6	1.8	0.7	3.9	1	0.4	0.0	2.4
	Injection site pruritus (10022093)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site rash (10022094)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	1	0.3	0.0	1.7	1	0.4	0.0	2.4
	Injection site swelling (10053425)	2	0.6	0.1	2.1	2	0.9	0.1	3.2	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	3	1.3	0.3	3.8
	Injection site warmth (10022112)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Oedema peripheral (10030124)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Peripheral swelling (10048959)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Pyrexia (10037660)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	3	1.3	0.3	3.8
	Swelling (10042674)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Vaccination site bruising (10069484)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	3	0.8	0.2	2.4	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Vaccination site erythema (10059079)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	4	1.1	0.3	2.7	0	0.0	0.0	1.9	2	0.6	0.1	2.1	1	0.4	0.0	2.4
	Vaccination site induration (10065117)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Vaccination site pain (10068879)	2	0.6	0.1	2.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	2	0.6	0.1	2.1	1	0.4	0.0	2.4
	Vaccination site swelling (10069620)	3	0.9	0.2	2.6	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	1	0.4	0.0	2.4
Infections and infestations (10021881)	Nasopharyngitis (10028810)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Upper respiratory tract infection (10046306)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Viral rash (10047476)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
Musculoskeletal and connective tissue disorders (10028395)	Pain in extremity (10033425)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Nervous system disorders (10029205)	Hyperreflexia (10020745)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Lethargy (10024264)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Poor quality sleep (10062519)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.3	0.0	1.6	0	0.0	0.0	1.6	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Cough (10011224)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Nasal congestion (10028735)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	1	0.4	0.0	2.4
	Respiratory arrest (10038669)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Rhinorrhoea (10039101)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	1	0.4	0.0	2.4
Skin and subcutaneous tissue disorders (10040785)	Erythema (10015150)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	0	0.0	0.0	1.0	1	0.5	0.0	2.8	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Rash (10037844)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	2	0.5	0.1	1.9	0	0.0	0.0	1.9	0	0.0	0.0	1.1	2	0.9	0.1	3.1

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.33 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses- by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	1.3	1	0.4	0.0	2.0	1	0.4	0.0	2.4	3	0.9	0.2	2.6	0	0.0	0.0	1.4	1	0.3	0.0	1.9
Gastrointestinal disorders (10017947)	Vomiting (10047700)	0	0.0	0.0	1.3	1	0.4	0.0	2.0	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site erythema (10022061)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site pain (10022086)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
	Injection site swelling (10053425)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Injection site warmth (10022112)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Respiratory, thoracic and mediastinal disorders (10038738)	Respiratory arrest (10038669)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	1	0.3	0.0	1.6	0	0.0	0.0	1.4	0	0.0	0.0	1.2

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.34 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship with vaccination, within the 31-day (Days 0-30) post-vaccination period following priming doses- by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 339				other N = 225				White Caucasian N = 370				other N = 197				White Caucasian N = 335				other N = 230			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	1.1	1	0.4	0.0	2.5	4	1.1	0.3	2.7	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
Gastrointestinal disorders (10017947)	Vomiting (10047700)	0	0.0	0.0	1.1	1	0.4	0.0	2.5	0	0.0	0.0	1.0	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
General disorders and administration site conditions (10018065)	Ill-defined disorder (10061520)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site erythema (10022061)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site pain (10022086)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	1	0.3	0.0	1.7	0	0.0	0.0	1.6
	Injection site swelling (10053425)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
	Injection site warmth (10022112)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Psychiatric disorders (10037175)	Irritability (10022998)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6
Respiratory, thoracic and mediastinal disorders (10038738)	Respiratory arrest (10038669)	0	0.0	0.0	1.1	0	0.0	0.0	1.6	1	0.3	0.0	1.5	0	0.0	0.0	1.9	0	0.0	0.0	1.1	0	0.0	0.0	1.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of administered doses
n/% = number/percentage of doses with the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 8.35 Percentage of subjects reporting at least one preferred term from broad MedDRA SMQ 'Hypotonic-Hyporesponsive Episode (HHE)', within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

		Hexa group N = 195				Pedia group N = 194				Penta group N = 196			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	1.9	0	0.0	0.0	1.9	2	1.0	0.1	3.6

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.36 Percentage of subjects reporting at least one preferred term from narrow MedDRA SMQ 'convulsion' within the 31-day (Days 0-30) post-vaccination period following priming doses (Primary Total vaccinated cohort)

No records exist in this table

Table 8.37 Percentage of subjects reporting at least one preferred term from broad MedDRA SMQ 'Hypotonic-Hyporesponsive Episode (HHE)', within the 31-day (Days 0-30) post-vaccination period following priming doses– by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	2	2.1	0.3	7.4	0	0.0	0.0	3.6
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	2	2.1	0.3	7.4	0	0.0	0.0	3.6

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.38 Percentage of subjects reporting at least one preferred term from broad MedDRA SMQ 'Hypotonic-Hyporesponsive Episode (HHE)', within the 31-day (Days 0-30) post-vaccination period following priming doses– by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	0	0.0	0.0	4.5
Cardiac disorders (10007541)	Cyanosis (10011703)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	2	1.7	0.2	6.1	0	0.0	0.0	4.5

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.39 Percentage of subjects reporting at least one preferred term from narrow MedDRA SMQ 'convulsion' within the 31-day (Days 0-30) post-vaccination period following priming doses– by gender (Primary Total vaccinated cohort)

No records exist in this table

Table 8.40 Percentage of subjects reporting at least one preferred term from narrow MedDRA SMQ 'convulsion' within the 31-day (Days 0-30) post-vaccination period following priming doses– by geographical ancestry (Primary Total vaccinated cohort)

No records exist in this table

Table 8.41 Percentage of subjects reporting the occurrence of New Onset of Chronic Illness (NOCI) from Dose 1 up to 6 months following priming doses- by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 101				Male N = 94				Female N = 80				Male N = 114				Female N = 95				Male N = 101			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	3.6	7	7.4	3.0	14.7	1	1.3	0.0	6.8	10	8.8	4.3	15.5	5	5.3	1.7	11.9	5	5.0	1.6	11.2
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Food allergy (10016946)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	1	1.1	0.0	5.7	0	0.0	0.0	3.6
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	1	1.0	0.0	5.4
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.6	2	2.1	0.3	7.5	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6
	Rhinitis allergic (10039085)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	0	0.0	0.0	3.2	1	1.1	0.0	5.7	0	0.0	0.0	3.6
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	0	0.0	0.0	3.6	5	5.3	1.7	12.0	1	1.3	0.0	6.8	6	5.3	2.0	11.1	3	3.2	0.7	9.0	4	4.0	1.1	9.8
	Urticaria (10046735)	0	0.0	0.0	3.6	0	0.0	0.0	3.8	0	0.0	0.0	4.5	1	0.9	0.0	4.8	0	0.0	0.0	3.8	0	0.0	0.0	3.6

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.42 Percentage of subjects reporting the occurrence of New Onset of Chronic Illness (NOCI) from Dose 1 up to 6 months following priming doses- by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	0.8	0.0	4.6	6	7.8	2.9	16.2	5	3.9	1.3	8.9	6	9.1	3.4	18.7	4	3.5	1.0	8.7	6	7.4	2.8	15.4
Immune system disorders (10021428)	Drug hypersensitivity (10013700)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Food allergy (10016946)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	1	0.8	0.0	4.3	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	3.1	2	2.6	0.3	9.1	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Rhinitis allergic (10039085)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	1	0.8	0.0	4.6	4	5.2	1.4	12.8	3	2.3	0.5	6.7	4	6.1	1.7	14.8	2	1.7	0.2	6.1	5	6.2	2.0	13.8
	Urticaria (10046735)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.43 Number and percentage of subjects with concomitant medication during the 31-day (Days 0-30) post-vaccination period following each priming dose and overall (Primary Total vaccinated cohort)

	Hexa group					Pedia group					Penta group				
				95% CI					95% CI					95% CI	
	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1															
Any	195	81	41.5	34.5	48.8	194	114	58.8	51.5	65.8	196	90	45.9	38.8	53.2
Any antipyretic	195	66	33.8	27.2	41.0	194	100	51.5	44.3	58.8	196	80	40.8	33.9	48.0
Prophylactic antipyretic	195	17	8.7	5.2	13.6	194	16	8.2	4.8	13.0	196	12	6.1	3.2	10.5
Dose 2															
Any	186	88	47.3	40.0	54.7	188	99	52.7	45.3	60.0	189	81	42.9	35.7	50.2
Any antipyretic	186	79	42.5	35.3	49.9	188	91	48.4	41.1	55.8	189	68	36.0	29.1	43.3
Prophylactic antipyretic	186	12	6.5	3.4	11.0	188	9	4.8	2.2	8.9	189	10	5.3	2.6	9.5
Dose 3															
Any	183	85	46.4	39.1	54.0	185	105	56.8	49.3	64.0	180	84	46.7	39.2	54.2
Any antipyretic	183	72	39.3	32.2	46.8	185	88	47.6	40.2	55.0	180	73	40.6	33.3	48.1
Prophylactic antipyretic	183	13	7.1	3.8	11.8	185	9	4.9	2.2	9.0	180	10	5.6	2.7	10.0
Overall/dose															
Any	564	254	45.0	40.9	49.2	567	318	56.1	51.9	60.2	565	255	45.1	41.0	49.3
Any antipyretic	564	217	38.5	34.4	42.6	567	279	49.2	45.0	53.4	565	221	39.1	35.1	43.3
Prophylactic antipyretic	564	42	7.4	5.4	9.9	567	34	6.0	4.2	8.3	565	32	5.7	3.9	7.9
Overall/subject															
Any	195	140	71.8	64.9	78.0	194	154	79.4	73.0	84.8	196	136	69.4	62.4	75.8
Any antipyretic	195	120	61.5	54.3	68.4	194	138	71.1	64.2	77.4	196	121	61.7	54.5	68.6
Prophylactic antipyretic	195	26	13.3	8.9	18.9	194	27	13.9	9.4	19.6	196	25	12.8	8.4	18.3

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines

Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines

Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

For each dose and overall/subject:

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects who started to take the specified concomitant medication at least once during the mentioned period

For overall/dose:

N = number of administered doses

n/% = number/percentage of doses after which the specified concomitant medication was started at least once during the mentioned period

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.44 Percentage of subjects reporting the occurrence of serious adverse event (SAE) from Dose 1 up to 6 months following priming doses-by gender (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 292				Male N = 272				Female N = 230				Male N = 337				Female N = 268				Male N = 297			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		7	2.4	1.0	4.9	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	6	2.2	0.8	4.8	1	0.3	0.0	1.9
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Gastrointestinal disorders (10017947)	Gastrooesophageal reflux disease (10017885)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Infections and infestations (10021881)	Gastroenteritis viral (10017918)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	1	0.4	0.0	2.4	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Meningitis viral (10027260)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	2	0.7	0.1	2.7	0	0.0	0.0	1.2
	Pneumonia (10035664)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Respiratory syncytial virus bronchiolitis (10038718)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
Injury, poisoning and procedural complications (10022117)	Road traffic accident (10039203)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	1	0.4	0.0	2.1	0	0.0	0.0	1.2
	Lethargy (10024264)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Seizure (10039906)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
Psychiatric disorders (10037175)	Mental status changes (10048294)	0	0.0	0.0	1.3	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	1	0.3	0.0	1.9
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Choking (10008589)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Hypoxia (10021143)	1	0.3	0.0	1.9	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2
	Respiratory distress (10038687)	2	0.7	0.1	2.5	0	0.0	0.0	1.3	0	0.0	0.0	1.6	0	0.0	0.0	1.1	0	0.0	0.0	1.4	0	0.0	0.0	1.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

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

Table 8.45 Percentage of subjects reporting the occurrence of serious adverse event (SAE) from Dose 1 up to 6 months following priming doses-by geographical ancestry (Primary Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		5	4.2	1.4	9.6	2	2.6	0.3	9.1	0	0.0	0.0	2.8	1	1.5	0.0	8.2	3	2.6	0.5	7.4	4	4.9	1.4	12.2
Blood and lymphatic system disorders (10005329)	Leukocytosis (10024378)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Gastrointestinal disorders (10017947)	Gastrooesophageal reflux disease (10017885)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Infections and infestations (10021881)	Gastroenteritis viral (10017918)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	1	1.5	0.0	8.2	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Meningitis viral (10027260)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Parainfluenzae virus infection (10061907)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	1	1.2	0.0	6.7
	Pneumonia (10035664)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Respiratory syncytial virus bronchiolitis (10038718)	0	0.0	0.0	3.1	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Respiratory syncytial virus infection (10061603)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
Injury, poisoning and procedural complications (10022117)	Road traffic accident (10039203)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
Metabolism and nutrition disorders (10027433)	Dehydration (10012174)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7
Nervous system disorders (10029205)	Febrile convulsion (10016284)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	1	0.9	0.0	4.7	0	0.0	0.0	4.5
	Lethargy (10024264)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Seizure (10039906)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
Psychiatric disorders (10037175)	Mental status changes (10048294)	0	0.0	0.0	3.1	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	1	1.2	0.0	6.7

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 118				other N = 77				White Caucasian N = 128				other N = 66				White Caucasian N = 115				other N = 81			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Respiratory, thoracic and mediastinal disorders (10038738)	Apparent life threatening event (10065044)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Choking (10008589)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Hypoxia (10021143)	1	0.8	0.0	4.6	0	0.0	0.0	4.7	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5
	Respiratory distress (10038687)	1	0.8	0.0	4.6	1	1.3	0.0	7.0	0	0.0	0.0	2.8	0	0.0	0.0	5.4	0	0.0	0.0	3.2	0	0.0	0.0	4.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one 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 8.46 Listing of SAE from dose 1 up to study end (Primary 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
Hexa group	PPD	F	United States	White - Caucasian / European Heritage	65	Hyponatremia	Hyponatraemia	Metabolism and nutrition disorders	HO	3	277	2	2	N	Recovered/resolved
					65	PPD	PPD	Injury, poisoning and procedural complications	HO	3	277	2	2	N	Recovered/resolved
					65	Respiratory distress	Respiratory distress	Respiratory, thoracic and mediastinal disorders	HO	3	277	2	2	N	Recovered/resolved
		F	United States	Asian - East Asian Heritage	31	Viral meningitis	Meningitis viral	Infections and infestations	HO	3	31	5	2	N	Recovered/resolved
		F	United States	African Heritage / African American	28	Repiratory syncitial virus bronchiolitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	3	28	12	3	N	Recovered/resolved
					29	Respiratory distress	Respiratory distress	Respiratory, thoracic and mediastinal disorders	HO	3	34	6	3	N	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	8	Lethargy event	Lethargy	Nervous system disorders	HO	1	0	1	1	Y	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	10	Apparent life-threatening event.	Apparent life threatening event	Respiratory, thoracic and mediastinal disorders	HO	1	0	1	2	Y	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				10	Elevated leukocytosis	Leukocytosis	Blood and lymphatic system disorders	HO	1	0	2	1	Y	Recovered/resolved
					71	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	4	41	3	3	N	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	51	Hypoxia	Hypoxia	Respiratory, thoracic and mediastinal disorders	HO	3	164	2	3	N	Recovered/resolved
					51	Rspiratory distress	Respiratory distress	Respiratory, thoracic and mediastinal disorders	HO	3	163	8	3	N	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	35	Viral gastroenteritis	Gastroenteritis viral	Infections and infestations	HO	3	64	6	3	N	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	46	Possible seizure	Seizure	Nervous system disorders	HO	3	140	2	2	N	Recovered/resolved
					47	choking episode	Choking	Respiratory, thoracic and mediastinal disorders	HO	3	147	3	2	N	Recovered/resolved with sequelae
					47	Gastroesophageal reflux	Gastrooesophageal reflux disease	Gastrointestinal disorders	HO	3	147	3	2	N	Recovered/resolved
					71	Petechial rash	Petechiae	Skin and subcutaneous tissue disorders	HO	4	19	74	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
Pedia group	PPD	F	United States	African Heritage / African American	36	viral gastroenteritis	Gastroenteritis viral	Infections and infestations	HO	3	63	6	3	N	Recovered/resolved
Penta group		F	United States	African Heritage / African American	19	Parainfluenza	Parainfluenzae virus infection	Infections and infestations	HO	2	5	33	2	N	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	50	Respiratory syncytial virus bronchialitis	Respiratory syncytial virus bronchiolitis	Infections and infestations	HO	3	140	11	1	N	Recovered/resolved
		F	United States	White - Caucasian / European Heritage	25	Febrile seizure	Febrile convulsion	Nervous system disorders	HO	2	33	2	3	N	Recovered/resolved
		F	United States	African Heritage / African American	68	observed seizure-like activity	Seizure like phenomena	Nervous system disorders	HO	4	25	9	2	N	Recovered/resolved
		M	United States	African Heritage / African American	41	Altered mental status	Mental status changes	Psychiatric disorders	HO	3	108	2	3	N	Recovered/resolved
		F	United States	Other	27	Dehydration	Dehydration	Metabolism and nutrition disorders	HO	2	68	4	2	N	Recovered/resolved
		F	United States	African Heritage / African American	21	PPD PPD	PPD	Injury, poisoning and procedural complications	HO	2	32	2	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	United States	White - Caucasian / European Heritage	49	Para influenza	Parainfluenzae virus infection	Infections and infestations	HO	3	152	12	2	N	Recovered/resolved
					49	Respiratory syncytial virus	Respiratory syncytial virus infection	Infections and infestations	HO	3	152	14	3	N	Recovered/resolved
					50	Community acquired pneumoina	Pneumonia	Infections and infestations	HO	3	158	6	2	N	Recovered/resolved

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
Med type = Type of medical advice; HO= Hospitalisation, ER = Emergemcy room

Table 8.47 Compliance in returning symptom sheets for the booster dose (Booster 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
Hexa group	167	0	153	91.6	154	92.2
Pedia group	158	0	150	94.9	151	95.6
Penta group	161	0	151	93.8	150	93.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.48 Incidence of grade 3 local symptoms (solicited and unsolicited) reported for Infanrix, Hiberix, ActHIB and Pentacel vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

	ACTHIB					PENTACEL					INFANRIX					HIBERIX				
				95% CI					95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Hexa group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	167	88	52.7	44.8	60.5	167	80	47.9	40.1	55.8
Pedia group	158	83	52.5	44.4	60.5	0	0	0.0	0.0	0.0	158	95	60.1	52.0	67.8	0	0	0.0	0.0	0.0
Penta group	0	0	0.0	0.0	0.0	161	76	47.2	39.3	55.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.49 Incidence and nature of grade 3 symptoms (solicited and unsolicited)that are causally related to vaccination reported during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster 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
Hexa group	167	13	7.8	4.2	12.9	167	3	1.8	0.4	5.2	167	10	6.0	2.9	10.7
Pedia group	158	17	10.8	6.4	16.7	158	6	3.8	1.4	8.1	158	12	7.6	4.0	12.9
Penta group	161	10	6.2	3.0	11.1	161	5	3.1	1.0	7.1	161	6	3.7	1.4	7.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.50 Incidence and nature of symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster 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
Hexa group	167	136	81.4	74.7	87.0	167	115	68.9	61.2	75.8	167	95	56.9	49.0	64.5
Pedia group	158	135	85.4	79.0	90.5	158	117	74.1	66.5	80.7	158	101	63.9	55.9	71.4
Penta group	161	123	76.4	69.1	82.7	161	114	70.8	63.1	77.7	161	76	47.2	39.3	55.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.51 Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster 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
Hexa group	167	13	7.8	4.2	12.9	167	3	1.8	0.4	5.2	167	10	6.0	2.9	10.7
Pedia group	158	17	10.8	6.4	16.7	158	6	3.8	1.4	8.1	158	12	7.6	4.0	12.9
Penta group	161	10	6.2	3.0	11.1	161	5	3.1	1.0	7.1	161	6	3.7	1.4	7.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.52 Incidence and nature of symptoms (solicited and unsolicited) that are causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster 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
Hexa group	167	125	74.9	67.6	81.2	167	99	59.3	51.4	66.8	167	95	56.9	49.0	64.5
Pedia group	158	128	81.0	74.0	86.8	158	107	67.7	59.8	74.9	158	101	63.9	55.9	71.4
Penta group	161	109	67.7	59.9	74.8	161	89	55.3	47.3	63.1	161	76	47.2	39.3	55.2

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.53 Incidence and nature of grade 3 symptoms (solicited and unsolicited)that are causally related to vaccination reported during the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster 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
Hexa group	167	13	7.8	4.2	12.9	167	3	1.8	0.4	5.2	167	10	6.0	2.9	10.7
Pedia group	158	17	10.8	6.4	16.7	158	6	3.8	1.4	8.1	158	12	7.6	4.0	12.9
Penta group	161	10	6.2	3.0	11.1	161	5	3.1	1.0	7.1	161	6	3.7	1.4	7.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.54 Incidence of local symptoms (solicited and unsolicited) that are causally related to vaccination reported for Infanrix, Hiberix, ActHIB and Pentacel vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

	ACTHIB					PENTACEL					INFANRIX					HIBERIX				
				95% CI					95% CI					95% CI					95% CI	
Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Hexa group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	167	88	52.7	44.8	60.5	167	80	47.9	40.1	55.8
Pedia group	158	83	52.5	44.4	60.5	0	0	0.0	0.0	0.0	158	95	60.1	52.0	67.8	0	0	0.0	0.0	0.0
Penta group	0	0	0.0	0.0	0.0	161	76	47.2	39.3	55.2	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.55 Incidence of grade 3 local symptoms (solicited and unsolicited) that are causally related to vaccination reported for Infanrix, Hiberix, ActHIB and Pentacel vaccines during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

	ACTHIB					PENTACEL					INFANRIX					HIBERIX				
				95% CI					95% CI					95% CI					95% CI	
Group	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Hexa group	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0	167	10	6.0	2.9	10.7	167	1	0.6	0.0	3.3
Pedia group	158	5	3.2	1.0	7.2	0	0	0.0	0.0	0.0	158	11	7.0	3.5	12.1	0	0	0.0	0.0	0.0
Penta group	0	0	0.0	0.0	0.0	161	6	3.7	1.4	7.9	0	0	0.0	0.0	0.0	0	0	0.0	0.0	0.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with the administered dose
n/% = number/percentage of subjects presenting at least one type of symptom at the study vaccine site
95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 8.56 Incidence of solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose -by gender (Booster Total vaccinated cohort)

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI				95 % CI					95 % CI				95 % CI				95 % CI			
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Pain	Total	All	79	36	45.6	34.3	57.2	75	36	48.0	36.3	59.8	54	27	50.0	36.1	63.9	97	50	51.5	41.2	61.8	66	25	37.9	26.2	50.7	84	34	40.5	29.9	51.7
		Grade 2 or 3	79	4	5.1	1.4	12.5	75	9	12.0	5.6	21.6	54	7	13.0	5.4	24.9	97	15	15.5	8.9	24.2	66	8	12.1	5.4	22.5	84	8	9.5	4.2	17.9
		Grade 3	79	1	1.3	0.0	6.9	75	1	1.3	0.0	7.2	54	1	1.9	0.0	9.9	97	2	2.1	0.3	7.3	66	0	0.0	0.0	5.4	84	2	2.4	0.3	8.3
		Medical advice	79	1	1.3	0.0	6.9	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7	66	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
	ActHIB/Hiberix	All	78	31	39.7	28.8	51.5	75	30	40.0	28.9	52.0	54	23	42.6	29.2	56.8	97	41	42.3	32.3	52.7										
		Grade 2 or 3	78	3	3.8	0.8	10.8	75	8	10.7	4.7	19.9	54	4	7.4	2.1	17.9	97	11	11.3	5.8	19.4										
		Grade 3	78	1	1.3	0.0	6.9	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	2	2.1	0.3	7.3										
		Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7										
	Infanrix/Pentacel	All	79	29	36.7	26.1	48.3	75	33	44.0	32.5	55.9	54	26	48.1	34.3	62.2	97	48	49.5	39.2	59.8	66	25	37.9	26.2	50.7	84	34	40.5	29.9	51.7
		Grade 2 or 3	79	4	5.1	1.4	12.5	75	8	10.7	4.7	19.9	54	7	13.0	5.4	24.9	97	12	12.4	6.6	20.6	66	8	12.1	5.4	22.5	84	8	9.5	4.2	17.9
		Grade 3	79	1	1.3	0.0	6.9	75	1	1.3	0.0	7.2	54	1	1.9	0.0	9.9	97	2	2.1	0.3	7.3	66	0	0.0	0.0	5.4	84	2	2.4	0.3	8.3
		Medical advice	79	1	1.3	0.0	6.9	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7	66	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
Redness (mm)	Total	All	79	24	30.4	20.5	41.8	75	31	41.3	30.1	53.3	54	24	44.4	30.9	58.6	97	42	43.3	33.3	53.7	66	23	34.8	23.5	47.6	84	24	28.6	19.2	39.5
		>5	79	7	8.9	3.6	17.4	75	12	16.0	8.6	26.3	54	3	5.6	1.2	15.4	97	13	13.4	7.3	21.8	66	7	10.6	4.4	20.6	84	6	7.1	2.7	14.9
		>20	79	2	2.5	0.3	8.8	75	6	8.0	3.0	16.6	54	0	0.0	0.0	6.6	97	6	6.2	2.3	13.0	66	0	0.0	0.0	5.4	84	2	2.4	0.3	8.3
		Medical advice	79	2	2.5	0.3	8.8	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7	66	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
	ActHIB/Hiberix	All	78	19	24.4	15.3	35.4	75	23	30.7	20.5	42.4	54	18	33.3	21.1	47.5	97	31	32.0	22.9	42.2										
		>5	78	4	5.1	1.4	12.6	75	3	4.0	0.8	11.2	54	0	0.0	0.0	6.6	97	4	4.1	1.1	10.2										
		>20	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	2	2.1	0.3	7.3										
		Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7										
	Infanrix/Pentacel	All	79	22	27.8	18.3	39.1	75	27	36.0	25.2	47.9	54	22	40.7	27.6	55.0	97	38	39.2	29.4	49.6	66	23	34.8	23.5	47.6	84	24	28.6	19.2	39.5
		>5	79	5	6.3	2.1	14.2	75	12	16.0	8.6	26.3	54	3	5.6	1.2	15.4	97	11	11.3	5.8	19.4	66	7	10.6	4.4	20.6	84	6	7.1	2.7	14.9
		>20	79	2	2.5	0.3	8.8	75	6	8.0	3.0	16.6	54	0	0.0	0.0	6.6	97	4	4.1	1.1	10.2	66	0	0.0	0.0	5.4	84	2	2.4	0.3	8.3
		Medical advice	79	2	2.5	0.3	8.8	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7	66	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
Swelling (mm)	Total	All	79	20	25.3	16.2	36.4	75	27	36.0	25.2	47.9	54	21	38.9	25.9	53.1	97	29	29.9	21.0	40.0	66	17	25.8	15.8	38.0	84	18	21.4	13.2	31.7
		>5	79	9	11.4	5.3	20.5	75	8	10.7	4.7	19.9	54	6	11.1	4.2	22.6	97	12	12.4	6.6	20.6	66	7	10.6	4.4	20.6	84	7	8.3	3.4	16.4
		>20	79	3	3.8	0.8	10.7	75	2	2.7	0.3	9.3	54	2	3.7	0.5	12.7	97	5	5.2	1.7	11.6	66	0	0.0	0.0	5.4	84	4	4.8	1.3	11.7
		Medical advice	79	2	2.5	0.3	8.8	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7	66	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3

			Hexa group										Pedia group										Penta group									
			Female					Male					Female					Male					Female					Male				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI	
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	ActHIB/Hiberix	All	78	14	17.9	10.2	28.3	75	15	20.0	11.6	30.8	54	10	18.5	9.3	31.4	97	19	19.6	12.2	28.9										
		>5	78	5	6.4	2.1	14.3	75	2	2.7	0.3	9.3	54	3	5.6	1.2	15.4	97	3	3.1	0.6	8.8										
		>20	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	2	2.1	0.3	7.3										
		Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7										
	Infanrix/Pentacel	All	79	18	22.8	14.1	33.6	75	24	32.0	21.7	43.8	54	20	37.0	24.3	51.3	97	24	24.7	16.5	34.5	66	17	25.8	15.8	38.0	84	18	21.4	13.2	31.7
		>5	79	6	7.6	2.8	15.8	75	7	9.3	3.8	18.3	54	5	9.3	3.1	20.3	97	12	12.4	6.6	20.6	66	7	10.6	4.4	20.6	84	7	8.3	3.4	16.4
		>20	79	3	3.8	0.8	10.7	75	2	2.7	0.3	9.3	54	2	3.7	0.5	12.7	97	5	5.2	1.7	11.6	66	0	0.0	0.0	5.4	84	4	4.8	1.3	11.7
		Medical advice	79	2	2.5	0.3	8.8	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	97	0	0.0	0.0	3.7	66	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 solicited local symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose-by geographical ancestry (Booster Total vaccinated cohort)

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	**Product**	**Type**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	Total	All	94	47	50.0	39.5	60.5	60	25	41.7	29.1	55.1	100	50	50.0	39.8	60.2	51	27	52.9	38.5	67.1	88	40	45.5	34.8	56.4	62	19	30.6	19.6	43.7
		Grade 2 or 3	94	9	9.6	4.5	17.4	60	4	6.7	1.8	16.2	100	15	15.0	8.6	23.5	51	7	13.7	5.7	26.3	88	11	12.5	6.4	21.3	62	5	8.1	2.7	17.8
		Grade 3	94	2	2.1	0.3	7.5	60	0	0.0	0.0	6.0	100	2	2.0	0.2	7.0	51	1	2.0	0.0	10.4	88	1	1.1	0.0	6.2	62	1	1.6	0.0	8.7
		Medical advice	94	1	1.1	0.0	5.8	60	0	0.0	0.0	6.0	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0	88	0	0.0	0.0	4.1	62	0	0.0	0.0	5.8
	ActHIB/Hiberix	All	94	38	40.4	30.4	51.0	59	23	39.0	26.5	52.6	100	42	42.0	32.2	52.3	51	22	43.1	29.3	57.8										
		Grade 2 or 3	94	8	8.5	3.7	16.1	59	3	5.1	1.1	14.1	100	10	10.0	4.9	17.6	51	5	9.8	3.3	21.4										
		Grade 3	94	1	1.1	0.0	5.8	59	0	0.0	0.0	6.1	100	2	2.0	0.2	7.0	51	0	0.0	0.0	7.0										
		Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0										
	Infanrix/Pentacel	All	94	42	44.7	34.4	55.3	60	20	33.3	21.7	46.7	100	49	49.0	38.9	59.2	51	25	49.0	34.8	63.4	88	40	45.5	34.8	56.4	62	19	30.6	19.6	43.7
		Grade 2 or 3	94	8	8.5	3.7	16.1	60	4	6.7	1.8	16.2	100	13	13.0	7.1	21.2	51	6	11.8	4.4	23.9	88	11	12.5	6.4	21.3	62	5	8.1	2.7	17.8
		Grade 3	94	2	2.1	0.3	7.5	60	0	0.0	0.0	6.0	100	2	2.0	0.2	7.0	51	1	2.0	0.0	10.4	88	1	1.1	0.0	6.2	62	1	1.6	0.0	8.7
		Medical advice	94	1	1.1	0.0	5.8	60	0	0.0	0.0	6.0	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0	88	0	0.0	0.0	4.1	62	0	0.0	0.0	5.8
Redness (mm)	Total	All	94	37	39.4	29.4	50.0	60	18	30.0	18.8	43.2	100	48	48.0	37.9	58.2	51	18	35.3	22.4	49.9	88	36	40.9	30.5	51.9	62	11	17.7	9.2	29.5
		>5	94	15	16.0	9.2	25.0	60	4	6.7	1.8	16.2	100	13	13.0	7.1	21.2	51	3	5.9	1.2	16.2	88	10	11.4	5.6	19.9	62	3	4.8	1.0	13.5
		>20	94	7	7.4	3.0	14.7	60	1	1.7	0.0	8.9	100	5	5.0	1.6	11.3	51	1	2.0	0.0	10.4	88	1	1.1	0.0	6.2	62	1	1.6	0.0	8.7
		Medical advice	94	2	2.1	0.3	7.5	60	0	0.0	0.0	6.0	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0	88	0	0.0	0.0	4.1	62	0	0.0	0.0	5.8
	ActHIB/Hiberix	All	94	25	26.6	18.0	36.7	59	17	28.8	17.8	42.1	100	37	37.0	27.6	47.2	51	12	23.5	12.8	37.5										
		>5	94	4	4.3	1.2	10.5	59	3	5.1	1.1	14.1	100	3	3.0	0.6	8.5	51	1	2.0	0.0	10.4										
		>20	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	1	1.0	0.0	5.4	51	1	2.0	0.0	10.4										
		Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0										
	Infanrix/Pentacel	All	94	34	36.2	26.5	46.7	60	15	25.0	14.7	37.9	100	45	45.0	35.0	55.3	51	15	29.4	17.5	43.8	88	36	40.9	30.5	51.9	62	11	17.7	9.2	29.5
		>5	94	14	14.9	8.4	23.7	60	3	5.0	1.0	13.9	100	11	11.0	5.6	18.8	51	3	5.9	1.2	16.2	88	10	11.4	5.6	19.9	62	3	4.8	1.0	13.5
		>20	94	7	7.4	3.0	14.7	60	1	1.7	0.0	8.9	100	4	4.0	1.1	9.9	51	0	0.0	0.0	7.0	88	1	1.1	0.0	6.2	62	1	1.6	0.0	8.7
		Medical advice	94	2	2.1	0.3	7.5	60	0	0.0	0.0	6.0	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0	88	0	0.0	0.0	4.1	62	0	0.0	0.0	5.8
Swelling (mm)	Total	All	94	32	34.0	24.6	44.5	60	15	25.0	14.7	37.9	100	30	30.0	21.2	40.0	51	20	39.2	25.8	53.9	88	25	28.4	19.3	39.0	62	10	16.1	8.0	27.7
		>5	94	14	14.9	8.4	23.7	60	3	5.0	1.0	13.9	100	11	11.0	5.6	18.8	51	7	13.7	5.7	26.3	88	9	10.2	4.8	18.5	62	5	8.1	2.7	17.8
		>20	94	4	4.3	1.2	10.5	60	1	1.7	0.0	8.9	100	4	4.0	1.1	9.9	51	3	5.9	1.2	16.2	88	3	3.4	0.7	9.6	62	1	1.6	0.0	8.7
		Medical advice	94	2	2.1	0.3	7.5	60	0	0.0	0.0	6.0	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0	88	0	0.0	0.0	4.1	62	0	0.0	0.0	5.8

			Hexa group										Pedia group										Penta group									
			White Caucasian					other					White Caucasian					other					White Caucasian					other				
						95 % CI					95 % CI					95 % CI				95 % CI					95 % CI					95 % CI		
Symptom	Product	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	ActHIB/Hiberix	All	94	18	19.1	11.8	28.6	59	11	18.6	9.7	30.9	100	19	19.0	11.8	28.1	51	10	19.6	9.8	33.1										
		>5	94	6	6.4	2.4	13.4	59	1	1.7	0.0	9.1	100	2	2.0	0.2	7.0	51	4	7.8	2.2	18.9										
		>20	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	51	2	3.9	0.5	13.5										
		Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0										
	Infanrix/Pentacel	All	94	29	30.9	21.7	41.2	60	13	21.7	12.1	34.2	100	25	25.0	16.9	34.7	51	19	37.3	24.1	51.9	88	25	28.4	19.3	39.0	62	10	16.1	8.0	27.7
		>5	94	11	11.7	6.0	20.0	60	2	3.3	0.4	11.5	100	10	10.0	4.9	17.6	51	7	13.7	5.7	26.3	88	9	10.2	4.8	18.5	62	5	8.1	2.7	17.8
		>20	94	4	4.3	1.2	10.5	60	1	1.7	0.0	8.9	100	4	4.0	1.1	9.9	51	3	5.9	1.2	16.2	88	3	3.4	0.7	9.6	62	1	1.6	0.0	8.7
		Medical advice	94	2	2.1	0.3	7.5	60	0	0.0	0.0	6.0	100	0	0.0	0.0	3.6	51	0	0.0	0.0	7.0	88	0	0.0	0.0	4.1	62	0	0.0	0.0	5.8

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 large injection site reaction reported during the 4-day (Days 0-3) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

	Hexa group N = 154				Pedia group N = 151				Penta group N = 150			
			95% CI				95% CI				95% CI	
Type of swelling	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Local swelling	2	1.3	0.2	4.6	1	0.7	0.0	3.6	0	0.0	0.0	2.4
Diffuse swelling	1	0.6	0.0	3.6	0	0.0	0.0	2.4	0	0.0	0.0	2.4
No swelling	151	98.1	94.4	99.6	150	99.3	96.4	100	150	100	97.6	100

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
N = number of subjects with at least one 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
Large injection site reaction - swelling with a diameter > 50 mm, noticeable diffuse swelling or increase in limb circumference of greater than 50 mm

Table 8.59 Incidence of solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose-by gender (Booster Total vaccinated cohort)

		Hexa group										Pedia group										Penta group									
		Female					Male					Female					Male					Female					Male				
					95 % CI				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**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	78	27	34.6	24.2	46.2	75	32	42.7	31.3	54.6	54	23	42.6	29.2	56.8	96	44	45.8	35.6	56.3	67	29	43.3	31.2	56.0	84	36	42.9	32.1	54.1
	Grade 2 or 3	78	9	11.5	5.4	20.8	75	9	12.0	5.6	21.6	54	6	11.1	4.2	22.6	96	14	14.6	8.2	23.3	67	6	9.0	3.4	18.5	84	11	13.1	6.7	22.2
	Grade 3	78	0	0.0	0.0	4.6	75	1	1.3	0.0	7.2	54	2	3.7	0.5	12.7	96	1	1.0	0.0	5.7	67	1	1.5	0.0	8.0	84	1	1.2	0.0	6.5
	Related	78	25	32.1	21.9	43.6	75	30	40.0	28.9	52.0	54	22	40.7	27.6	55.0	96	43	44.8	34.6	55.3	67	28	41.8	29.8	54.5	84	33	39.3	28.8	50.5
	Grade 3 Related	78	0	0.0	0.0	4.6	75	1	1.3	0.0	7.2	54	2	3.7	0.5	12.7	96	1	1.0	0.0	5.7	67	1	1.5	0.0	8.0	84	1	1.2	0.0	6.5
	Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	96	0	0.0	0.0	3.8	67	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
Irritability / Fussiness	All	78	45	57.7	46.0	68.8	75	41	54.7	42.7	66.2	54	34	63.0	48.7	75.7	96	60	62.5	52.0	72.2	67	35	52.2	39.7	64.6	84	41	48.8	37.7	60.0
	Grade 2 or 3	78	15	19.2	11.2	29.7	75	11	14.7	7.6	24.7	54	13	24.1	13.5	37.6	96	22	22.9	15.0	32.6	67	8	11.9	5.3	22.2	84	15	17.9	10.4	27.7
	Grade 3	78	1	1.3	0.0	6.9	75	2	2.7	0.3	9.3	54	3	5.6	1.2	15.4	96	1	1.0	0.0	5.7	67	1	1.5	0.0	8.0	84	3	3.6	0.7	10.1
	Related	78	44	56.4	44.7	67.6	75	41	54.7	42.7	66.2	54	33	61.1	46.9	74.1	96	59	61.5	51.0	71.2	67	31	46.3	34.0	58.9	84	37	44.0	33.2	55.3
	Grade 3 Related	78	1	1.3	0.0	6.9	75	2	2.7	0.3	9.3	54	3	5.6	1.2	15.4	96	1	1.0	0.0	5.7	67	1	1.5	0.0	8.0	84	3	3.6	0.7	10.1
	Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	96	0	0.0	0.0	3.8	67	0	0.0	0.0	5.4	84	1	1.2	0.0	6.5
Loss Of Appetite	All	78	26	33.3	23.1	44.9	75	21	28.0	18.2	39.6	54	12	22.2	12.0	35.6	96	35	36.5	26.9	46.9	67	19	28.4	18.0	40.7	84	27	32.1	22.4	43.2
	Grade 2 or 3	78	6	7.7	2.9	16.0	75	2	2.7	0.3	9.3	54	2	3.7	0.5	12.7	96	7	7.3	3.0	14.4	67	6	9.0	3.4	18.5	84	5	6.0	2.0	13.3
	Grade 3	78	0	0.0	0.0	4.6	75	1	1.3	0.0	7.2	54	1	1.9	0.0	9.9	96	1	1.0	0.0	5.7	67	1	1.5	0.0	8.0	84	1	1.2	0.0	6.5
	Related	78	24	30.8	20.8	42.2	75	20	26.7	17.1	38.1	54	12	22.2	12.0	35.6	96	32	33.3	24.0	43.7	67	16	23.9	14.3	35.9	84	25	29.8	20.3	40.7
	Grade 3 Related	78	0	0.0	0.0	4.6	75	1	1.3	0.0	7.2	54	1	1.9	0.0	9.9	96	1	1.0	0.0	5.7	67	1	1.5	0.0	8.0	84	1	1.2	0.0	6.5
	Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	96	0	0.0	0.0	3.8	67	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
Temperature/(Axillary) (°C)	All	78	1	1.3	0.0	6.9	75	3	4.0	0.8	11.2	54	2	3.7	0.5	12.7	96	8	8.3	3.7	15.8	67	4	6.0	1.7	14.6	84	7	8.3	3.4	16.4
	>38.5	78	0	0.0	0.0	4.6	75	2	2.7	0.3	9.3	54	1	1.9	0.0	9.9	96	4	4.2	1.1	10.3	67	2	3.0	0.4	10.4	84	2	2.4	0.3	8.3
	>39.0	78	0	0.0	0.0	4.6	75	1	1.3	0.0	7.2	54	1	1.9	0.0	9.9	96	0	0.0	0.0	3.8	67	1	1.5	0.0	8.0	84	0	0.0	0.0	4.3
	>39.5	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	96	0	0.0	0.0	3.8	67	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
	>40.0	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	96	0	0.0	0.0	3.8	67	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
	Related	78	0	0.0	0.0	4.6	75	2	2.7	0.3	9.3	54	2	3.7	0.5	12.7	96	8	8.3	3.7	15.8	67	3	4.5	0.9	12.5	84	6	7.1	2.7	14.9
	>40.0 Related	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	0	0.0	0.0	6.6	96	0	0.0	0.0	3.8	67	0	0.0	0.0	5.4	84	0	0.0	0.0	4.3
	Medical advice	78	0	0.0	0.0	4.6	75	0	0.0	0.0	4.8	54	1	1.9	0.0	9.9	96	1	1.0	0.0	5.7	67	0	0.0	0.0	5.4	84	1	1.2	0.0	6.5

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

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 solicited general symptoms reported during the 4-day (Days 0-3) post-vaccination period following the booster dose-by geographical ancestry (Booster Total vaccinated cohort)

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI					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**	**N**	**n**	**%**	**LL**	**UL**
Drowsiness	All	94	38	40.4	30.4	51.0	59	21	35.6	23.6	49.1	100	45	45.0	35.0	55.3	50	22	44.0	30.0	58.7	90	38	42.2	31.9	53.1	61	27	44.3	31.5	57.6
	Grade 2 or 3	94	11	11.7	6.0	20.0	59	7	11.9	4.9	22.9	100	12	12.0	6.4	20.0	50	8	16.0	7.2	29.1	90	9	10.0	4.7	18.1	61	8	13.1	5.8	24.2
	Grade 3	94	1	1.1	0.0	5.8	59	0	0.0	0.0	6.1	100	1	1.0	0.0	5.4	50	2	4.0	0.5	13.7	90	1	1.1	0.0	6.0	61	1	1.6	0.0	8.8
	Related	94	35	37.2	27.5	47.8	59	20	33.9	22.1	47.4	100	44	44.0	34.1	54.3	50	21	42.0	28.2	56.8	90	34	37.8	27.8	48.6	61	27	44.3	31.5	57.6
	Grade 3 Related	94	1	1.1	0.0	5.8	59	0	0.0	0.0	6.1	100	1	1.0	0.0	5.4	50	2	4.0	0.5	13.7	90	1	1.1	0.0	6.0	61	1	1.6	0.0	8.8
	Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	0	0.0	0.0	7.1	90	0	0.0	0.0	4.0	61	0	0.0	0.0	5.9
Irritability / Fussiness	All	94	57	60.6	50.0	70.6	59	29	49.2	35.9	62.5	100	60	60.0	49.7	69.7	50	34	68.0	53.3	80.5	90	50	55.6	44.7	66.0	61	26	42.6	30.0	55.9
	Grade 2 or 3	94	19	20.2	12.6	29.8	59	7	11.9	4.9	22.9	100	23	23.0	15.2	32.5	50	12	24.0	13.1	38.2	90	16	17.8	10.5	27.3	61	7	11.5	4.7	22.2
	Grade 3	94	2	2.1	0.3	7.5	59	1	1.7	0.0	9.1	100	3	3.0	0.6	8.5	50	1	2.0	0.1	10.6	90	2	2.2	0.3	7.8	61	2	3.3	0.4	11.3
	Related	94	56	59.6	49.0	69.6	59	29	49.2	35.9	62.5	100	60	60.0	49.7	69.7	50	32	64.0	49.2	77.1	90	43	47.8	37.1	58.6	61	25	41.0	28.6	54.3
	Grade 3 Related	94	2	2.1	0.3	7.5	59	1	1.7	0.0	9.1	100	3	3.0	0.6	8.5	50	1	2.0	0.1	10.6	90	2	2.2	0.3	7.8	61	2	3.3	0.4	11.3
	Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	0	0.0	0.0	7.1	90	1	1.1	0.0	6.0	61	0	0.0	0.0	5.9
Loss Of Appetite	All	94	33	35.1	25.5	45.6	59	14	23.7	13.6	36.6	100	31	31.0	22.1	41.0	50	16	32.0	19.5	46.7	90	29	32.2	22.8	42.9	61	17	27.9	17.1	40.8
	Grade 2 or 3	94	3	3.2	0.7	9.0	59	5	8.5	2.8	18.7	100	5	5.0	1.6	11.3	50	4	8.0	2.2	19.2	90	5	5.6	1.8	12.5	61	6	9.8	3.7	20.2
	Grade 3	94	1	1.1	0.0	5.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	2	4.0	0.5	13.7	90	1	1.1	0.0	6.0	61	1	1.6	0.0	8.8
	Related	94	30	31.9	22.7	42.3	59	14	23.7	13.6	36.6	100	29	29.0	20.4	38.9	50	15	30.0	17.9	44.6	90	24	26.7	17.9	37.0	61	17	27.9	17.1	40.8
	Grade 3 Related	94	1	1.1	0.0	5.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	2	4.0	0.5	13.7	90	1	1.1	0.0	6.0	61	1	1.6	0.0	8.8
	Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	0	0.0	0.0	7.1	90	0	0.0	0.0	4.0	61	0	0.0	0.0	5.9

		Hexa group										Pedia group										Penta group									
		White Caucasian					other					White Caucasian					other					White Caucasian					other				
					95 % CI				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**	**N**	**n**	**%**	**LL**	**UL**
Temperature/(Axillary) (°C)	All	94	2	2.1	0.3	7.5	59	2	3.4	0.4	11.7	100	5	5.0	1.6	11.3	50	5	10.0	3.3	21.8	90	4	4.4	1.2	11.0	61	7	11.5	4.7	22.2
	>38.5	94	2	2.1	0.3	7.5	59	0	0.0	0.0	6.1	100	2	2.0	0.2	7.0	50	3	6.0	1.3	16.5	90	1	1.1	0.0	6.0	61	3	4.9	1.0	13.7
	>39.0	94	1	1.1	0.0	5.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	1	2.0	0.1	10.6	90	0	0.0	0.0	4.0	61	1	1.6	0.0	8.8
	>39.5	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	0	0.0	0.0	7.1	90	0	0.0	0.0	4.0	61	0	0.0	0.0	5.9
	>40.0	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	0	0.0	0.0	7.1	90	0	0.0	0.0	4.0	61	0	0.0	0.0	5.9
	Related	94	1	1.1	0.0	5.8	59	1	1.7	0.0	9.1	100	5	5.0	1.6	11.3	50	5	10.0	3.3	21.8	90	3	3.3	0.7	9.4	61	6	9.8	3.7	20.2
	>40.0 Related	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	0	0.0	0.0	7.1	90	0	0.0	0.0	4.0	61	0	0.0	0.0	5.9
	Medical advice	94	0	0.0	0.0	3.8	59	0	0.0	0.0	6.1	100	0	0.0	0.0	3.6	50	2	4.0	0.5	13.7	90	1	1.1	0.0	6.0	61	0	0.0	0.0	5.9

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 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 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		3	1.8	0.4	5.2	3	1.9	0.4	5.4	3	1.9	0.4	5.3
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Teething (10043183)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Vomiting (10047700)	1	0.6	0.0	3.3	1	0.6	0.0	3.5	1	0.6	0.0	3.4
General disorders and administration site conditions (10018065)	Injection site nodule (10057880)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
	Vaccination site erythema (10059079)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3
	Rash erythematous (10037855)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.62 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

No records exist in this table

Table 8.63 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following the booster dose-by gender (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		19	21.8	13.7	32.0	18	22.5	13.9	33.2	13	22.4	12.5	35.3	22	22.0	14.3	31.4	20	27.4	17.6	39.1	21	23.9	15.4	34.1
Blood and lymphatic system disorders (10005329)	Iron deficiency anaemia (10022972)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
Congenital, familial and genetic disorders (10010331)	Dacryostenosis congenital (10011850)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Phimosis (10034878)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Tympanic membrane perforation (10045210)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Eye disorders (10015919)	Chalazion (10008388)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	2	2.0	0.2	7.0	3	4.1	0.9	11.5	0	0.0	0.0	4.1
	Nausea (10028813)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Stomatitis (10042128)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Teething (10043183)	1	1.1	0.0	6.2	3	3.8	0.8	10.6	1	1.7	0.0	9.2	1	1.0	0.0	5.4	2	2.7	0.3	9.5	1	1.1	0.0	6.2
	Vomiting (10047700)	1	1.1	0.0	6.2	3	3.8	0.8	10.6	2	3.4	0.4	11.9	1	1.0	0.0	5.4	1	1.4	0.0	7.4	1	1.1	0.0	6.2
General disorders and administration site conditions (10018065)	Injection site induration (10022075)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Injection site nodule (10057880)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Injection site scab (10066210)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Pyrexia (10037660)	3	3.4	0.7	9.7	2	2.5	0.3	8.7	2	3.4	0.4	11.9	3	3.0	0.6	8.5	2	2.7	0.3	9.5	0	0.0	0.0	4.1
	Vaccination site erythema (10059079)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Immune system disorders (10021428)	Seasonal allergy (10048908)	1	1.1	0.0	6.2	2	2.5	0.3	8.7	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Cellulitis (10007882)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Conjunctivitis (10010741)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	2	2.0	0.2	7.0	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Croup infectious (10011416)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	1	1.1	0.0	6.2
	Eye infection (10015929)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Folliculitis (10016936)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Gastroenteritis (10017888)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Herpangina (10019936)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Hordeolum (10020377)	2	2.3	0.3	8.1	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Nasopharyngitis (10028810)	1	1.1	0.0	6.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Otitis media (10033078)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	4	4.0	1.1	9.9	0	0.0	0.0	4.9	3	3.4	0.7	9.6
	Otitis media acute (10033079)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Pharyngitis (10034835)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Rhinitis (10039083)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	2	2.7	0.3	9.5	0	0.0	0.0	4.1
	Sinusitis (10040753)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Staphylococcal infection (10058080)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Upper respiratory tract infection (10046306)	2	2.3	0.3	8.1	1	1.3	0.0	6.8	1	1.7	0.0	9.2	4	4.0	1.1	9.9	5	6.8	2.3	15.3	3	3.4	0.7	9.6
	Viral infection (10047461)	1	1.1	0.0	6.2	1	1.3	0.0	6.8	2	3.4	0.4	11.9	0	0.0	0.0	3.6	2	2.7	0.3	9.5	3	3.4	0.7	9.6
	Viral rash (10047476)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Contusion (10050584)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Corneal abrasion (10010984)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Foreign body (10070245)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Head injury (10019196)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Mouth injury (10049294)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Skin abrasion (10064990)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Speech disorder developmental (10041467)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
Reproductive system and breast disorders (10038604)	Genital labial adhesions (10064162)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Cough (10011224)	1	1.1	0.0	6.2	1	1.3	0.0	6.8	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Nasal congestion (10028735)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Rhinitis allergic (10039085)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Rhinorrhoea (10039101)	1	1.1	0.0	6.2	1	1.3	0.0	6.8	1	1.7	0.0	9.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Wheezing (10047924)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Dermatitis atopic (10012438)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Dermatitis contact (10012442)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Dermatitis diaper (10012444)	2	2.3	0.3	8.1	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Eczema (10014184)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Ingrowing nail (10022013)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Petechiae (10034754)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Pruritus (10037087)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Rash (10037844)	1	1.1	0.0	6.2	1	1.3	0.0	6.8	1	1.7	0.0	9.2	3	3.0	0.6	8.5	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Rash erythematous (10037855)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rash generalised (10037858)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Urticaria (10046735)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.64 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following the booster dose-by geographical ancestry (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		24	23.8	15.9	33.3	13	19.7	10.9	31.3	23	22.8	15.0	32.2	12	21.1	11.4	33.9	23	24.5	16.2	34.4	18	26.9	16.8	39.1
Blood and lymphatic system disorders (10005329)	Iron deficiency anaemia (10022972)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
Congenital, familial and genetic disorders (10010331)	Dacryostenosis congenital (10011850)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Phimosis (10034878)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Ear and labyrinth disorders (10013993)	Ear pain (10014020)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Tympanic membrane perforation (10045210)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Eye disorders (10015919)	Chalazion (10008388)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	2	2.0	0.2	7.0	0	0.0	0.0	6.3	2	2.1	0.3	7.5	1	1.5	0.0	8.0
	Nausea (10028813)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Stomatitis (10042128)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Teething (10043183)	4	4.0	1.1	9.8	0	0.0	0.0	5.4	2	2.0	0.2	7.0	0	0.0	0.0	6.3	2	2.1	0.3	7.5	1	1.5	0.0	8.0
	Vomiting (10047700)	4	4.0	1.1	9.8	0	0.0	0.0	5.4	0	0.0	0.0	3.6	3	5.3	1.1	14.6	1	1.1	0.0	5.8	1	1.5	0.0	8.0
General disorders and administration site conditions (10018065)	Injection site induration (10022075)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Injection site nodule (10057880)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Injection site scab (10066210)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Pyrexia (10037660)	3	3.0	0.6	8.4	2	3.0	0.4	10.5	3	3.0	0.6	8.4	2	3.5	0.4	12.1	1	1.1	0.0	5.8	1	1.5	0.0	8.0
	Vaccination site erythema (10059079)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Immune system disorders (10021428)	Seasonal allergy (10048908)	3	3.0	0.6	8.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
Infections and infestations (10021881)	Bronchitis (10006451)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Cellulitis (10007882)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Conjunctivitis (10010741)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	2	3.5	0.4	12.1	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Croup infectious (10011416)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	2	2.1	0.3	7.5	0	0.0	0.0	5.4
	Eye infection (10015929)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Folliculitis (10016936)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Gastroenteritis (10017888)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Herpangina (10019936)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Hordeolum (10020377)	0	0.0	0.0	3.6	2	3.0	0.4	10.5	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Nasopharyngitis (10028810)	1	1.0	0.0	5.4	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Otitis media (10033078)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	4	4.0	1.1	9.8	1	1.8	0.0	9.4	1	1.1	0.0	5.8	2	3.0	0.4	10.4
	Otitis media acute (10033079)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Pharyngitis (10034835)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Rhinitis (10039083)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	1	1.5	0.0	8.0
	Sinusitis (10040753)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Staphylococcal infection (10058080)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.6	3	4.5	0.9	12.7	4	4.0	1.1	9.8	1	1.8	0.0	9.4	5	5.3	1.7	12.0	3	4.5	0.9	12.5
	Viral infection (10047461)	2	2.0	0.2	7.0	0	0.0	0.0	5.4	0	0.0	0.0	3.6	2	3.5	0.4	12.1	3	3.2	0.7	9.0	2	3.0	0.4	10.4
	Viral rash (10047476)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
Injury, poisoning and procedural complications (10022117)	Arthropod bite (10003399)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Contusion (10050584)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Corneal abrasion (10010984)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Foreign body (10070245)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Foreign body in gastrointestinal tract (10079846)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	1	1.8	0.0	9.4	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Head injury (10019196)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Mouth injury (10049294)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Skin abrasion (10064990)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Speech disorder developmental (10041467)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
Reproductive system and breast disorders (10038604)	Genital labial adhesions (10064162)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Cough (10011224)	2	2.0	0.2	7.0	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Nasal congestion (10028735)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Rhinitis allergic (10039085)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Rhinorrhoea (10039101)	2	2.0	0.2	7.0	0	0.0	0.0	5.4	1	1.0	0.0	5.4	1	1.8	0.0	9.4	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Wheezing (10047924)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
Skin and subcutaneous tissue disorders (10040785)	Dermatitis (10012431)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Dermatitis atopic (10012438)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Dermatitis contact (10012442)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Dermatitis diaper (10012444)	2	2.0	0.2	7.0	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Eczema (10014184)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Ingrowing nail (10022013)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Petechiae (10034754)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Pruritus (10037087)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Rash (10037844)	1	1.0	0.0	5.4	1	1.5	0.0	8.2	4	4.0	1.1	9.8	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
	Rash erythematous (10037855)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
	Rash generalised (10037858)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Urticaria (10046735)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.65 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following the booster dose-by gender (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Female N = 100				Female N = 73				Male N = 88			
				95% CI			95% CI					95% CI				95% CI					95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	1.1	0.0	6.2	4	5.0	1.4	12.3	2	3.4	0.4	11.9	1	1.0	0.0	5.4	3	4.1	0.9	11.5	0	0.0	0.0	4.1
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Vomiting (10047700)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Infections and infestations (10021881)	Croup infectious (10011416)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Sinusitis (10040753)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Upper respiratory tract infection (10046306)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
	Viral infection (10047461)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Injury, poisoning and procedural complications (10022117)	Corneal abrasion (10010984)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Head injury (10019196)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.66 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 31-day (Days 0-30) post-vaccination period following the booster dose-by geographical ancestry (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		4	4.0	1.1	9.8	1	1.5	0.0	8.2	2	2.0	0.2	7.0	1	1.8	0.0	9.4	3	3.2	0.7	9.0	0	0.0	0.0	5.4
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Vomiting (10047700)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
General disorders and administration site conditions (10018065)	Pyrexia (10037660)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Infections and infestations (10021881)	Croup infectious (10011416)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Sinusitis (10040753)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Upper respiratory tract infection (10046306)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Viral infection (10047461)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Injury, poisoning and procedural complications (10022117)	Corneal abrasion (10010984)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Head injury (10019196)	0	0.0	0.0	3.6	1	1.5	0.0	8.2	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.67 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 31-day (Days 0-30) post-vaccination period following the booster dose -by gender (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		0	0.0	0.0	4.2	3	3.8	0.8	10.6	1	1.7	0.0	9.2	2	2.0	0.2	7.0	2	2.7	0.3	9.5	1	1.1	0.0	6.2
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Teething (10043183)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Vomiting (10047700)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	1	1.7	0.0	9.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
General disorders and administration site conditions (10018065)	Injection site nodule (10057880)	0	0.0	0.0	4.2	1	1.3	0.0	6.8	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Vaccination site erythema (10059079)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	1	1.0	0.0	5.4	0	0.0	0.0	4.9	0	0.0	0.0	4.1
	Rash erythematous (10037855)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1

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Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.68 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 31-day (Days 0-30) post-vaccination period following the booster dose -by geographical ancestry (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		3	3.0	0.6	8.4	0	0.0	0.0	5.4	2	2.0	0.2	7.0	1	1.8	0.0	9.4	1	1.1	0.0	5.8	2	3.0	0.4	10.4
Gastrointestinal disorders (10017947)	Diarrhoea (10012735)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Teething (10043183)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Vomiting (10047700)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	1	1.8	0.0	9.4	0	0.0	0.0	3.8	1	1.5	0.0	8.0
General disorders and administration site conditions (10018065)	Injection site nodule (10057880)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Vaccination site erythema (10059079)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Skin and subcutaneous tissue disorders (10040785)	Rash (10037844)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
	Rash erythematous (10037855)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0

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Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.69 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination within the 31-day (Days 0-30) post-vaccination period following the booster dose -by gender (Booster Total vaccinated cohort)

No records exist in this table

Table 8.70 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination within the 31-day (Days 0-30) post-vaccination period following the booster dose -by geographical ancestry (Booster Total vaccinated cohort)

No records exist in this table

Table 8.71 Percentage of subjects reporting at least one preferred term from broad MedDRA SMQ 'Hypotonic-Hyporesponsive Episode (HHE)', within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

No records exist in this table

Table 8.72 Percentage of subjects reporting at least one preferred term from narrow MedDRA SMQ 'convulsion' within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.73 Percentage of subjects reporting at least one preferred term from broad MedDRA SMQ 'Hypotonic-Hyporesponsive Episode (HHE)', within the 31-day (Days 0-30) post-vaccination period following the booster dose– by gender (Booster Total vaccinated cohort)

No records exist in this table

Table 8.74 Percentage of subjects reporting at least one preferred term from narrow MedDRA SMQ 'convulsion' within the 31-day (Days 0-30) post-vaccination period following the booster dose– by gender (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.75 Percentage of subjects reporting at least one preferred term from broad MedDRA SMQ 'Hypotonic-Hyporesponsive Episode (HHE)', within the 31-day (Days 0-30) post-vaccination period following the booster dose– by geographical ancestry (Booster Total vaccinated cohort)

No records exist in this table

Table 8.76 Percentage of subjects reporting at least one preferred term from narrow MedDRA SMQ 'convulsion' within the 31-day (Days 0-30) post-vaccination period following the booster dose– by geographical ancestry (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	1	1.5	0.0	8.0

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.77 Percentage of subjects reporting the occurrence of New Onset of Chronic Illness (NOCI) within the 31-day (Days 0-30) post-vaccination period following the booster dose (Booster Total vaccinated cohort)

		Hexa group N = 167				Pedia group N = 158				Penta group N = 161			
				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		4	2.4	0.7	6.0	1	0.6	0.0	3.5	1	0.6	0.0	3.4
Immune system disorders (10021428)	Seasonal allergy (10048908)	3	1.8	0.4	5.2	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	2.2	0	0.0	0.0	2.3	1	0.6	0.0	3.4
	Rhinitis allergic (10039085)	1	0.6	0.0	3.3	0	0.0	0.0	2.3	0	0.0	0.0	2.3
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	0	0.0	0.0	2.2	1	0.6	0.0	3.5	0	0.0	0.0	2.3

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.78 Percentage of subjects reporting the occurrence of New Onset of Chronic Illness (NOCI) within the 31-day (Days 0-30) post-vaccination period following the booster dose- by gender (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
			95% CI				95% CI				95% CI				95% CI				95% CI				95% CI		
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		2	2.3	0.3	8.1	2	2.5	0.3	8.7	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
Immune system disorders (10021428)	Seasonal allergy (10048908)	1	1.1	0.0	6.2	2	2.5	0.3	8.7	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	1	1.1	0.0	6.2
	Rhinitis allergic (10039085)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	1	1.7	0.0	9.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.79 Percentage of subjects reporting the occurrence of New Onset of Chronic Illness (NOCI) within the 31-day (Days 0-30) post-vaccination period following the booster dose- by geographical ancestry (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		White Caucasian N = 101				other N = 66				White Caucasian N = 101				other N = 57				White Caucasian N = 94				other N = 67			
				95% CI			95% CI					95% CI				95% CI				95% CI				95% CI	
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		4	4.0	1.1	9.8	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
Immune system disorders (10021428)	Seasonal allergy (10048908)	3	3.0	0.6	8.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Respiratory, thoracic and mediastinal disorders (10038738)	Asthma (10003553)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	1	1.1	0.0	5.8	0	0.0	0.0	5.4
	Rhinitis allergic (10039085)	1	1.0	0.0	5.4	0	0.0	0.0	5.4	0	0.0	0.0	3.6	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4
Skin and subcutaneous tissue disorders (10040785)	Dermatitis atopic (10012438)	0	0.0	0.0	3.6	0	0.0	0.0	5.4	1	1.0	0.0	5.4	0	0.0	0.0	6.3	0	0.0	0.0	3.8	0	0.0	0.0	5.4

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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 8.80 Number (%) of subjects reporting the occurrence of serious adverse event (SAE) within the 31-day (Days 0-30) post-vaccination period following the booster dose-by gender (Booster Total vaccinated cohort)

		Hexa group								Pedia group								Penta group							
		Female N = 87				Male N = 80				Female N = 58				Male N = 100				Female N = 73				Male N = 88			
			95% CI				95% CI				95% CI				95% CI				95% CI				95% CI		
Primary System Organ Class (CODE)	**Preferred Term (CODE)**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**	**n**	**%**	**LL**	**UL**
At least one symptom		1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
Nervous system disorders (10029205)	Seizure like phenomena (10071048)	0	0.0	0.0	4.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	1	1.4	0.0	7.4	0	0.0	0.0	4.1
Skin and subcutaneous tissue disorders (10040785)	Petechiae (10034754)	1	1.1	0.0	6.2	0	0.0	0.0	4.5	0	0.0	0.0	6.2	0	0.0	0.0	3.6	0	0.0	0.0	4.9	0	0.0	0.0	4.1

Hexa group = Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
Pedia group = Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
Penta group = Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine
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

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 (unique pages only).	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 (patient identification and treatment assigned).	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
Study Administrative Table	-

Protocol and Protocol Amendments

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117119 (DTPA-HBV-IPV-135)
Protocol Amendment 2 Final Version 02

Clinical Study Protocol

Sponsor:
GlaxoSmithKline Biologicals
Rue de l'Institut 89
1330 Rixensart, Belgium

Primary Study vaccine and number	GlaxoSmithKline (GSK) Biologicals' Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine (DTPa-HBV-IPV/Hib) (SB217744, *Infanrix hexa*™).
Other Study vaccines	• Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine (*Pediarix*®, GSK Biologicals) • *Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate) (*ActHIB*®, Sanofi Pasteur SA) • Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus* b Conjugate (Tetanus Toxoid Conjugate) vaccine (*Pentacel*®, Sanofi Pasteur SA) • Hepatitis B Vaccine (Recombinant) (*Engerix-B*®, GSK Biologicals) • Pneumoccocal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) (*Prevnar13*®, Manufactured by Wyeth Pharmaceuticals Inc. Marketed by Pfizer Inc.) • Rotavirus Vaccine, Live, Oral (*Rotarix*®, GSK Biologicals) • Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (*Infanrix*®, GSK Biologicals) • *Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate) (*Hiberix*™, GSK Biologicals)
eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
Investigational New Drug (IND) number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol	Final Version 01: 18 October 2013
Date of protocol amendment	Amendment 1 Final: 18 September 2014 Amendment 2 Final Version 02: 17 April 2015
Title	Immunogenicity and safety study of GSK Biologicals' Infanrix hexa™ at 2, 4 and 6 months of age in healthy infants.

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117119 (DTPA-HBV-IPV-135)
Protocol Amendment 2 Final Version 02

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
Investigational New Drug (IND) number	BB-IND 006687
EudraCT number:	2013-004304-19
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Co-ordinating author	Prapti Bose, Scientific Writer
Contributing authors	• PPD Clinical Research and Development Lead (CRDL) • PPD Senior Director and Head, Portfolio Head CRDL • PPD Project Statistician • PPD Director, Biostatistics • PPD Study Delivery Manager • PPD Study Delivery Lead • PPD GVCL Project Manager • PPD Clinical Safety representative • PPD Study Data Manager • PPD Global Regulatory Lead • PPD Global Patents representative • PPD Global Regulatory Affairs, GSK Vaccines • PPD Director, Clinical Medical Affairs, Pediatric Vaccines, US, GSK Vaccines • PPD Director, Clinical Medical Affairs, US, GSK Vaccines • PPD Local Delivery Lead • PPD US Medical Affairs Lead

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117119 (DTPA-HBV-IPV-135)
Protocol Amendment 2 Final Version 02

Protocol Amendment 2 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 2 Final Version 02: 17 April 2015
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Sponsor signatory	Narcisa Elena Mesaros Project level CRDL, DTP/Polio Vaccines Late Clinical Development, Vaccine Discovery and Development, GlaxoSmithKline Biologicals.
Signature	_____
Date	_____

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Protocol Amendment 2 Rationale

Amendment number: Amendment 2
Rationale/background for changes: The amendment 2 has been implemented to amend the following sections of the protocol: • The assay for testing antibodies against polyribosyl ribitol phosphate (anti-PRP) has been re-developed but is not yet qualified or validated for testing the one month post dose-3 samples. This has been clarified in the protocol in Table 7 Humoral immunity (antibody determination) and Section 5.7.3 Laboratory assays. • Investigator sign-off on the patient identification (PIDS) will be done after Visit 4 instead of extended safety follow-up (ESFU). In Table 4 List of study procedures, the bullets pertaining to investigator sign-off and analysis of Epoch 001 has been removed from the ESFU visit and retained at Visit 4 to reflect this change. • The collection of baseline measurement of limb length has been removed since it will not be used in analysis; only limb circumference will be used in analysis. Accordingly, text related to this has been amended in Table 4 List of study procedures, Sections 5.6.2.11, Baseline measurement of limb circumference after booster vaccination at visit 5 and 5.6.2.13 Recording of AEs, SAEs and NOCDs. • Errors in the vaccines dictionary of Study Master Repository (SMR) have been rectified for *Infanrix hexa*, *Pediarix* and *Pentacel* vaccines. The corresponding correction has been made in Table 9 Study vaccines. • The sequence of analysis in Section 10.9.1 Sequence of analyses, has been amended to reflect that there will first be an analysis of immunogencity for anti-PRP and safety for Epoch 001, followed by a final analysis covering both Epochs at the end of the study.

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Protocol Amendment 2 Investigator Agreement

I agree:

- To conduct the study in compliance with this protocol, any future protocol amendments or protocol administrative changes, with the terms of the clinical trial agreement and with any other study conduct procedures and/or study conduct documents provided by GlaxoSmithKline (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 vaccine 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 subject and/or the subject's legally acceptable representative.
- To perform no other biological assays on the clinical samples except those described in the protocol or its amendment(s).
- To co-operate 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 vaccine, 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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eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 2 Final Version 02: 17 April 2015
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Investigator name	_____
Signature	_____
Date	_____

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117119 (DTPA-HBV-IPV-135)
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Sponsor Information

1. Sponsor

GlaxoSmithKline Biologicals, Rue de l'Institut 89, 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 8.4.2.

SYNOPSIS

Detailed Title

A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Indication

Active immunization against diphtheria, tetanus, pertussis infection caused by all known subtypes of hepatitis B virus, poliomyelitis, and invasive disease caused by *Haemophilus influenzae* type B (Hib) in infants.

Rationale for the study and study design

- **Rationale for the study**

Infanrix hexa was first licensed in the European Union in 2000. More than 100 million doses have been distributed to date and the benefit/risk profile remains favorable. Licensure of *Infanrix hexa* combination vaccine in the United States (US) will provide an additional option for vaccination within the routine US pediatric schedule with the fewest number of injections, which would create opportunities to add further injections in case other novel vaccines against important pediatric diseases become available. Furthermore, *Infanrix hexa* will provide an additional source of DTaP, hepatitis B, poliovirus, and Hib-containing vaccine to the US market, which will help ensure a more stable supply.

The present study 117119 (DTPA-HBV-IPV-135) is intended to generate pivotal immunogenicity data demonstrating non-inferiority of the immune responses against pertussis antigens of *Infanrix hexa* compared to *Pediarix,* which is currently one of the DTaP combination vaccines widely used as a standard of care in the US. Additionally, this study will also provide descriptive data with regard to the immunogenicity of the other vaccine antigens and the safety profile in US subjects. These pivotal immunogenicity non-inferiority data for pertussis and descriptive safety data are intended to support the registration of GSK Biologicals' combined DTPa-HBV-IPV/Hib (*Infanrix hexa*) vaccine in the US. A subsequent Phase III study is planned to provide pivotal data regarding lot-to-lot consistency, safety and the immunogenicity of the other vaccine antigens.

Comparison of immunogenicity data from separate clinical studies for *Infanrix hexa* and *Pentacel*, given on a 2-4-6 month schedule, suggests that the immune response to the Hib

component of these vaccines is similar. This study will provide descriptive information regarding the immune response to the Hib components of *Infanrix hexa* and *Pentacel* following a 3 dose primary series, prior to further evaluation in Phase III studies.

- **Rationale for the study design**

Design of Epoch 001 (primary vaccination):

The study is designed as a randomized, controlled, open-label study with five parallel groups:

- The first three groups (Hexa_1, Hexa_2 and Hexa_3 group) will receive three doses of the *Infanrix hexa* vaccine (either lot A, lot B or lot C, respectively). These three groups will be pooled together for the analyses and the pooled group will be called the Hexa group.
- The Pedia Group (Control 1) will receive three doses of the US-licensed control vaccines, *Pediarix* and *ActHIB*.
- The Penta Group (Control 2) will receive three doses of the US-licensed control vaccines, *Pentacel* (only two doses of *Engerix-B* will be administered if a subject has received a birth dose of hepatitis B vaccine).

Three distinct vaccine lots manufactured according to the same procedures will be used in the Hexa group in order to obtain more representative data for the vaccine.

The study will be open-label due to the differences in the number of injections and the appearance of the vaccines administered.

Vaccines (i.e., *Prevnar13* and *Rotarix*) that are recommended for children in the US during the first year of life will be administered concomitantly with the other study vaccines as part of the study.

Design of Epoch 002 (booster vaccination):

In Epoch 002, the subjects will be assessed for antibody persistence to the vaccine antigens of *Infanrix hexa*. This epoch will also assess the adequacy of priming subjects with *Infanrix hexa* by evaluating the boostability of D, T, Pa and Hib antigens with the US-licensed vaccines. The pooled Hexa Group will receive booster doses of *Infanrix* and *Hiberix* vaccines at 15 through 18 months of age, the subjects in the Penta Group will receive *Pentacel* vaccine as a booster, and

the subjects in the Pedia Group will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15 through 18 months of age.

The study will continue to be open-label in Epoch 002.

Objectives

Primary

Epoch 001 (primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] is ≤ 1.5.

Secondary

Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D, T, HBs, pertussis, poliovirus types 1, 2 and 3 and PRP antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa,* of *Pentacel* co-administered with *Engerix-B,* and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic diseases (NOCDs) and serious adverse events.

Epoch 002 (Booster vaccination)

- To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB,* in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.

- To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel,* in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.

Study design

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups.
- Duration of the study: The intended duration of the study per subject is approximately 14-17 months.
  - **Epoch 001**: Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10),
  - **Epoch 002**: Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).
- Study groups: The study groups are presented in Synopsis Table 1.

Synopsis Table 1 Study groups and epochs foreseen in the study

Study groups	Number of subjects	Age (Min/Max) at Visit 1	Epochs	
			Epoch 001	Epoch 002
Hexa_1	65	6 WEEK -12weeks	x	x
Hexa_2	65	6 WEEK -12weeks	x	x
Hexa_3	65	6 WEEK -12weeks	x	x
Pedia	195	6 WEEK -12weeks	x	x
Penta	195	6 WEEK -12weeks	x	x

The study groups and treatment foreseen in the study is presented in Synopsis Table 2.

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Synopsis Table 2 Study groups and treatment foreseen in the study

Treatment name	Vaccine/Product name	Study Groups				
		Hexa_1	Hexa_2	Hexa_3	Pedia	Penta
Epoch 001						
Infanrix hexa		x	x	x		
	Hib					
Pediarix					x	
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					
Engerix-B*	HBV					x
Prevnar13	Prevenar 13	x	x	x	x	x
Rotarix	HRV	x	x	x	x	x
	$CaCO_3$					
Epoch 002						
Infanrix	DTPa	x	x	x	x	
Hiberix	Hib	x	x	x		
	NaCl					
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					

* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group.

- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*
- Vaccination schedules:

  <u>*Epoch 001*</u>
  - **Hexa Group:** Subjects in this group will receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
    - Hexa_1 Group: Subjects will receive lot A of *Infanrix hexa,*
    - Hexa_2 Group: Subjects will receive lot B of *Infanrix hexa*
    - Hexa_3 Group: Subjects will receive lot C of *Infanrix hexa*.

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– **Pedia Group:** Subjects in this group will receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

– **Penta Group**: Subjects in this group will receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

*Subjects in the Penta Group who have received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not receive *Engerix-B* at 4 months of age (Visit 2).

Epoch 002

– **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.

– **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.

– **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls will be given in this study at 15-18 months of age, the fourth dose of *Prevnar13* will not be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) will be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

As the analyses will be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups will be pooled together for the analysis and will be called the Hexa group.

- Treatment allocation: The subjects will be randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This will be done at study entry using GSK Biologicals' central randomization system on internet (SBIR).
- Blinding: The study is open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the

laboratory in charge of the serology testing will be blinded to the treatment, and codes will be used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

The blinding of study epochs is presented in Synopsis Table 3.

Synopsis Table 3 Blinding of study epochs

Study Epochs	Blinding
Epoch 001	open
Epoch 002	open

- Sampling schedule: Blood samples will be drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) will be collected.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

Number of subjects The total number of subjects planned to be enrolled is 585 subjects (65 each in Hexa_1, Hexa_2, Hexa_3 groups and 195 each in Pedia and Penta groups).

Endpoints **Primary**

Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

Secondary

Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the **Med**ical **D**ictionary for **R**egulatory **A**ctivities (MedDRA) classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.

- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).

- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

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APPENDIX B AMENDMENTS AND ADMINISTRATIVE CHANGES TO THE PROTOCOL 101

LIST OF ABBREVIATIONS

ACIP:	Advisory Committee on Immunization Practices
AE:	Adverse Event
ANCOVA:	Analysis of Co-variance
ANOVA:	Analysis of Variance
ATP:	According-To-Protocol
CDC:	Centers for Disease Control and Prevention, United States of America
CI:	Confidence Interval
CSR:	Clinical Study Report
D:	Diphtheria
DTPa-HBV-IPV/Hib:	Combined diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus and *Haemophilus influenzae* type b vaccine (*Infanrix hexa*).
eCRF:	electronic Case Report Form
EL.U:	ELISA unit(s)
ELISA:	Enzyme-linked immunosorbent assay
ESFU:	Extended safety follow-up
eTDF:	electronic Temperature excursion Decision Form
FHA:	Filamentous hemagglutinin
GCP:	Good Clinical Practice
GMC:	Geometric Mean Concentration
GMT:	Geometric Mean Titer
GSK:	GlaxoSmithKline
HBs:	Hepatitis B surface antigen
Hib:	*Haemophilus influenzae* (*H. influenzae*) type b
HRV:	Human Rotavirus

IB:	Investigator Brochure
ICF:	Informed Consent Form
ICH:	International Conference on Harmonisation
IEC:	Independent Ethics Committee
IM:	Intramuscular
IMP:	Investigational Medicinal Product
IND:	Investigational New Drug
IRB:	Institutional Review Board
IU:	International unit(s)
LAR:	Legally Acceptable Representative
Lf:	Limits of flocculation unit(s)
LSLV:	Last Subject Last Visit
MedDRA:	Medical Dictionary for Regulatory Activities
NI:	Non-inferiority
NOCD:	New Onset of Chronic Disease
Pa:	Acellular *Bordetella pertussis* component
PI:	Product Information
PRN:	Pertactin
PRP:	Polyribosyl-Ribitol-Phosphate: polysaccharide component of the Hib bacterium capsule
PT:	Pertussis toxoid: a secreted exotoxin of the *Bordetella pertussis* bacterium
RCC:	Reverse Cumulative Curve
RDE:	Remote Data Entry
SAE:	Serious Adverse Event
SBIR:	Randomization System on Internet

SCID:	Severe Combined Immunodeficiency Disease
SDV:	Source Document Verification
SPC:	Summary of Product Characteristics
SPM:	Study Procedures Manual
T:	Tetanus
TVC:	Total Vaccinated cohort
US:	United States

GLOSSARY OF TERMS

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

An adverse event (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 open-label study, no blind is used. Both the investigator and the subject know the identity of the treatment assigned.

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 legal guardian.

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

Epoch: An epoch is a self-contained set of consecutive timepoints or a single timepoint from a single protocol. Self-contained means that data collected for all subjects at all timepoints within that epoch allows to draw a complete conclusion to define or precise the targeted label of the product. Typical examples of epochs are primary vaccinations, boosters, yearly immunogenicity follow-ups, and surveillance periods for efficacy or safety.

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 (see Sections 6.7.2 and 10.4 for details on criteria for evaluability).
Immunological correlate of protection:	The defined humoral antibody response above which there is a high likelihood of protection in the absence of any host factors that might increase susceptibility to the infectious agent.
Intercurrent medical condition:	A condition that has the capability of altering a subject's immune response or are confirmed to have an immunodeficiency condition during the study.
Investigational vaccine/product: **(Synonym of Investigational Medicinal Product)**	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Primary completion date:	The date that the final subject was examined or received an intervention for the purpose of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.
Randomization:	Process of random attribution of treatment to subjects in order to reduce bias of selection.
Self-contained study:	Study with objectives not linked to the data of another study.
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:	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.

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Subject:	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 vaccines or as a control.
Subject number:	A unique number identifying a subject, assigned to each subject consenting to participate in the study.
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.
Treatment number:	A number identifying a treatment to a subject, according to the study randomization or treatment allocation.
Unsolicited adverse event:	Any 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 protocol.

In the body of the protocol (including the synopsis), the names of the vaccines will be written without the superscript symbol ™ or ® and in *italics*.

Trademarks of the GlaxoSmithKline group of companies	Generic description
Engerix-B®	Hepatitis B vaccine (recombinant)
Hiberix™	*Haemophilus* b conjugate vaccine (tetanus toxoid conjugate)
Infanrix®	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed
Infanrix hexa™	Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine
Pediarix®	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine
Rotarix®	Rotavirus Vaccine, Live, Oral

Trademarks not owned by the GlaxoSmithKline group of companies	Generic description
ActHIB® **(Sanofi Pasteur SA)**	*Haemophilus* type b conjugate vaccine (tetanus toxoid conjugate)
Pentacel® **(Sanofi Pasteur SA)**	Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus* b conjugate (tetanus toxoid conjugate)
Prevnar® **(Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)**	Pneumoccocal 7-valent conjugate vaccine (diphtheria CRM_{197} protein)
Prevnar13® **(Wyeth Pharmaceuticals Inc.; Marketed by Pfizer Inc.)**	Pneumoccocal 13-valent conjugate vaccine (diphtheria CRM_{197} protein)

1. INTRODUCTION

1.1. Background

Combination vaccines have been developed to provide multiple immunizations in a single injection. They can simplify vaccine administration and have the potential to promote compliance and cost-effectiveness by decreasing the number of injections needed to immunize a child [Zinke, 2010; Kalies, 2006]. Use of combination vaccines can alleviate concerns associated with the number of injections to be given at one time [ACIP, 2011].

GlaxoSmithKline (GSK) Biologicals' *Infanrix hexa* vaccine helps prevent six diseases in a single injection. *Infanrix hexa* is licensed for primary and booster vaccination in more than 98 countries around the globe, including the entire European Union. The vaccine complies with the WHO requirements for manufacture of biological substances for all of its antigenic components. The *Infanrix hexa* vaccine consists of a combination of GSK's *Pediarix* (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined); STN 103907, approved in the United States (US) on December 13, 2002 and a Hib vaccine consisting of purified polyribosyl-ribitol-phosphate (PRP) capsular polysaccharide of *Haemophilus influenzae* type b covalently bound to tetanus toxoid (TT). The conjugated Hib-TT is the same as that used for the formulation of *Hiberix* [*Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate)] (licensed in the US as a booster dose in August 2009), with the only difference that in *Infanrix hexa*, the Hib-conjugate is adsorbed onto aluminum phosphate.

The *Infanrix hexa* combination vaccine would provide an additional source of DTaP, hepatitis B, poliovirus, and Hib containing vaccines for the US market and would potentially reduce the number of injections required to provide infants with recommended vaccinations.

GSK has an extensive clinical safety database for *Infanrix hexa*. The safety and immunogenicity data of the vaccine have been evaluated in numerous controlled studies [Dhillon, 2010; Zepp, 2009], of which 4 were conducted in the US with approximately 3000 US subjects exposed to a primary vaccination with *Infanrix hexa*.

Please refer to the current Investigator Brochure for information regarding the pre-clinical and clinical studies and the potential risks and benefits of *Infanrix hexa*.

1.2. Rationale for the study and study design

1.2.1. Rationale for the study

Infanrix hexa was first licensed in the European Union in 2000. More than 100 million doses have been distributed to date and the benefit/risk profile remains favorable. Licensure of *Infanrix hexa* combination vaccine in the US will provide an additional option for vaccination within the routine US pediatric schedule with the fewest number of injections, which would create opportunities to add further injections in case other novel vaccines against important pediatric diseases become available. Furthermore, *Infanrix hexa* will provide an additional source of DTaP, hepatitis B, poliovirus, and Hib-containing vaccine to the US market, which will help ensure a more stable supply.

The present study 117119 (DTPA-HBV-IPV-135) is intended to generate pivotal immunogenicity data demonstrating non-inferiority of the immune responses against pertussis antigens of *Infanrix hexa* compared to *Pediarix,* which is currently one of the DTaP combination vaccines widely used as a standard of care in the US. Additionally, this study will also provide descriptive data with regard to the immunogenicity of the other vaccine antigens and the safety profile in US subjects. These pivotal immunogenicity non-inferiority data for pertussis and descriptive safety data are intended to support the registration of GSK Biologicals' combined DTPa-HBV-IPV/Hib (*Infanrix hexa*) vaccine in the US. A subsequent Phase III study is planned to provide pivotal data regarding lot-to-lot consistency, safety and the immunogenicity of the other vaccine antigens.

Comparison of immunogenicity data from separate clinical studies for *Infanrix hexa* and *Pentacel*, given on a 2-4-6 month schedule, suggests that the immune response to the Hib component of these vaccines is similar. This study will provide descriptive information regarding the immune response to the Hib components of *Infanrix hexa* and *Pentacel* following a 3-dose primary series, prior to further evaluation in Phase III studies.

1.2.2. Rationale for the study design

1.2.2.1. Design of Epoch 001 (primary vaccination):

The study is designed as a randomized, controlled, open-label study with five parallel groups:

- The first three groups (Hexa_1, Hexa_2 and Hexa_3 group) will receive three doses of the *Infanrix hexa* vaccine (either lot A, lot B or lot C, respectively). These three groups will be pooled together for the analyses and the pooled group will be called the Hexa group.
- The Pedia Group (Control 1) will receive three doses of the US-licensed control vaccines, *Pediarix* and *ActHIB*.
- The Penta Group (Control 2) will receive three doses of the US-licensed control vaccines, *Pentacel* (only two doses of *Engerix-B* will be administered if a subject has received a birth dose of hepatitis B vaccine).

Three distinct vaccine lots manufactured according to the same procedures will be used in the Hexa group in order to obtain more representative data for the vaccine.

The study will be open-label due to the differences in the number of injections and the appearance of the vaccines administered.

Vaccines (i.e., *Prevnar13* and *Rotarix*) that are recommended for children in the US during the first year of life will be administered concomitantly with the other study vaccines as part of the study.

1.2.2.2. Design of Epoch 002 (booster vaccination):

In Epoch 002, the subjects will be assessed for antibody persistence to the vaccine antigens of *Infanrix hexa*. This epoch will also assess the adequacy of priming subjects with *Infanrix hexa* by evaluating the boostability of D, T, Pa and Hib antigens with the US-licensed vaccines. The pooled Hexa Group will receive booster doses of *Infanrix* and *Hiberix* vaccines at 15 through 18 months of age, the subjects in the Penta Group will receive *Pentacel* vaccine as a booster, and the subjects in the Pedia Group will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15 through 18 months of age.

The study will continue to be open-label in Epoch 002.

2. OBJECTIVES

2.1. Primary objective

2.1.1. Epoch 001 (Primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] is ≤ 1.5.

Refer to Section 10.1 for the definition of the primary endpoint.

2.2. Secondary objectives

2.2.1. Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D, T, HBs, pertussis, poliovirus types 1, 2 and 3 and PRP antigens, one month after the third dose of the primary vaccination.

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- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa,* of *Pentacel* co-administered with *Engerix-B,* and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic diseases (NOCDs) and serious adverse events.

2.2.2. Epoch 002 (Booster vaccination)

- To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB,* in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.
- To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel,* in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.

Refer to Section 10.2 for the definition of the secondary endpoints.

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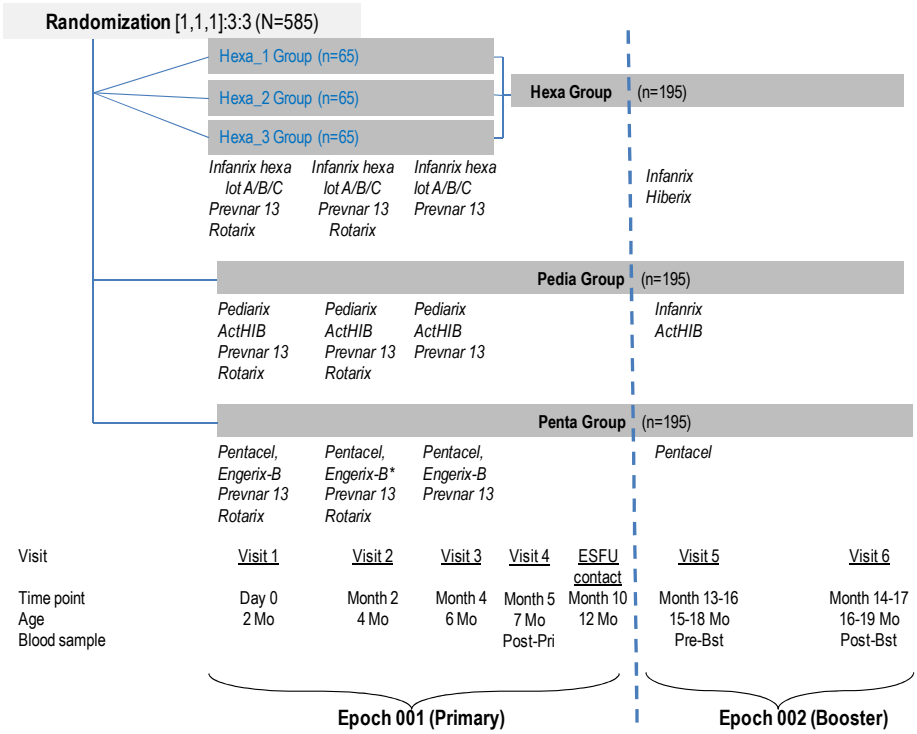
3. STUDY DESIGN OVERVIEW



N = number of subjects in the study; n = number of subjects in each group; Mo = months
Visit 3 should be conducted at least 8 weeks after Visit 2, with subjects at least 24 weeks of age, in order to comply with US recommendations on hepatitis B dosing
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002
* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group
ESFU = Extended safety follow-up

Protocol waivers or exemptions are not allowed with the exception of immediate safety concerns. Therefore, adherence to the study design requirements, including those specified in the outline of study procedures (Section 5.5), are essential and required for study conduct.

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups.
- Duration of the study: The intended duration of the study per subject is approximately 14-17 months.
  - **Epoch 001:** Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10),

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- **Epoch 002:** Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).

- Study groups: The study groups and epochs foreseen in the study are presented in Table 1.

Table 1 Study groups and epochs foreseen in the study

Study groups	Number of subjects	Age (Min/Max) at Visit 1	Epochs	
			Epoch 001	Epoch 002
Hexa_1	65	6 WEEK -12weeks	x	x
Hexa_2	65	6 WEEK -12weeks	x	x
Hexa_3	65	6 WEEK -12weeks	x	x
Pedia	195	6 WEEK -12weeks	x	x
Penta	195	6 WEEK -12weeks	x	x

The study groups and treatment foreseen in the study are presented in Table 2.

Table 2 Study groups and treatment foreseen in the study

Treatment name	Vaccine/Product name	Study Groups				
		Hexa_1	Hexa_2	Hexa_3	Pedia	Penta
Epoch 001						
Infanrix hexa		x	x	x		
	Hib					
Pediarix					x	
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					
Engerix-B*	HBV					x
Prevnar13	Prevenar 13	x	x	x	x	x
Rotarix	HRV	x	x	x	x	x
	$CaCO_3$					
Epoch 002						
Infanrix	DTPa	x	x	x	x	
Hiberix	Hib	x	x	x		
	NaCl					
ActHIB	ActHIB				x	
	NaCl					
Pentacel	DTaP-IPV (Sanofi Pasteur)					x
	ActHIB					

** Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group.

- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*.

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Vaccination schedules:

Epoch 001

- **Hexa Group:** Subjects in this group will receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - Hexa_1 Group: Subjects will receive lot A of *Infanrix hexa,*
  - Hexa_2 Group: Subjects will receive lot B of *Infanrix hexa*
  - Hexa_3 Group: Subjects will receive lot C of *Infanrix hexa*.
- **Pedia Group:** Subjects in this group will receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
- **Penta Group**: Subjects in this group will receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

*Subjects in the Penta Group who have received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not receive *Engerix-B* at 4 months of age (Visit 2).

Epoch 002

- **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
- **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
- **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls will be given in this study at 15-18 months of age, the fourth dose of *Prevnar13* will not be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) will be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.

- As the analyses will be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups will be pooled together for the analysis and will be called the Hexa group.

- Treatment allocation: The subjects will be randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This will be done at study entry using GSK Biologicals' central randomization system on internet (SBIR).

- Blinding: The study is open-label for both epochs (Table 3) due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing will be blinded to the treatment, and

codes will be used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

The blinding of study epochs is presented in Table 3.

Table 3 Blinding of study epochs

Study Epochs	Blinding
Epoch 001	open
Epoch 002	open

- Sampling schedule: Blood samples will be drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) will be collected.
- Type of study: self-contained.
- Data collection: electronic Case Report Form (eCRF).

4. STUDY COHORT

4.1. Number of subjects/centers

Target enrolment will be 585 subjects (65 each in Hexa_1, Hexa_2, Hexa_3 groups and 195 each in Pedia and Penta groups). Enrolment will be terminated when the target number of subjects has been enrolled. Refer to Section 10.3 for a detailed description of the criteria used in the estimation of sample size.

This study will be conducted at multiple centers in the US.

Actual numbers of subjects enrolled versus target will be monitored by the site monitor using SBIR.

4.2. Inclusion criteria for enrolment

Deviations from inclusion criteria are not allowed because they can potentially jeopardize the scientific integrity of the study, regulatory acceptability or subject safety. Therefore, adherence to the criteria as specified in the protocol is essential.

All subjects must satisfy ALL the following criteria at study entry:

- Subjects' parent(s)/ LAR(s) who, in the opinion of the investigator, can and will comply, with the requirements of the protocol (e.g. completion of the diary cards, return for follow-up visits).
- A male or female between, and including, 6 and 12 weeks of age at the time of the first vaccination.
- Born full-term (i.e. after a gestation period of 37 weeks to less than 42 completed weeks [259 to 293 days]).
- Written informed consent obtained from parent(s)/LAR(s) of the subject.
- Healthy subjects as established by medical history and clinical examination before entering into the study.
- Infants who have not received a previous dose of hepatitis B vaccine or those who have received only 1 dose of hepatitis B vaccine administered at least 30 days prior to enrolment.

4.3. Exclusion criteria for enrolment

Deviations from exclusion criteria are not allowed because they can potentially jeopardize the scientific integrity of the study, regulatory acceptability or subject safety. Therefore, adherence to the criteria as specified in the protocol is essential.

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

  Please 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 vaccines within 30 days preceding the first dose of study vaccines, or planned use during the study period.
- Chronic administration (defined as more than 14 days in total) of immunosuppressants or other immune-modifying drugs since birth. 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 within the period starting from 30 days before the first vaccination until 30 days after Dose 3 (Epoch 001, primary vaccination) and from 30 days before the booster Dose 4 until 30 days after booster Dose 4 (Epoch 002, booster vaccination), i.e. the end of the study:
  - Inactivated influenza and hepatitis A vaccines are allowed throughout the study.
  - Routine administration(s) of vaccines are allowed from 30 days after the last dose of primary vaccination until 30 days before the booster dose and after post-booster blood sampling. Routine administration of measles-mumps-rubella

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vaccine, varicella, pneumococcal vaccines are allowed from 30 days after last dose of primary vaccine until 30 days before booster dose and from post-booster blood sampling, as well as according to the recommended immunization schedule in US.

- Concurrently participating in another clinical study, at any time during the study period, in which the subject has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device).
- History of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and hepatitis B diseases.
- Previous vaccination against Hib, diphtheria, tetanus, pertussis, pneumococcus, rotavirus and/or poliovirus; more than one previous dose of hepatitis B vaccine.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
- Family history of congenital or hereditary immunodeficiency.
- History of any reaction or hypersensitivity likely to be exacerbated by any component of the vaccines (including yeast).
- Hypersensitivity to latex.
- Major congenital defects or serious chronic illness.
- History of any neurological disorders including seizures.
- Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period.
- History of intussusception or of any uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception.
- History of Severe Combined Immunodeficiency Disease (SCID).
- Acute disease and/or fever at the time of enrolment.
  - Fever is defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.
  - Subjects with a minor illness (such as mild diarrhea, mild upper respiratory infection) without fever may, be enrolled at the discretion of the investigator.

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 ICH Guideline for Good Clinical Practice (GCP), all applicable subject 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 Harmonised Tripartite Guideline for clinical investigation of medicinal products in the paediatric 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.
- Subject'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 subject's parent(s)/LAR(s) 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 judgement, 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

5.2.1. Subject identification

After checking the inclusion/exclusion criteria, subject numbers will be assigned sequentially to subjects whose parent(s)/LAR(s) give consent for their child to participate in the study, according to the range of subject numbers allocated to each study center. Subject numbers will also be used to identify blood samples collected during the study.

5.2.2. Randomization of treatment

5.2.2.1. Randomization of supplies

The numbering of supplies will be performed at GSK Biologicals, using MATerial EXcellence (MATEX), a program developed for use in Statistical Analysis System (SAS®) (Cary, NC, USA) by GSK Biologicals.

To allow GSK Biologicals to take advantage of greater rates of recruitment than anticipated at individual centers in this multi-center study and to thus reduce the overall study recruitment period, an over-randomization of supplies will be prepared.

5.2.2.1.1. Epoch 001

A first list based on a randomization blocking scheme using a [1:1:1]:3:3 randomization ratio will be used to number the following vaccines for Doses 1, 2 and 3.

- DTPa-HBV-IPV/Hib lot A
- DTPa-HBV-IPV/Hib lot B
- DTPa-HBV-IPV/Hib lot C
- *Pediarix*
- *Pentacel*

The vaccines from this list will be distributed to the study center while respecting the randomization block size.

ActHIB, Engerix-B, Prevnar13 and *Rotarix* will be numbered independently using a sequential numbering.

5.2.2.1.2. Epoch 002

Four sequential lists (one for *Infanrix*, one for *Hiberix*, one for *ActHIB* and one for *Pentacel*) will be used to number the vaccine doses for the Epoch 002.

The study staff in charge of the vaccine administration will access SBIR, provide the subject identification number and the dose number. The system will provide a new treatment number for all the vaccines to be administered to a subject (*Pentacel, Infanrix* + *ActHIB* or *Infanrix* + *Hiberix*). This will be consistent with the allocated study group.

5.2.2.2. Treatment allocation to the subject

The treatment numbers will be allocated by dose.

5.2.2.2.1. Study group and treatment number allocation

The target is to enroll 585 subjects to be randomly assigned to five study groups in a [1:1:1]:3:3 ratio (195 subjects in the pooled lots group).

Allocation of the subject to a study group at the investigator site will be performed using SBIR. The randomization algorithm will use a minimization procedure accounting for the study as a whole and each of the centers.

After obtaining the signed and dated ICF from the subject's parent(s)/LAR(s) and having checked the eligibility of the subject, the site staff in charge of the vaccine administration will access SBIR. Upon providing the subject identification number, the randomization system will ask whether the subject had a previous hepatitis B vaccination and will use the minimization algorithm to determine the group allocation and the appropriate treatment number for *Pentacel*, *Pediarix* or for *Infanrix hexa* (lot A, lot B or lot C) to be used for the subject.

SBIR will also provide treatment numbers for co-administered vaccines *Engerix B, ActHib, Prevnar13* vaccine and a *Rotarix* vaccine, each one labelled with a different treatment number. Therefore a subject will have three or four different treatment numbers allocated at dose 1.

The number of each administered treatment must be recorded in the eCRF on the Vaccine Administration screen.

When SBIR is not available, please refer to the SBIR user guide or the Study Procedures Manual (SPM) for specific instructions.

5.2.2.2.2. Treatment number allocation for subsequent doses

For each dose subsequent to the first dose, the study staff in charge of the vaccine administration will access SBIR, provide the subject identification number, the dose number and the system will provide new treatment numbers consistent with the allocated study group.

Each vaccine will be labeled with a different treatment number.

The number of each administered treatment must be recorded in the eCRF on the Vaccine Administration screen.

Note that in the Penta Group, the investigator will be reminded that *Engerix-B* is not allowed at dose 2 for subjects with previous hepatitis B vaccination. So for these subjects, the treatment identified by SBIR for dose 2 should not be used.

5.3. Method of blinding

The study will be open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing will be blinded to the treatment, and codes will be used to link the subject and study (without any link to the treatment attributed to the subject) 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 subjects.

5.5. Outline of study procedures

The outline of study procedures is presented in Table 4.

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Table 4 List of study procedures

(Amendment 2: 17 April 2015)

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Informed consent	●						
Check inclusion/exclusion criteria	●						
Medical history	●						
Collect demography data	●						
Vaccination history including HepB vaccination history	●						
Informed consent for Tdap vaccination history of mother[α]	●						
Last Tdap vaccination history of mother[β]	●						
History directed physical examination including length and weight	●					●	
Study group and treatment number allocation (Randomization)	O						
Treatment number allocation for subsequent doses		O	O			O	
Recording of administered treatment number	●	●	●			●	
Pre-vaccination body temperature	●	●	●			●	
Blood sampling				●		●	●
Check warnings and precautions	O	O	O			O	
Check contraindications to subsequent vaccination		●	●			●	
Pre-vaccination measurement of circumference of limb(s) at site of injection by investigator[δ]						●	
Vaccination	●	● **	●			●	
Distribution of thermometer	O						
Distribution of measuring device	O					O	
Distribution of diary cards	O	O	O			O	

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	Epoch 001 (Primary Vaccination)					Epoch 002 (Booster Vaccination)	
Age	**2 Months**	**4 Months**	**6 Months**	**7 Months**	**12 Months**	**15-18 Months**	**16-19 Months**
Visit	**Visit 1**	**Visit 2**	**Visit 3 †**	**Visit 4**	**ESFU contact (phone)**	**Visit 5**	**Visit 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Daily post-vaccination recording of solicited adverse events during the 4-day (Day 0–3) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of non-serious (unsolicited) adverse events during the 31-day (Day 0–30) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of any large injection site reactions in the eCRF by the investigator*						●	
Return of diary cards and transcription by the investigator		●	●	●			●
Record any concomitant medication and vaccination §	●	●	●	●	●	●	●
Record any intercurrent medical conditions‖		●	●	●	●	●	●
Recording of serious adverse events including related to study participation or to a concurrent GSK medication/vaccine	●	●	●	●	●	●	●
Recording of NOCDs‡	●	●	●	●	●	●	●
Investigator sign-off				●			●
Analysis of the Epoch 001 #				O			
Analysis of the Epoch 002 #							O
Study Conclusion							●

Note: The double-line border indicates the analyses which will be performed on all data obtained up to that visit or contact.
● is used to indicate a study procedure that requires documentation in the individual eCRF
○ is used to indicate a study procedure that does not require documentation in the individual eCRF
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002
† Visit 3 should be conducted at least 8 weeks after Visit 2 and when the subject is at least 24 weeks of age
$^{\alpha}$ The child can still continue in the study even if the mother does not wish to provide consent to record her Tdap vaccination history.
$^{\beta}$ Only the Tdap vaccination history (during the pregnancy of the enrolled child) from mothers who have given consent to provide this information will be obtained and recorded in the eCRF.

δ For the Penta group, which receives only one vaccine at Visit 5, baseline measurement of only the limb receiving the vaccine is required
** If subject in the Penta Group received a birth dose of Hep B vaccine, no administration of *Engerix-B* is foreseen at Visit 2 (4-months of age)
* Refer to Section 8.1.3.1 and 5.6.2.11 for detailed explanation on the reporting of large injection site reactions
§ Refer to Section 6.7 for details
‖ Refer to Section 6.8 for details
‡ New onset of chronic disease (NOCD) includes events such as autoimmune disorders, asthma, type I diabetes and allergies
# Refer to Section 10.9.1 for details

.

It is the investigator's responsibility to ensure that intervals between visits are strictly followed. The intervals between study visits are presented in Table 5.

Table 5 Intervals between study visits

Interval	Optimal length of interval[1]
Birth→Visit 1	6-12 weeks (42-90 days) of age[2]
Visit 1 →Visit 2	49-83 days[2]
Visit 2 →Visit 3 *	56-90 days[2]
Visit 3 → Visit 4	30-48 days[2] †
Visit 3 → Phone call (ESFU contact)	180-210 days**
Birth→ Visit 5^	15-18 months of age[2]
Visit 5 → Visit 6	30-48 days[2] †

[1] Whenever possible the investigator should arrange within this interval;
[2] Subjects may not be eligible for inclusion in one or more cohorts for analysis if they make the study visit outside this interval. For Visit 3-Visit 4 and Visit 5-Visit 6, an interval of 21-48 days will be considered for the According-to-protocol (ATP) cohort of immunogenicity. Refer to Section 10.4 for the definition of the cohorts for analysis;
* Advisory Committee on Immunization Practices (ACIP) recommendation states that minimum age of last Hep B dose is 24 weeks and this last dose should be administered at least 8 weeks after the previous dose. So, Visit 3 should be conducted at least 8 weeks after Visit 2 and when the subject is at least 24 weeks of age
† It is preferred that subjects come in for Visit 4 and Visit 6, at least 30 days after Visits 3 and 5, respectively. If subjects return for the visit prior to 30 days, they should take home the diary card and continue to record unsolicited safety information until 30 days post-vaccination and mail/send it upon completion. Investigators will make an attempt to retrieve diary cards from subjects who have not mailed/sent them in.
^ Visit 5 should occur after the ESFU. ESFU must occur prior to vaccination if Visit 5 coincides with the 6 months post-Visit 3 time-point
** Adherence to the interval pertaining to phone contact is only indicative and will not determine a subject's eligibility for inclusion for ATP analysis. However, the interval should be respected in order to obtain safety information over the complete 6 months extended safety follow up period.

5.6. Detailed description of study procedures

5.6.1. Procedures prior to study participation

5.6.1.1. Informed consent

The signed informed consent of the subject's parent(s)/LAR(s) must be obtained before study participation.

5.6.2. Procedures during the study

5.6.2.1. Check inclusion and exclusion criteria

Check all inclusion and exclusion criteria as described in Sections 4.2 and 4.3 before enrolment.

5.6.2.2. Collect demographic data

Record demographic data such as date of birth, gender, geographic ancestry and ethnicity in the subject's eCRF.

5.6.2.3. Medical history

Obtain the subject's medical history by interview and/or review of the subject's medical records and record any pre-existing conditions or signs and/or symptoms present in a subject prior to the first study vaccination in the eCRF.

5.6.2.4. Vaccination history

Obtain the subject's vaccination history by interview and/or review of the subject's medical records and record any vaccinations given to the subject, including hepatitis B vaccines, prior to the first study vaccination in the eCRF. The Tdap vaccination history of the mother during pregnancy will also be collected and recorded in the eCRF (provided that the mother has consented to provide this information).

Note: Maternal vaccination is requested in order to be able to summarize the responses of the subjects to pertussis antigens according to whether or not the mothers received a pertussis vaccine during their pregnancy. This information will aid in understanding the effect of transplacentally transferred antibodies on the childs' immune response to vaccination.

5.6.2.5. History directed physical examination

Perform a history directed physical examination at Visit 1 (Epoch 001) and Visit 5 (Epoch 002). If the investigator determines that the subject's health on the day of vaccination temporarily precludes vaccination, the visit will be rescheduled. Collected information, including length and weight, needs to be recorded in the eCRF.

Treatment of any abnormality observed during this examination has to be performed according to local medical practice outside this study or by referral to an appropriate health care provider.

5.6.2.6. Study group and treatment number allocation

Study group and treatment number allocation will be performed as described in Section 5.2.2. The number of each administered treatment must be recorded in the eCRF.

5.6.2.7. Treatment number allocation for subsequent doses

The treatment number allocation for subsequent doses will be performed at Visits 2, 3 and 5 as described in Section 5.2.2. The number of each administered treatment must be recorded in the eCRF.

5.6.2.8. Assess pre-vaccination body temperature

The axillary, rectal, oral or tympanic body temperature of all subjects needs to be measured prior to the study vaccine administration at Visits 1, 2, 3 and 5. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002. If the subject has fever [fever is defined as temperature ≥38.0°C /100.4°F by any route] on the day of vaccination, the vaccination visit will be rescheduled within the allowed interval for this visit (see Table 5).

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5.6.2.9. Sampling

Refer to the Module on Biospecimen Management in the SPM for detailed instructions for the collection, handling and processing of the samples.

5.6.2.9.1. Blood sampling for immune response assessments

Blood samples will be taken during certain study visits as specified in Section 5.5 List of Study Procedures.

- A volume of approximately 5.0 mL of whole blood to provide approximately 1.7 mL of serum should be drawn from all subjects for the analysis of humoral immune response at Visits 4 and 5. At least 3.5 mL of whole blood to provide approximately 1.2 mL of serum should be drawn from all subjects for the analysis of humoral immune response at Visit 6. After centrifugation, serum samples should be kept at –20°C/ –4°F or below until shipment. Refer to the SPM for more details on sample storage conditions.

5.6.2.10. Check contraindications, warnings and precautions to vaccination

Contraindications, warnings and precautions to vaccination must be checked at the beginning of each vaccination visit. Refer to Sections 6.5 and 6.6 for more details.

5.6.2.11. Baseline measurement of limb circumference after booster vaccination at visit 5

(Amendment 2: 17 April 2015)

During Epoch 002, baseline measurement of limb circumference (arms or legs according to where the vaccine was administered) at the level of the injection site should be obtained. For the Penta group, baseline measurement is only required for the limb that will be vaccinated. Clothing should be removed so as not to interfere with the measurement of the limb circumference. For measuring upper arm circumference, the measurement will be performed while the arm is held parallel to the trunk and the elbow is flexed in front at 90° (as if the subject is carrying a tray) [Kohl, 2007]. For measuring leg circumference the child should be standing or lying flat, as appropriate, as long as the leg is straight.

5.6.2.12. Study Vaccines administration

- After completing all prerequisite procedures prior to vaccination, one dose of study vaccine/control vaccines will be administered intramuscularly (IM) (refer to Section 6.3 for detailed description of the vaccines administration procedure). If the investigator or delegate determines that the subject's health on the day of administration temporarily precludes vaccine administration, the visit will be rescheduled within the allowed interval for this visit (refer to Table 5).

- The subjects will be observed closely for at least 30 minutes following the administration of the vaccines, with appropriate medical treatment readily available in case of anaphylaxis.

5.6.2.13. Recording of AEs, SAEs and NOCDs

(Amendment 2: 17 April 2015)

- Refer to Section 8.3 for procedures for the investigator to record AEs, SAEs and NOCDs. NOCDs include events such as autoimmune disorders, asthma, type I diabetes and allergies. Refer to Section 8.4 for guidelines on how to submit SAE reports to GSK Biologicals.

The subjects' parent(s)/LAR(s) will be instructed to contact the investigator immediately should the subjects manifest any signs or symptoms they perceive as serious.

- At each vaccination visit, diary cards will be provided to the subject's parent(s)/LAR(s). The subject's parent(s)/LAR(s) will record body (rectal for subjects in Epoch 001 and axillary for subjects in Epoch 002) temperature and any solicited local/general AEs (i.e. on the day of vaccination and during the next 3 days) or any unsolicited AEs (i.e. on the day of vaccination and during the next 30 days occurring after vaccination). The subject's parent(s)/LAR(s) will be instructed to return the completed diary card to the investigator at the next study visit.
- Collect and verify completed diary cards during discussion with the subject's parent(s)/LAR(s) on Visits 2, 3, 4 and 6.
- During Epoch 002, following the fourth dose vaccination, the parents/LAR(s) should be provided with a measurement device for recording circumference of injected limbs (arms or legs according to where vaccine was administered) at the level of the injection site on the day of vaccination and during the next three days on a diary card. The parents/LAR(s) should be instructed on how and where to perform the measurement of the circumference of the vaccinated limb. Daily measurements should be performed in the same manner preferably by the same person and at the same time of day during the 4-day follow-up (Day 0-Day 3) period.
- If the parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of limb circumference) during the 4-day follow-up (Day 0-Day 3) period they are to contact study personnel and to visit the investigator's office for evaluation as soon as possible and to bring the diary card with them.

- In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms, the parent(s)/LAR(s) will record the following additional symptoms/characteristics that may be associated with large injection site swelling reactions on the diary card:
  - Type of swelling (local swelling only around the injection site, diffuse swelling not involving the elbow or knee joint, swelling involving the elbow or knee joint)
  - Induration at injection site (largest diameter)
  - Pruritis at the injection site (intensity – scale provided)
  - Functional impairment (intensity – scale and description provided)
- The study personnel's evaluation will be recorded in the medical chart. In case the diary card score is not in line with the medical chart score, the medical chart will indicate what is the most intense score. The largest or most intense score for a given day will be recorded in the eCRF at the level of the solicited symptoms and at the level of the large swelling report form.
- Any unreturned diary cards will be sought from the subject's parent(s)/LAR(s) through telephone call(s) or any other convenient procedure. The investigator will transcribe the collected information into the eCRF in English.

5.6.2.14. Check and record concomitant medication/vaccination and intercurrent medical conditions

Concomitant medication/vaccination must be checked and recorded in the eCRF as described in Section 6.7.

Intercurrent medical conditions must be checked and recorded in the eCRF as described in Section 6.8.

5.6.2.15. Study conclusion

The investigator will:

- review data collected to ensure accuracy and completeness at ESFU contact and Visit 6
- complete the Study Conclusion screen in the eCRF.

At study completion, post-trial commercial vaccines will not be provided to the subjects.

5.7. Biological sample handling and analysis

Please refer to the SPM for details on biospecimen management (handling, storage and shipment).

Samples will not be labelled with information that directly identifies the subject but will be coded with the identification number for the subject (subject number).

Under the following circumstances, additional testing on the samples may be performed by GSK Biologicals outside the scope of this protocol:

- Collected samples may be used in other assays, for test improvement or development of analytical methods related to the study vaccines and its constituents or the disease under study.
- Collected samples may be used for purposes related to the quality assurance of data generated linked to the study vaccines or the disease under study, such as for maintenance of assays described in this protocol and comparison between analytical methods and/or laboratories.

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 subject's parent(s)/LAR(s).

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 a maximum of 20 years (counting from when the last subject 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 subject 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 subject from the ATP analysis (See Section 10.4 for the definition of study cohorts/ data sets to be analysed). 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

Table 6 Biological samples

Sample type	Quantity*	Unit	Timepoint
Blood	5	mL	Month 5 (Post-Pri)
Blood	5	mL	Month 13-16 (Pre-Bst)
Blood	3.5	mL	Month 14-17 (Post-Bst)

* Approximate quantity
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

5.7.3. Laboratory assays

(Amendment 2: 17 April 2015)

Please refer to APPENDIX A for the address of the clinical laboratories used for sample analysis.

At Visits 4, 5 and 6, blood will be collected for measurement of immune response. Total blood volume to be taken from each subject over the study period is approximately 13.5 mL (approximately 5.0 mL of whole blood to provide approximately 1.7 mL of serum at Visits 4 and 5 and at least 3.5 mL of whole blood to provide approximately 1.2 mL of serum at Visit 6). All serology will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized procedures with adequate controls. ***All serology for primary endpoints will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized, validated procedures with adequate controls.***

The laboratory assays for humoral immunity are presented in Table 7.

Table 7 Humoral Immunity (Antibody determination)

(Amendment 2: 17 April 2015)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off†	Laboratory**
Serum	Bordetella pertussis.Pertussis Toxin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Filamentous Hemaglutinin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Pertactin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Corynebacterium diphtheriae.Diphtheria Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Clostridium tetani.Tetanus Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Hepatitis B Virus.Surface Ab	CLIA	Centaur (Siemens Healthcare)	mIU/mL	6.2	GSK Biologicals§
Serum	Poliovirus Sabin Types 1, 2 and 3	NEUTRA	In-house*	ED_{50}	8	GSK Biologicals§
Serum	Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab ‡	ELISA	In-house*	µg/mL	0.15	GSK Biologicals§

*In-house refers to assays developed internally by GSK which can be performed at GSK Biologicals' laboratories or external laboratory designated by GSK
**Refer to APPENDIX A for the laboratory addresses.
§GSK Biologicals laboratory refers to the Global Vaccines Clinical Laboratories (GVCL) in Rixensart, Belgium; Wavre, †
†Due to ongoing re-validation of all assays, the cut-offs may be subject to change.
‡For anti-PRP post-dose 3, the assay is not yet qualified or validated.
Belgium and Laval, Canada.
ELISA = Enzyme-Linked Immunosorbent Assay
NEUTRA = Neutralization Assay
CLIA = ChemiLuminescence ImmunoAssay

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.

5.7.4. Biological samples evaluation

5.7.4.1. Immunological read-outs

The immunological read-outs are presented in Table 8.

Table 8 Immunological read-outs

Blood sampling time point		No. of subjects	Components and priority rank
Type of contact and time point	Sampling time point		
Visit 4 (Month 5)	Post-Pri	585 (All)	PRN, FHA, PT PRP, D, T, HBs, Poliovirus type 1, Poliovirus type 2, Poliovirus type 3
Visit 5 (Month 13-16)	Pre-Bst	585 (All)	PRN, FHA, PT PRP, D, T, HBs, Poliovirus type 1, Poliovirus type 2, Poliovirus type 3
Visit 6 (Month 14-17)	Post-Bst	585 (All)	PRN, FHA, PT, PRP, D, T

Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002

In case of insufficient blood sample volume to perform assays for all antibodies, the samples will be analysed according to priority ranking provided in Table 8.

5.7.5. Immunological correlates of protection

The following cut-offs are accepted as immunological correlates of protection:

- Specific antibodies against diphtheria toxoid (anti-diphtheria) and tetanus toxoid (anti-tetanus) will be measured by enzyme-linked immunosorbent assay (ELISA). The assay cut-off of ELISA is set at 0.1 International Units per ml (IU/ml), which provides a conservative estimate of the percentage of subjects deemed to be protected [Camargo, 1984; Melville-Smith, 1983].
- Antibodies to the hepatitis B surface antigen (anti-HBs) will be measured using CLIA. The cut-off of the test is set at 6.2 mIU/ml. An antibody concentration ≥10 mIU/ml defines seroprotection [CDC, 1991; WHO, 1988].
- Antibodies against poliovirus types 1, 2 and 3 will be determined by a virus micro-neutralization test adapted from the World Health Organization Guidelines for WHO/EPI Collaborative Studies on Poliomyelitis [WHO, 1993]. The lowest dilution at which serum samples will be tested is 1:8, from which a test will be considered positive. Titers will be expressed in terms of the reciprocal of the dilution resulting in 50% inhibition. Antibody titers greater than or equal to this value are considered as protective.
- Data from subjects given unconjugated Hib vaccine suggest that, in the absence of induction of immunological memory, a concentration of 0.15 µg/mL is indicative of short-term protection, with 1 µg/mL considered indicative of long-term protection [Käyhty, 1983; Anderson, 1984].
- No serological correlate of protection against pertussis has been established [Granström, 1987; Karpinsky, 1987]. Antibodies against the pertussis components

s PT, FHA and PRN will be measured by ELISA. The seropositivity cut-off for all three pertussis antibodies in ELISA is 5 EL.U/ml. Subjects with antibody concentration below the cut-off will be considered seronegative.

For the purpose of identification of sub-optimal responders and communication to the investigators, anti-HBs and anti-poliovirus types 1, 2 and 3 assessment of the protection level will be done for each subject on samples taken approximately 4 weeks after the 3rd dose of the primary vaccination. For PRP, D and T antigens, the assessment of the protection level will be done for each subject on samples taken approximately 4 weeks after the administration of the booster dose. In addition a listing of subjects who did not seroconvert to anti-PT, anti-FHA and anti-PRN will be provided.

The immunological assay results will be communicated to the investigator within one year following the last subject visit for the relevant time point (Visit 4 for HBV and poliovirus; Visit 6 for PRP, D, T and pertussis antigens).

The investigator is encouraged to share the immunological assay results for non-responders with the study subjects' parent(s)/LAR(s).

For the study subjects identified as non-responders, it remains the responsibility of the study investigator in charge of the subject's clinical management to determine the medical need for re-vaccination and to re-vaccinate the subjects as per local/regional practices.

6. STUDY VACCINES AND ADMINISTRATION

6.1. Description of study vaccines

All candidate vaccines to be used have been developed and manufactured by GSK Biologicals.

The Quality Control Standards and Requirements for each candidate vaccine are described in separate Quality Assurance documents (e.g. release protocols, certificate of analysis) 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 9 Study vaccines

(Amendment 2: 17 April 2015)

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix hexa	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	full volume^	3
	Hib	PRP=10µG; TT~=25µG Aluminum as salts = 0.12 mg	The lyophilized Hib component is presented as a white pellet in a glass vial; it must be reconstituted before use with the DTPa-HBV-IPV component.		
Pediarix	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	0.5 mL	3
ActHIB	ActHIB	Hib=10µg TT, TT=24µg	White lyophilized pellet in a single dose vial, it must be reconstituted before use with sterile 0.4% saline solution	0.5 mL*	4
	NaCl	NaCl=60mM	Sterile 0.4% saline solution		
Pentacel	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial. ***The lyophilized Hib component is presented as a white pellet in a separate glass vial. It must be reconstituted with the liquid DTaP-IPV component before use.***	0.5 mL*	4
Engerix-B	HBV	HBsAg=10µg; $Al(OH)_3$=250µg Al3+	Suspension pre-filled syringe	0.5 mL	2 or 3**

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Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix	DTPa	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; $AlPO_4$=500µg Al3+	Homogeneous, turbid, white suspension in a pre-filled syringe	0.5 mL	1
Hiberix	Hib	PRP=10µG; TT~=25µG	The lyophilized Hib component is presented as a white pellet in a glass vial; it must be reconstituted before use with sterile 0.9% saline solution.	0.5 mL*	1
	NaCl	NaCl=150mM	Sterile 0.9% saline solution		
Prevnar13	Prevenar 13	PS1=2.2µg CRM197; PS3=2.2µg CRM197; PS4=2.2µg CRM197; PS5=2.2µg CRM197; PS6A=2.2µg CRM197; PS6B=4.4µg CRM197; PS7F=2.2µg CRM197; PS9V=2.2µg CRM197; PS14=2.2µg CRM197; PS18C=2.2µg CRM197; PS19A=2.2µg CRM197; PS19F=2.2µg CRM197; PS23F=2.2µg CRM197; $AlPO_4$=125µg Al3+	Suspension for injection in a pre-filled syringe.	0.5 mL	3
Rotarix	HRV	HRV RIX4144=$10^{6.0}$ $CCID_{50}$	Lyophilized vaccine in a monodose glass vial to be reconstituted with the calcium carbonate buffer diluent)	1.0 mL*	2
	$CaCO_3$	$CaCO_3$=60µg	Diluent (calcium carbonate liquid buffer) supplied separately in prefilled syringe		

$CCID_{50}$ = median Cell Culture Infective Dose; DMEM = Dulbecco's Modified Eagle Medium
* After reconstitution
** Subjects in the Penta Group who receive a birth dose of hepatitis B vaccine should not receive *Engerix-B* at the Month 4 visit (Visit 2)
^ Full volume after reconstitution (approximately 0.5 mL) to be administered

6.2. Storage and handling of study vaccines

The study vaccines must be stored at the respective label storage temperature conditions in a safe and locked place. Access to the storage space should be limited to authorized study personnel. The storage conditions will be assessed during pre-study activities under the responsibility of the sponsor study contact. The storage temperature should be continuously monitored with calibrated (if not validated) temperature monitoring device(s) and recorded. Refer to the Module on Clinical Trial Supplies in the SPM for more details on storage of the study vaccines.

Temperature excursions must be reported in degree Celsius.

Any temperature excursion outside the range of 0.0 to +8.0°C (for +2 to +8°C/+36 to +46°F label storage condition) impacting investigational medicinal products (IMPs) must

be reported in the appropriate (electronic) temperature excursion decision form ([e]TDF). The impacted IMPs must not be used and must be stored in quarantine at label temperature conditions until usage approval has been obtained from the sponsor.

In case of temperature excursion below +2.0°C down to 0.0°C impacting IMP(s) there is no need to report in (e)TDF, but adequate actions must be taken to restore the +2 to +8°C/+36 to +46°F label storage temperature conditions. The impacted IMP(s) may still be administered, but the site should avoid re-occurrence of such temperature excursion. Refer to the Module on Clinical Trial Supplies in the SPM for more details on actions to take.

Refer to the Module on Clinical Trial Supplies in the SPM for details and instructions on the temperature excursion reporting and usage decision process, packaging and accountability of the study vaccines.

6.3. Dosage and administration of study vaccines

The injectable vaccines must be administered intramuscularly, at a 90-degree angle into the anterolateral side of the thigh [CDC, 2002] on the side stated in Table 10. The buttock should not be used.

In order to ensure proper intramuscular injection of the vaccines, a needle of at least 1 inch (2.54 cm) length, 25 gauge will be used [Diggle, 2006; Zuckerman, 2000].

For reconstitution of *Infanrix hexa* vaccine, an appropriate needle should be attached to the prefilled syringe containing the DTPa-HBV-IPV liquid vaccine and inserted into the vial containing the lyophilized Hib vaccine. The entire contents of the syringe should be transferred to the vial. With needle still inserted, the vial should be vigorously shaken. After reconstitution, the full volume of the vial (approximately 0.5 mL) is then withdrawn using the same syringe. A new needle should then be affixed to the syringe for administration of the vaccine.

NOTE: After reconstitution, *Infanrix hexa* should be injected immediately. However the vaccine may be kept for up to 8 hours at room temperature (21°C).

The vaccinees 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.

Rotarix must be exclusively administered orally. DO NOT INJECT.

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Table 10 Dosage and administration

Visit	Study Group	Treatment name	Route [1]	Site [2]	Side [3]
Epoch 001					
1, 2, 3	Hexa Group	*Infanrix hexa* (lot A, lot B or lot C)	IM	T	R
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
1, 2, 3	Pedia Group	*Pediarix*	IM	T	R
1, 2, 3		*ActHIB*	IM	T	UpL
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
1, 2, 3	Penta Group	*Pentacel*	IM	T	R
1, 2, 3		*Engerix-B*†	IM	T	UpL
1, 2, 3		*Prevnar13*	IM	T	LoL
1, 2		*Rotarix*	O	-	-
Epoch 002*					
5	Hexa Group	*Infanrix*	IM	T	R
		Hiberix	IM	T	L
5	Pedia Group	*Infanrix*	IM	T	R
		ActHIB	IM	T	L
5	Penta Group	*Pentacel*	IM	T	R

[1]Oral (O), Intramuscular (IM); [2]Thigh (T), [3]Left (L), Right (R), Upper Left (UpL), Lower Left (LoL)
Note: Vaccination can be performed in the opposite side in case of medical indication preventing vaccination in the side stated in the table, as judged by the investigator
†Subjects in the Penta Group who receive a birth dose of hepatitis B vaccine should not receive *Engerix-B* at the Month 4 visit (Visit 2).
* Toddlers (12 Months through 2 Years): For toddlers, the vastus lateralis muscle in the anterolateral thigh is preferred. The needle should be at least 1-inch long. The deltoid muscle can be used if the muscle mass is adequate.

6.4. Replacement of unusable vaccine doses

In addition to the vaccine doses provided for the planned number of subjects (including over-randomization when applicable), at least 60% additional vaccine doses will be supplied to replace those that are unusable.

6.5. Contraindications to subsequent vaccination

6.5.1. Absolute contraindications:

The following events constitute absolute contraindications to further administration of the study and co-administration vaccines. If any of these events occur during the study, the subject must not receive additional doses of vaccine but may continue other study procedures at the discretion of the investigator.

- Anaphylaxis following the administration of vaccine(s).
- Other hypersensitivity reaction to any component of the vaccine(s) and any excipients in the formulation, including yeast.
- Hypersensitivity to latex.

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- Contraindication for pertussis-containing vaccines:
  - Encephalopathy of unknown etiology, defined as an acute, severe central nervous system disorder, occurring within 7 days following previous vaccination with pertussis-containing vaccine and generally consisting of major alterations in consciousness, unresponsiveness, generalised or focal seizures that persist more than a few hours, with failure to recover within 24 hours.
  - Individuals with progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy should not receive a pertussis-containing vaccine until a treatment regimen has been established and the condition has stabilized.
- Contraindications to *Rotarix*:
  - Subjects with uncorrected congenital malformation (such as Meckel's diverticulum) of the gastrointestinal tract that would predispose for intussusceptions.
  - History of intussusception or history of SCID.

6.5.2. Temporary contraindications:

The following events constitute contraindications to administration of the study and co-administration vaccines at that point in time; if any of these events occur at the time scheduled for vaccination, the subject may be vaccinated at a later date, within the time window specified in the protocol, or withdrawn at the discretion of the investigator.

- Acute disease and/or fever at the time of vaccination.
  - Fever is defined as temperature ≥ 38.0°C/100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.
  - Subjects with a minor illness (such as mild upper respiratory infection) without fever can be administered all vaccines.
- Acute diarrhea or vomiting is a contra-indication to the administration of *Rotarix* at that point in time.

6.6. Warnings and precautions

The information below presents, in addition to the contraindications in Section 6.5, warnings and precautions to administration of *Infanrix hexa.*

- As with other vaccines, administration of *Infanrix hexa* should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contra-indication.
- Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

- If any of the following events are known to have occurred in temporal relation to receipt of pertussis-containing vaccine, the decision to give further doses of pertussis-containing vaccines should be carefully considered:
  - Temperature of ≥ 40.0°C within 48 hours, not due to another identifiable cause.
  - Collapse or shock-like state (hypotonic-hyporesponsiveness episode) within 48 hours of vaccination.
  - Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours of vaccination.
  - Convulsions with or without fever, occurring within 3 days of vaccination.
- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
- *Infanrix hexa* should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.
- *Infanrix hexa* should under no circumstances be administered intravascularly or intradermally.
- A protective immune response may not be elicited in all vaccinees.
- A history of febrile convulsions, a family history of convulsions or Sudden Infant Death Syndrome (SIDS) do not constitute contraindications for the use of *Infanrix hexa*. Vaccinees with a history of febrile convulsions should be closely followed up as such adverse events may occur within 2 to 3 days post vaccination.
- Since the Hib capsular polysaccharide antigen is excreted in the urine a positive urine test can be observed within 1-2 weeks following vaccination. Other tests should be performed in order to confirm Hib infection during this period.
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Refer to the approved product label/package insert for warnings and precautions for the use of *Pediarix, ActHIB, Pentacel, Engerix-B, Prevnar13, Rotarix, Hiberix* and *Infanrix* vaccines.

6.7. Concomitant medication/product and concomitant vaccination

At each study visit/contact, the investigator should question the subject's parent(s)/LAR(s) about any medication/product taken and vaccination received by the subject.

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6.7.1. Recording of concomitant medications/products and concomitant vaccination

The following concomitant medications/products/vaccines must be recorded in the eCRF if administered during the indicated recording period:

- All concomitant medications/products, except vitamins and dietary supplements, administered within 30 days following each dose of study vaccine.
- Any concomitant vaccination administered since birth and ending 30 days after the booster dose (Visit 6). Vaccinations listed prior to the first dose of study vaccine are to be recorded as vaccination history. The fourth dose of *Prevnar 13* will be recorded as concomitant vaccination.
- Prophylactic medication (i.e. 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 by any route].
- Any concomitant medications/products/vaccines listed in Section 6.7.2.
- Any concomitant medication/product/vaccine relevant to a SAE* or administered at any time during the study period for the treatment of a SAE*.

  * Refer to those SAEs that are required to be reported per protocol.

6.7.2. Concomitant medications/products/vaccines that may lead to the elimination of a subject from ATP analyses

The use of the following concomitant medications/products/vaccines will not require withdrawal of the subject from the study but may determine a subject's evaluability in the ATP analysis. See Section 10.4 for study cohorts/ data sets to be analysed.

- Any investigational or non-registered product (drug or vaccine) other than the study vaccines used during the study period (starting from Visit 1 and ending at Visit 6).
- Immunosuppressants or other immune-modifying drugs administered chronically (i.e. more than 14 days) during the study period until the final blood sample (Visit 6). For corticosteroids, this will mean prednisone ≥ 0.5 mg/kg/day, or equivalent. Inhaled and topical steroids are allowed.
- A vaccine not foreseen by the study protocol administered during the period starting from 30 days before the first vaccination until Post-Pri blood sampling i.e. approximately 30 days after Dose 3 (Epoch 001) and from 30 days before Pre-Bst until Post-Bst blood sampling i.e. approximately 30 days after Dose 4 (Epoch 002). Thus, routine administration(s) of measles-mumps-rubella, varicella and pneumococcal vaccines are allowed from 30 days after the last dose of primary vaccination (after Post-Pri blood sampling) until 30 days before the booster dose and from 30 days after the booster dose (after Post-Bst blood sampling), as well as according to the recommended immunization schedule in the US.

- Exceptions:
  - Inactivated influenza vaccine and hepatitis A vaccines are allowed throughout the study.

  In case an emergency mass vaccination for an unforeseen public health threat (e.g.: a pandemic) is organized by the public health authorities, outside the routine immunization program, the time period described above can be reduced if necessary for that vaccine provided it is licensed and used according to its SPC or PI and according to the local governmental recommendations and provided a written approval of the Sponsor is obtained.
- Immunoglobulins and/or any blood products administered during the study period until the final blood sample (Visit 6).

6.8. Intercurrent medical conditions that may lead to elimination of a subject from ATP analyses

At each study visit subsequent to the first vaccination visit, it must be verified if the subject has experienced or is experiencing any intercurrent medical condition. If it is the case, the condition(s) must be recorded in the eCRF.

- Subjects may be eliminated from the ATP cohort for immunogenicity if they incur a condition that has the capability of altering their immune response or are confirmed to have an immunodeficiency condition.
- Subjects will be eliminated from the ATP cohort for immunogenicity if they experience intercurrent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and/or Hib prior to the post-dose 3 blood draw and diphtheria, tetanus, pertussis and/or Hib post-dose 4 blood draw.

7. HEALTH ECONOMICS

Not applicable.

8. SAFETY

The investigator or site staff is/are responsible for the detection, documentation and reporting of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE) as provided in this protocol.

Each subject's parent(s)/LAR(s) will be instructed to contact the investigator immediately should the subject 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.
- New conditions detected or diagnosed after investigational vaccines 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 vaccines 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.
- Pre- or post-treatment events that occur as a result of protocol-mandated procedures (i.e. invasive procedures, modification of subject's previous therapeutic regimen).

AEs to be recorded as endpoints (solicited AEs) are described in Section 8.1.3. All other AEs will be recorded as UNSOLICITED AEs.

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/SAE.
- Situations where an untoward medical occurrence did not occur (e.g. social and/or 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.
- Pre-existing conditions or signs and/or symptoms present in a subject prior to the first study vaccination. These events will be recorded in the medical history section of the eCRF**.**

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,

   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, had it been more severe.

c. Requires hospitalisation or prolongation of existing hospitalisation,

   Note: In general, hospitalisation signifies that the subject 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 hospitalisation are also considered AEs. If a complication prolongs hospitalisation or fulfils any other serious criteria, the event will also be considered serious. When in doubt as to whether 'hospitalisation' occurred or was necessary, the AE should be considered serious.

   Hospitalisation 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,

   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, 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 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 hospitalisation but may jeopardise 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 hospitalisation.

8.1.3. Solicited adverse events

A 4-day follow-up (Day 0-Day 3) of solicited local (at each injection site) and general AEs will be performed after administration of the vaccine. Data concerning the following AEs will be solicited using diary cards provided by the sponsor.

8.1.3.1. Solicited local (injection-site) adverse events

The following local (injection-site) AEs will be solicited (Table 11):

Table 11 Solicited local adverse events

Pain at injection site
Redness at injection site
Swelling at injection site
Post-dose 4 measurements of circumference of limbs (arm or leg according to where vaccine was administered)

N.B. If parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of limb circumference) after the booster dose at Visit 5, they are to contact study personnel and to visit the investigator's office for evaluation as soon as possible and bring the diary card with them. The investigator will record detailed information describing the AE on a specific large injection site reaction form in the eCRF. In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms the parent(s)/LAR(s) will need to record additional symptoms/characteristics as mentioned in Section 5.6.2.13.

Note: local AEs will not be solicited for co-administered vaccines like *Prevnar 13*.

8.1.3.2. Solicited general adverse events

The following general AEs will be solicited (Table 12):

Table 12 Solicited general adverse events

Drowsiness
Fever
Irritability/Fussiness
Loss of appetite

Note: Temperature will be recorded in the evening. Should additional temperature measurements be performed at other times of day, the highest temperature will be recorded. Fever is defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.

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

In absence of diagnosis, abnormal laboratory findings (e.g. clinical chemistry, haematology, urinalysis) or other abnormal assessments (e.g. vital signs etc.) that are judged by the investigator to be clinically significant will be recorded as AE or SAE if they meet the definition of an AE or SAE (refer to Sections 8.1.1 and 8.1.2). Clinically significant abnormal laboratory findings or other abnormal assessments that are present at

baseline and significantly worsen following the start of the study will also be reported as AEs or SAEs. However, clinically significant abnormal laboratory findings or other abnormal assessments that are associated with the disease being studied, unless judged by the investigator as more severe than expected for the subject's condition, or that are present or detected at the start of the study and do not worsen, will not be reported as AEs or SAEs.

The investigator will exercise his or her medical and scientific judgement in deciding whether an abnormal laboratory finding or other abnormal assessment is clinically significant.

8.1.5. Adverse events of specific interest

Adverse events of specific interest (i.e. NOCDs such as autoimmune disorders, asthma, type I diabetes and allergies) will be recorded from Day 0 up to 6 months after the last primary vaccination (Epoch 001) and from booster dose up to one month after booster vaccination (Epoch 002). NOCDs will be reported as either AEs or SAEs, as appropriate in the eCRF.

8.2. Events or outcomes not qualifying as adverse events or serious adverse events

Not applicable.

8.3. Detecting and recording adverse events and serious adverse events

8.3.1. Time period for detecting and recording adverse events and serious adverse events

All AEs starting within 30 days following administration of each dose of study vaccine/comparator must be recorded into the appropriate section of the eCRF, irrespective of intensity or whether or not they are considered vaccination-related.

The time period for collecting and recording SAEs and AEs of specific interest will begin at the first receipt of study vaccine/comparator and will end 180 days following administration of the last dose of study vaccine/comparator of the primary vaccination course for each subject and 30 days following administration of the booster dose. See Section 8.4 for instructions on reporting of SAEs.

All AEs/SAEs leading to withdrawal from the study will be collected and recorded from the time of the first receipt of study vaccine/comparator.

In addition to the above-mentioned reporting requirements and in order to fulfil 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 will be collected and recorded from the time the subject consents to participate in the study until she/he is discharged from the study.

Note: With the exception of AEs/SAEs leading to withdrawal, study participation and concurrent GSK medications or vaccines, there is no reporting of SAEs from the time of the Epoch 1 ESFU phone contact and administration of dose 4 (approximately three months).

An overview of the protocol-required reporting periods for AEs and SAEs is given in Table 13.

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Table 13 Reporting periods for adverse events and serious adverse events

Study activity	C.O	V1	4-days post vac	31-days post-vac	V2	4-days post vac	31-days post-vac	V3	4-days post- vac	31-days post-vac	Phone call 6 months post-V3	V5	4-days post- vac	31-days post-vac
Age of subject		2 months			4 months			6 months		7 months	12 months	15-18 months		16-19 months
Solicited local and general AEs														
Large injection site reactions														
Unsolicited AEs														
AEs/SAEs leading to withdrawal from the study														
NOCDs														
SAEs														
SAEs related to study participation or concurrent GSK medication/vaccine														

NOCD: New Onset of Chronic Diseases; C.O: consent obtained; V: Visit; Post-V: Post-Visit; vac: vaccination

8.3.2. Post-Study adverse events and serious adverse events

A post-study AE/SAE is defined as any event that occurs outside of the AE/SAE reporting period defined in Table 13. 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 subject has been discharged from the study, and he/she considers the event reasonably related to the investigational vaccine/product, the investigator will promptly notify the Study Contact for Reporting SAEs.

8.3.3. Evaluation of adverse events and serious adverse events

8.3.3.1. Active questioning to detect adverse events and serious adverse events

As a consistent method of collecting AEs, the subject'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 in the eCRF. The investigator is not allowed to send photocopies of the subject's medical records to GSK Biologicals instead of appropriately completing the eCRF. However, there may be instances when copies of medical records for certain cases are requested by GSK Biologicals. In this instance, all subject 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.

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8.3.3.2. Assessment of adverse events

8.3.3.2.1. Assessment of intensity

The intensity of the following solicited AEs will be assessed as described:

Table 14 Intensity scales for solicited symptoms in infants/toddlers

Infant/Toddler (15–24 months)		
Adverse Event	**Intensity grade**	**Parameter**
Pain at injection site	0	None
	1	Mild: Minor reaction to touch
	2	Moderate: Cries/protests on touch
	3	Severe: Cries when limb is moved/spontaneously painful
Redness at injection site		Record greatest surface diameter in mm
Swelling at injection site		Record greatest surface diameter in mm
Increase in limb circumference post-dose 4 (arm or leg according to where vaccine was administered)		Record the limb circumference at the level of the injection site
Fever*		Record temperature in °C/°F
Irritability/Fussiness	0	Behaviour as usual
	1	Mild: Crying more than usual/no effect on normal activity
	2	Moderate: Crying more than usual/interferes with normal activity
	3	Severe: Crying that cannot be comforted/prevents normal activity
Drowsiness	0	Behaviour as usual
	1	Mild: Drowsiness easily tolerated
	2	Moderate: Drowsiness that interferes with normal activity
	3	Severe: Drowsiness that prevents normal activity
Loss of appetite	0	Appetite as usual
	1	Mild: Eating less than usual/no effect on normal activity
	2	Moderate: Eating less than usual/interferes with normal activity
	3	Severe: Not eating at all

* Fever is defined as temperature ≥38.0°C /100.4°F by any route. The preferred route for recording temperature in this study will be rectal for Epoch 001 and axillary for Epoch 002.

The maximum intensity of local injection site redness/swelling/fever will be scored at GSK Biologicals as follows:

0 : Absent
1 : ≤ 5 mm
2 : > 5 mm and ≤ 20 mm
3 : > 20 mm

The maximum intensity of fever will be scored at GSK Biologicals as follows:

0	=	<100.4°F	<38.0°C
1	=	≥100.4°F to ≤102.2°F	≥38.0°C to ≤39.0°C
2	=	>102.2°F to ≤104.0°F	>39.0°C to ≤40.0°C
3	=	> 104.0°F	> 40.0°C

Following each vaccination (3 doses during the primary vaccination course and one booster dose) during the 4 days after the vaccine dose has been administered (day of vaccination and subsequent 3 days), the child's temperature will be screened each evening, at bedtime, for signs of fever by means of the rectal/axillary thermometer. Children < 15 months will have their temperature taken rectally and children ≥ 15 months will have their temperature taken by the axillary route. Rectal/axillary temperatures will be recorded on the diary card. Temperature measured by any route will be presented in 0.5°C increments starting at 38°C/100.4°F.

Prior to analysis, the increase in limb circumference of each limb as compared to the baseline pre-vaccination measurement will be scored for each subject at GSK Biologicals' as follows:

Grade 0 = Increase in limb circumference ≤5 mm

1 = Increase in limb circumference >5 mm but ≤20 mm

2 = Increase in limb circumference >20 mm but ≤40 mm

3 = Increase in limb circumference >40 mm

The investigator will assess the maximum intensity that occurred over the duration of the event for all unsolicited AEs (including SAEs) recorded during the study. The assessment will be based on the investigator's clinical judgement.

For unsolicited symptoms and adverse events associated with large injection site reactions (e.g. pruritus, induration and functional impairment, the intensity should be assigned to one of the following categories:

1 (mild)	=	An AE which is easily tolerated by the subject, 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/kindergarten/a day-care center 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 used 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.

8.3.3.2.2. Assessment of causality

The investigator is obligated to assess the relationship between investigational vaccines and the occurrence of each AE/SAE. The investigator will use clinical judgement to determine the relationship. Alternative plausible causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors, and the temporal relationship of the event to the investigational vaccines will be considered and investigated. The investigator will also consult the IB and/or PI for marketed products to determine his/her assessment. Investigational vaccines include vaccines such as *Infanrix hexa*, *Pediarix*, *Pentacel*, *ActHIB*, *Engerix-B*, *Rotarix*, *Prevnar 13*, *Infanrix* and *Hiberix*.

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 report to GSK Biologicals. The investigator may change his/her opinion of causality in light of follow-up information and update 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.

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:

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

YES	:	There is a reasonable possibility that the vaccines contributed to the AE.
NO	:	There is no reasonable possibility that the AE is causally related to the 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.

If an event meets the criteria to be determined as 'serious' (see Section 8.1.2), additional examinations/tests will be performed by the investigator in order to determine ALL possible contributing factors for 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 vaccines, if applicable.
- Erroneous administration.
- Other cause (specify).

8.3.3.3. Assessment of outcomes

The investigator will assess the outcome of all unsolicited AEs (including SAEs) recorded during the study as:

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

8.3.3.4. Medically attended visits

For each solicited and unsolicited symptom the subject experiences, the subject's parent(s)/LAR(s) will be asked if the subject received medical attention defined as hospitalisation, or an otherwise unscheduled visit to or from medical personnel for any reason, including emergency room visits. This information will be recorded in the eCRF.

8.4. Reporting of serious adverse events and other events

8.4.1. Prompt reporting of serious adverse events and other events to GSK Biologicals

SAEs that occur in the time period defined in Section 8.3 will be reported promptly to GSK within the timeframes described in Table 15, once the investigator determines that the event meets the protocol definition of a SAE.

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

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

* Timeframe allowed after receipt or awareness of the information.

8.4.2. Contact information for reporting serious adverse events and other events to GSK Biologicals

Back-up Study Contact for Reporting SAEs
24/24 hour and 7/7 day availability: GSK Biologicals Clinical Safety & Pharmacovigilance Fax: PPD or PPD Please refer to the Study Procedure Manual for the dedicated US Fax Machine number.

8.4.3. Completion and transmission of SAE reports to GSK Biologicals

Once an investigator becomes aware that a SAE has occurred in a study subject, the investigator (or designate) must complete the information in the electronic SAE report WITHIN 24 HOURS. The SAE report 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 report should still be completed within 24 hours. Once additional relevant information is received, the report should be updated WITHIN 24 HOURS.

The investigator will always provide an assessment of causality at the time of the initial report.

8.4.3.1. 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 paper SAE report and fax it to the GSK Biologicals Clinical Safety and Pharmacovigilance department within 24 hours. Please refer to the Study Procedure Manual for the dedicated US Fax Machine number.

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 electronic SAE report within 24 hours. The final valid information for regulatory reporting will be the information reported through the electronic SAE reporting system.

8.4.4. Updating of SAE information after freezing of the subject's eCRF

When additional SAE information is received after freezing of the subject's eCRF, new or updated information should be recorded on a paper report, with all changes signed and dated by the investigator. The updated report 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 the designated reporting time frames specified in Table 15.

8.4.5. 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 subjects 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 vaccine/product and unexpected. The purpose of the report is to fulfil specific regulatory and GCP requirements, regarding the product under investigation.

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

8.5.1. Follow-up during the study

After the initial AE/SAE report, the investigator is required to proactively follow each subject and provide additional relevant information on the subject's condition to GSK Biologicals (within 24 hours for SAEs; refer to Table 15).

All SAEs documented at a previous visit/contact 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/contact and designated as not recovered/not resolved or recovering/resolving will be reviewed at subsequent visits/contacts until 30 days after the last vaccination.

New onset of chronic diseases (such as autoimmune disorders, asthma, type I diabetes and allergies) documented at a previous visit/contact and designated as not recovered/not

resolved or recovering/resolving will be reviewed at subsequent visits/contacts until end of the study.

8.5.2. Follow-up after the subject is discharged from the study

The investigator will follow subjects:

- with SAEs, or subjects 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 subject is lost to follow-up.
- with other non-serious AEs of specific interest, i.e. NOCDs, such as autoimmune disorders, asthma, type I diabetes and allergies, until the end of the study period or they are lost to follow-up.

If the investigator receives additional relevant information on a previously reported SAE, he/she will provide this information to GSK Biologicals using a paper SAE form.

GSK Biologicals may request that the investigator performs or arranges the conduct of additional clinical examinations/tests and/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 subject dies during participation in the study or during a recognized follow-up period, GSK Biologicals will be provided with any available post-mortem findings, including histopathology.

8.6. 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 subject's eCRF (refer to Section 6.7).

8.7. Subject card

Study subjects' 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 subject's parent(s)/LAR(s). In an emergency situation this card serves to inform the responsible attending physician that the subject is in a clinical study and that relevant information may be obtained by contacting the investigator.

Subjects' parent(s)/LAR(s) must be instructed to keep subject cards in their possession at all times.

9. SUBJECT COMPLETION AND WITHDRAWAL

9.1. Subject completion

A subject who returns for the concluding visit/is available for the concluding contact foreseen in the protocol is considered to have completed the study.

9.2. Subject withdrawal

Withdrawals will not be replaced.

9.2.1. Subject withdrawal from the study

From an analysis perspective, a 'withdrawal' from the study refers to any subject who did not come back for the concluding visit/was not available for the concluding contact foreseen in the protocol.

All data collected until the date of withdrawal/last contact of the subject will be used for the analysis.

A subject 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 subject from the date of withdrawal/last contact.

Investigators will make an attempt to contact those subjects 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 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).

*In case a subject is withdrawn from the study because the subject's parent(s) has withdrawn consent, the investigator will document the reason for withdrawal of consent, if specified by the subject, in the eCRF.

Subjects who are withdrawn from the study because of SAEs/AEs must be clearly distinguished from subjects who are withdrawn for other reasons. Investigators will follow subjects who are withdrawn from the study as result of a SAE/AE until resolution of the event (see Section 8.5.2).

9.2.2. Subject withdrawal from investigational vaccine

A 'withdrawal' from the investigational vaccine refers to any subject who does not receive the complete treatment, i.e. when no further planned dose is administered from

the date of withdrawal. A subject withdrawn from the investigational vaccine may not necessarily be withdrawn from the study as further study procedures or follow-up may be performed (safety or immunogenicity) if planned in the study protocol.

Information relative to premature discontinuation of the investigational vaccine will be documented on the Vaccine Administration screen of the eCRF. The investigator will document whether the decision to discontinue further vaccination/treatment 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.
- Other (specify).

10. STATISTICAL METHODS

10.1. Primary endpoint

10.1.1. Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

10.2. Secondary endpoints

10.2.1. Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.

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- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the **Med**ical **D**ictionary for **R**egulatory **A**ctivities (MedDRA) classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

10.2.2. Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix.*
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).

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  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4)
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

10.3. Determination of sample size

Target enrolment will be 585 subjects. Assuming 65% of the subjects will be evaluable post-dose 3, this will provide approximately 378 subjects (126 subjects in each group) evaluable for immunogenicity in the Epoch 001.

The sample size has been estimated in order to obtain at least 94% power to demonstrate the primary inferential objective (i.e. non-inferiority of the response to the pertussis antigens). The power associated to the target sample size for the conclusion on the inferential primary objective of this study is detailed in the next section.

10.3.1. Control on type I error

A 2.5% nominal type I error will be used for each pertussis non-inferiority (NI) evaluation. Since NI has to be met simultaneously for the 3 pertussis antigens, the global type I error will be below 2.5%.

10.3.2. References for sample size

References were chosen based on observed standard deviations observed in studies Hib-MenCY-TT-005 (101858) and Hib-MenCY-TT-009 (103813) one month post-dose 3 from the subjects that receive *ActHIB* co-administered with *Pediarix* and *Prevnar*, and from study DTPa-HBV-IPV-027 (217744/027) one month post-dose 3 from the DTPa-HBV-IPV/Hib pooled groups. All these studies enrolled subjects in the US.

The standard deviation for $\log_{10}$ transformed concentrations post vaccination for pertussis antigens is presented in Table 16.

Table 16 Standard deviation for $\log_{10}$ transformed concentration post vaccination

Study	Antigen					
	PT		FHA		PRN	
	N	SD	N	SD	N	SD
Hib-MenCY-TT-005-US	215	0.274	213	0.312	217	0.392
Hib-MenCY-TT-009 – US cohort	100	0.258	97	0.252	101	0.482
DTPa-HBV-IPV-027-US	865	0.274	802	0.254	869	0.376
Reference taken		0.274		0.307		0.392

N: Number of subjects; SD: standard deviation

10.3.3. Power computation

Out of the 585 subjects enrolled, 65% (126 in each pooled group) are expected to be evaluable post-Dose 3.

The individual type II error for each pertussis antigen was obtained using PASS 2005, one-sided non-inferiority test for 2 means from normal data with common variance between groups, under the alternative of equal means and alpha=2.5% (Table 17).

To account for the multiplicity of comparisons, the global type II error was conservatively estimated as the sum of individual type II errors, ensuring a global power for the study of 94.02% as presented in Table 17.

Table 17 Power for pertussis NI post-Dose 3

Antigen	Margin	SD on $\log_{10}$ transformed titer	Type I error	N evaluable per pooled group	Type II error
PT	1.5	0.274	2.5%	126	0.08%
FHA	1.5	0.307	2.5%	126	0.48%
PRN	1.5	0.392	2.5%	126	5.42%
Global Power = 100-(0.08+0.48+5.42) % = 94.02%					

10.4. Study cohorts/ data sets to be analysed

Six cohorts are defined for the purpose of the analysis:

- Primary Total Vaccinated cohort
- Primary ATP cohort for analysis of safety
- Primary ATP cohort for analysis of immunogenicity
- Booster Total Vaccinated cohort
- Booster ATP cohort for analysis of safety
- Booster ATP cohort for analysis of immunogenicity

10.4.1. Primary Total vaccinated cohort

The Primary Total Vaccinated cohort (TVC) will include all vaccinated subjects for whom data are available.

- A safety analysis based on the Primary TVC will include all subjects with at least one vaccine administration documented.
- An immunogenicity analysis based on the Primary TVC will include all vaccinated subjects for whom data concerning at least one immunogenicity endpoint measure is available.

10.4.2. Primary ATP cohort for analysis of safety

The Primary ATP cohort for safety will consist of all subjects from the Primary TVC who complied with the protocol up to the end of Epoch 001, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received all planned study vaccines for each completed vaccination visit in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;
- who did not receive a product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2.

Note that for the purpose of ATP cohort definition, the Epoch 001 ends at Visit 4.

Adherence to the interval related to ESFU phone contact will not be taken into account for inclusion in ATP cohort for safety.

10.4.3. Primary ATP cohort for analysis of immunogenicity

The Primary ATP cohort for immunogenicity will consist of all subjects from the Primary ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 for the definition of the intervals) up to the post-dose 3 blood sample and had immunogenicity results for the post-dose 3 blood sample. The analysis will be performed per treatment (first dose) actually administered.

More specifically, the analysis post-dose 3 based on the ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 3 as per the vaccination schedule;
- for whom administration site and route of study vaccines up to dose 3 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2
- who did not present with a medical condition before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.8.
- who comply with the post-dose 3 blood sample schedule, i.e. 21-48 days post-dose 3.
- who were not administered a vaccine not foreseen by the study protocol before the corresponding post-vaccination blood sample.
- who have immunogenicity results post-dose 3.

10.4.4. Booster Total vaccinated cohort

The Booster TVC will include all subjects from primary TVC that received the booster vaccine dose.

- For the Booster-TVC analysis of safety, this will include all subjects with booster vaccine administration documented.
- For the Booster-TVC analysis of immunogenicity, this will include vaccinated subjects for whom data concerning immunogenicity endpoint measures are available.

10.4.5. Booster ATP cohort for analysis of safety

The Booster ATP cohort for safety will consist of all subjects from the Booster TVC who complied with the protocol up to the end of Epoch 002, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received the planned booster dose at 15-18 months of age;
- who received 3 doses in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;

- who did not receive a product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis as listed in Section 6.7.2.

10.4.6. Booster ATP cohort for analysis of immunogenicity

The Booster ATP cohort for immunogenicity will consist of all subjects from the Booster ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 for the definition of the intervals) up to the post-dose 4 blood sample and had immunogenicity results for the post-dose 4 blood sample.

More specifically, the analysis pre- and post-dose 4 based on the Booster ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 4 as per the vaccination schedule;
- for whom administration site and route of the study vaccines up to dose 4 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.7.2);
- who did not present with a medical condition before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.8);
- who comply with the booster vaccination schedule at 15-18 months of age and with the post-dose 4 blood sample schedule i.e. 21-48 days for post-dose 4;
- who have immunogenicity results post-dose 4.

10.5. Derived and transformed data

- A seronegative subject is a subject whose antibody concentration/titer is below the assay cut-off.
- A seropositive subject is a subject whose antibody concentration/titer is greater than or equal to the assay cut-off defined in Table 7.

  Note: Due to ongoing re-validation of all assays, these cut-offs may be subject to change.
- A seroprotected subject is a subject whose antibody concentration/titer is greater than or equal to the level defining clinical protection. The following seroprotection thresholds are applicable:
  - Anti-diphtheria antibody concentrations ≥ 0.1 IU/mL.
  - Anti-tetanus antibody concentrations ≥ 0.1 IU/mL.
  - Anti-HBs antibody concentrations ≥ 10 mIU/mL.
  - Anti-poliovirus types 1, 2 and 3 antibody titers ≥ 8.
  - Anti-PRP antibody concentrations ≥ 0.15 µg/mL.
- Other cut-offs to be considered:
  - Anti-PRP antibody concentrations ≥ 1.0 µg/mL.

- Anti-diphtheria and anti-tetanus antibody concentrations ≥ 1.0 IU/mL

- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies are defined as:
  - initially seronegative subjects (pre-booster antibody concentration below cut-off: < 5 ELISA EL.U/mL) with an increase of at least four times the cut-off one month after vaccination (post-booster antibody concentration ≥20 EL.U/mL), and
  - initially seropositive subjects with pre-booster antibody concentration ≥ 5 EL.U./mL and < 20 EL.U/mL with an increase of at least four times the pre-booster antibody concentration one month after vaccination, and,
  - For initially seropositive subjects with pre-booster antibody concentration ≥ 20 EL.U/mL with an increase of at least two times the pre-booster antibody concentration, one month after vaccination.

  Note: Due to ongoing re-validation of pertussis assays, the definition of booster responses may be subject to change.

- The GMC/GMT calculations will be performed by taking the anti-log of the mean of the $\log_{10}$ titer/ concentration transformations. Antibody titers/concentrations below the cut-off of the assay will be given an arbitrary value of half the cut-off for the purpose of GMC/GMT calculation.

Handling of missing data:

Immunogenicity:

- For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements will not be replaced.

Safety/reactogenicity:

- For a given subject and the analysis of solicited symptom within 4 days post-vaccination, 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 vaccinated subjects and doses with documented safety data (i.e. symptom screen completed).
- For analysis of unsolicited adverse events, such as serious adverse events or adverse events by primary MedDRA term, and for the analysis of concomitant medications, all vaccinated subjects will be considered. Subjects who did not report the event or the concomitant medication will be considered as subjects without the event or the concomitant medication respectively.
- For summaries reporting both solicited and unsolicited adverse events, all vaccinated subjects will be considered. Subjects for whom the event will not be reported will be considered as subjects without the event.

10.6. Final analysis of the Epoch 001

10.6.1. Analysis of demographics

Demographic characteristics (age [weeks], gender, geographical ancestry, height in length [cm], weight [kg] at first dose, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status will be summarised by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as center;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects enrolled among the study sites will be tabulated as a whole and per group.

10.6.2. Analysis of immunogenicity

The primary analysis will be based on the primary ATP cohort for immunogenicity. An analysis on the primary Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point, more than 5% of the vaccinated subjects with immunological data post-dose 3 are excluded from the primary ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

10.6.2.1. Within group assessment

For each group, one month post-dose 3 and for each assay for which a serological result is available:

- Seropositivity and seroprotection rates with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.
- For D,T and pertussis antigens, additional summaries will be provided according to the Tdap vaccination history of mother during pregnancy.

For each antigen, antibody concentration or titer distribution one month post-vaccination will be tabulated and displayed using reverse cumulative curves (RCCs).

10.6.2.2. Between group assessment

At one month post-dose 3,

- The asymptotic standardized 95% CI for the group difference in the seropositivity/ seroprotection rates will be computed for each antigen.
- The 95% CI for each group GMC/GMT ratio will be computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of

Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis b at birth vaccine dose status will also be used as regressor.

10.6.2.3. Interpretation of analyses

Except for analyses addressing criteria specified in the primary objective, comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

10.6.3. Analysis of safety

The primary analysis will be based on the primary Total Vaccinated cohort. If, in any vaccine group and at any time point of the Epoch 001, the percentage of vaccinated subjects excluded from the primary ATP cohort for safety is more than 5%, a second analysis based on the primary ATP cohort for safety will be performed to complement the primary Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period will be tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period will be tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses with local AEs (solicited and unsolicited) will be calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered).
- The percentage of subjects/doses reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

  The exact 95% CIs will be calculated assuming independence between doses.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit.

- For fever, analyses will be performed by 0.5°C increments.
- The percentage of subjects/doses with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated after each dose and over the Epoch 001.
- The verbatim reports of unsolicited AEs will be reviewed by a clinical development manager and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE reported before the database lock for the Epoch 001 analysis with an onset date in the Epoch 001 will be reported and the SAE will be described in detail.

10.7. Final analysis of the Epoch 002

10.7.1. Analysis of demographics/baseline characteristics

Demographic characteristics (age in months at Visit 5) and withdrawal status will be summarized by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as race/ethnicity;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects vaccinated at Visit 5 among the study sites will be tabulated as a whole and per group.

For enrolled subjects that do not participate in the Epoch 002, the reason for not participating will be summarized.

10.7.2. Analysis of immunogenicity

The primary analysis will be based on the booster ATP cohort for immunogenicity. An analysis on the booster Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point of the Epoch 002, more than 5% of the vaccinated subjects with immunological data are excluded from the booster ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

10.7.2.1. Within group assessment

For each group, prior to the booster dose and one month post-booster dose and for each assay for which a serological result is available:

- Seropositivity and seroprotection rates and booster response rates for pertussis with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.

For D,T and pertussis antigens, additional summaries will be provided according to the Tdap vaccination history of mother during pregnancy.

For each antigen, antibody concentration or titer distribution before and one month Post-booster (when available) will be tabulated and displayed using RCCs.

10.7.2.2. Between group assessment

At pre-booster and at one month post-booster,

- The asymptotic standardized 95% CI for the group difference in the seroprotection/ seropositivity rates will be computed for each antigen.
- The 95% CI for each group GMC/GMT ratio will be computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor.

10.7.2.3. Interpretation of analyses

In Epoch 002, all comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

10.7.3. Analysis of safety

The primary analysis for the Epoch 002 will be based on the booster Total Vaccinated cohort and will only look at the booster dose. If, in any vaccine group, the percentage of vaccinated subjects excluded from the booster ATP cohort for safety is more than 5%, a second analysis based on the booster ATP cohort for safety will be performed to complement the booster Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose, will be tabulated with exact 95% CI for each group.

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- The incidence of local AEs (solicited and unsolicited) will be calculated at each injection site as well as overall (all sites considered) for each group.
- The percentage of subjects reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated with its exact 95% CI for each group.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit.
- For fever, analyses will be performed by 0.5°C increments.
- The percentage of subjects with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated for each group.
- The verbatim reports of unsolicited AEs will be reviewed by a clinical development manager and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects with unsolicited AEs occurring within 31 days following the booster dose with its exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Additionally,

- Any large injection site reaction (defined as a swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase in limb circumference) reported within 4 days (Days 0-3) following the booster dose will be described in detail.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from booster dose up to one month after booster vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE from the booster dose to study end will be reported and the SAEs will be described in detail.

10.8. Statistical methods

- The exact CIs for a proportion within a group will be calculated from Proc StatXact [Clopper, 1934].
- The standardized asymptotic CI for the group difference in proportion is the method implemented in Proc StatXact 7.0. It corresponds to method 6 in the Newcombe paper [Newcombe, 1998].
- The CI for GMTs/GMCs will be obtained within each group separately. The 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 CI for

the GMTs/GMCs will then be obtained by exponential-transformation of the CI for the mean of log-transformed titer/concentration.

- The GMT/GMC group ratio will be obtained using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B status at birth vaccine dose will also be used as regressor. The GMC/GMT group ratio and its CI will be derived as exponential-transformation of the corresponding group contrast in the model.

10.9. 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.

10.9.1. Sequence of analyses

(Amendment 2: 17 April 2015)

The analyses will be performed ***stepwise***:

1. ***A partial analysis of Epoch 001 up to one month after the third primary vaccine dose will be conducted. This analysis will include the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis will be displayed on GSK clinical trial registry as soon as possible.***
2. ***The final data analysis of the study covering both the epochs will be conducted at the end of the study. All these analyses will be presented in a final clinical study report.***

10.9.2. Statistical considerations for interim analyses

All analyses will be conducted on final data and therefore no statistical adjustment for interim analyses is required.

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. Remote Data Entry instructions

RDE, a validated computer application, will be used as the method for data collection.

In all cases, subject initials will not be collected nor transmitted to GSK. Subject 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 GSK Biologicals' 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.

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.

11.2. Study Monitoring by GSK Biologicals

GSK will monitor the study to verify that, amongst others, the:

- Data are authentic, accurate, and complete.
- Safety and rights of subjects are being protected.
- Study is conducted in accordance with the currently approved protocol, 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.

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 a RDE review and a Source Document Verification (SDV). By SDV we understand verifying RDE 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 RDE. 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 RDE will serve as the source must be identified, agreed and documented in the source documentation agreement form.

For RDE, the monitor will mark completed and approved screens at each visit.

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.

11.3. Record retention

Following closure of the study, the investigator must maintain all site study records (except for those required by local regulations to be maintained elsewhere) in a safe and secure location. The records must be easily accessible, when needed (e.g. audit or inspection), and must be available for review 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); however, caution needs to be exercised before such action is taken. The investigator must ensure 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 that an acceptable back-up of the reproductions exists and that there is an acceptable quality control procedure in place 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 a particular site, as dictated by ICH GCP, any institutional requirements, 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 archival at an off-site facility, transfer of ownership of the records in the event the investigator leaves the site.

11.4. Quality assurance

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 publicly available clinical trial registers and publication policy

Study information from this protocol will be posted on publicly available clinical trial registers before enrolment of subjects begins.

Summaries of the results of GSK interventional studies (phase I-IV) are posted on publicly available results registers within 12 months of the primary completion date for studies of authorized vaccines and 18 months for studies of non-authorized vaccines.

GSK also aims to publish the results of these studies in the searchable, peer reviewed scientific literature. Manuscripts are submitted for publication within 24 months of the last subject's last visit.

11.6. Provision of study results to investigators

Where required by applicable regulatory requirements, an investigator signatory will be identified for the approval of the 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 Biologicals 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 subjects, as appropriate.

12. COUNTRY SPECIFIC REQUIREMENTS

Not applicable.

13. REFERENCES

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APPENDIX A CLINICAL LABORATORIES

Table 18 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

Table 19 Outsourced laboratories

Laboratory	Address
Quest Diagnostics Clinical Trials (US)	27027 Tourney Road, Suite 2E Valencia, CA 91355 USA
Quest Diagnostics Clinical Trials (Biomarkers)	27027 Tourney Road, Suite 2E Valencia, CA 91355 USA
Quest Diagnostics Nichols Institute	33608 Ortega Highway San Juan Capistrano, CA 92675-2042 USA
Quest Diagnostics, Inc.	1 Malcolm Way Teterboro, NJ 07608 USA
Quest Diagnostics Nichols Institute	14225 Newbrook Drive Chantilly, VA 20153 USA

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APPENDIX B AMENDMENTS AND ADMINISTRATIVE CHANGES TO THE PROTOCOL

GlaxoSmithKline Biologicals

Clinical Research & Development

Protocol Amendment 1

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number	2013-004304-19
Amendment number:	Amendment 1
Amendment date:	Final: 18 September 2014
Co-ordinating author:	PPD Scientific Writer

Rationale/background for changes:

- Clarification has been provided that large injection site reactions and measurement of the injected limb should be collected as a solicited symptom. Specific instructions regarding measurement of limb circumference and clinical details of large injection site reactions have been added.
- Additional minor clarifications of study procedures and data analyses have been made throughout the document.
- Instructions regarding interval between preparation and administration of vaccine has been aligned with the stability data described in the current Investigator Brochure.
- Due to ongoing re-validation of serological assays for antibodies to diphtheria and tetanus toxoids, pertussis antigens, poliovirus, hepatitis B surface antigen and polyribosyl ribitol phosphate, the cut-offs for these assays could potentially change and hence a note has been added in the protocol regarding this. The definition of booster response to pertussis antigens could also potentially be revised.
- Sequence of reporting the results has been clarified.
- The contributing authors and sponsor signatory were updated to reflect changes in the study team.

Amended text has been included in *bold italics* and deleted text in ~~strikethrough~~ in the following sections:

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Primary study vaccine and number	GlaxoSmithKline (GSK) Biologicals' Combined Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, Poliovirus and *Haemophilus influenzae* type b vaccine (DTPa-HBV-IPV/Hib) (~~GSK~~ ***SB***217744, *Infanrix hexa*™).
Section 1.2.1 Rationale for the study More than ~~73~~ ***100*** million doses have been distributed to date and the benefit/risk profile remains favorable.	

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Section 5.5 Outline of study procedures

Table 4 List of study procedures

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Informed consent	●						
Check inclusion/exclusion criteria	●						
Medical history	●						
Collect demography data	●						
Vaccination history including HepB vaccination history	●						
Informed consent for Tdap vaccination history of mother[α]	●						
Last Tdap vaccination history of mother[β]	●						
History directed physical examination including length and weight	●					●	
Study group and treatment number allocation (Randomization)	O						
Treatment number allocation for subsequent doses		O	O			O	
Recording of administered treatment number	●	●	●			●	
Pre-vaccination body temperature	●	●	●			●	
Blood sampling				●		●	●
Check warnings and precautions	O	O	O			O	
Check contraindications to subsequent vaccination		●	●			●	
Pre-vaccination measurement of limb length and circumference of limb(s) at site of injection by investigator[δ]						●	
Vaccination	●	● **	●			●	
Distribution of thermometer	O						
Distribution of measuring device	O					O	
Distribution of diary cards	O	O	O			O	

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	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Daily post-vaccination recording of solicited adverse events during the 4-day (Day 0–3) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of non-serious (unsolicited) adverse events during the 31-day (Day 0–30) follow-up period, recorded by the subjects' parent(s)/LAR(s) in diary card	●	●	●			●	
Recording of any large injection site reactions in the eCRF by the investigator*						●	
Return of diary cards and transcription by the investigator		●	●	●			●
Record any concomitant medication and vaccination §	●	●	●	●	●	●	●
Record any intercurrent medical conditions‖		●	●	●	●	●	●
Recording of serious adverse events including related to study participation	●	●					
Investigator sign-off					●		O
Analysis of the Epoch 001 #				O	O		
Analysis of the Epoch 002 #							O
Study Conclusion							●

α Child can still continue in the study if the mother does not wish to provide consent to record her Tdap vaccination history.

β Only the Tdap vaccination history (during the pregnancy of the enrolled child) from mothers who have given consent to provide this information will be obtained and recorded in the eCRF..

δ For the Penta group, which receives only one vaccine at Visit 5, baseline measurement of only the limb receiving the vaccine is required

* Refer to Section 8.1.3.1 ***and 5.6.2.9*** for detailed explanation on the reporting of large injection site reaction

Section 5.6.2.4 Vaccination history

The Tdap vaccination history of the mother during pregnancy will also be collected and recorded in the eCRF ***(provided that the mother has consented to provide this information).***

Note: Maternal vaccination is requested in order to be able to summarize the responses of the subjects to pertussis antigens according to whether or not the mothers received a pertussis vaccine during their pregnancy. This information will aid in understanding the effect of transplacentally transferred antibodies on the childs' immune response to vaccination.

Section 5.6.2.9.1 Blood sampling for immune response assessments

- A volume of approximately 5.0 mL of whole blood ~~(~~to provide approximately 1.7 mL of serum~~)~~ should be drawn from all subjects for the analysis of humoral immune response at Visits 4 and 5. At least 3.5 mL of whole blood ~~(~~to provide ~~atleast~~ ***approximately*** 1.2 mL of serum~~)~~ should be drawn from all subjects for the analysis of humoral immune response at Visit 6. After centrifugation, serum samples should be kept at –20°C/ –4°F or below until shipment. Refer to the SPM for more details on sample storage conditions.

Section 5.6.2.11 Baseline measurement of limb length and circumference after booster vaccination at visit 5

During Epoch 002, baseline measurement of length of limb(s) and circumference (arms or legs according to where the vaccine was administered) at the level of the injection site should be obtained. For the Penta group, baseline measurement is only required for the limb that will be vaccinated. Clothing should be removed so as not to interfere with the measurement of the length of the limb and the circumference. Upper arm length will be determined from the acromion process of the scapula to the tip of the elbow and thigh length will be determined from the midpoint of the abdomen thigh flexure crease and the proximal end of the patella. For measuring upper arm circumference, the measurement will be performed while the arm is held parallel to the trunk and the elbow is flexed in front at 90° (as if the subject is carrying a tray) [Kohl, 2007]. For measuring leg circumference the child should be standing or lying flat, as appropriate, as long as the leg is straight.

Section 5.6.2.13 Recording of AEs, SAEs and NOCDs

- ***During Epoch 002, following the fourth dose vaccination, the parents/LAR(s) should be provided with a measurement device for recording circumference of injected limbs (arms or legs according to where vaccine was administered) at the level of the injection site on the day of vaccination and during the next three days on a diary card. The parents/LAR(s) should be instructed on how and where to perform the measurement of the circumference of the vaccinated limb. Daily measurements should be performed in the same manner preferably by the same person and at the same time of day during the 4-day follow-up (Day 0-Day3) period.***
- ~~During Epoch 002, i~~***If*** the parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of ~~arm~~ ***limb*** circumference) during the 4-day follow-up (Day 0-Day 3) period, they ~~will be asked~~ ***are*** to contact study personnel and to visit the investigator's office for evaluation as soon as possible ***and to bring the diary card with them.*** ~~. The investigator will record detailed information describing the AE on a specific large injection site reaction in the eCRF.~~
- ***In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms, the parents(s)/LAR(s) will record the following additional symptoms/characteristics that may be associated with large injection site swelling reactions on the diary card:***
  - ***Type of swelling (local swelling only around the injection site, diffuse swelling not involving the elbow or knee joint, swelling involving the elbow or knee joint)***
  - ***Whether or not the diameter of the swelling involves more than 50% of the limb (baseline measurement of the length of the limb taken by study personnel at the vaccination visit will be provided on the diary cards)***
  - ***Induration at injection site (largest diameter)***
  - ***Pruritis at the injection site (intensity – scale provided)***
  - ***Functional impairment (intensity – scale and description provided)***
- ***The study personnel's evaluation will be recorded in the medical chart. In case the diary card score is not in line with the medical chart score, the medical chart will indicate what is the most intense score. The largest or most intense score for a given day will be recorded in the eCRF at the level of the solicited symptoms and at the level of the large swelling report form.***

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Section 5.7.3 Laboratory assays

At Visits 4, 5 and 6, blood will be collected for measurement of immune response. Total blood volume to be taken from each subject over the study period is approximately 13.5 mL (approximately 5.0 mL of whole blood ***to provide approximately 1.7 mL of serum*** at Visits 4 and 5 and at least 3.5 mL of whole blood ***to provide approximately 1.2 mL of serum*** at Visit 6).

Table 7 Humoral Immunity (Antibody determination)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off†	Laboratory**
Serum	Bordetella pertussis.Pertussis Toxin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Filamentous Hemaglutinin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Bordetella pertussis.Pertactin Ab.IgG	ELISA	In-house*	EL.U/mL	5	GSK Biologicals§
Serum	Corynebacterium diphtheriae.Diphtheria Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Clostridium tetani.Tetanus Toxoid Ab.IgG	ELISA	In-house*	IU/mL	0.1	GSK Biologicals§
Serum	Hepatitis B Virus.Surface Ab	CLIA	Centaur (Siemens Healthcare)	mIU/mL	6.2	GSK Biologicals§
Serum	Poliovirus Sabin Types 1, 2 and 3	NEUTRA	In-house*	ED50	8	GSK Biologicals§
Serum	Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab	ELISA	In-house*	µg/mL	0.15	GSK Biologicals§

*In-house refers to ***assays developed internally by GSK which can be performed at*** GSK Biologicals' laboratories or ***external*** laboratory designated by GSK
**Refer to APPENDIX A for the laboratory addresses.
§GSK Biologicals laboratory refers to the Global Vaccines Clinical Laboratories (GVCL) in Rixensart, Belgium; Wavre,
†Due to ongoing re-validation of all assays, the cut-offs may be subject to change.
Belgium ***and*** Laval, Canada.

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Section 6.1 Description of study vaccines

Table 9 Study vaccines

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Pentacel	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial	0.5 mL*	4
	~~ActHIB~~ ***Hib***	~~Hib=10µg TT, TT=24µg~~ ***PRP=10µG; TT~=25µG***	~~White lyophilized pellet in a single dose vial, it must be reconstituted before use with the liquid DTaP- IPV component.~~ ***The lyophilized Hib component is presented as a white pellet in a glass vial; it must be reconstituted with the liquid DTaP-IPV component before use***		

Section 6.3 Dosage and administration of study vaccines

NOTE: After reconstitution, *Infanrix hexa* should be ~~administered promptly or stored refrigerated between 2° and 8°C and administered within 24 hours. If the vaccine is not administered promptly, shake the solution vigorously again before injection~~ ***injected immediately. However the vaccine may be kept for up to 8 hours at room temperature (21°C).***

Section 6.7.1 Recording of concomitant medications/products and concomitant vaccination

- Any concomitant vaccination administered ***since birth*** ~~in the period starting 30 days before the first dose of the study vaccine~~ and ending 30 days after the booster dose (Visit 6). ~~Notes: 1).~~ Vaccinations listed prior to the first dose of study vaccine are to be recorded as vaccination history. ~~2)~~ The fourth dose of *Prevnar 13* will be recorded as concomitant vaccination.

  * ***Refer to those*** SAEs that are required to be reported per protocol.

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Section 8.1.3.1 Solicited local (injection-site) adverse events

Table 11 Solicited local adverse events

Pain at injection site
Redness at injection site
Swelling at injection site
Post-dose 4 measurements of circumference of limbs (arm or leg according to where vaccine was administered)

N.B. If parent(s) /LAR(s) of infants observe any large injection site reaction (defined as swelling with a diameter > 50 mm, noticeable diffuse swelling or noticeable increase of ~~arm~~ ***limb*** circumference) after the booster dose at Visit 5, they ~~will be asked~~ ***are*** to contact study personnel and to visit the investigator's office for evaluation as soon as possible ***and bring the diary card with them***. The investigator will record detailed information describing the AE on a specific large injection site reaction ***form*** in the eCRF. ***In addition to the diameter of the swelling and the circumference of the limb that are reported as solicited symptoms the parent(s)/LAR(s) will need to record additional symptoms/characteristics as mentioned in Section 5.6.2.13.***

Note: local AEs will not be ~~collected~~ ***solicited*** for co-administered vaccines like *Prevnar 13* ~~and *Rotarix*~~.

Section 8.3.1 Time period for detecting and recording adverse events and serious adverse events

Note: With the exception of AEs/SAEs leading to withdrawal, study participation and concurrent GSK medications or vaccines, there is no reporting of SAEs from the time of the Epoch 1 ESFU phone contact and administration of dose 4 (approximately three months).

Section 8.3.3.2.1 Assessment of intensity

Table 14 Intensity scales for solicited symptoms in infants/toddlers

Infant/Toddler (15–24 months)		
Adverse Event	**Intensity grade**	**Parameter**
Pain at injection site	0	None
	1	Mild: Minor reaction to touch
	2	Moderate: Cries/protests on touch
	3	Severe: Cries when limb is moved/spontaneously painful
Redness at injection site		Record greatest surface diameter in mm
Swelling at injection site		Record greatest surface diameter in mm
Increase in limb circumference post-dose 4 (arm or leg according to where vaccine was administered)		***Record the limb circumference at the level of the injection site***

The maximum intensity of fever ~~was~~ ***will be*** scored at GSK Biologicals as follows:

0	=	***<100.4°F***	***<38.0°C***
1	=	***≥100.4°F to ≤102.2°F***	***≥38.0°C to ≤39.0°C***
2	=	***>102.2°F to ≤104.0°F***	***>39.0°C to ≤40.0°C***
3	=	***> 104.0°F***	***> 40.0°C***

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Prior to analysis, the increase in limb circumference of each limb as compared to the baseline pre-vaccination measurement will be scored for each subject at GSK Biologicals' as follows:

Grade 0 = Increase in limb circumference ≤5 mm
1 = Increase in limb circumference >5 mm but ≤20 mm
2 = Increase in limb circumference >20 mm but ≤40 mm
3 = Increase in limb circumference >40 mm

For unsolicited symptoms and adverse events associated with large injection site reactions (e.g. pruritus, induration and functional impairment, t~~T~~he intensity should be assigned to one of the following categories:

Section 10.4.2 Primary ATP cohort for analysis of safety

- who have received all ***planned*** study vaccines ~~as planned~~ ***for each completed vaccination visit in*** ~~up to the end of~~ Epoch 001;

Section 10.4.5 Booster ATP cohort for analysis of safety

- who have received the ***planned*** booster dose at 15-18 months of age;

Section 10.5 Derived and transformed data

- A seropositive subject is a subject whose antibody concentration/titer is greater than or equal to the assay cut-off defined in Table 7.
  Note: Due to ongoing re-validation of all assays, these cut-offs may be subject to change.
- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies are defined as:
  – For initially seropositive subjects with pre-booster antibody concentration ≥ 20 EL.U/mL with an increase of at least two times the pre-booster antibody concentration, one month after vaccination.

  Note: Due to ongoing re-validation of pertussis assays, the definition of booster responses may be subject to change.

Section 10.6.2.2 Between group assessment

- The 95% CI for each group GMC/GMT ratio will be computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect ***and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model***.. For hepatitis B antigen, the hepatitis b at birth vaccine dose status will also be used as regressor ~~leading to an Analysis of Co-variance (ANCOVA) model~~.

Section 10.7.2.2 Between group assessments

- The 95% CI for each group GMC/GMT ratio will be computed using an ANOVA model on the logarithm-transformed concentrations/titers. The ANOVA model will include the vaccine group as fixed effect ***and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model***. For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor ~~leading to an ANCOVA model.~~

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Section 10.8 Statistical methods

- The GMT/GMC group ratio will be obtained using an ANOVA model on the logarithm-transformed concentrations/titers. ***The ANOVA model will include the vaccine group as fixed effect and the DTP vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model.*** For hepatitis B antigen, the hepatitis B status at birth vaccine dose will also be used as regressor ~~leading to an Analysis of Co-variance (ANCOVA) model~~.

Section 10.9.1 Sequence of analyses

1. The final data analysis of Epoch 001 including all as clean as possible data, up to one month after the third primary vaccine dose, and some partial data from the ESFU contact will be conducted as soon as possible. This analysis will include the final analysis of immunogenicity and the final analysis of solicited symptoms for the primary vaccination course. ~~All analyses will be presented in Clinical Study Report (CSR). The CSR will be shared with the investigators.~~

2. All these analyses will be presented in a~~n Epoch 002 specific~~ ***final*** CSR. ~~The final CSR will be shared with the investigators.~~

Section 13 References

Kohl KS, Walop W, Gidudu J, et al. Swelling at or near injection site: case definition and guidelines for collection, analysis and presentation of immunization safety data. Vaccine. 2007; 25(31):5858-74.

Appendix A Clinical laboratories

Table 19 Outsourced laboratories

Laboratory	Address
~~BARC USA Inc~~	~~5, Delaware Drive~~ ~~Lake Success~~ ~~NY 11042-1114~~ ~~USA~~

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GlaxoSmithKline Biologicals

Clinical Research & Development

Protocol Amendment 2

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number	2013-004304-19
Amendment number:	Amendment 2
Amendment date:	Final Version 02: 17 April 2015
Co-ordinating author:	PPD Scientific Writer

Rationale/background for changes:
The amendment 2 has been implemented to amend the following sections of the protocol:

- The assay for testing antibodies against polyribosyl ribitol phosphate (anti-PRP) has been re-developed but is not yet qualified or validated for testing the one month post dose-3 samples. This has been clarified in the protocol in Table 7 Humoral immunity (antibody determination) and Section 5.7.3 Laboratory assays.
- Investigator sign-off on the patient identification (PIDS) will be done after Visit 4 instead of extended safety follow-up (ESFU). In Table 4 List of study procedures, the bullets pertaining to investigator sign-off and analysis of Epoch 001 has been removed from the ESFU visit and retained at Visit 4 to reflect this change.
- The collection of baseline measurement of limb length has been removed since it will not be used in analysis; only limb circumference will be used in analysis. Accordingly, text related to this has been amended in Table 4 List of study procedures, Sections 5.6.2.11, Baseline measurement of limb circumference after booster vaccination at visit 5 and 5.6.2.13 Recording of AEs, SAEs and NOCDs.
- Errors in the vaccines dictionary of Study Master Repository (SMR) have been rectified for *Infanrix hexa*, *Pediarix* and *Pentacel* vaccines. The corresponding correction has been made in Table 9 Study vaccines.
- The sequence of analysis in Section 10.9.1 Sequence of analyses, has been amended to reflect that there will first be an analysis of immunogencity for anti-PRP and safety for Epoch 001, followed by a final analysis covering both Epochs at the end of the study.

Amended text has been included in *bold italics* and deleted text in ~~strikethrough~~ in the following sections:

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Section 5.5 Outline of study procedures:
Table 4 List of study procedures

	EPOCH 001 (PRIMARY VACCINATION)					EPOCH 002 (BOOSTER VACCINATION)	
Age	**2 MONTHS**	**4 MONTHS**	**6 MONTHS**	**7 MONTHS**	**12 MONTHS**	**15-18 MONTHS**	**16-19 MONTHS**
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3 †**	**VISIT 4**	**ESFU CONTACT (PHONE)**	**VISIT 5**	**VISIT 6**
Time point	**Day 0**	**Month 2**	**Month 4**	**Month 5**	**Month 10**	**Month 13 -16**	**Month 14 - 17**
Sampling time point				**Post-Pri**		**Pre-Bst**	**Post-Bst**
Pre-vaccination measurement of ~~limb length and~~ circumference of limb(s) at site of injection by investigator[δ]						●	
Investigator sign-off				●	~~●~~		●
Analysis of the Epoch 001 #				O	~~O~~		

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In Section 5.6.2.11 Baseline measurement of limb circumference after booster vaccination at visit 5

In Section 5.6.2.11 Baseline measurement of limb ~~length and~~ circumference after booster vaccination at visit 5

During Epoch 002, baseline measurement of ~~length of~~ limb~~(s) and~~ circumference (arms or legs according to where the vaccine was administered) at the level of the injection site should be obtained. For the Penta group, baseline measurement is only required for the limb that will be vaccinated. Clothing should be removed so as not to interfere with the measurement of the ~~length of the~~ limb ~~and the~~ circumference. ~~Upper arm length will be determined from the acromion process of the scapula to the tip of the elbow and thigh length will be determined from the midpoint of the abdomen thigh flexure crease and the proximal end of the patella.~~

In Section 5.6.2.13 Recording of AEs, SAEs and NOCDs:

- ~~Whether or not the diameter of the swelling involves more than 50% of the limb (baseline measurement of the length of the limb taken by study personnel at the vaccination visit will be provided on the diary cards).~~

In Section 5.7.3 Laboratory assays

All serology will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized ~~validated~~ procedures with adequate controls. ***All serology for primary endpoints will be determined in GSK Biologicals' laboratories, or in a laboratory designated by GSK, using standardized, validated procedures with adequate controls.***

Table 7 Humoral immunity (antibody determination)

System	Component	Method	Test kit/ Manufacturer	Unit	Cut-off†	Laboratory**
Serum	Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab ‡	**ELISA**	**In-house***	**µg/mL**	**0.15**	**GSK Biologicals§**

‡For anti-PRP post-dose 3, the assay is not yet qualified or validated.

Section 6.1 Description of study vaccines

Table 9 Study vaccines

Treatment name	Vaccine/ Product name	Formulation	Presentation	Volume	Number of doses
Infanrix hexa	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=***32DU***; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	full volume^	3
Pediarix	DTPa-HBV-IPV	DT>=30IU; TT>=40IU; PT=25µg; FHA=25µg; PRN=8µg; HBsAg=10µg; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=***32DU***; Aluminium=700µg Al3+	The DTPa-HBV-IPV component is presented as a turbid white suspension in a pre-filled syringe.	0.5 mL	3
Pentacel	DTaP-IPV (Sanofi Pasteur)	PT=20µg; FHA=20µg; FIM=5µg; PRN=3µg; DT=15Lf; TT=5Lf; Inactivated Poliovirus type 1 (Mahoney strain)=40DU; Inactivated Poliovirus type 2 (MEF-1 strain)=8DU; Inactivated Poliovirus type 3 (Saukett strain)=32DU; PRP=10µg TT,TT=24µg; $AlPO_4$=330µg Al3+	Suspension for injection (0.5-mL dose) supplied as a liquid vaccine component in a single dose vial***. The lyophilized Hib component is presented as a white pellet in a separate glass vial. It must be reconstituted with the liquid DTaP-IPV component before use.***	0.5 mL*	4
	~~Hib~~	~~PRP=10µG; TT~=25µG~~			

Section 10.9.1 Sequence of analyses

The analyses will be performed ***stepwise*** ~~in 2 steps~~:

~~**1.** The final data analysis of Epoch 001 including all as clean as possible data, up to one month after the third primary vaccine dose, and some partial data from the ESFU contact will be conducted as soon as possible. This analysis will include the final analysis of immunogenicity and the final analysis of solicited symptoms for the primary vaccination course.~~ ***A partial analysis of Epoch 001 up to one month after the third primary vaccine dose will be conducted. This analysis will include the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis will be displayed on GSK clinical trial registry as soon as possible.***

2. ~~The final data analysis of Epoch 002 will be conducted subsequently. This analysis will include final analysis of the ESFU from Epoch 001 and the final analysis of immunogenicity and safety from Epoch 002. All these analyses will be presented in a final CSR~~. ***The final data analysis of the study covering both the epochs will be conducted at the end of the study. All these analyses will be presented in a final clinical study report.***

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Protocol Sponsor Signatory Approval

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol	Final Version 01: 18 October 2013
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Sponsor signatory	Jacqueline Miller, MD, Senior Director and Head, Portfolio Head CRDL, DTP/Polio/Meningococcal/Rotavirus/ Travellers' Vaccines Late Clinical Development, Vaccine Discovery and Development, GlaxoSmithKline Biologicals.
Signature	PPD
Date	29 October 2013

For internal use only

- ----------Checksum----------!Ver.!Created On - -
9ec4fb051440e8a47d4c37738037a452e6ff4873 2.0 10/29/2013 5:50:54 AM - -
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117119 (DTPA-HBV-IPV-135)
Protocol Amendment 1 Final

Protocol Amendment 1 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 1 Final: 18 September 2014
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Sponsor signatory	Narcisa Elena Mesaros Project level CRDL, DTP/Polio Vaccines Late Clinical Development, Vaccine Discovery and Development, GlaxoSmithKline Biologicals.
Signature	PPD
Date	10-Oct-2014

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Protocol Amendment 2 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
IND number	BB-IND 006687
EudraCT number:	2013-004304-19
Date of protocol amendment	Amendment 2 Final Version 02: 17 April 2015
Detailed Title	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.
Sponsor signatory	Narcisa Elena Mesaros Project level CRDL, DTP/Polio Vaccines Late Clinical Development, Vaccine Discovery and PPD ent, GlaxoSmithKline Biologicals.
Signature	PPD
Date	6.04.2015

For internal use only

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Sample Case Report Form

Annotated Study Book for Study Design: DTPA-HBV-IPV-135 (117119)

Study Design Version: 1.0

Sponsor: GlaxoSmithKline Vaccines

Protocol: DTPA-HBV-IPV-135 (117119)

Generic Drug Name: DTPA-HBV-IPV Vaccine

Trade Drug Name: Infanrix Hexa

A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age.

Generated by Central Designer ™

June 8, 2015 1:31

PPD

DTPA-HBV-IPV-135 (117119): SCREENING (Screening)		
SCREENING		
1.* ✔	Please tick box to confirm CRF creation:	**[CRF_FLG]** *[A:Y]* ☐

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): ENROLLMENT (Enrollment)		
ENROLLMENT		
1.* ✔	Subject Number: [Subj Nr]	**[PID]** N9

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SUBJECT IDENTIFICATION (Subj ID)		
SUBJECT IDENTIFICATION		
1.* ✔	Subject Number: [Subj Nr]	**[PID]** N9

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): DEMOGRAPHICS (Demog)

DEMOGRAPHICS

1.* ✔	Date of birth: [DOB]	**[DOB_RAW]** Req/Unk / Req/Unk / Req (2013-2018)
2.* ✔	Gender: [Gender]	**[SEX]** *[A:M]* Male *[A:F]* Female
3.* ✔	Ethnicity: [Ethnicity]	**[ETHNIC]** *[A:1]* American Hispanic or Latino *[A:2]* Not American Hispanic or Latino
4.* ✔	Geographic Ancestry: [Geographic Ancestry]	**[RACE]** *[A:1]* African Heritage / African American *[A:2]* American Indian or Alaskan Native *[A:3]* Asian - Central/South Asian Heritage *[A:4]* Asian - East Asian Heritage *[A:5]* Asian - Japanese Heritage *[A:6]* Asian - South East Asian Heritage *[A:7]* Native Hawaiian or Other Pacific Islander *[A:8]* White - Arabic / North African Heritage *[A:9]* White - Caucasian / European Heritage *[A:99]* **[RACE_OTH]** Other, Specify: A40
5.* ✔	Please specify subject group: [Please specify subject group:]	**[SUBSET]** *[A:1]* HEXA GROUP *[A:2]* PEDIA GROUP *[A:3]* PENTA GROUP

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

PPD

DTPA-HBV-IPV-135 (117119): INFORMED CONSENT (IC)		
DATE OF VISIT		
1.* ✔	Date of visit: [DOV]	**[ACTRDATE]** Req / Req / Req (2013-2018)
INFORMED CONSENT		
I certify that Informed Consent has been obtained prior to any study procedure.		
2.* ✔	Informed Consent Date: [IC date]	**[CONS_DAT]** Req / Req / Req (2013-2018)
3.* ✔	Did the subjects' parent(s)/Legally Acceptable Representative(s) agree that subjects' biological sample(s) may be used by GSK Biologicals for future research? (Type 4 tests) [Did the subject's parent(s)/Legally Acceptable Representative(s) agree that subject's biological sample(s) may be used by GSK Biologicals for future research? (Type 4 tests)]	**[CONS_LAB_Q4]** *[A:Y]* ◯ Yes *[A:N]* ◯ No *[A:NA]* ◯ Not applicable

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

PPD

DTPA-HBV-IPV-135 (117119): GENERAL MEDICAL HISTORY / EXAMINATION (Gen med hist)

GENERAL MEDICAL HISTORY / EXAMINATION

1.* ✔	Are you aware of any pre-existing conditions, signs or symptoms having started before first study vaccination? [Are you aware of any pre-existing conditions, signs or symptoms having started before first study vaccination?]	**[MED_COND]** *[A:N]* ◯ No *[A:Y]* ◯ Yes -> Please give diagnosis and tick appropriate Past/Current box in the table below

	MedDRA SYSTEM ORGAN CLASS	Diagnosis	Past / Current?
2. ✔			

DIAGNOSIS Entry

Please report medication(s) as specified in the protocol and fill in the medication section.

2.1* ✔	MedDRA SYSTEM ORGAN CLASS: [MedDRA SYSTEM ORGAN CLASS]	**[DIAGTERM]** **[MEDHIST]**
2.2* ✔	Diagnosis: [Diagnosis]	**[DIAGNOSI]** A80
2.3* ✔	Past / Current? [Past / Current?]	**[DIAGSTAT]** *[A:P]* ◯ Past *[A:C]* ◯ Current

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: GENERAL MEDICAL HISTORY / EXAMINATION

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
MEDHIST	String	Skin and subcutaneous tissue	1	SKINANDSUBCUTANEOUSTISSUE	DIAGTERM
		Musculoskeletal and connective tissue	2	MUSCULOSKELETALANDCONNECTIVETISSUE	
		Cardiac	3	CARDIAC	
		Vascular	4	VASCULAR	
		Respiratory, thoracic and mediastinal	5	RESPIRATORYTHORACICANDMEDIASTINAL	
		Gastrointestinal	6	GASTROINTESTINAL	
		Hepatobiliary	7	HEPATOBILIARY	
		Renal and urinary	8	RENALANDURINARY	
		Nervous system	9	NERVOUSSYSTEM	
		Eye	10	EYE	
		Ear and labyrinth	11	EARANDLABYRINTH	
		Endocrine	12	ENDOCRINE	

PPD

		Metabolism and nutrition	13	METABOLISMANDNUTRITION	
		Blood and lymphatic system	14	BLOODLYMPHATICSYSTEM	
		Immune system	15	IMMUNESYSTEM	
		Infections and infestations	16	INFECTIONSINFESTATIONS	
		Neoplasm benign, malignant and unspecified	17	NEOPLASMBENIGNMALIGNANTANDUNSPECIFIED	
		Surgical and medical procedures	18	SURGICALANDMEDICALPROCEDURES	
		Other	99	OTHER_99	

DTPA-HBV-IPV-135 (117119): DISEASE HISTORY (Dis Hist)

DISEASE HISTORY

Please note that If disease history is answered Yes, then exclusion criteria 12 needs to be ticked.

1.* ✔	Has the subject had history of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and/or hepatitis B diseases? [DTP-Hib-Pn-Rot-Pol-HB disease history?]	**[DIS_HIST_FLG_X]** *[A:Y]* ◯ Yes -> Please complete table below with appropriate information *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

	Disease	Date(s) of diagnosis
2. ✔		

DISEASE DETAILS Entry

2.1* ✔	Disease: [Disease]	**[DIS_HIST_TYP]** *[A:DT]* ◯ DIPHTHERIA *[A:PT]* ◯ PERTUSSIS *[A:TT]* ◯ TETANUS *[A:PNE]* ◯ PNEUMOCOCCAL *[A:ROT]* ◯ ROTAVIRUS *[A:PV]* ◯ POLIOVIRUS *[A:H_B]* ◯ HEPATITIS-B *[A:HIB]* ◯ HIB
2.2* ✔	Date(s) of diagnosis [Date(s) of diagnosis]	**[HIST_DAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

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DTPA-HBV-IPV-135 (117119): MOTHERS INFORMED CONSENT (Mot Inf Cons)		
MOTHERS INFORMED CONSENT		
1.* ✔	Did the Mother give her consent to collect the Tdap Vaccination History Information ? [Did the Mother give her consent to collect the Tdap Vaccination History Information ?]	**[MOTH_INF_CONS_Q]** *[A:N]* ◯ No *[A:Y]* ◯ Yes
2. ✔	Mother's Informed Consent date : [Mother's Informed Consent date :]	**[MOTHERS INFORMED CONSENT DATE]** NReq / NReq / NReq (2013-2018)

Key: [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): MOTHER'S TDAP VACCINATION HISTORY (Mot Tdap hist)

MOTHERS VACCINATION HISTORY FLAG

1.* ✔	Has the mother of the subject received Tdap vaccination during pregnancy before enrolment? [Has the mother of the subject received Tdap vaccination during pregnancy before enrolment?]	**[VACC_HIST_FLG]** *[A:Y]* ◯ Yes *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

	Vaccine name	Route	Dose number	Date of administration
2. ✔				

VACCINATION HISTORY DETAILS Entry

2.1* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	**[CVACC_TRADNAME]** A60
2.2* ✔	Route: [Route]	**[CVACC_ROUTE]** **[MEDROUT_CVACC]**
2.3* ✔	Dose number: [Dose number]	**[NB_DOSE]** N10
2.4* ✔	Date of administration: [Date of administration]	**[CVACC_RDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: MOTHER'S TDAP VACCINATION HISTORY

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	CVACC_ROUTE
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

PPD

PPD

DTPA-HBV-IPV-135 (117119): HEPATITIS B VACCINATION HISTORY (HepB Hist)

1.* ✔	Has the subject received any vaccination against Hepatitis B before enrolment? [Has the subject received any vaccination against Hepatitis B before enrolment?]	**[VACC_HIST_FLG]** *[A:Y]* ◯ Yes -> Please complete the following table *[A:N]* ◯ No *[A:U]* ◯ Unknown

	Vaccine name	Route	Dose number	Date of administration
2. ✔				

2.1* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	**[CVACC_TRADNAME]** A60
2.2* ✔	Route: [Route]	**[CVACC_ROUTE]** **[MEDROUT_CVACC]**
2.3* ✔	Dose number: [Dose number]	**[NB_DOSE]** N10
2.4* ✔	Date of administration: [Date of administration]	**[CVACC_RDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: HEPATITIS B VACCINATION HISTORY

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	CVACC_ROUTE
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

PPD

DTPA-HBV-IPV-135 (117119): OTHER VACCINATION HISTORY (Oth Hist)

VACCINATION HISTORY FLAG

1.* ✔	Has the subject received any other vaccination before enrolment? [Has the subject received any other vaccination before enrolment?]	**[VACC_HIST_FLG]** *[A:Y]* ◯ Yes *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

	Vaccine name	Route	Dose number	Date of administration
2. ✔				

2.1* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	**[CVACC_TRADNAME]** A60
2.2* ✔	Route: [Route]	**[CVACC_ROUTE]** **[MEDROUT_CVACC]**
2.3* ✔	Dose number: [Dose number]	**[NB_DOSE]** N10
2.4* ✔	Date of administration: [Date of administration]	**[CVACC_RDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: OTHER VACCINATION HISTORY

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	CVACC_ROUTE
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

PPD

DTPA-HBV-IPV-135 (117119): PHYSICAL EXAMINATION / VITAL SIGNS (VS)		
HEIGHT / WEIGHT		
1.* ✔	Height: [Height]	**[HEIGHT_US]** **[FEET]** **[INCHES]** N2 feet xxx. inches
2.* ✔	Weight: [Weight]	**[WEIGHT]** **[POUNDS]** **[OUNCES]** N3 pounds N2 ounces

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: PHYSICAL EXAMINATION / VITAL SIGNS

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	FEET_UNI, INCHES_UNI, POUNDS_UNI, OUNCES_UNI
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VSTEST	String				VSTEST

PPD

		Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	

PPD

DTPA-HBV-IPV-135 (117119): ELIGIBILITY CHECK (Eligibility)

ELIGIBILITY CHECK

1.* ✔ Did the subject meet all the entry criteria?
[Eligible]

[ELIGIBIL]

[A:Y] ◯ Yes

[A:N] ◯ **[INCL_EXCL_CRITERIA]**

No -> 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.

[INCL_CRITERIA]

INCLUSION CRITERIA

Tick the boxes corresponding to any of the inclusion criteria the subject failed.

[A:1]	☐	1.Subjects' parent(s)/Legally Acceptable Representative(s) [LAR(s)] who, in the opinion of the investigator, can and will comply with the requirements of the protocol (e.g. completion of the diary cards, return for follow-up visits).
[A:2]	☐	2. A male or female between, and including, 6 and 12 weeks of age at the time of first vaccination.
[A:3]	☐	3. Born full-term (i.e. after a gestation period of 37 weeks to less than 42 completed weeks [259 to 293 days]).
[A:4]	☐	4. Written informed consent obtained from the parent(s)/LAR(s) of the subject
[A:5]	☐	5. Healthy subjects as established by medical history and clinical examination before entering into the study.
[A:6]	☐	6. Infants who have not received a previous dose of hepatitis B vaccine or those who have received only 1 dose of hepatitis B vaccine administered at least 30 days prior to enrolment.

[EXCL_CRITERIA]

EXCLUSION CRITERIA

Tick the boxes corresponding to any of the exclusion criteria that disqualified the subject from entry.

[A:7]	☐	7. Child in care
[A:8]	☐	8. Use of any investigational or non-registered product (drug or vaccine) other than the study vaccines within 30 days preceding the first dose of study vaccines, or planned use during the study period
[A:9]	☐	9. Chronic administration (defined as more than 14 days in total) of immunosupp. or other immune-modifying drugs since birth. (For corticosteroids, this will mean prednisone > or = 0.5 mg/kg/day, or equivalent). Inhaled and topical steroids are allowed.
[A:10]	☐	10. Planed adm/adm of vac not forseen by prot 30d before dose1 till 30d after dose3 & 30d before/after booster. Inactiv. flu & HepA vac allowed. Rout.admin. of MMR, varicella, pneumo vac allowed 30d after last pri vacc till 30d before Bst&post-bst samplng
[A:11]	☐	11. Concurrently participating in another clinical study, at any time during the study period, in which the subject has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device).
[A:12]	☐	12. History of Hib, diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus and hepatitis B diseases.
[A:13]	☐	13. Previous vaccination against Hib, diphtheria, tetanus, pertussis, pneumococcus, rotavirus and/or poliovirus; more than one previous dose of hepatitis B vaccine.
[A:14]	☐	14. Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
[A:15]	☐	15. Family history of congenital or hereditary immunodeficiency.
[A:16]	☐	16. History of any reaction or hypersensitivity likely to be exacerbated by any component of the vaccines (including yeast).
[A:17]	☐	17. Hypersensitivity to latex.

PPD

	[A:18]	☐	18. Major congenital defects or serious chronic illness.
	[A:19]	☐	19. History of any neurological disorders including seizures.
	[A:20]	☐	20. Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period.
	[A:21]	☐	21. History of intussusception or of any uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant to intussusception.
	[A:22]	☐	22. History of Severe Combined Immunodeficiency Disease (SCID).
	[A:23]	☐	23. Acute disease and/or fever at time of enrol.– Fever: temp>or=38.0°C /100.4°F by any rout. Pref route: rectal for pri & axilary for bst. Sub. with minor illnes (eg: mild diar, mild uper resp.infection) with no fever may be enrol. at discretion of INV

Key: [*] = Item is required [✔] = Source verification required
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DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 1 (HEXA GROUP) (vac adm hexa-dose1)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Infanrix Hexa Vaccine

2.* ✔ Has Infanrix Hexa Vaccine been administered? [Vaccinated]

[V_ADM_HEXA]
[A:Y] ◯ **[VACC_DET_3VACC_HEXA]**
Yes **[V_TRT_HEXA]**
-> Administered treatment number: N10

[P_AP_HEXA]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_HEXA]**
Not according to protocol -> **[P_APSITE_HEXA]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_HEXA]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_HEXA]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_HEXA]
If relevant, comment on administration:
A200

[A:N] ◯ No

Prevnar13 Vaccine

3.* ✔ Has Prevnar13 Vaccine been administered? [Vaccinated]

[V_ADM_PREVNAR13]
[A:Y] ◯ **[VACC_DET_3VACC_PREVNAR13]**
Yes **[V_TRT_PREVNAR13]**
-> Administered treatment number: N10

[P_AP_PREVNAR13]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Lower Left - IM)
[A:N] ◯ **[P_AP_DET_PREVNAR13]**
Not according to protocol -> **[P_APSITE_PREVNAR13]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PREVNAR13]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PREVNAR13]

PPD

		Route: *[A:IM]* Intramuscular *[A:SC]* Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* No
Rotarix Vaccine		
4.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	**[V_ADM_ROTARIX]** *[A:Y]* **[VACC_DET_3VACC_ROTARIX]** Yes - **[V_TRT_ROTARIX]** > Administered treatment number: N10 **[P_AP_ROTARIX]** *[A:Y]* According to protocol (Oral) *[A:N]* Not according to protocol **[VADM_COM_ROTARIX]** If relevant, comment on administration: A200 *[A:N]* No
VACCINATION DETAILS		
5. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered **[VACCRDAT]** Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]*
6. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* **[AE_NB]** Non-Serious Adverse Event -> Please complete Non-Serious Adverse Event section and specify AE No. N2 *[A:OTH]* **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* Investigator *[A:P]* Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.

PPD

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 1 (HEXA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	

PPD

		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_HEXA, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_HEXA, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_HEXA, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_HEXA, P_CODE_PREVNAR13, P_CODE_ROTARIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	P_ROUTE_ROTARIX
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

PPD

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 1 (PENTA GROUP) (vac adm penta-dose1)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Pentacel Vaccine

2.* ✔ Has Pentacel Vaccine been administered? [Vaccinated]

[V_ADM_PENTACEL]
[A:Y] ◯ **[VACC_DET_4VACC_PENTACEL]**
Yes **[V_TRT_PENTACEL]**
-> Administered treatment number: N10

[P_AP_PENTACEL]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_PENTACEL]**
Not according to protocol ->

[P_APSITE_PENTACEL]
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PENTACEL]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PENTACEL]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_PENTACEL]
If relevant, comment on administration: A200

[A:N] ◯ No

Engerix-B Vaccine

3.* ✔ Has Engerix-B Vaccine been administered? [Vaccinated]

[V_ADM_ENGERIX_B]
[A:Y] ◯ **[VACC_DET_4VACC_ENGERIX_B]**
Yes **[V_TRT_ENGERIX_B]**
-> Administered treatment number: N10

[P_AP_ENGERIX_B]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Upper Left - IM)
[A:N] ◯ **[P_AP_DET_ENGERIX_B]**
Not according to protocol ->

[P_APSITE_ENGERIX_B]
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_ENGERIX_B]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_ENGERIX_B]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_ENGERIX_B] If relevant, comment on administration: A200 *[A:N]* ◯ No
Prevnar13 Vaccine		
4.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* ◯ **[VACC_DET_3VACC_PREVNAR13]** Yes -> **[V_TRT_PREVNAR13]** Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* ◯ According to protocol (Thigh – Lower Left - IM) *[A:N]* ◯ **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* ◯ No
Rotarix Vaccine		
5.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	**[V_ADM_ROTARIX]** *[A:Y]* ◯ **[VACC_DET_3VACC_ROTARIX]** Yes -> **[V_TRT_ROTARIX]** Administered treatment number: N10 **[P_AP_ROTARIX]** *[A:Y]* ◯ According to protocol (Oral) *[A:N]* ◯ Not according to protocol **[VADM_COM_ROTARIX]** If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
6. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered

PPD

		[VACCRDAT] Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
7. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event -> Please complete Non-Serious Adverse Event section and specify AE No. N2 *[A:OTH]* ◯ **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 1 (PENTA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	

PPD

		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_PENTACEL, P_SITE_ENGERIX_B, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PENTACEL, P_SIDE_ENGERIX_B, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PENTACEL, P_ROUTE_ENGERIX_B, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PENTACEL, P_CODE_ENGERIX_B, P_CODE_PREVNAR13, P_CODE_ROTARIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	

PPD

		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	P_ROUTE_ROTARIX
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 1 (PEDIA GROUP) (vac adm pedia-dose1)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Pediarix Vaccine

2.* ✔ Has Pediarix Vaccine been administered? [Vaccinated]

[V_ADM_PEDIARIX]
[A:Y] ◯ **[VACC_DET_4VACC_PEDIARIX]**
Yes **[V_TRT_PEDIARIX]**
-> Administered treatment number: N10

[P_AP_PEDIARIX]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_PEDIARIX]**
Not according to protocol -> **[P_APSITE_PEDIARIX]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PEDIARIX]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PEDIARIX]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_PEDIARIX]
If relevant, comment on administration: A200

[A:N] ◯ No

ActHib Vaccine

3.* ✔ Has ActHib Vaccine been administered? [Vaccinated]

[V_ADM_ACTHIB]
[A:Y] ◯ **[VACC_DET_4VACC_ACTHIB]**
Yes **[V_TRT_ACTHIB]**
-> Administered treatment number: N10

[P_AP_ACTHIB]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Upper Left - IM)
[A:N] ◯ **[P_AP_DET_ACTHIB]**
Not according to protocol -> **[P_APSITE_ACTHIB]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_ACTHIB]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_ACTHIB]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_ACTHIB] If relevant, comment on administration: A200 *[A:N]* ◯ No
Prevnar13 Vaccine		
4.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* ◯ **[VACC_DET_3VACC_PREVNAR13]** Yes -> **[V_TRT_PREVNAR13]** Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* ◯ According to protocol (Thigh – Lower Left - IM) *[A:N]* ◯ **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* ◯ No
Rotarix Vaccine		
5.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	**[V_ADM_ROTARIX]** *[A:Y]* ◯ **[VACC_DET_3VACC_ROTARIX]** Yes -> **[V_TRT_ROTARIX]** Administered treatment number: N10 **[P_AP_ROTARIX]** *[A:Y]* ◯ According to protocol (Oral) *[A:N]* ◯ Not according to protocol **[VADM_COM_ROTARIX]** If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
6. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered

PPD

		[VACCRDAT] Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
7. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event -> Please complete Non-Serious Adverse Event section and specify AE No. N2 *[A:OTH]* ◯ **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 1 (PEDIA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	

PPD

		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_PEDIARIX, P_SITE_ACTHIB, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PEDIARIX, P_SIDE_ACTHIB, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PEDIARIX, P_ROUTE_ACTHIB, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PEDIARIX, P_CODE_ACTHIB, P_CODE_PREVNAR13, P_CODE_ROTARIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	

PPD

		Hiberix	95	Hiberix	
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	P_ROUTE_ROTARIX
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - HEXA (Loc symp flg Hexa)		
LOCAL SIGNS/SYMPTOMS FLAG - HEXA		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Infanrix Hexa]	**[LOCSOL_YN_HEXA]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (INFANRIX HEXA) (Loc symp-Hexa)

Infanrix Hexa vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**

PPD

Intensity: Day 0: [INTENSITYSOL] Day 1: [INTENSITYSOL] Day 2: [INTENSITYSOL] Day 3: [INTENSITYSOL]

[PA_ONG]

After Day 3: Ongoing? *[A:N]* No

[A:Y] **[SYMP_ONG_INTEN]**

Yes -> **[SYMP_MAX_INTEN]**

Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]

Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]

Continuing at the end of the study? *[A:Y]*

[MED_TYPE]

Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (INFANRIX HEXA)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN
		2	2	2	

PPD

		3	3	3	

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - PEDIARIX (Loc symp flg Pediarix)		
LOCAL SIGNS/SYMPTOMS FLAG - PEDIARIX		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Pediarix]	**[LOCSOL_YN_PEDIARIX]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PEDIARIX) (Loc symp-Pediarix)

Pediarix vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**

PPD

Intensity: Day 0: [INTENSITYSOL] Day 1: [INTENSITYSOL] Day 2: [INTENSITYSOL] Day 3: [INTENSITYSOL]

[PA_ONG]

After Day 3: Ongoing? *[A:N]* No

[A:Y] **[SYMP_ONG_INTEN]**

Yes -> **[SYMP_MAX_INTEN]**

Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]

Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]

Continuing at the end of the study? *[A:Y]*

[MED_TYPE]

Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PEDIARIX)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN
		2	2	2	

PPD

		3	3	3	

PPD

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib)		
LOCSYMPTOMS_FLG_ACTHIB		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	**[LOCSOL_YN_ACTHIB]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ACTHIB) (Loc symp-ActHib)

ActHib vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**

PPD

Intensity: Day 0: [INTENSITYSOL] Day 1: [INTENSITYSOL] Day 2: [INTENSITYSOL] Day 3: [INTENSITYSOL]

[PA_ONG]

After Day 3: Ongoing? *[A:N]* No

[A:Y] **[SYMP_ONG_INTEN]**

Yes -> **[SYMP_MAX_INTEN]**

Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]

Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]

Continuing at the end of the study? *[A:Y]*

[MED_TYPE]

Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ACTHIB)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN
		2	2	2	

PPD

		3	3	3	

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - PENTACEL (Loc symp flg Pentacel)		
LOCAL SIGNS/SYMPTOMS FLAG - PENTACEL		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Pentacel]	**[LOCSOL_YN_PENTACEL]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PENTACEL) (Loc symp-Pentacel)

Pentacel vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**

PPD

Intensity: Day 0: [INTENSITYSOL] Day 1: [INTENSITYSOL] Day 2: [INTENSITYSOL] Day 3: [INTENSITYSOL]

[PA_ONG]

After Day 3: Ongoing? *[A:N]* No

[A:Y] **[SYMP_ONG_INTEN]**

Yes -> **[SYMP_MAX_INTEN]**

Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]

Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]

Continuing at the end of the study? *[A:Y]*

[MED_TYPE]

Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PENTACEL)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN
		2	2	2	

PPD

		3	3	3	

PPD

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ENGERIX B (Loc symp flg Engerix-B)		
LOCAL SIGNS/SYMPTOMS FLAG - ENGERIX B		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Engerix-B]	**[LOCSOL_YN_ENGERIX_B]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ENGERIX-B) (Loc symp-Engerix-B)

Engerix-B vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**

PPD

Intensity: Day 0: [INTENSITYSOL] Day 1: [INTENSITYSOL] Day 2: [INTENSITYSOL] Day 3: [INTENSITYSOL]

[PA_ONG]

After Day 3: Ongoing? *[A:N]* No

[A:Y] **[SYMP_ONG_INTEN]**

Yes -> **[SYMP_MAX_INTEN]**

Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]

Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]

Continuing at the end of the study? *[A:Y]*

[MED_TYPE]

Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ENGERIX-B)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN
		2	2	2	

PPD

PPD

DTPA-HBV-IPV-135 (117119): GENERAL SIGNS/SYMPTOMS FLAG (Gen symp flg)		
GENERAL SIGNS/SYMPTOMS FLAG		
1.* ✔	Has the subject experienced any of the General Solicited signs/symptoms between Day 0 and Day 3?	**[GENSOL_YN]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS (Gen symp)

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

TEMPERATURE (°F)

Record temperatures if during the solicited period at least one axillary/oral/tympanic/rectal measure is above or equal to 100.4 °F

1.* ✔ Occurred?

[FE_YN]
[A:N] ◯ No
[A:NT] ◯ Not taken
[A:Y] ◯ **[SYMP_VAL_TEMP]**
Yes -> **[FE_VAL_D0]** Day 0: **[FE_VAL]** | **[FE_VAL_D1]** Day 1: **[FE_VAL]** | **[FE_VAL_D2]** Day 2: **[FE_VAL]** | **[FE_VAL_D3]** Day 3: **[FE_VAL]**
Not taken xxx.x | xxx.x | xxx.x | xxx.x
[FE_NT] *[A:Y]* ☐ | **[FE_NT]** *[A:Y]* ☐ | **[FE_NT]** *[A:Y]* ☐ | **[FE_NT]** *[A:Y]* ☐
[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic
[FE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_TEMP]**
Yes -> **[SYMP_MAX_TEMP]**
Max temperature: xxx.x
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[CAUSAL]
Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No
[A:Y] ◯ Yes
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

DROWSINESS

2.* ✔ Occurred?

[DR_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** Day 0: **[SYMP_VAL_D1]** Day 1: **[SYMP_VAL_INTEN_D2]** Day 2: **[SYMP_VAL_INTEN_D3]** Day 3:
Intensity: **[INTENSITYSOL]** | **[INTENSITYSOL]** | **[INTENSITYSOL]** | **[INTENSITYSOL]**
[DR_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_INTEN]**
Yes -> **[SYMP_MAX_INTEN]**
Maximum intensity: **[INTENSITYSOLMAX]**
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

PPD

		[CONT_END] Continuing at the end of the study? *[A:Y]* ☐ **[CAUSAL]** Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes **[MED_TYPE]** Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None
IRRITABILITY/FUSSINESS		
3.* ✔	Occurred?	**[IF_YN]** *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_VAL_INTEN]** Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]** Intensity: Day 0: Day 1: Day 2: Day 3: **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[IF_ONG]** **After Day 3**: Ongoing? *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_ONG_INTEN]** Yes -> **[SYMP_MAX_INTEN]** Maximum intensity: **[INTENSITYSOLMAX]** **[ERDAT]** Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) **[CONT_END]** Continuing at the end of the study? *[A:Y]* ☐ **[CAUSAL]** Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes **[MED_TYPE]** Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None
LOSS OF APPETITE		
4.* ✔	Occurred?	**[LO_YN]** *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_VAL_INTEN]** Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]** Intensity: Day 0: Day 1: Day 2: Day 3: **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[LO_ONG]** **After Day 3**: Ongoing? *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_ONG_INTEN]** Yes -> **[SYMP_MAX_INTEN]** Maximum intensity: **[INTENSITYSOLMAX]** **[ERDAT]** Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) **[CONT_END]** Continuing at the end of the study? *[A:Y]* ☐ **[CAUSAL]**

PPD

Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes

[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3, SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3, SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN, SYMP_MAX_INTEN, SYMP_MAX_INTEN
		2	2	2	
		3	3	3	

PPD

DTPA-HBV-IPV-135 (117119): CHECK FOR STUDY CONTINUATION (Study Cont.)

CHECK FOR STUDY CONTINUATION

1.* ✔ Did the subject return for this visit?

[VIS_FLG]

[A:Y] **[ACTRDATE]**
Yes -> Date of visit: Req / Req / Req (2013-2018)

[A:N] **[VIS_REAS]**
No **[VIS_REAS]**
-> Please select the major reason:

[A:SAE] **[SAE_CASE]**
Serious Adverse Event **[SAE_CASE]**
-> Please complete a **SAE** Report and specify SAE Report No. N2

[FATAL]
-> Tick box if SAE is fatal: *[A:Y]*

[A:AEX] **[AE_NB]**
[AE_NB]
-> Please complete Non-Serious Adverse Event section and specify AE No. N2

[SYMP_COD]
or Solicited AE code: **[SYMPCODE]**

Non-Serious Adverse Event

[A:PTV] **[PTV_SP]**
Protocol violation, please specify:
A50

[A:CWS] **[CWS]**
Consent Withdrawal not due to an adverse event
->Please specify the reason (only if the Subject's parents / Legally Acceptable Representative has / have spontaneously explained it):
[CWS_SP]
A50

[CWS_NA]
Or tick box if reason not provided *[A:N]*

[A:MIG] Migrated / moved from the study area

[A:LFU] Lost to follow-up

[A:SST] Sponsor study termination

[A:OTH] **[V_OTH]**
Other, please specify
A100

[DECISION]
-> For serious (except death), non-serious adverse events and Other reasons only:
Please select who made the decision:

[A:I] Investigator

[A:P] Subject's parents / Legally Acceptable Representatives

PERMANENT DISCONTINUATION

2. ✔ Study discontinuation:

[DISCNT]
-> **[DISCNT]**
[A:Y] Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study

PPD

		☐ In this case, terminate the CRF: Complete Medication, Concomitant Vaccination, (S)AE sections and Study Conclusion.

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: CHECK FOR STUDY CONTINUATION

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 2 (HEXA GROUP) (vac adm hexa-dose2)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Infanrix Hexa Vaccine

2.* ✔ Has Infanrix Hexa Vaccine been administered? [Vaccinated]

[V_ADM_HEXA]
[A:Y] ◯ **[VACC_DET_3VACC_HEXA]**
Yes **[V_TRT_HEXA]**
-> Administered treatment number: N10

[P_AP_HEXA]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_HEXA]**
Not according to protocol -> **[P_APSITE_HEXA]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_HEXA]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_HEXA]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_HEXA]
If relevant, comment on administration: A200

[A:N] ◯ No

Prevnar13 Vaccine

3.* ✔ Has Prevnar13 Vaccine been administered? [Vaccinated]

[V_ADM_PREVNAR13]
[A:Y] ◯ **[VACC_DET_3VACC_PREVNAR13]**
Yes **[V_TRT_PREVNAR13]**
-> Administered treatment number: N10

[P_AP_PREVNAR13]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Lower Left - IM)
[A:N] ◯ **[P_AP_DET_PREVNAR13]**
Not according to protocol -> **[P_APSITE_PREVNAR13]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PREVNAR13]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PREVNAR13]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_PREVNAR13] If relevant, comment on administration: A200 *[A:N]* ◯ No
Rotarix Vaccine		
4.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	**[V_ADM_ROTARIX]** *[A:Y]* ◯ **[VACC_DET_3VACC_ROTARIX]** Yes - **[V_TRT_ROTARIX]** > Administered treatment number: N10 **[P_AP_ROTARIX]** *[A:Y]* ◯ According to protocol (Oral) *[A:N]* ◯ Not according to protocol **[VADM_COM_ROTARIX]** If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
5. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered **[VACCRDAT]** Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
6. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** or Solicited AE code: **[SYMPCODE]** *[A:OTH]* ◯ **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

PPD

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 2 (HEXA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	

PPD

		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_HEXA, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_HEXA, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_HEXA, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_HEXA, P_CODE_PREVNAR13, P_CODE_ROTARIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	P_ROUTE_ROTARIX
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD

PPD

		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

PPD

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 2 (PEDIA GROUP) (vac adm pedia-dose2)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Pediarix Vaccine

2.* ✔ Has Pediarix Vaccine been administered? [Vaccinated]

[V_ADM_PEDIARIX]
[A:Y] ◯ **[VACC_DET_4VACC_PEDIARIX]**
Yes **[V_TRT_PEDIARIX]**
-> Administered treatment number: N10

[P_AP_PEDIARIX]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_PEDIARIX]**
Not according to protocol -> **[P_APSITE_PEDIARIX]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PEDIARIX]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PEDIARIX]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_PEDIARIX]
If relevant, comment on administration: A200

[A:N] ◯ No

ActHib Vaccine

3.* ✔ Has ActHib Vaccine been administered? [Vaccinated]

[V_ADM_ACTHIB]
[A:Y] ◯ **[VACC_DET_4VACC_ACTHIB]**
Yes **[V_TRT_ACTHIB]**
-> Administered treatment number: N10

[P_AP_ACTHIB]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Upper Left - IM)
[A:N] ◯ **[P_AP_DET_ACTHIB]**
Not according to protocol -> **[P_APSITE_ACTHIB]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_ACTHIB]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_ACTHIB]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_ACTHIB] If relevant, comment on administration: A200 *[A:N]* No
Prevnar13 Vaccine		
4.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* **[VACC_DET_3VACC_PREVNAR13]** Yes -> **[V_TRT_PREVNAR13]** Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* According to protocol (Thigh – Lower Left - IM) *[A:N]* **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* Deltoid *[A:3]* Thigh *[A:6]* Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* Left *[A:R]* Right *[A:UL]* Upper Left *[A:LL]* Lower Left *[A:UR]* Upper Right *[A:LR]* Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* Intramuscular *[A:SC]* Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* No
Rotarix Vaccine		
5.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	**[V_ADM_ROTARIX]** *[A:Y]* **[VACC_DET_3VACC_ROTARIX]** Yes -> **[V_TRT_ROTARIX]** Administered treatment number: N10 **[P_AP_ROTARIX]** *[A:Y]* According to protocol (Oral) *[A:N]* Not according to protocol **[VADM_COM_ROTARIX]** If relevant, comment on administration: A200 *[A:N]* No
VACCINATION DETAILS		
6. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered

PPD

		[VACCRDAT] Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
7. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** Or Solicited AE code: **[SYMPCODE]** *[A:OTH]* ◯ **[V_OTH]** Other, please specify A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 2 (PEDIA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	

PPD

		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_PEDIARIX, P_SITE_ACTHIB, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PEDIARIX, P_SIDE_ACTHIB, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PEDIARIX, P_ROUTE_ACTHIB, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PEDIARIX, P_CODE_ACTHIB, P_CODE_PREVNAR13, P_CODE_ROTARIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	

PPD

		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	P_ROUTE_ROTARIX
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 2 (PENTA GROUP) (vac adm penta-dose2)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Pentacel Vaccine

2.* ✔ Has Pentacel Vaccine been administered? [Vaccinated]

[V_ADM_PENTACEL]
[A:Y] ◯ **[VACC_DET_4VACC_PENTACEL]**
Yes **[V_TRT_PENTACEL]**
-> Administered treatment number: N10

[P_AP_PENTACEL]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_PENTACEL]**
Not according to protocol ->

[P_APSITE_PENTACEL]
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PENTACEL]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PENTACEL]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_PENTACEL]
If relevant, comment on administration: A200

[A:N] ◯ No

Engerix-B Vaccine (should not be given at Month 2 (4 months of age) if a dose of Hepatitis B vaccine was given at birth up to 30 days prior to study dose 1)

3.* ✔ Has Engerix-B Vaccine been administered? [Vaccinated]

[V_ADM_ENGERIX_B]
[A:Y] ◯ **[VACC_DET_4VACC_ENGERIX_B]**
Yes **[V_TRT_ENGERIX_B]**
-> Administered treatment number: N10

[P_AP_ENGERIX_B]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Upper Left - IM)
[A:N] ◯ **[P_AP_DET_ENGERIX_B]**
Not according to protocol ->

[P_APSITE_ENGERIX_B]
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_ENGERIX_B]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_ENGERIX_B]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_ENGERIX_B] If relevant, comment on administration: A200 *[A:N]* ◯ No
Prevnar13 Vaccine		
4.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* ◯ **[VACC_DET_3VACC_PREVNAR13]** Yes -> **[V_TRT_PREVNAR13]** Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* ◯ According to protocol (Thigh – Lower Left - IM) *[A:N]* ◯ **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* ◯ No
Rotarix Vaccine		
5.* ✔	Has Rotarix Vaccine been administered? [Vaccinated]	**[V_ADM_ROTARIX]** *[A:Y]* ◯ **[VACC_DET_3VACC_ROTARIX]** Yes -> **[V_TRT_ROTARIX]** Administered treatment number: N10 **[P_AP_ROTARIX]** *[A:Y]* ◯ According to protocol (Oral) *[A:N]* ◯ Not according to protocol **[VADM_COM_ROTARIX]** If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
6. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered

PPD

		[VACCRDAT] Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
7. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** > Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** Or Solicited AE code: **[SYMPCODE]** *[A:OTH]* ◯ **[V_OTH]** Other, please specify A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 2 (PENTA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	

PPD

		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_PENTACEL, P_SITE_ENGERIX_B, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PENTACEL, P_SIDE_ENGERIX_B, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PENTACEL, P_ROUTE_ENGERIX_B, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PENTACEL, P_CODE_ENGERIX_B, P_CODE_PREVNAR13, P_CODE_ROTARIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	

PPD

		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	P_ROUTE_ROTARIX
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib)		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	**[LOCSOL_YN_ACTHIB]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 3 (HEXA GROUP) (vac adm hexa-dose3)

PRE-VACC TEMPERATURE

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	**[PRE_TEMP]** **[PRE_TEMP]** Temperature (°F) xxx.x **[TEMP_ROUTE]** Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic
Infanrix Hexa		
2.* ✔	Has Infanrix Hexa Vaccine been administered? [Vaccinated]	**[V_ADM_HEXA]** *[A:Y]* ◯ **[VACC_DET_3VACC_HEXA]** Yes **[V_TRT_HEXA]** -> Administered treatment number: N10 **[P_AP_HEXA]** Injection Site/Side/Route: *[A:Y]* ◯ According to protocol (Thigh - Right - IM) *[A:N]* ◯ **[P_AP_DET_HEXA]** Not according to protocol -> **[P_APSITE_HEXA]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_HEXA]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_HEXA]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_HEXA]** If relevant, comment on administration: A200 *[A:N]* ◯ No
Prevnar13 Vaccine		
3.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* ◯ **[VACC_DET_3VACC_PREVNAR13]** Yes **[V_TRT_PREVNAR13]** -> Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* ◯ According to protocol (Thigh – Lower Left - IM) *[A:N]* ◯ **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_PREVNAR13] If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
4. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered **[VACCRDAT]** Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
5. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** or Solicited AE code: **[SYMPCODE]** *[A:OTH]* ◯ **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 3 (HEXA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	

PPD

		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_HEXA, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_HEXA, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	

PPD

MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_HEXA, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_HEXA, P_CODE_PREVNAR13
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 3 (PEDIA GROUP) (vac adm pedia-dose3)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

VACCINE ADMINISTRATION - PEDIARIX

2.* ✔ Has Pediarix Vaccine been administered? [Vaccinated]

[V_ADM_PEDIARIX]
[A:Y] ◯ **[VACC_DET_4VACC_PEDIARIX]**
Yes **[V_TRT_PEDIARIX]**
-> Administered treatment number: N10

[P_AP_PEDIARIX]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_PEDIARIX]**
Not according to protocol -> **[P_APSITE_PEDIARIX]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PEDIARIX]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PEDIARIX]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_PEDIARIX]
If relevant, comment on administration: A200

[A:N] ◯ No

ActHib Vaccine

3.* ✔ Has ActHib Vaccine been administered? [Vaccinated]

[V_ADM_ACTHIB]
[A:Y] ◯ **[VACC_DET_4VACC_ACTHIB]**
Yes **[V_TRT_ACTHIB]**
-> Administered treatment number: N10

[P_AP_ACTHIB]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Upper Left - IM)
[A:N] ◯ **[P_AP_DET_ACTHIB]**
Not according to protocol -> **[P_APSITE_ACTHIB]**
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_ACTHIB]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_ACTHIB]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_ACTHIB] If relevant, comment on administration: A200 *[A:N]* ○ No
Prevnar13 Vaccine		
4.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* ○ **[VACC_DET_3VACC_PREVNAR13]** Yes **[V_TRT_PREVNAR13]** -> Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* ○ According to protocol (Thigh – Lower Left - IM) *[A:N]* ○ **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* ○ Deltoid *[A:3]* ○ Thigh *[A:6]* ○ Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* ○ Left *[A:R]* ○ Right *[A:UL]* ○ Upper Left *[A:LL]* ○ Lower Left *[A:UR]* ○ Upper Right *[A:LR]* ○ Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* ○ Intramuscular *[A:SC]* ○ Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* ○ No
VACCINATION DETAILS		
5. ✔	Date of administration:	**[VACCRDAT]** **[VACCRDAT]** If at least one vaccine administered Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
6. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ○ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ○ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** Solicited AE code: **[SYMPCODE]**

PPD

[A:OTH] **[V_OTH]**
Other, please specify A100

[DECISION]
Please select who made the decision: *[A:I]* Investigator
[A:P] Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 3 (PEDIA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	

PPD

		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_PEDIARIX, P_SITE_ACTHIB, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PEDIARIX, P_SIDE_ACTHIB, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PEDIARIX, P_ROUTE_ACTHIB, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PEDIARIX, P_CODE_ACTHIB, P_CODE_PREVNAR13
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

PPD

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 3 (PENTA GROUP) (vac adm penta-dose3)

PRE-VACC TEMPERATURE

1.* ✔ Pre-vaccination temperature: [Pre-vacc temp]

[PRE_TEMP]
[PRE_TEMP]
Temperature (°F) xxx.x

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary *[A:O]* ◯ Oral *[A:R]* ◯ Rectal (Preferred) *[A:T]* ◯ Tympanic

Pentacel Vaccine

2.* ✔ Has Pentacel Vaccine been administered? [Vaccinated]

[V_ADM_PENTACEL]
[A:Y] ◯ **[VACC_DET_4VACC_PENTACEL]**
Yes **[V_TRT_PENTACEL]**
-> Administered treatment number: N10

[P_AP_PENTACEL]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh - Right - IM)
[A:N] ◯ **[P_AP_DET_PENTACEL]**
Not according to protocol ->

[P_APSITE_PENTACEL]
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_PENTACEL]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_PENTACEL]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

[VADM_COM_PENTACEL]
If relevant, comment on administration: A200

[A:N] ◯ No

Engerix-B Vaccine

3.* ✔ Has Engerix-B Vaccine been administered? [Vaccinated]

[V_ADM_ENGERIX_B]
[A:Y] ◯ **[VACC_DET_4VACC_ENGERIX_B]**
Yes **[V_TRT_ENGERIX_B]**
-> Administered treatment number: N10

[P_AP_ENGERIX_B]
Injection Site/Side/Route:
[A:Y] ◯ According to protocol (Thigh – Upper Left - IM)
[A:N] ◯ **[P_AP_DET_ENGERIX_B]**
Not according to protocol ->

[P_APSITE_ENGERIX_B]
Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock

[P_APSIDE_ENGERIX_B]
Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right

[P_APROUTE_ENGERIX_B]
Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous

PPD

		[VADM_COM_ENGERIX_B] If relevant, comment on administration: A200 *[A:N]* ◯ No
Prevnar13 Vaccine been administered?		
4.* ✔	Has Prevnar13 Vaccine been administered? [Vaccinated]	**[V_ADM_PREVNAR13]** *[A:Y]* ◯ **[VACC_DET_3VACC_PREVNAR13]** Yes **[V_TRT_PREVNAR13]** -> Administered treatment number: N10 **[P_AP_PREVNAR13]** Injection Site/Side/Route: *[A:Y]* ◯ According to protocol (Thigh – Lower Left - IM) *[A:N]* ◯ **[P_AP_DET_PREVNAR13]** Not according to protocol -> **[P_APSITE_PREVNAR13]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_PREVNAR13]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_PREVNAR13]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_PREVNAR13]** If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
5. ✔	Date of administration:	**[VACCRDAT]** **[VACCRDAT]** If at least one vaccine administered Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
6. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** Solicited AE code: **[SYMPCODE]**

PPD

[A:OTH] **[V_OTH]**
Other, please specify A100

[DECISION]
Please select who made the decision: *[A:I]* Investigator
[A:P] Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 3 (PENTA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	

PPD

		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_PENTACEL, P_SITE_ENGERIX_B, P_SITE_PREVNAR13
		Thigh	3	Thigh	
		Buttock	6	Buttock	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PENTACEL, P_SIDE_ENGERIX_B, P_SIDE_PREVNAR13
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PENTACEL, P_ROUTE_ENGERIX_B, P_ROUTE_PREVNAR13
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PENTACEL, P_CODE_ENGERIX_B, P_CODE_PREVNAR13
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

PPD

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib)		
LOCSYMPTOMS_FLG_ACTHIB		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	**[LOCSOL_YN_ACTHIB]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LABORATORY TESTS (Labo tests)

BLOOD SAMPLE

1.* ✔	Has a blood sample been taken? [SER sample taken]	**[SAMPTAKE_SER]** *[A:Y]* ◯ **[SAMPLE_DET_SER]** Yes -> **[SAMPRDAT_D]** Date of collection: Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐ **[NB_TUBES]** Number of tube(s) taken: N2 **[REQ_NUM]** Requisition number: A9 *[A:N]* ◯ No

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: LABORATORY TESTS

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYSTEMCD	String	Peripheral blood mononuclear cells	PBMC	PBMC	EVENTTYP_HID
		Serum	SER	SER	
		Serum 1	SER01	SER01	
		Serum 2	SER02	SER02	
		Pregnancy test	PRG	PRG	
		Urine	URI	URI	
		Whole blood	WHB	WHB	

PPD

DTPA-HBV-IPV-135 (117119): INVESTIGATOR SIGNATURE (Inv sign)		
INVESTIGATOR SIGNATURE		
1.* ✔	Is this casebook ready to sign? If not, click on the **RETURN** button below	**[INVSIGN]** *[A:Y]* ☐ Ready to sign

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): ESFU CONTACT (M10) (ESFU contact)

ESFU CONTACT (M10)

Please contact the subject's parent(s) / guardian(s) by phone to follow up on the administration of medication or vaccination and to check on the occurrence of intercurrent medical conditions or NOCDs or SAEs .

1.* ✔	Has safety information been obtained?	**[PHCT_FLG]** *[A:Y]* ◯ **[ACTRDATE]** Yes -> Date of contact Req / Req / Req (2013-2018) *[A:N]* ◯ **[VIS_REAS]** No **[VIS_REAS]** **-> Please tick the major reason:** *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event **[SAE_CASE]** -> Please complete a **SAE** Report and specify SAE Report No. N2 **[FATAL]** -> Tick box if SAE is fatal: *[A:Y]* ☐ *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete **Non-Serious Adverse Event** section and specify AE No. N2 **[SYMP_COD]** or Solicited AE code: **[SYMPCODE]** *[A:PTV]* ◯ **[PTV_SP]** Protocol violation, please specify: A50 *[A:CWS]* ◯ **[CWS]** Consent Withdrawal not due to an adverse event ->Please specify the reason (only if the Subject's parents / Legally Acceptable Representative has / have spontaneously explained it): **[CWS_SP]** A50 **[CWS_NA]** Or tick box if reason not provided *[A:N]* ☐ *[A:MIG]* ◯ Migrated / moved from the study area *[A:LFU]* ◯ Lost to follow-up *[A:SST]* ◯ Sponsor study termination *[A:OTH]* ◯ **[V_OTH]** Other, please specify A100 **[DECISION]** **-> For serious (except death), non-serious adverse events and Other reasons only:** **Please select who made the decision:** *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives
PERMANENT DISCONTINUATION		
2.	Study discontinuation:	**[DISCNT]**

PPD

✔		-> **[DISCNT]** *[A:Y]* ☐ Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study In this case, terminate the CRF: Complete Medication, Concomitant Vaccination, (S)AE sections and Study Conclusion.

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: ESFU CONTACT (M10)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): CHECK FOR STUDY CONTINUATION (BOOSTER EPOCH) (Study Cont)

CHECK FOR STUDY CONTINUATION (BOOSTER EPOCH)

1.* ✔ Did the subject return for the booster epoch?

[VIS_FLG_EPOCH]

[A:Y] ○ **[ACTRDATE]**
Yes -> Date of visit: Req / Req / Req (2013-2018)

[A:N] ○ **[VIS_REAS_EPOCH]**
No **[VIS_REAS_EPOCH]**
-> Please select the major reason:

[A:SAE1] ○ **[SAE_CASE]**
Serious Adverse Event onset in the course or after primary epoch leading to withdrawal from the study, please specify:
[SAE_CASE]
-> Please complete a **SAE** Report and specify SAE Report No. N2

[FATAL]
-> Tick box if SAE is fatal: *[A:Y]* ☐

[A:AEX1] ○ **[AE_NB]**
Non-Serious Adverse Event in the course or after previous study epoch leading to withdrawal from the study, please specify:
[AE_NB] **[SYMP_COD]**
AE No. N2 Solicited AE code: **[SYMPCODE]**

[A:PTV] ○ **[PTV_SP]**
Protocol violation, please specify:
A50

[A:CWS1] ○ **[CWS]**
Consent Withdrawal / not willing to participate, not due to a (S)AE
->Please specify the reason (only if the Subject's parents / Legally Acceptable Representatives has / have spontaneously explained it):
[CWS_SP]
A50

[CWS_NA]
Or tick box if reason not provided *[A:N]* ☐

[A:MIG] ○ Migrated / moved from the study area

[A:LFU] ○ Lost to follow-up

[A:DED] ○ **[DEATHDAT]**
Subject died
--> Date of death:
NReq / NReq / NReq (2013-2018)

[A:SST] ○ Sponsor study termination

[A:OTH] ○ **[V_OTH]**
Other, please specify:
A100

[DECISION]
Please select who made the decision: *[A:I]* ○ Investigator
[A:P] ○ Subject's parents / Legally Acceptable Representatives

PERMANENT DISCONTINUATION

2. Study discontinuation: **[DISCNT]**

PPD

✔		**[DISCNT]** *[A:Y]* ☐ Tick box only if permanent discontinuation, i.e. if the subject definitively withdraws from the study If Yes, please sign off booster epoch

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: CHECK FOR STUDY CONTINUATION (BOOSTER EPOCH)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 4 (HEXA GROUP) (vac adm hexa-dose4)

PRE-VACC TEMPERATURE

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	**[PRE_TEMP]** **[PRE_TEMP]** Temperature (°F) xxx.x **[TEMP_ROUTE]** Route: *[A:A]* ◯ Axillary (Preferred) *[A:O]* ◯ Oral *[A:R]* ◯ Rectal *[A:T]* ◯ Tympanic
Infanrix Vaccine		
2.* ✔	Pre vaccination Limb Circumference measurement (Infanrix):	**[PRE_VACC_LIMB_INF]** **[NT_LIMB] [CIRC_LIMB]** Not taken *[A:Y]* ☐ Circumference of Injected Limb (in mm) N10
3.* ✔	Has Infanrix Vaccine been administered? [Vaccinated]	**[V_ADM_INFANRIX]** *[A:Y]* ◯ **[VACC_DET_3VACC_INFANRIX]** Yes -> **[V_TRT_INFANRIX]** Administered treatment number: N10 **[P_AP_INFANRIX]** Injection Site/Side/Route: *[A:Y]* ◯ **[P_SITE_INFANRIX]** According to protocol: (Deltoid/Thigh - Right - IM) *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:N]* ◯ **[P_AP_DET_INFANRIX]** Not according to protocol -> **[P_APSITE_INFANRIX]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_INFANRIX]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_INFANRIX]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_INFANRIX]** If relevant, comment on administration: A200 *[A:N]* ◯ No
Hiberix Vaccine		
4.* ✔	Pre vaccination Limb Circumference measurement (Hiberix):	**[PRE_VACC_LIMB_HIB]** **[NT_LIMB] [CIRC_LIMB]** Not taken *[A:Y]* ☐ Circumference of Injected Limb (in mm) N10
5.* ✔	Has Hiberix Vaccine been administered? [Vaccinated]	**[V_ADM_HIBERIX]** *[A:Y]* ◯ **[VACC_DET_2VACC_HIBERIX]** Yes -> **[V_TRT_HIBERIX]** Administered treatment number:

PPD

N10

[P_AP_HIBERIX]
Injection Site/Side/Route:
[A:Y] ○ According to protocol: (Deltoid/Thigh - Left - IM) **[P_SITE_HIBERIX]** **[VACCSITE]**
[A:N] ○ **[P_AP_DET_HIBERIX]**
Not according to protocol ->
[P_APSITE_HIBERIX]
Site: *[A:1]* ○ Deltoid *[A:3]* ○ Thigh *[A:6]* ○ Buttock
[P_APSIDE_HIBERIX]
Side: *[A:L]* ○ Left *[A:R]* ○ Right *[A:UL]* ○ Upper Left *[A:LL]* ○ Lower Left *[A:UR]* ○ Upper Right *[A:LR]* ○ Lower Right
[P_APROUTE_HIBERIX]
Route: *[A:IM]* ○ Intramuscular *[A:SC]* ○ Subcutaneous

[VADM_COM_HIBERIX]
If relevant, comment on administration: A200

[A:N] ○ No

VACCINATION DETAILS

6. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered **[VACCRDAT]** Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
7. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ○ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ○ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** or Solicited AE code: **[SYMPCODE]** *[A:OTH]* ○ **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* ○ Investigator *[A:P]* ○ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

PPD

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 4 (HEXA GROUP)					
Codelist	**Codelist Data Type**	**Label**	**Code**	**Codelist Item**	**Data Variable**
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	

PPD

VACCSIDE	String	Left	L	LEFT	P_SIDE_INFANRIX, P_SIDE_HIBERIX
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_INFANRIX, P_ROUTE_HIBERIX
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_INFANRIX, P_CODE_HIBERIX
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
VACCSITE	String	Deltoid	1	Deltoid	P_SITE_HIBERIX
		Thigh	3	Thigh	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

PPD

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 4 (PEDIA GROUP) (vac adm pedia-dose4)

PRE-VACC TEMPERATURE

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	**[PRE_TEMP]** **[PRE_TEMP]** Temperature (°F) xxx.x **[TEMP_ROUTE]** Route: *[A:A]* ◯ Axillary (Preferred) *[A:O]* ◯ Oral *[A:R]* ◯ Rectal *[A:T]* ◯ Tympanic
Infanrix Vaccine		
2.* ✔	Pre vaccination Limb Circumference measurement (Infanrix):	**[PRE_VACC_LIMB_INF]** **[NT_LIMB] [CIRC_LIMB]** Not taken *[A:Y]* ☐ Circumference of Injected Limb (in mm) N10
3.* ✔	Has Infanrix Vaccine been administered? [Vaccinated]	**[V_ADM_INFANRIX]** *[A:Y]* ◯ **[VACC_DET_3VACC_INFANRIX]** Yes -> **[V_TRT_INFANRIX]** Administered treatment number: N10 **[P_AP_INFANRIX]** Injection Site/Side/Route: *[A:Y]* ◯ **[P_SITE_INFANRIX]** According to protocol: (Deltoid/Thigh - Right - IM) *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:N]* ◯ **[P_AP_DET_INFANRIX]** Not according to protocol -> **[P_APSITE_INFANRIX]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_INFANRIX]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_INFANRIX]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_INFANRIX]** If relevant, comment on administration: A200 *[A:N]* ◯ No
ActHib Vaccine		
4.* ✔	Pre vaccination Limb Circumference measurement (ActHib):	**[PRE_VACC_LIMB_ACT]** **[NT_LIMB] [CIRC_LIMB]** Not taken *[A:Y]* ☐ Circumference of Injected Limb (in mm) N10
5.* ✔	Has ActHib Vaccine been administered? [Vaccinated]	**[V_ADM_ACTHIB]** *[A:Y]* ◯ **[VACC_DET_4VACC_ACTHIB]** Yes -> **[V_TRT_ACTHIB]** Administered treatment number:

PPD

		N10 **[P_AP_ACTHIB]** Injection Site/Side/Route: *[A:Y]* ◯ **[P_SITE_ACTHIB_BST]** According to protocol: (Deltoid/Thigh - Left - IM) *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:N]* ◯ **[P_AP_DET_ACTHIB]** Not according to protocol -> **[P_APSITE_ACTHIB]** Site: *[A:1]* ◯ Deltoid *[A:3]* ◯ Thigh *[A:6]* ◯ Buttock **[P_APSIDE_ACTHIB]** Side: *[A:L]* ◯ Left *[A:R]* ◯ Right *[A:UL]* ◯ Upper Left *[A:LL]* ◯ Lower Left *[A:UR]* ◯ Upper Right *[A:LR]* ◯ Lower Right **[P_APROUTE_ACTHIB]** Route: *[A:IM]* ◯ Intramuscular *[A:SC]* ◯ Subcutaneous **[VADM_COM_ACTHIB]** If relevant, comment on administration: A200 *[A:N]* ◯ No
VACCINATION DETAILS		
6. ✔	Date of administration:	**[VACCRDAT]** If at least one vaccine administered **[VACCRDAT]** Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐
7. ✔	If at least one vaccination not done: [Reason for non-admin]	**[VACC_REAS]** **[VACC_REAS]** Please select the major reason for non administration: *[A:SAE]* ◯ **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* ◯ **[AE_NB]** Non-Serious Adverse Event **[AE_NB]** -> Please complete Non-Serious Adverse Event section and specify AE No. N2 **[SYMP_COD]** or Solicited AE code: **[SYMPCODE]** *[A:OTH]* ◯ **[V_OTH]** Other, please specify (e.g.: consent withdrawal, Protocol violation, ...) A100 **[DECISION]** Please select who made the decision: *[A:I]* ◯ Investigator *[A:P]* ◯ Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

PPD

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 4 (PEDIA GROUP)					
Codelist	**Codelist Data Type**	**Label**	**Code**	**Codelist Item**	**Data Variable**
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	
		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	

PPD

VACCSIDE	String	Left	L	LEFT	P_SIDE_INFANRIX, P_SIDE_ACTHIB
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_INFANRIX, P_ROUTE_ACTHIB
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_INFANRIX, P_CODE_ACTHIB
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): VACCINE ADMINISTRATION - DOSE 4 (PENTA GROUP) (vac adm penta-dose4)

PRE-VACC TEMPERATURE

1.* ✔	Pre-vaccination temperature: [Pre-vacc temp]	**[PRE_TEMP]** **[PRE_TEMP]** Temperature (°F) xxx.x **[TEMP_ROUTE]** Route: *[A:A]* Axillary (Preferred) *[A:O]* Oral *[A:R]* Rectal *[A:T]* Tympanic
Pentacel Vaccine		
2.* ✔	Pre vaccination Limb Circumference measurement (Pentacel):	**[PRE_VACC_LIMB_PENTA]** **[NT_LIMB]** **[CIRC_LIMB]** Not Taken *[A:Y]* ☐ Circumference of Injected Limb (in mm) N10
3.* ✔	Has Pentacel Vaccine been administered? [Vaccinated]	**[V_ADM_PENTACEL]** *[A:Y]* **[VACC_DET_4VACC_PENTACEL]** **[VACCRDAT]** **[VACCRDAT]** Yes -> Req / Req / Req (2013-2018) **[SAME_DATE]** Or tick box if date is the same as visit date *[A:Y]* ☐ **[V_TRT_PENTACEL]** Administered treatment number: N10 **[P_AP_PENTACEL]** Injection Site/Side/Route: *[A:Y]* **[P_SITE_PENTACEL]** According to protocol: (Deltoid/Thigh - Right - IM) *[A:1]* Deltoid *[A:3]* Thigh *[A:N]* **[P_AP_DET_PENTACEL]** Not according to protocol -> **[P_APSITE_PENTACEL]** Site: *[A:1]* Deltoid *[A:3]* Thigh *[A:6]* Buttock **[P_APSIDE_PENTACEL]** Side: *[A:L]* Left *[A:R]* Right *[A:UL]* Upper Left *[A:LL]* Lower Left *[A:UR]* Upper Right *[A:LR]* Lower Right **[P_APROUTE_PENTACEL]** Route: *[A:IM]* Intramuscular *[A:SC]* Subcutaneous **[VADM_COM_PENTACEL]** If relevant, comment on administration: A200 *[A:N]* **[VACC_REAS]** **[VACC_REAS]** No -> Please select the major reason for non administration: *[A:SAE]* **[SAE_CASE]** Serious Adverse Event-> Please complete a SAE Report and specify SAE Report No. N2 *[A:AEX]* **[AE_NB]**

PPD

Non-Serious Adverse Event **[AE_NB]**
-> Please complete Non-Serious Adverse Event section and specify AE No. N2

[SYMP_COD]
or Solicited AE code: **[SYMPCODE]**

[A:OTH] **[V_OTH]**
Other, please specify (e.g.: consent withdrawal, Protocol violation, ...)
A100

[DECISION]
Please select who made the decision: *[A:I]* Investigator
[A:P] Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: VACCINE ADMINISTRATION - DOSE 4 (PENTA GROUP)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
VSORRESU	String	beats per minute	BPM	BPM	TEMP_UNIT_HID
		breaths per minute	BRTH	BRTH	
		Celsius	CE	CE	
		Fahrenheit	FA	FAR	
		feet	FT	FT	
		inches	IN	INCH	
		kg	KG	KG	
		ounces	OZ	OZ	
		pounds	LB	LB	
		cm	CM	CM	
		mmHg	MMHG	MMHG	
		grams	G	GRAM	
VSTEST	String	Diastolic Blood Pressure	DIASTOLIC BLOOD PRESSURE	DIASTOLIC BLOOD PRESSURE	VSTEST
		Heart Rate	HEART RATE	HEART RATE	
		Height	HEIGHT	HEIGHT	
		Mid Upper Arm Circumference	MUAC	MUAC	
		Respiratory Rate	RESPIRATORY RATE	RESPIRATORY RATE	
		Systolic Blood Pressure	SYSTOLIC BLOOD PRESSURE	SYSTOLIC BLOOD PRESSURE	
		Temperature	TEMPERATURE	TEMPERATURE	
		Weight	WEIGHT	WEIGHT	
		Cranial Perimeter	CRANIAL PERIMETER	CRANIAL PERIMETER	

		Apgar Score	APGAR SCORE	APGAR SCORE	
VSTESTCD	String	DIABP	DBP	DBP	VSTESTCD
		HEART RATE	HR	HR	
		HEIGHT	HE	HEI	
		MUAC	MUAC	MAUC2	
		RESP RATE	RR	RESPR	
		SYSBP	SBP	SBP	
		TEMP	TE	TEMP	
		WEIGHT	WE	WEIGHT2	
		CRANIAL PERIMETER	CRP	CRP	
		APGAR SCORE	APGAR	APGAR	
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
VACCSIDE	String	Left	L	LEFT	P_SIDE_PENTACEL
		Right	R	RIGHT	
		Upper Left	UL	UPPER LEFT	
		Lower Left	LL	LOWER LEFT	
		Upper Right	UR	UPPER RIGHT	
		Lower Right	LR	LOWER RIGHT	
MEDROUT_VACC	String	Intramuscular	IM	Intramuscular	P_ROUTE_PENTACEL
		Subcutaneous	SC	Subcutaneous	
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE_PENTACEL
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	

PPD

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - INFANRIX (Loc symp flg Infanrix)		
LOCAL SIGNS/SYMPTOMS FLAG - INFANRIX		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Infanrix]	**[LOCSOL_YN_INFANRIX]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (INFANRIX) (Loc symp-Infanrix)

Infanrix vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**

PPD

Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**
Intensity: Day 0: Day 1: Day 2: Day 3:
[INTENSITYSOL] **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]**

[PA_ONG]
After Day 3: Ongoing? *[A:N]* No
[A:Y] **[SYMP_ONG_INTEN]**
Yes -> **[SYMP_MAX_INTEN]**
Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]
Continuing at the end of the study? *[A:Y]*

[MED_TYPE]
Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (INFANRIX)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN

PPD

		2	2	2	
		3	3	3	

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - HIBERIX (Loc symp flg Hiberix)		
LOCAL SIGNS/SYMPTOMS FLAG - HIBERIX		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for Hiberix]	**[LOCSOL_YN_HIBERIX]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (HIBERIX) (Loc symp-Hiberix)

Hiberix vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**

PPD

Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**
Intensity: Day 0: Day 1: Day 2: Day 3:
[INTENSITYSOL] **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]**

[PA_ONG]
After Day 3: Ongoing? *[A:N]* No
[A:Y] **[SYMP_ONG_INTEN]**
Yes -> **[SYMP_MAX_INTEN]**
Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]
Continuing at the end of the study? *[A:Y]*

[MED_TYPE]
Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (HIBERIX)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN

PPD

		2	2	2	
		3	3	3	

DTPA-HBV-IPV-135 (117119): LOCAL SIGNS/SYMPTOMS FLAG - ACTHIB (Loc symp flg ActHib)		
LOCSYMPTOMS_FLG_ACTHIB		
1.* ✔	Has the subject experienced any of the Local Solicited signs/symptoms between Day 0 and Day 3? [Local Symp flag for ActHib]	**[LOCSOL_YN_ACTHIB]** *[A:Y]* ◯ Yes -> Please tick No/Yes for each sign/symptom and complete further as necessary *[A:N]* ◯ No *[A:U]* ◯ Unknown, no information available

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ACTHIB) (Loc symp-ActHib)

ActHib vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**

PPD

Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**
Intensity: Day 0: Day 1: Day 2: Day 3:
[INTENSITYSOL] **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]**

[PA_ONG]
After Day 3: Ongoing? *[A:N]* No
[A:Y] **[SYMP_ONG_INTEN]**
Yes -> **[SYMP_MAX_INTEN]**
Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]
Continuing at the end of the study? *[A:Y]*

[MED_TYPE]
Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (ACTHIB)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN

PPD

		2	2	2	
		3	3	3	

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PENTACEL) (Loc symp-Pentacel)

Pentacel vaccine injection site.
If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

REDNESS

1.* ✔ Occurred?

[RE_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[RE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

SWELLING

In case of large swelling reaction at the injection limb, please fill in ALSO the large Swelling Reaction form

2.* ✔ Occurred?

[SW_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_MM]**
Yes -> **[SYMP_VAL_MM_D0]** **[SYMP_VAL_MM_D1]** **[SYMP_VAL_MM_D2]** **[SYM_VAL_MM_D3]**
Size (mm): Day 0: N5 Day 1: N5 Day 2: N5 Day 3: N5
[SW_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_MM]**
Yes -> **[SYMP_MAX_SIZE]**
Maximum size: N5
[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)
[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐
[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

PAIN

3.* ✔ Occurred?

[PA_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**

PPD

Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]**
Intensity: Day 0: Day 1: Day 2: Day 3:
[INTENSITYSOL] **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]**

[PA_ONG]
After Day 3: Ongoing? *[A:N]* No
[A:Y] **[SYMP_ONG_INTEN]**
Yes -> **[SYMP_MAX_INTEN]**
Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]
Continuing at the end of the study? *[A:Y]*

[MED_TYPE]
Medically attended visit: *[A:ER]* Emergency Room *[A:HO]* Hospitalisation *[A:MD]* Medical Personnel *[A:NO]* None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - LOCAL SIGNS/SYMPTOMS (PENTACEL)

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI, SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN

PPD

		2	2	2	
		3	3	3	

DTPA-HBV-IPV-135 (117119): SOLICITED SYMPTOMS (Large swell flg)		
LARGE SWELLING REACTION_FLG		
Definition of a Large swelling reaction: - any local swelling with diameter >50 mm - and/or any noticeable diffuse injection site swelling (diameter not measurable) - and/or any noticeable increased circumference of the injected limb		
1.* ✔	Is a large swelling reaction as defined above present? [Large swelling reaction]	**[LARGESWELLING_FLAG]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): LARGE SWELLING REACTION (Large swelling) - Repeating Form

#	Vaccine	Date of physical examination	Start date of swelling	Size of swelling	Type of swelling	Circumference	Temperature	Redness	Induration	Pruritis	Pain	Functional impairment	Case description	Last date when the swelling was still considered to be a large swelling reaction:	Outcome of the large swelling reaction	Is there an alternative explanation for the swelling?
1																

If hospitalisation is required, please also complete a Serious Adverse Event Report.

VACCINE

1.* ✔ Vaccine: [Vaccine]
[P_CODE]
[PRODNAMES]

2.* ✔ Date of physical examination: [Date of physical examination]
[PHYSICAL EXAMDATE]
[PHYSDAT]
NReq / NReq / NReq (2013-2018)
[Examination performed]
Was the examination performed by a member of study personnel during the large swelling reaction period?
[A:N] No *[A:Y]* Yes

3.* ✔ Date when the swelling was first considered to be a large swelling reaction: [Start date of swelling]
[FIRST SWELLING DATE]
[SWFDAT]
NReq / NReq / NReq (2013-2018)

4.* ✔ Size of swelling: [Size of swelling]
[SIZE OF SWELLING]
Measurement of the greatest diameter: mm N10

5.* ✔ Type of swelling: *Please specify in the case description section* [Type of swelling]
[TYPE OF SWELLING]
[A:1] Local swelling around injection site, not involving adjacent joint
[A:2] Diffuse swelling, not involving adjacent joint
[A:3] Swelling, involving adjacent joint

6.* ✔ Circumference: [Circumference]
[CIRCUMFERENCE]
[CIRCUMFERENCE SWOLLEN LIMB]
Circumference of swollen limb (at the site of maximum swelling): mm N10

ASSOCIATED SIGNS

For Redness, Induration, Pruritis, Pain and Functional impairment, please select the Yes/No box for each symptom occurring during the large swelling reaction period. If other symptoms are associated with the large swelling, please specify in the case description section.

7.* ✔ Temperature: *Please record the temperature. If temperature has been taken more than once a day please report the highest value.* *[Temperature]*
[TEMP]
[Temperature Value]
Temperature (°F) xxx.x
[TEMP_ROUTE]
Route: *[A:A]* Axillary (Preferred) *[A:O]* Oral *[A:R]* Rectal *[A:T]* Tympanic

8.* ✔ Redness [Redness]
[REDNESS]
[A:N] No
[A:Y] **[DIAMETER for REDNESS]**
Yes -> Largest diameter: mm N10

PPD

9.* ✔	Induration [Induration]	**[INDURATION]** *[A:N]* ◯ No *[A:Y]* ◯ **[DIAMETER for INDURATION]** Yes -> Largest diameter: mm N10
10.* ✔	Pruritis [Pruritis]	**[PRURITIS]** *[A:N]* ◯ No *[A:Y]* ◯ **[INTENSITY PRURITIS]** Yes -> Intensity *[A:1]* ◯ Grade 1(An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) *[A:2]* ◯ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) *[A:3]* ◯ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
11.* ✔	Pain (at administration site): [Pain]	**[PAIN AT ADMINISTRATION SITE]** *[A:N]* ◯ No *[A:Y]* ◯ **[INSTENSITY FOR PAIN]** Yes -> Intensity *[A:1]* ◯ Grade 1 (Minor reaction to touch) *[A:2]* ◯ Grade 2 (Cries / protests on touch) *[A:3]* ◯ Grade 3 (Cries when limb is moved / spontaneously painful)
12.* ✔	Functional impairment: [Functional impairment]	**[FUNCTIONAL IMPAIRMENT]** *[A:N]* ◯ No *[A:Y]* ◯ **[INSTENSITY FOR FUNCTIONAL IMPAIRMENT]** Yes -> Intensity *[A:1]* ◯ Grade 1(An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) *[A:2]* ◯ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) *[A:3]* ◯ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
CLINICAL CASE DESCRIPTION		
13.* ✔	Case description [Case description]	**[CASE DESCRIPTION]** Please give a clinical description of the observed swelling reaction, including a description of the joint involved and specific associated symptoms. Please mention also eventual diagnostic(s) procedures and therapeutic interventions. A500
14. ✔	Last date when the swelling was still considered to be a large swelling reaction: [Last date when the swelling was still considered to be a large swelling reaction:]	**[LAST SWELLING DATE]** **[SWLDAT]** NReq / NReq / NReq (2013-2018)
15.*	Outcome of the large swelling reaction: [Outcome of the large swelling reaction]	**[OUTCOME_SW]**

PPD

✔		*[A:1]* ◯ Recovered / Resolved *[A:2]* ◯ Recovering / Resolving *[A:3]* ◯ Not recovered / Not resolved -> Please provide further follow-up data *[A:4]* ◯ Recovered / Resolved with sequelae -> Please specify in the case description section
16.* ✔	Is there an alternative explanation for the swelling? (e.g.: allergy, infection, trauma, underlying conditions) [Is there an alternative explanation for the swelling?]	**[SWELLING ALTERNATIVE]** *[A:N]* ◯ No *[A:Y]* ◯ **[SWELLING EXPLANATION]** Yes -> Please specify: A500

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: LARGE SWELLING REACTION

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
PRODNAMES	String	Acthib	3	Acthib	P_CODE
		Pentacel	404	Pentacel	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
SYMPUNITS	String	Celsius	CE	CE	SIZE OF SWELLING_UNI, CIRCUMFERENCE SWOLLEN LIMB_UNI_HD, CIRCUMFERENCE OPPOSITE LIMB_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	

PPD

DTPA-HBV-IPV-135 (117119): SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS (Gen symp)

If any of these adverse events meets the definition of serious, complete a Serious Adverse Event Report.

TEMPERATURE (°F)

Record temperatures if during the solicited period at least one axillary/oral/tympanic/rectal measure is above or equal to 100.4 °F

1.* ✔ Occurred?

[FE_YN]
[A:N] ◯ No
[A:NT] ◯ Not taken
[A:Y] ◯ **[SYMP_VAL_TEMP]**
Yes -> **[FE_VAL_D0]** Day 0: **[FE_VAL]** xxx.x | **[FE_VAL_D1]** Day 1: **[FE_VAL]** xxx.x | **[FE_VAL_D2]** Day 2: **[FE_VAL]** xxx.x | **[FE_VAL_D3]** Day 3: **[FE_VAL]** xxx.x
Not taken
[FE_NT] *[A:Y]* ☐ | **[FE_NT]** *[A:Y]* ☐ | **[FE_NT]** *[A:Y]* ☐ | **[FE_NT]** *[A:Y]* ☐

[TEMP_ROUTE]
Route: *[A:A]* ◯ Axillary (Preferred) *[A:O]* ◯ Oral *[A:R]* ◯ Rectal *[A:T]* ◯ Tympanic

[FE_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_TEMP]**
Yes -> **[SYMP_MAX_TEMP]**
Max temperature: xxx.x

[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

[CONT_END]
Continuing at the end of the study? *[A:Y]* ☐

[CAUSAL]
Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes

[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

DROWSINESS

2.* ✔ Occurred?

[DR_YN]
[A:N] ◯ No
[A:Y] ◯ **[SYMP_VAL_INTEN]**
Yes -> **[SYMP_VAL_INTEN_D0]** Day 0: **[INTENSITYSOL]** | **[SYMP_VAL_D1]** Day 1: **[INTENSITYSOL]** | **[SYMP_VAL_INTEN_D2]** Day 2: **[INTENSITYSOL]** | **[SYMP_VAL_INTEN_D3]** Day 3: **[INTENSITYSOL]**
Intensity:

[DR_ONG]
After Day 3: Ongoing? *[A:N]* ◯ No
[A:Y] ◯ **[SYMP_ONG_INTEN]**
Yes -> **[SYMP_MAX_INTEN]**
Maximum intensity: **[INTENSITYSOLMAX]**

[ERDAT]
Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018)

PPD

		[CONT_END] Continuing at the end of the study? *[A:Y]* ☐ **[CAUSAL]** Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes **[MED_TYPE]** Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None
IRRITABILITY/FUSSINESS		
3.* ✔	Occurred?	**[IF_YN]** *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_VAL_INTEN]** Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]** Intensity: Day 0: Day 1: Day 2: Day 3: **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[IF_ONG]** **After Day 3**: Ongoing? *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_ONG_INTEN]** Yes -> **[SYMP_MAX_INTEN]** Maximum intensity: **[INTENSITYSOLMAX]** **[ERDAT]** Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) **[CONT_END]** Continuing at the end of the study? *[A:Y]* ☐ **[CAUSAL]** Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes **[MED_TYPE]** Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None
LOSS OF APPETITE		
4.* ✔	Occurred?	**[LO_YN]** *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_VAL_INTEN]** Yes -> **[SYMP_VAL_INTEN_D0]** **[SYMP_VAL_D1]** **[SYMP_VAL_INTEN_D2]** **[SYMP_VAL_INTEN_D3]** Intensity: Day 0: Day 1: Day 2: Day 3: **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[INTENSITYSOL]** **[LO_ONG]** **After Day 3**: Ongoing? *[A:N]* ◯ No *[A:Y]* ◯ **[SYMP_ONG_INTEN]** Yes -> **[SYMP_MAX_INTEN]** Maximum intensity: **[INTENSITYSOLMAX]** **[ERDAT]** Date of last day of sign/symptom: Req/Unk / Req/Unk / Req/Unk (2013-2018) **[CONT_END]** Continuing at the end of the study? *[A:Y]* ☐ **[CAUSAL]**

PPD

Is there a reasonable possibility that the AE may have been caused by the investigational product? *[A:N]* ◯ No *[A:Y]* ◯ Yes

[MED_TYPE]
Medically attended visit: *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SOLICITED ADVERSE EVENTS - GENERAL SIGNS/SYMPTOMS

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID, SYMP_COD_HID
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	
SYMPUNITS	String	Celsius	CE	CE	SYMP_UNI
		Coded	CO	CODED	
		Fahrenheit	FA	FAR	
		inches	IN	INCH	
		Millimeters	MM	MM	
		Occurence	OC	OC	
		Score	SC	SCORE	
INTENSITYSOL	String	0	0	0	SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3, SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3, SYMP_VAL_INTEN_D0, SYMP_VAL_D1, SYMP_VAL_INTEN_D2, SYMP_VAL_INTEN_D3
		1	1	1	
		2	2	2	
		3	3	3	
INTENSITYSOLMAX	String	1	1	1	SYMP_MAX_INTEN, SYMP_MAX_INTEN, SYMP_MAX_INTEN
		2	2	2	
		3	3	3	

DTPA-HBV-IPV-135 (117119): CHECK FOR STUDY CONTINUATION (Study cont.)

CHECK FOR STUDY CONTINUATION

1.* ✔ Did the subject return for this visit?

[VIS_FLG]

[A:Y] **[ACTRDATE]**
Yes -> Date of visit: Req / Req / Req (2013-2018)

[A:N] **[VIS_REAS]**
No **[VIS_REAS]**
-> Please select the major reason:

[A:SAE] **[SAE_CASE]**
Serious Adverse Event **[SAE_CASE]**
-> Please complete a **SAE** Report and specify SAE Report No. N2

[FATAL]
-> Tick box if SAE is fatal: *[A:Y]*

[A:AEX] **[AE_NB]**
Non-Serious Adverse Event **[AE_NB]**
-> Please complete **Non-Serious Adverse Event** section and specify AE No. N2

[SYMP_COD]
or Solicited AE code: **[SYMPCODE]**

[A:PTV] **[PTV_SP]**
Protocol violation, please specify:
A50

[A:CWS] **[CWS]**
Consent Withdrawal not due to an adverse event
->Please specify the reason (only if the Subject's parents / Legally Acceptable Representative has / have spontaneously explained it):
[CWS_SP]
A50

[CWS_NA]
Or tick box if reason not provided *[A:N]*

[A:MIG] Migrated / moved from the study area

[A:LFU] Lost to follow-up

[A:SST] Sponsor study termination

[A:OTH] **[V_OTH]**
Other, please specify
A100

[DECISION]
-> For serious (except death), non-serious adverse events and Other reasons only:
Please select who made the decision:

[A:I] Investigator

[A:P] Subject's parents / Legally Acceptable Representatives

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: CHECK FOR STUDY CONTINUATION

PPD

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
SYMPCODE	String	Drowsiness	DR	DR	SYMP_COD
		Fever	FE	FE	
		Loss Of Appetite	LO	LO	
		Pain	PA	PA	
		Redness	RE	RE	
		Swelling	SW	SW	
		Irritability / Fussiness	IF	IF	

DTPA-HBV-IPV-135 (117119): LOG STATUS (Log status)		
CONCOMITANT VACCINATION		
1.* ✔	Have any vaccines required to be reported as per protocol other than the study vaccine(s) been administered?	**[CV_FLAG]** *[A:Y]* ◯ Yes -> Please complete the following page *[A:N]* ◯ No
MEDICATION		
2.* ✔	Have any medications that are required to be reported per protocol been administered?	**[MD_FLAG]** *[A:Y]* ◯ Yes -> Please complete the following page *[A:N]* ◯ No
NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS		
Please report serious adverse events only in the Serious Adverse Events Report, not here.		
3.* ✔	Have any non-serious adverse events that are required to be reported per protocol occurred?	**[AE_FLAG]** *[A:Y]* ◯ Yes -> Please complete the following page *[A:N]* ◯ No

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

PPD

DTPA-HBV-IPV-135 (117119): CONCOMITANT VACCINATION (Conc vacc) - Repeating Form			
#	Vaccine name	Route	Date of administration
1			

CONCOMITANT VACCINATION

Please record any concomitant vaccination according to the protocol reporting requirements. **Vaccination admistered prior to the first dose of study vaccine are to be recorded in vaccination history section**

1.* ✔	Vaccine name: (Trade name is preferred) [Vaccine name]	**[CVACC_TRADNAME]** A60
2.* ✔	Route: [Route]	**[CVACC_ROUTE]** **[MEDROUT_CVACC]**
3.* ✔	Date of administration: [Date of administration]	**[CVACC_RDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: CONCOMITANT VACCINATION

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
MEDROUT_CVACC	String	Inhalation	IH	Inhalation	CVACC_ROUTE
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	
		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Transdermal	TD	Transdermal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

PPD

DTPA-HBV-IPV-135 (117119): MEDICATION (Medic) - Repeating Form

#	Drug Name	Medical indication:	Total daily dose	Route	Start date	End date
1						

MEDICATION

Please record any concomitant medication according to the protocol reporting requirements.

1.* ✔	Drug name: [Drug Name]	**[CMTERM]** A100
2.* ✔	Medical indication:	**[MEDINDIC]** **[MEDINDIC]** A80 **[PROPH_CK]** In anticipation of study vaccine reaction *[A:Y]* ☐ **[CHRON_CK]** Chronic use *[A:Y]* ☐
3.* ✔	Total daily dose: [Total daily dose]	**[TOTDDOSE]** **[MED_DOSE]** Dose: A20 **[MED_UNIT]** Unit: A20
4.* ✔	Route: [Route]	**[MED_ROUT]** **[MEDROUT_MED]**
5.* ✔	Start date: [Start date]	**[SRDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)
6.* ✔	End date: or tick box if continuing at the end of the study [End date]	**[MEDERDAT]** **[ERDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018) **[CONT_END]** Continuing at the end of the study *[A:Y]* ☐

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: MEDICATION

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
MEDROUT_MED	String	Inhalation	IH	Inhalation	MED_ROUT
		Intraarticular	IR	Intraarticular	
		Intradermal	ID	Intradermal	
		Intramuscular	IM	Intramuscular	

		Intranasal	IN	Intranasal	
		Intravenous	IV	Intravenous	
		Oral	PO	Oral	
		Parenteral	PE	Parenteral	
		Rectal	PR	Rectal	
		Subcutaneous	SC	Subcutaneous	
		Sublingual	SL	Sublingual	
		Topical	TO	Topical	
		Transdermal	TD	Transdermal	
		Vaginal	VA	Vaginal	
		Other	OTH	OTHER_OTH	
		Unknown	UNK	Unknown	

PPD

DTPA-HBV-IPV-135 (117119): NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS (Non-Ser AE) - Repeating Form

#	AE No.	Event	Site:	Start date:	Outcome	End date	Maximum intensity	Is there a reasonable possibility that the AE may have been caused by the investigational product?	Medically attended visit
1									

NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS

Please record any non-serious AEs to the protocol reporting requirements.

1.	AE No. *[read-only]*	**[AE_NO]** N3
2.* ✔	Event: Diagnosis only (if known), otherwise sign/symptom [Event]	**[AETERM]** A100
3.* ✔	Site:	**[AE_LG]** *[A:L]* ◯ **[P_CODE]** Administration site: **[PRODNAMES]** *[A:G]* ◯ Non-administration site
4.* ✔	Start date:	**[AE_SRDAT]** **[SRDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018) **[AEPOSTVC]** 30 minutes immediate post-vaccination *[A:Y]* ☐
5.* ✔	Outcome: [Outcome]	**[OUTCOME_NSAE]** *[A:1]* ◯ Recovered/resolved *[A:2]* ◯ Recovering/resolving *[A:3]* ◯ Not recovered/not resolved *[A:4]* ◯ Recovered/resolved with sequelae
6. ✔	End date: [End date]	**[ERDAT]** Req/Unk / Req/Unk / Req/Unk (2013-2018)
7.* ✔	Maximum intensity: [Maximum intensity]	**[AE_INTEN]** *[A:1]* ◯ Mild *[A:2]* ◯ Moderate *[A:3]* ◯ Severe
8.* ✔	Is there a reasonable possibility that the AE may have been caused by the investigational product?	**[CAUSAL]** *[A:N]* ◯ No *[A:Y]* ◯ Yes
9.* ✔	Medically attended visit: [Medically attended visit]	**[MED_TYPE]** *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel

PPD

		[A:NO] ◯ None	

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: NON-SERIOUS ADVERSE EVENTS AND INTERCURRENT MEDICAL CONDITIONS

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
PRODNAMES	String	Infanrix Hexa	158	Infanrix Hexa	P_CODE
		Prevnar 13	406	Prevnar 13	
		Pediarix	198	Pediarix	
		Acthib	3	Acthib	
		Pentacel	404	Pentacel	
		Rotarix	270	Rotarix	
		Engerix-B	5	Engerix-B	
		Infanrix	9	Infanrix	
		Hiberix	95	Hiberix	
AFTER / BEFORE	String	After vaccination	A	After	AE_VACC
		Before vaccination	B	Before	

DTPA-HBV-IPV-135 (117119): OCCURRENCE OF SERIOUS ADVERSE EVENTS (SAE Flg)		
OCCURRENCE OF SERIOUS ADVERSE EVENTS		
1.* ✔	Did the subject experience any Serious Adverse Events that are required to be reported per protocol?	**[SAE_FLG]** *[A:Y]* ◯ Yes -> Please remember to complete a SAE Report *[A:N]* ◯ No

Key: [*] = Item is required [✔] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): SERIOUS ADVERSE EVENTS (SAE) - Repeating Form

#	SAE Report No.	Did SAE occur after initiation of study medication?	SERIOUS ADVERSE EVENT	Seriousness	RELEVANT CONCOMITANT/TREATMENT MEDICATIONS/VACCINATIONS	RELEVANT MEDICAL CONDITIONS/RISK FACTORS	RELEVANT DIAGNOSTIC RESULTS	Relevant diagnostic results not noted on the left columns	General narrative comments
1									

If you wish to record a new SAE please determine if the new SAE is clinically or temporally related to an SAE previously entered on this form.
If yes, record the details below using the 'Add Entry' button in this form.
If not clinically or temporally related, create a new SAE form for this subject by clicking on the 'New' button at the top of the page.
Do not record pre and post randomization events on the same form.

SAE REPORT NO.

1. ✔ SAE Report No. *[read-only]*
[SAE Report No.]
[SAE_NB]
N2

TYPE OF REPORT

RANDOMIZATION

2.* Did the event occur after initiation of investigational product(s)?
[Did SAE occur after initiation of study medication?]
[rdcSAERAND]
[A:N] ○ No
[A:Y] ○ Yes

	No.	Event	Start date and time	Outcome / End date and time	Maximum Intensity	Action taken with investigational product(s) as a result of the event	Did the subject withdraw from study due to this event?	Is there a reasonable possibility that the event may have been caused by the investigational product(s)?	Was the AE caused by activities related to study participation other than investigational product?	Medically attended visit
3. ✔										

SERIOUS ADVERSE EVENT Entry

Use the 'Add Entry' button to enter details of the SAE. For additional SAEs that are clinically or temporally related (e.g., SAEs that occur during the same hospitalization) use the 'Add Entry' button to create a new row for entry of the additional SAE. Enter ONE event per row.

3.1 No. *[read-only]*
[No.]
[AESEQ]
N5

3.2* ✔ Event:
Diagnosis only (if known), otherwise sign/symptom
[Event]
[AETERM]
A100

3.3* Start date and time
Hr:Min (00:00-23:59)
[Start date and time]
[AESTDTTM]
Req/Unk / Req/Unk / Req (2013-2018)
NReq : NReq *24-hour clock*

3.4* Outcome / End date and time
Hr:Min (00:23-59)
[Outcome / End date and time]
[AEOUTCD1]
[A:1] ○ **[AEENDTTM1]**
Recovered/resolved, provide End date and time
Req/Unk / Req/Unk / Req/Unk (2013-2018)
NReq : NReq *24-hour clock*
[A:2] ○ Recovering/resolving
[A:3] ○ Not recovered/not resolved

PPD

		[A:4] ◯ **[AEENDTTM2]** Recovered/resolved with sequelae, provide End date and time Req/Unk / Req/Unk / Req/Unk (2013-2018) NReq : NReq *24-hour clock* *[A:5]* ◯ **[AEENDTTM3]** Fatal, record Date and time of Death Req/Unk / Req/Unk / Req/Unk (2013-2018) NReq : NReq *24-hour clock*
3.5*	Maximum Intensity **Record maximum intensity throughout duration of event** [Maximum Intensity]	**[AESEVCD]** *[A:1]* ◯ Mild *[A:2]* ◯ Moderate *[A:3]* ◯ Severe *[A:X]* ◯ Not applicable
3.6*	Action taken with investigational product(s) as a result of the event: [Action taken with investigational product(s) as a result of the event]	**[AEACTRCD]** *[A:1]* ◯ Investigational product(s) withdrawn *[A:4]* ◯ Dose not changed *[A:5]* ◯ Dose delayed *[A:X]* ◯ Not applicable
3.7*	Did the subject withdraw from study due to this event? [Did the subject withdraw from study due to this event?]	**[AEWD]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
3.8*	Is there a reasonable possibility that the event may have been caused by the investigational product(s)? ***Use best judgment at initial entry. May be amended when additional information becomes available.*** [Is there a reasonable possibility that the event may have been caused by the investigational product(s)?]	**[AEREL]** *[A:N]* ◯ No *[A:Y]* ◯ Yes
3.9*	Was the AE caused by activities related to study participation other than investigational product? [Was the AE caused by activities related to study participation other than investigational product?]	**[rdcAESREL]** *[A:Y]* ◯ Yes *[A:N]* ◯ No
3.10* ✔	Medically attended visit: [Medically attended visit]	**[MED_TYPE]** *[A:ER]* ◯ Emergency Room *[A:HO]* ◯ Hospitalisation *[A:MD]* ◯ Medical Personnel *[A:NO]* ◯ None
SERIOUSNESS		
4. ✔	Specify the reason for considering this event as SAE. (Tick all that apply)	**[chkAESER]** *[A:A]* ☐ Results in death

PPD

	[Seriousness]	[A:B] ☐ Is life-threatening (subject was at risk of death at time of event) [A:C] ☐ Requires hospitalisation or prolongation of hospitalisation (Provide admission and discharge date(s) in narrative) [A:D] ☐ Results in disability/incapacity (substantial / permanent) [A:E] ☐ Congenital anomaly/birth defect (in offspring of subject) [A:F] ☐ Other, specify within general narrative comment

	Drug Name	Total daily dose	Route	Start Date	End date	Medical Indication	Drug type
5. ✔							

RELEVANT CONCOMITANT/TREATMENT MEDICATIONS/VACCINATIONS Entry

Use the 'Add Entry' button to enter details of any medication/vaccine that may help to explain the SAE, may have caused the SAE or was used to treat the SAE. Ensure each concomitant vaccination or medication recorded in this section is also recorded in the corresponding form located in the LOGS section of the eCRF.

5.1* ✔	Drug name: [Drug Name]	**[CMTERM]** (Trade name is preferred) A100
5.2 ✔	Total daily dose: [Total daily dose]	**[SAECMDOS]** **[txtSAECMDOS]** Dose: xxxxxxxxx. **[pdcCMUNIT]** Unit: **[clCMUNITSAE]**
5.3*	Route [Route]	**[pdcCMROUTCD]** **[MEDROUT_MEDSAE]**
5.4*	Start Date [Start Date]	**[dtmSAECMSTD]** NReq/Unk / NReq/Unk / NReq/Unk (2002-2018)
5.5 ✔	End date: or tick box if continuing at the end of the study [End date]	**[SAECMEND]** **[dtmSAECMEND]** NReq/Unk / NReq/Unk / NReq/Unk (2002-2018) **[rdcSAECMONG]** Continuing at the end of the study [A:Y] ☐
5.6	Medical indication *Enter a medical diagnosis not description* [Medical Indication]	**[txtCMIND]** A50
5.7*	Drug type: [Drug type]	**[pdcCMDRGTYP]** **[clDRUGTYP]**

	Condition	Start date	Continuing at time of SAE?
6. ✔			

RELEVANT MEDICAL CONDITIONS/RISK FACTORS Entry

Use the 'Add Entry' button to enter each past or current medical disorder, allergy or surgery that may be RELEVANT to the SAE. Enter a diagnosis, not description. Relevant family or social history shoud be described in the 'General Narrative Comments' at the bottom of this form. Ensure each medical condition/risk factor recorded in this section is also recorded in the General Medical History form located at the beginning of the eCRF.

PPD

6.1*	Condition ***Enter a medical diagnosis not description.*** [Condition]	**[txtSAEMHTRM]** A100
6.2*	Start date: [Start date]	**[dtmMHSTDTM]** Req/Unk / Req/Unk / Req/Unk (2002-2018)
6.3*	Continuing at time of SAE? [Continuing at time of SAE?]	**[rdcMHCONT]** *[A:Y]* Yes *[A:N]* **[dtmMHLSTOC]** No, specify end date or date of last occurrence Req/Unk / Req/Unk / Req/Unk (2002-2018) *[A:U]* Unknown, no information available

	Test name	Test date	Test result	Test units	Normal low range	Normal high range
7. ✔						

RELEVANT DIAGNOSTIC RESULTS Entry

Use the 'Add Entry' button to enter details of relevant tests or procedures carried out to diagnose or confirm the SAE or rule out other diagnoses

7.1*	Test name [Test name]	**[pdcLBTST]** **[clSAELBTST]**
7.2*	Test date [Test date]	**[dtmLABDTM]** Req/Unk / Req/Unk / Req (2002-2018)
7.3*	Test result [Test result]	**[txtLABRES]** A12
7.4*	Test units [Test units]	**[txtLABUNIT]** A12
7.5*	Normal low range [Normal low range]	**[txtLABNLR]** xxxxxxxxx.xx
7.6*	Normal high range [Normal high range]	**[txtLABNHR]** xxxxxxxxx.xx
8.	Enter here only the diagnostic results that could not be entered in the above grid, including procedure such as ECG, X rays, etc and tests on stool, CSF etc. Also provide dates. [Relevant diagnostic results not noted on the left columns]	**[cmpLABTEXT]** **[txtLABTEXT]** A1000 **[txtLABTEXT1]** A1000

PPD

GENERAL NARRATIVE COMMENTS		
Provide a clear (this narrative will be provided to regulatory authorities) and brief chronological description (with dates) of the clinical course of the event including: - Associated signs and symptoms - Clinical evolution (hospitalisation, outcome, description of sequelae if any, autopsy results, etc.) - Non-drug treatment such as surgery - Other information useful for the medical assessment of the case (e.g. reason for diagnosis if not obvious or if diagnosis changed) - Relevant additional risk factors including family or social history (negative sentence can also be helpful) - Possible cause(s) of the event - Rationale for relationship when SAE is possibly related to study product, concomitant product or study procedure, etc. Complete a new box only when the previous one is full.		
9.*	General narrative comments	**[cmpNARRATIVE]** **[txtSAECOMM]** A1000 **[txtSAECOMM1]** A1000 **[txtSAECOMM2]** A1000

PPD

[txtSAECOMM3]
A1000

NON CLINICAL

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SERIOUS ADVERSE EVENTS

Codelist	Codelist Data Type	Label	Code	Codelist Item	Data Variable
clCMUNITSAE	String	ACTU	ACTU	clCMUNIT_ACTU	pdcCMUNIT
		AMP	AMP	clCMUNIT_AMP	
		application(s)	AP	clCMUNIT_AP	
		BT	BT	clCMUNIT_BT	
		capsule	CAP	clCMUNIT_CAP	
		Cubic centimeter	CC	clCMUNIT_CC	
		MBecquerel	16	citmCMUNIT_MBQ	
		Variable dose	VA	citmCMUNIT_VA	
		blister	BLS	citmCMUNIT_BLS	
		caplet(s)	CAPL	citmCMUNIT_CAPL	
		cg	CG	citmCMUNIT_CG	

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		drop(s)	31	citmCMUNIT_DROP
		elisa unit	EU	citmCMUNIT_EU
		g/L	GML	citmCMUNIT_GM/L
		g/M2	GM/M2	citmCMUNIT_GM/M2
		g/kg	GM/KG	citmCMUNIT_GM/KG
		grain	GR	citmCMUNIT_GR
		gram(s)	2	citmCMUNIT_G
		inch	INCH	citmCMUNIT_INCH
		injection	INJ	citmCMUNIT_INJ
		iu	25	citmCMUNIT_IU
		iu x 10**3	26	citmCMUNIT_IU3
		iu x 10**6	27	citmCMUNIT_IU6
		liter	11	citmCMUNIT_L
		lozenge	LOZ	citmCMUNIT_LOZ
		mCi	19	citmCMUNIT_MCI
		mEq	29	citmCMUNIT_MEQ
		mcg	4	citmCMUNIT_MCG
		mcg/mg	MCG/MG	citmCMUNIT_MCG/MG
		Megaunits (million units)	MEGU	citmCMUNIT_MEGU
		mg	3	citmCMUNIT_MG
		mg/kg	7	citmCMUNIT_MGK
		mg/m2	9	citmCMUNIT_MGM2
		mg/min	MGM	citmCMUNIT_MGM
		mg/ml	MGML	citmCMUNIT_MGML
		micro unit	MCRU	citmCMUNIT_MCU
		ml	12	citmCMUNIT_ML
		ml/hr	MLH	citmCMUNIT_MLH
		mm	MM	citmCMUNIT_MM
		mmol	23	citmCMUNIT_MMOL
		nebule(s)	NEB	citmCMUNIT_NEB
		ng	5	citmCMUNIT_NG
		ng/kg	NGK	citmCMUNIT_NGK
		ounce	OZ	citmCMUNIT_OZ
		patch	PAT	citmCMUNIT_PAT
		percent	30	citmCMUNIT_PCT
		puff(s)		

PPD

			PUFF	citmCMUNIT_PUFF	
		sachet	SAC	citmCMUNIT_SAC	
		spray	SPR	citmCMUNIT_SPR	
		suppository	SUP	citmCMUNIT_SUP	
		tablespoon	TBS	citmCMUNIT_TBS	
		tablet	TAB	citmCMUNIT_TAB	
		teaspoon	TSP	citmCMUNIT_TSP	
		uBecquerel	14	citmCMUNIT_UBQ	
		ugk	8	citmCMUNIT_UGK	
		umol	24	citmCMUNIT_UMOL	
		unit	UNT	citmCMUNIT_UNT	
		unknown	U	citmCMUNIT_U	
		vial(s)	VIA	citmCMUNIT_VIA	
clSAECMFRQ	String	2 times per week	2W	clSAECMFRQ_2W	pdcSAECMFRQ
		3 times per week	3W	clSAECMFRQ_3W	
		4 times per week	4W	clSAECMFRQ_4W	
		5 times per day	5D	clSAECMFRQ_5D	
		5 times per week	5W	clSAECMFRQ_5W	
		AC	AC	clSAECMFRQ_AC	
		BID	2D	clSAECMFRQ_2D	
		Continuous infusion	CO	clSAECMFRQ_CO	
		Every 2 weeks	FO	clSAECMFRQ_FO	
		Every 3 weeks	Q3W	clSAECMFRQ_Q3W	
		Every 3 months	Q3M	clSAECMFRQ_Q3M	
		Every other day	AD	clSAECMFRQ_AD	
		Once a month	MO	clSAECMFRQ_MO	
		Once a week	WE	clSAECMFRQ_WE	
		Once daily	1D	clSAECMFRQ_1D	
		Once only	1S	clSAECMFRQ_1S	
		PC	PC	clSAECMFRQ_PC	
		PRN	PRN	clSAECMFRQ_PRN	
		Q2H	12D	clSAECMFRQ_Q2H	
		Q3D	Q3D	clSAECMFRQ_Q3D	
		Q4D	Q4D	clSAECMFRQ_Q4D	
		Q4H	6D	clSAECMFRQ_Q4H	

PPD

		QAM	1M	clSAECMFRQ_QAM	
		QH	24D	clSAECMFRQ_QH	
		QID	4D	clSAECMFRQ_QID	
		QPM	1N	clSAECMFRQ_QPM	
		TID	3D	clSAECMFRQ_TID	
MEDROUT_MEDSAE	String	Inhalation	055	Inhalation	pdcCMROUTCD
		Intraarticular	014	Intraarticular	
		Intradermal	023	Intradermal	
		Intramuscular	030	Intramuscular	
		Intranasal	045	Intranasal	
		Intravenous	042	Intravenous	
		Oral	048	Oral	
		Parenteral	051	Parenteral	
		Rectal	054	Rectal	
		Subcutaneous	058	Subcutaneous	
		Sublingual	060	Sublingual	
		Topical	061	Topical	
		Transdermal	062	Transdermal	
		Vaginal	067	Vaginal	
		Other	050	Other	
		Unknown	065	Unknown	
clDRUGTYP	String	Concomitant	2	clDRUGTYP_01	pdcCMDRGTYP
		Treatment	T	clDRUGTYP_02	
		Cause of AE	1	clDRUGTYP_03	
clSAELBTST	String	Activated partial thromboplastin time	Activated partial thromboplastin time	SAELBTST01	pdcLBTST
		Alanine aminotransferase	Alanine Amino Transferase	SAELBTST79	
		Albumin	Albumin	SAELBTST02	
		Alkaline phosphatase	Alkaline phosphatase	SAELBTST03	
		Amylase	Amylase	SAELBTST04	
		Aspartate Amino Transferase	Aspartate Amino Transferase	SAELBTST80	
		Band Neutrophil count	Band Neutrophil count	SAELBTST81	
		Base Excess	Base Excess	SAELBTST82	
		Basophils	Basophils	SAELBTST05	
		Bicarbonate	Bicarbonate	SAELBTST06	
		Bilirubin	Bilirubin	SAELBTST07	

PPD

		Bilirubin direct	Bilirubin direct	SAELBTST08
		Bilirubin total	Bilirubin total	SAELBTST09
		Blood glucose	Blood glucose	SAELBTST83
		Blood myoglobin	Blood myoglobin	SAELBTST10
		Blood pH	Blood pH	SAELBTST11
		Blood pressure	Blood pressure	SAELBTST12
		Blood urea nitrogen	Blood urea nitrogen	SAELBTST13
		Body temperature	Body temperature	SAELBTST14
		Calcium	Calcium	SAELBTST15
		Carbone dioxide	Carbone dioxide	SAELBTST84
		CD4 lymphocytes	CD4 lymphocytes	SAELBTST16
		CD8 lymphocytes	CD8 lymphocytes	SAELBTST17
		Chloride	Chloride	SAELBTST18
		Cholesterol total	Cholesterol total	SAELBTST19
		C-reactive protein	C-reactive protein	SAELBTST20
		Creatine	Creatine	SAELBTST21
		Creatine phosphokinase	Creatine phosphokinase	SAELBTST22
		Creatine phosphokinase MB	Creatine phosphokinase MB	SAELBTST23
		Creatinine	Creatinine	SAELBTST24
		Creatinine clearance	Creatinine clearance	SAELBTST25
		Diastolic blood pressure	Diastolic blood pressure	SAELBTST26
		Eosinophils	Eosinophils	SAELBTST27
		Erythrocyte sedimentation rate	Erythrocyte sedimentation rate	SAELBTST28
		Fasting blood glucose	Fasting blood glucose	SAELBTST29
		FEV 1	FEV 1	SAELBTST30
		Gamma-glutamyltransferase	Gamma-glutamyltransferase	SAELBTST31
		Granulocyte count	Granulocyte count	SAELBTST85
		HbA1c	HbA1c	SAELBTST34
		HBV-DNA decreased	HBV-DNA decreased	SAELBTST35
		HBV-DNA increased	HBV-DNA increased	SAELBTST36
		Heart rate	Heart rate	SAELBTST37
		Hematocrit	Hematocrit	SAELBTST38
		Hemoglobin	Hemoglobin	SAELBTST39
		High density lipoprotein	High density lipoprotein	SAELBTST40
		HIV viral load	HIV viral load	SAELBTST41
		INR		

PPD

	INR	SAELBTST42
International normalized ratio	International normalized ratio	SAELBTST88
Lactate dehydrogenase	Lactate dehydrogenase	SAELBTST43
Lipase	Lipase	SAELBTST44
Low density lipoprotein	Low density lipoprotein	SAELBTST45
Lymphocytes	Lymphocytes	SAELBTST46
Magnesium	Magnesium	SAELBTST47
Mean cell hemoglobin concentration	Mean cell hemoglobin concentration	SAELBTST48
Mean corpuscular hemoglobin	Mean corpuscular hemoglobin	SAELBTST49
Mean corpuscular volume	Mean corpuscular volume	SAELBTST50
Mean Platelet Volume	Mean Platelet Volume	SAELBTST89
Monocytes	Monocytes	SAELBTST51
Myoglobin urine	Myoglobin urine	SAELBTST90
Neutrophils	Neutrophils	SAELBTST52
Oxygen saturation	Oxygen saturation	SAELBTST53
pCO2	pCO2	SAELBTST54
pH	pH	SAELBTST55
pH urine	pH urine	SAELBTST91
Phosphate	Phosphate	SAELBTST56
Platelet count	Platelet count	SAELBTST57
pO2	pO2	SAELBTST58
Polymerase Chain Reaction	Polymerase Chain Reaction	SAELBTST92
Polymorphonuclear Count	Polymorphonuclear Count	SAELBTST93
Potassium	Potassium	SAELBTST59
Protein total	Protein total	SAELBTST60
Prothrombin time	Prothrombin time	SAELBTST61
Red blood cell count	Red blood cell count	SAELBTST62
Red Cell Distribution Width	Red Cell Distribution Width	SAELBTST94
Respiratory rate	Respiratory rate	SAELBTST63
Reticulocyte count	Reticulocyte count	SAELBTST64
Segmented Neutrophil Count	Segmented Neutrophil Count	SAELBTST95
Serum glucose	Serum glucose	SAELBTST65
Serum uric acid	Serum uric acid	SAELBTST66
Sodium	Sodium	SAELBTST67
Systolic blood pressure	Systolic blood pressure	SAELBTST68
Thrombin time		

PPD

			Thrombin time	SAELBTST69	
		Total lung capacity	Total lung capacity	SAELBTST70	
		Triglycerides	Triglycerides	SAELBTST71	
		Troponin	Troponin	SAELBTST72	
		Troponin I	Troponin I	SAELBTST73	
		Troponin T	Troponin T	SAELBTST74	
		Urine myoglobin	Urine myoglobin	SAELBTST75	
		Urine pH	Urine pH	SAELBTST76	
		Vital capacity	Vital capacity	SAELBTST77	
		White blood cell count	White blood cell count	SAELBTST78	

DTPA-HBV-IPV-135 (117119): STUDY CONCLUSION (Conclusion)		
STUDY CONCLUSION		
1.* ✔	Date of subject completion or withdrawal (or date of death if applicable):	**[LC_RDAT]** Req / Req / Req (2013-2018)

Key: [*] = Item is required [✔] = Source verification required
Note: Hidden items are not displayed.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

DTPA-HBV-IPV-135 (117119): USE OF HUMAN SAMPLES (UHS) - Repeating Form

#	Text 3A	Text 3B	Text 4	Please check GSK Biologicals sample storage period specified in the ICF in use at your centre.	If new version of UHS: Date at which the new ICF version was first signed by a Subject :
1					

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.

TYPE 3A TESTS

1.* ✔	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. [Text 3A]	**[CONS_YN_3A]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

TYPE 3B TESTS

2.* ✔	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. [Text 3B]	**[CONS_YN_3B]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

TYPE 4 TESTS

3.* ✔	With the prior permission of the Subject's parents / Legally Acceptable Representatives: 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. [Text 4]	**[CONS_YN_4]** *[A:Y]* ◯ Yes *[A:N]* ◯ No

SAMPLE STORAGE PERIOD

4.* ✔	Please check GSK Biologicals sample storage period specified in the ICF in use at your centre. [Please check GSK Biologicals sample storage period specified in the ICF in use at your centre.]	**[PERIOD]** *[A:20]* ◯ For a maximum of 20 years *[A:9]* ◯ **[PERIODSP]** Other, please specify: A200

IF NEW VERSION OF UHS FORM

Complete and submit a new Use of Human Samples by GSK form for each change in the ICF that affects the use of samples.

5. ✔	Date at which the new ICF version was first signed by a Subject : [If new version of UHS: Date at which the new ICF version was first signed by a Subject :]	**[UHS_DATE]** NReq / NReq / NReq (2013-2018)

Key: [✔] = Source verification required
Note: Hidden items are not displayed.

PPD

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

CONFIDENTIAL

GlaxoSmithKline

Diary Cards

Subject number

|__|__|__|__|__|__|__|__|

To be completed by the Investigator or delegate

***Protocol* 117119**

(DTPA-HBV-IPV-135)

Hexa GROUP- BOOSTER

PLEASE DO NOT FORGET TO BRING BACK THE DIARY CARD AT THE NEXT VISIT

CONFIDENTIAL

General Instructions

Thank you for your child's participation in this clinical trial.

During your child's last study visit, you received a "Diary Card" to fill in every day for a defined period, so that your child's study doctor or the study staff will know your child's general health status after the vaccination.

Here below you will find general instructions on how to complete the "Diary Card". There are also other specific instructions relative to each part of the "Diary Card" that you will need to fill in.

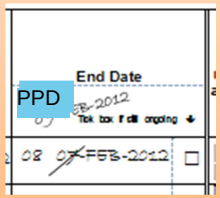
INSTRUCTIONS TO COMPLETE THE "DIARY CARD"

- Write in clearly, use a pen (never pencil).
- The grey areas are dedicated to the investigator or delegate only. Do not write in these areas.

Illness/Sign/Symptom ☑ if at vaccine injection site ↓	Worst Intensity 1/2/3	Start Date	End Date Tick box if still ongoing ↓	Did you receive medical attention?	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
Tendinitis ☐	2	04-FEB-2012	08-FEB-2012 ☐	☐ No ☒ Yes	HOERMD ☐☐	☐ No ☐ Yes

➢ *HOW TO CORRECT MISTAKES?*

- Cross out the mistake with a single line.
- Don't hide the mistake. Don't use correction fluid or don't make inkblots.
- Write the correct response close to the mistaken one.
- If the correct response is written outside of the box, circle it and point to it with an arrow towards the box.
- **Put your initials near the correction.**
- **Date the correction**



➢ *WHO TO CONTACT IN CASE OF QUESTIONS?*

If you have any questions, please contact your child's study doctor or the study staff on the following phone number:

[insert phone n° of the study doctor or study staff]

Please contact your child's study doctor or the study staff immediately if your child has any symptoms you think are serious.

Instructions to complete:
Local and general symptoms

- If your child experience(s) any other symptoms than those listed in the local symptoms or general symptoms pages, please write these symptoms down in the Adverse Event section.
- If a symptom <u>appears only after</u> day 3, please write this symptom down in the Adverse Event section.

➢ *<u>HOW TO COMPLETE DIARY CARD FOR ANY SYMPTOM "AFTER DAY 3"?</u>*

- In the columns "After day 3", if the symptom is still ongoing* after day 3, tick "Yes". Otherwise, tick "No".

* The symptom is ongoing if after day 3:
- The intensity of the symptom is 1 or higher
- The oral (in the mouth), axillary (under the armpit), tympanic (in the ear) or rectal (in the anus) temperature is higher or equal to 100.4°F.

- If Yes,
  - Please write the worst intensity for pain, the highest temperature or the greatest measurement of Redness or swelling recorded for the respective symptom during this follow-up period, after day 3.
  - And note the date when the symptom has disappeared or tick the box "still ongoing".
- If No, then leave empty the columns "Worst intensity/ greatest size/ highest temperature" and "End Date".

➢ *<u>BOX "STILL ONGOING" IN COLUMN "END DATE" – WHEN TO TICK IT?</u>*

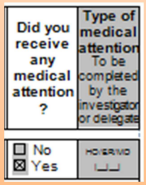
- Tick the box "Still ongoing" if the illness /sign /symptom is still present at the time you return the diary card to the site

	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	Worst Intensity/ Greatest size	End Date Tick box if still ongoing ↓		
Injection site **Redness** → size (mm)	mm 10	mm 8	mm 5	mm 3	☐ No ☒ Yes →	mm 2	☒	☐ No ☒ Yes	HO/ERMD ___

➢ *DID YOUR CHILD RECEIVE ANY MEDICAL ATTENTION? HOW TO COMPLETE THIS QUESTION?*

- Medical attention means hospitalisation, an emergency room visit or a visit to or from medical personnel.
- Tick the box "No" if your child did not visit medical personnel or was not visited by medical personnel or did not go to the hospital or an emergency room for the symptom.
- Tick the box "Yes" if your child went to the hospital, an emergency room, if your child visited medical personnel or was visited by medical personnel for the symptom.

  Keep the type of medical attention (grey column) empty. It will be completed by the study doctor or study staff.



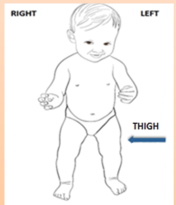
Instructions to complete:
Local symptoms

- If your child receive(s) more than one vaccine, you will have to fill in one section for each administered vaccine.

- Redness, swelling and pain may appear around the area where your child received the vaccine (administration site(s)). These are called LOCAL symptoms.
- If similar symptoms appear on another part of your child's body than this/those corresponding to the administration site(s), please report them in the Adverse Event section.

  [The study doctor or study staff should show in the drawing where is/are the administration site(s).]

For Infanrix



For Hiberix

- Write down the size of the redness and swelling in millimetres (mm) only. Use the ruler given to you by the site staff.

  Please note that in case a swelling greater than 50 mm is observed please describe the swelling on the page titled the Large Swelling Reaction

➢ *HOW TO COMPLETE THE DAILY VALUE?*

- Write down a value for each symptom and each day (measure or intensity). **Don't leave any field empty.**
- If there is no symptom, please write "0".

Injection site **Swelling** → size (mm)	mm 2	mm 0	mm 0	mm 0	☒ No ☐ Yes →	mm		☐	☒ No ☐ Yes	HOERMD __
Measure and record the greatest surface diameter (in mm).										

Daily measurement of circumference: Every day, using the tape provided to you, please measure around the vaccinated arm or leg.

INTENSITY DEFINITIONS

- Redness and swelling:

  Measure and record the greatest surface diameter in millimetres (mm).
- Pain:

  0: Absent

  1: Minor reaction to touch

  2: Cries/protests on touch

  3: Cries when limb is moved / spontaneously painful

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

LOCAL SYMPTOMS (*HEXA GROUP-Booster*)

Infanrix

To be completed by the investigator or delegate:

Date of vaccination = Day 0: _____ **Injection Site**: _____ **Side**: _____

Baseline Circumference of injected limb (In mm) = _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did your child receive any medical attention ?	Type of medical attention To be completed by the investigator or delegate
					Ongoing	Worst Intensity/ Greatest size	End Date Tick box if still ongoing ↓		
Injection site **Redness** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘
Injection site **Swelling** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘
Injection site **Pain** → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Daily Circumferential measurement- Infanrix

* Please measure the circumference using the tape provided to you, around the vaccinated arm or leg.

	Day 0	Day 1	Day 2	Day 3	After Day 3		
					Is large swelling reaction ongoing	**If Yes then please enter the maximum circumference observed**	**End Date** **Tick box if still ongoing ↓**
Daily measurement of Injection site **Circumference→** size (mm)					☐ No ☐ Yes →		☐

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

➢ *LARGE SWELLING REACTION*

- A large swelling reaction is a swelling at the place where your child received the vaccination that has a diameter greater than 50 mm, or a large swelling that is very spread out and cannot be measured or a noticeable swelling of the vaccinated arm or thigh circumference.
- If your child has a large swelling please call the study doctor immediately.
- Please fill in the data in the large swelling reaction section. In the section below, please enter the day, month and year when the large swelling reaction was first observed.

➢ *DESCRIBE THE TYPE OF SWELLING*.

- If the swelling occurred only around the place where the vaccination shot was given and did not spread to the adjacent joint, check the first box. Adjacent joint means the shoulder or elbow (in cases where the vaccination was given in the arm) or the knee or hip joint(in cases where the vaccination was given in the thigh)
- If the swelling was spread out over a large area, but did not spread to adjacent joint, check the middle box.
- If the swelling spread to the adjacent joint

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

INDURATION

- If the large swelling is hard to the touch, measure and record daily the greatest surface diameter in millimetres (mm) of the hard area.

  If the swelling is not hard, check the "No" box.

PRURITIS MEANS ITCHING

- If you notice your child has itching at the large injection site (e.g. your child is scratching or vigorously rubbing the swelling), please check "Yes" and the type of Grade it is. If there is no itch check the "No" box

FUNCTIONAL IMPAIRMENT

- If the large swelling changes the way your child moves or uses the swollen arm or leg as they normally would, please check "Yes" and the type of Grade it is. If there is no change to your child's use of the swollen arm or leg, check the "No" box.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Large Swelling Reaction (*HEXA GROUP-Booster*)

Infanrix

Date when the swelling was first considered to be a large swelling reaction*: *:To be completed by the investigator or delegate	|__|__| |__|__|__| |__|__|__|__| day month year Please enter the date in DD/MMM/YYYY format Was the examination performed by a member of study personnel during the large swelling reaction period? ☐ No ☐ Yes
Type of swelling and Location of swelling	☐ Local swelling only around the injection site, not involving adjacent joint ☐ Diffuse swelling, not involving adjacent joint ☐ Swelling involving adjacent joint
Induration at injection site (in mm)	☐ No ☐ Yes → If Yes then, Day 0 Day 1 Day 2 Day 3 |__|__|__| |__|__|__| |__|__|__| |__|__|__| Not Taken Not Taken Not Taken Not Taken ☐ ☐ ☐ ☐ Is Induration ongoing ? ☐ No ☐ Yes . If Yes then please enter the Largest Diameter observed |__|__|__|

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___|___| To be completed by the investigator or delegate

Pruritis at injection site	☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Functional impairment	Has the swelling episode resulted in functional impairment? ☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Last date when the swelling was still considered a large swelling reaction * *:To be completed by the investigator or delegate	|___|___| |___|___|___| |___|___|___|___| day month year Please enter the date in DD/MMM/YYYY format
Outcome of the extensive swelling	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered with ongoing events / Resolved with ongoing events

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

LOCAL SYMPTOMS *(HEXA GROUP-Booster)*
Hiberix

To be completed by the investigator or delegate:
Date of vaccination = Day 0: _____ **Injection Site**: _____ **Side**: _____
Baseline Circumference of injected limb (In mm) = _____

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing	After Day 3: Worst Intensity/ Greatest size	After Day 3: End Date (Tick box if still ongoing ↓)	Did your child receive any medical attention ?	Type of medical attention (To be completed by the investigator or delegate)
Injection site **Redness** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD ⌊_⌋⌊_⌋
Injection site **Swelling** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD ⌊_⌋⌊_⌋
Injection site **Pain** → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD ⌊_⌋⌊_⌋

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Daily Circumferential measurement- *Hiberix*

* Please measure the circumference using the tape provided to you, around the vaccinated arm or leg.

	Day 0	Day 1	Day 2	Day 3	After Day 3		
					Is large swelling reaction ongoing	**If Yes then please enter the maximum circumference observed**	**End Date** Tick box if still ongoing ↓
Daily measurement of Injection site **Circumference**→ size (mm)					☐ No ☐ Yes →		☐

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

Large Swelling Reaction *(HEXA GROUP-Booster)*
Hiberix

Date when the swelling was first considered to be a large swelling reaction*: *:To be completed by the investigator or delegate	|__|__| |__|__|__| |__|__|__|__| day month year Please enter the date in DD/MMM/YYYY format Was the examination performed by a member of study personnel during the large swelling reaction period? ☐ No ☐ Yes
Type of swelling and Location of swelling	☐ Local swelling only around the injection site, not involving adjacent joint ☐ Diffuse swelling, not involving adjacent joint ☐ Swelling involving adjacent joint
Induration at injection site (in mm)	☐ No ☐ Yes → If Yes then, Day 0 Day 1 Day 2 Day 3 |__|__|__| |__|__|__| |__|__|__| |__|__|__| Not Taken Not Taken Not Taken Not Taken ☐ ☐ ☐ ☐ Is Induration ongoing ? ☐ No ☐ Yes . If Yes then please enter the Largest Diameter observed |__|__|__|

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

Pruritis at injection site	☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Functional impairment	Has the swelling episode resulted in functional impairment? ☐ No ☐ Yes -> If yes then: ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Last date when the swelling was still considered a large swelling reaction *:To be completed by the investigator or delegate	|__|__| |__|__|__| |__|__|__|__| day month year Please enter the date in DD/MMM/YYYY format
Outcome of the extensive swelling	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered with ongoing events / Resolved with ongoing events

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Instructions to complete:

General symptoms

➢ *HOW TO COMPLETE THE DAILY VALUE?*

- Write down a value for each symptom and each day (measure or intensity). **Don't leave any field empty.**
- Write "0" if there is no increase in intensity compared to normal

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing	After Day 3: Worst Intensity	After Day 3: End Date	Did you receive medical attention?*	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
							Tick box if still ongoing →			
Drowsiness → 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	HOSPMED ☐	☐ No ☐ Yes

➢ *GENERAL SYMPTOMS: TEMPERATURE*

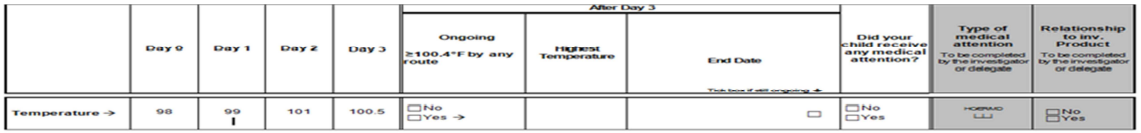
- Please use the provided thermometer.
- Take your child's temperature each day from day of vaccination (day 0) until day 3, and write down the values.
- If you took more than once a day your child's temperature, then write down the highest one.
- The preferred route for recording temperature in this study will be Axillary for Booster vaccination.

Example: if on Day 0
- At 8 am: 98.8°F
- At 1 pm: 99.3°F
- At 7 pm: 99.7°F

→ 99.7°F is to be recorded in for Day 0

- Please write down NT (Not Taken) if you did not take the temperature.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___| To be completed by the investigator or delegate



	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing ≥100.4°F by any route	After Day 3: Highest Temperature	After Day 3: End Date	Did your child receive any medical attention?	Type of medical attention	Relationship to inv. Product
Temperature →	98	99	101	100.5	☐ No ☐ Yes →			☐ No ☐ Yes		☐ No ☐ Yes

GENERAL SYMPTOMS

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing ≥100.4°F by any route	After Day 3: Highest Temperature	After Day 3: End Date (Tick box if still ongoing)	Did your child receive any medical attention?	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Temperature →					☐ No ☐ Yes →			☐ No ☐ Yes	HO/ER/MD ___	☐ No ☐ Yes

Temperature:	Route of measurement: (The same route must be used for all your measurements.)
☐ Fahrenheit	

Clarification(s) for Investigator or delegate only:

➢ *INTENSITY DEFINITIONS*

- Drowsiness:
  - 0: Behaviour as usual
  - 1: Mild: Drowsiness easily tolerated
  - 2: Moderate: Drowsiness that interferes with normal activity
  - 3: Severe: Drowsiness that prevents normal activity
- Irritability/Fussiness:
  - 0: Behaviour as usual
  - 1: Mild: Crying more than usual/no effect on normal activity
  - 2: Moderate: Crying more than usual/interferes with normal activity
  - 3: Severe: Crying that cannot be comforted/prevents normal activity
- Loss of appetite:
  - 0: Appetite as usual
  - 1: Mild: Eating less than usual/no effect on normal activity
  - 2: Moderate: Eating less than usual/interferes with normal activity
  - 3: Severe: Not eating at all

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

GENERAL SYMPTOMS

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did your child receive medical attention?*	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
					Ongoing	Worst Intensity	End Date Tick box if still ongoing ↓			
Drowsiness → Intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes
Irritability/Fussiness → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes
Loss of appetite → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Instructions to complete:

Adverse Events

- If your child experience(s) any other symptoms than those listed in the local symptoms or general symptoms pages, please write these symptoms down in this section.
- If a symptom appears only after day 3, please write this symptom down in this section.
- If redness, swelling or pain appears on another area than area where your child received the vaccine, please report these symptoms in this section.

INTENSITY DEFINITIONS

- **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 centre and would cause the parents/guardians to seek medical advice).

BOX "STILL ONGOING" IN THE COLUMN "END DATE" – WHEN TO TICK IT?

- Tick the box "Still ongoing" if the illness / sign / symptom is still present at the time you return the diary card to the site.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

DID YOUR CHILD RECEIVE ANY MEDICAL ATTENTION? HOW TO COMPLETE THIS QUESTION?

- Medical attention means hospitalisation, an emergency room visit or a visit to or from medical personnel (medical doctor).
- Tick the box “No” if your child did not visit a doctor or go to the hospital or an emergency room for the symptom.
- Tick the box “Yes” if your child went to the hospital, an emergency room or if your child visited a doctor for the symptom. Keep the type of medical attention (grey column) empty. It will be completed by the study doctor or study staff.

DTPA-HBV-IPV-135 **117119** GlaxoSmithKline	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

ADVERSE EVENTS – MULTIPLE INJECTIONS

Record any adverse event (= any illness, sign, symptom) other than the local and general symptoms listed on the previous pages, which may have started or any medical condition which may have worsened since the last study vaccination.

Illness/Sign/Symptom	to be filled in case of reaction at vaccine administration site		**Worst Intensity** 1/2/3	**Start Date**	**End Date**		**Did your child receive medical attention?**	**Type of medical attention** To be completed by the investigator or delegate	**Relationship to inv. Product** To be completed by the investigator or delegate
	Site	**Side**				Tick box if still ongoing ↓			
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

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], intradermal [ID], intramuscular [IM], intranasal [IN], intravenous [IV], oral [PO], parenteral [PE], subcutaneous [SC], sublingual [SL], transdermal [TD], other [OTH], unknown [UNK]

Clarification(s) for Investigator or delegate only:

Instructions to complete:
Medication

➢ *DOSE, UNIT AND FREQUENCY*

- Write the amount of the medication your child took.

Dose, unit and frequency
200mg pill 3 times a day
2 coffee spoon 100mg once per day
3 suppositories per day
Nasal drops 4 times per day

- Most of this information can be found on the label of the medication. You may want to bring the medication to your child's next visit with the study doctor or study staff. Then they can help you to fill in the required information.

➢ *BOX "STILL ONGOING" IN THE COLUMN "END DATE" – WHEN TO TICK IT?*

- Tick the box "Still ongoing" if the medication is still taken at the time you return the diary card to the site.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___| To be completed by the investigator or delegate

MEDICATION

Record any medication taken since the last study vaccination.

Medication	Reason	Dose, unit and frequency	Start Date	End Date Tick box if still ongoing↓	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:

GlaxoSmithKline DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

NOTES

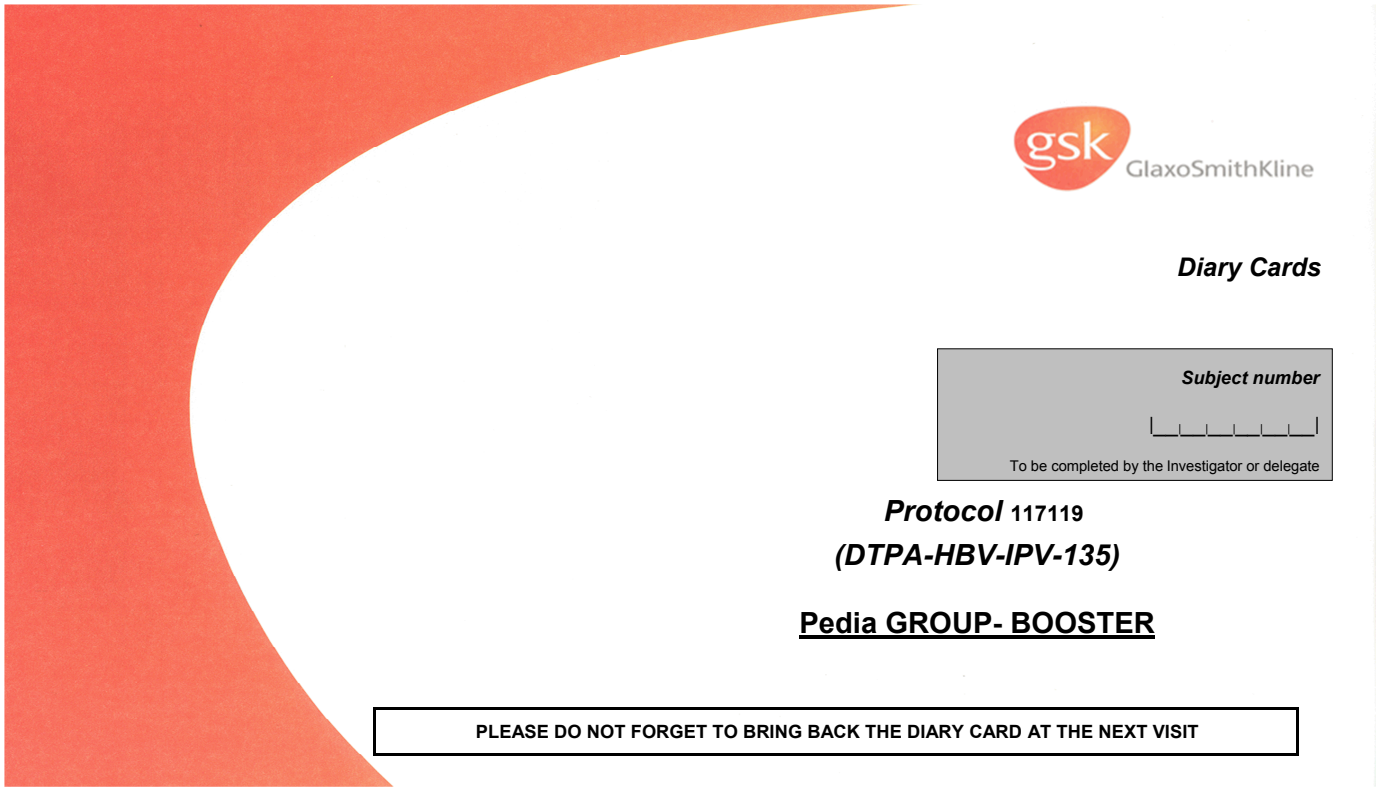
INVESTIGATOR'S OR DELEGATE'S SIGNATURE

Investigator's or delegate's signature: _____

Date: |__|__|/|__|__|/|__|__|__|__|

Printed Investigator's or delegate's name: _____

CONFIDENTIAL



GlaxoSmithKline

Diary Cards

Subject number

|__|__|__|__|__|__|__|

To be completed by the Investigator or delegate

***Protocol* 117119**

(DTPA-HBV-IPV-135)

Pedia GROUP- BOOSTER

PLEASE DO NOT FORGET TO BRING BACK THE DIARY CARD AT THE NEXT VISIT

CONFIDENTIAL

General Instructions

Thank you for your child's participation in this clinical trial.

During your child's last study visit, you received a "Diary Card" to fill in every day for a defined period, so that your child's study doctor or the study staff will know your child's general health status after the vaccination.

Here below you will find general instructions on how to complete the "Diary Card". There are also other specific instructions relative to each part of the "Diary Card" that you will need to fill in.

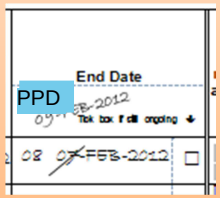
INSTRUCTIONS TO COMPLETE THE "DIARY CARD"

- Write in clearly, use a pen (never pencil).
- The grey areas are dedicated to the investigator or delegate only. Do not write in these areas.

Illness/Sign/Symptom ☑ if at vaccine injection site ↓	Worst Intensity 1/2/3	Start Date	End Date Tick box if still ongoing ↓	Did you receive medical attention?	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
Tendinitis ☐	2	04-FEB-2012	08-FEB-2012 ☐	☐ No ☒ Yes	HOERMD ☐☐	☐ No ☐ Yes

➢ *HOW TO CORRECT MISTAKES?*

- Cross out the mistake with a single line.
- Don't hide the mistake. Don't use correction fluid or don't make inkblots.
- Write the correct response close to the mistaken one.
- If the correct response is written outside of the box, circle it and point to it with an arrow towards the box.
- **Put your initials near the correction.**
- **Date the correction**



➢ *WHO TO CONTACT IN CASE OF QUESTIONS?*

If you have any questions, please contact your child's study doctor or the study staff on the following phone number:

[insert phone n° of the study doctor or study staff]

Please contact your child's study doctor or the study staff immediately if your child has any symptoms you think are serious.

Instructions to complete:
Local and general symptoms

- If your child experience(s) any other symptoms than those listed in the local symptoms or general symptoms pages, please write these symptoms down in the Adverse Event section.
- If a symptom <u>appears only after</u> day 3, please write this symptom down in the Adverse Event section.

➢ *<u>HOW TO COMPLETE DIARY CARD FOR ANY SYMPTOM "AFTER DAY 3"?</u>*

- In the columns "After day 3", if the symptom is still ongoing* after day 3, tick "Yes". Otherwise, tick "No".

* The symptom is ongoing if after day 3:
- The intensity of the symptom is 1 or higher
- The oral (in the mouth), axillary (under the armpit), tympanic (in the ear) or rectal (in the anus) temperature is higher or equal to 100.4°F.

- If Yes,
  - Please write the worst intensity for pain, the highest temperature or the greatest measurement of Redness or swelling recorded for the respective symptom during this follow-up period, after day 3.
  - And note the date when the symptom has disappeared or tick the box "still ongoing".
- If No, then leave empty the columns "Worst intensity/ greatest size/ highest temperature" and "End Date".

➢ *<u>BOX "STILL ONGOING" IN COLUMN "END DATE" – WHEN TO TICK IT?</u>*

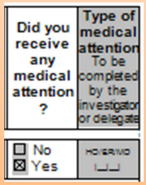
- Tick the box "Still ongoing" if the illness /sign /symptom is still present at the time you return the diary card to the site

	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	Worst Intensity/ Greatest size	End Date Tick box if still ongoing ↓		
Injection site **Redness** → size (mm)	mm 10	mm 8	mm 5	mm 3	☐ No ☒ Yes →	mm 2	☒	☐ No ☒ Yes	HO/ERMD ___

➢ *DID YOUR CHILD RECEIVE ANY MEDICAL ATTENTION? HOW TO COMPLETE THIS QUESTION?*

- Medical attention means hospitalisation, an emergency room visit or a visit to or from medical personnel.
- Tick the box "No" if your child did not visit medical personnel or was not visited by medical personnel or did not go to the hospital or an emergency room for the symptom.
- Tick the box "Yes" if your child went to the hospital, an emergency room, if your child visited medical personnel or was visited by medical personnel for the symptom.

  Keep the type of medical attention (grey column) empty. It will be completed by the study doctor or study staff.



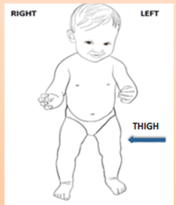
Instructions to complete:
Local symptoms

- If your child receive(s) more than one vaccine, you will have to fill in one section for each administered vaccine.

- Redness, swelling and pain may appear around the area where your child received the vaccine (administration site(s)). These are called LOCAL symptoms.
- If similar symptoms appear on another part of your child's body than this/those corresponding to the administration site(s), please report them in the Adverse Event section.

  [The study doctor or study staff should show in the drawing where is/are the administration site(s).]

For Infanrix



For ActHib

- Write down the size of the redness and swelling in millimetres (mm) only. Use the ruler given to you by the site staff.

  Please note that in case a swelling greater than 50 mm is observed please describe the swelling on the page titled the Large Swelling Reaction

➢ *HOW TO COMPLETE THE DAILY VALUE?*

- Write down a value for each symptom and each day (measure or intensity). **Don't leave any field empty.**
- If there is no symptom, please write "0".

Injection site **Swelling** → size (mm)	mm 2	mm 0	mm 0	mm 0	☒ No ☐ Yes →	mm		☐	☒ No ☐ Yes	HOERMD ⌊_⌋⌊_⌋
Measure and record the greatest surface diameter (in mm).										

Daily measurement of circumference: Every day, using the tape provided to you, please measure around the vaccinated arm or leg.

INTENSITY DEFINITIONS

- Redness and swelling:

  Measure and record the greatest surface diameter in millimetres (mm).
- Pain:

  0: Absent

  1: Minor reaction to touch

  2: Cries/protests on touch

  3: Cries when limb is moved / spontaneously painful

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

LOCAL SYMPTOMS (*PEDIA GROUP-Booster*)

Infanrix

To be completed by the investigator or delegate:

Date of vaccination = Day 0: _____ **Injection Site**: _____ **Side**: _____

Baseline Circumference of injected limb (In mm) = _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did your child receive any medical attention ?	Type of medical attention To be completed by the investigator or delegate
					Ongoing	Worst Intensity/ Greatest size	End Date Tick box if still ongoing ↓		
Injection site **Redness** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘
Injection site **Swelling** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘
Injection site **Pain** → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Daily Circumferential measurement- Infanrix

* Please measure the circumference using the tape provided to you, around the vaccinated arm or leg.

	Day 0	Day 1	Day 2	Day 3	After Day 3		
					Is large swelling reaction ongoing	**If Yes then please enter the maximum circumference observed**	**End Date** **Tick box if still ongoing ↓**
Daily measurement of Injection site **Circumference→** size (mm)					☐ No ☐ Yes →		☐

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

➢ *LARGE SWELLING REACTION*

- A large swelling reaction is a swelling at the place where your child received the vaccination that has a diameter greater than 50 mm, or a large swelling that is very spread out and cannot be measured or a noticeable swelling of the vaccinated arm or thigh circumference.
- If your child has a large swelling please call the study doctor immediately.
- Please fill in the data in the large swelling reaction section. In the section below, please enter the day, month and year when the large swelling reaction was first observed.

➢ *DESCRIBE THE TYPE OF SWELLING*.

- If the swelling occurred only around the place where the vaccination shot was given and did not spread to the adjacent joint, check the first box. Adjacent joint means the shoulder or elbow (in cases where the vaccination was given in the arm) or the knee or hip joint (in cases where the vaccination was given in the thigh)
- If the swelling was spread out over a large area, but did not spread to adjacent joint, check the middle box.
- If the swelling spread to the adjacent joint

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

INDURATION

- If the large swelling is hard to the touch, measure and record daily the greatest surface diameter in millimetres (mm) of the hard area.

  If the swelling is not hard, check the "No" box.

PRURITIS MEANS ITCHING

- If you notice your child has itching at the large injection site (e.g. your child is scratching or vigorously rubbing the swelling), please check "Yes" and the type of Grade it is. If there is no itch check the "No" box

FUNCTIONAL IMPAIRMENT

- If the large swelling changes the way your child moves or uses the swollen arm or leg as they normally would, please check "Yes" and the type of Grade it is. If there is no change to your child's use of the swollen arm or leg, check the "No" box.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Large Swelling Reaction (*PEDIA GROUP-Booster*)

Infanrix

Date when the swelling was first considered to be a large swelling reaction*: *:To be completed by the investigator or delegate	|__|__| |__|__|__| |__|__|__|__| day month year Please enter the date in DD/MMM/YYYY format Was the examination performed by a member of study personnel during the large swelling reaction period? ☐ No ☐ Yes
Type of swelling and Location of swelling	☐ Local swelling only around the injection site, not involving adjacent joint ☐ Diffuse swelling, not involving adjacent joint ☐ Swelling involving adjacent joint
Induration at injection site (in mm)	☐ No ☐ Yes → If Yes then, Day 0 Day 1 Day 2 Day 3 |__|__|__| |__|__|__| |__|__|__| |__|__|__| Not Taken Not Taken Not Taken Not Taken ☐ ☐ ☐ ☐ Is Induration ongoing ? ☐ No ☐ Yes . If Yes then please enter the Largest Diameter observed |__|__|__|

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___|___| To be completed by the investigator or delegate

Pruritis at injection site	☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Functional impairment	Has the swelling episode resulted in functional impairment? ☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Last date when the swelling was still considered a large swelling reaction * *:To be completed by the investigator or delegate	|___|___| |___|___|___| |___|___|___|___| day month year Please enter the date in DD/MMM/YYYY format
Outcome of the extensive swelling	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered with ongoing events / Resolved with ongoing events

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

LOCAL SYMPTOMS *(PEDIA GROUP-Booster)*
ActHib

To be completed by the investigator or delegate:
Date of vaccination = Day 0: _____ **Injection Site**: _____ **Side**: _____
Baseline Circumference of injected limb (In mm) = _____

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing	After Day 3: Worst Intensity/ Greatest size	After Day 3: End Date (Tick box if still ongoing ↓)	Did your child receive any medical attention ?	Type of medical attention (To be completed by the investigator or delegate)
Injection site **Redness** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD _|_|
Injection site **Swelling** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD _|_|
Injection site **Pain** → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD _|_|

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Daily Circumferential measurement- *ActHib*

* Please measure the circumference using the tape provided to you, around the vaccinated arm or leg.

	Day 0	Day 1	Day 2	Day 3	After Day 3		
					Is large swelling reaction ongoing	**If Yes then please enter the maximum circumference observed**	**End Date** Tick box if still ongoing ↓
Daily measurement of Injection site **Circumference**→ size (mm)					☐ No ☐ Yes →		☐

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

Large Swelling Reaction *(PEDIA GROUP-Booster)*
ActHib

Date when the swelling was first considered to be a large swelling reaction*: *:To be completed by the investigator or delegate	|__|__| |__|__|__| |__|__|__|__| day month year Please enter the date in DD/MMM/YYYY format Was the examination performed by a member of study personnel during the large swelling reaction period? ☐ No ☐ Yes
Type of swelling and Location of swelling	☐ Local swelling only around the injection site, not involving adjacent joint ☐ Diffuse swelling, not involving adjacent joint ☐ Swelling involving adjacent joint
Induration at injection site (in mm)	☐ No ☐ Yes → If Yes then, Day 0 Day 1 Day 2 Day 3 |__|__|__| |__|__|__| |__|__|__| |__|__|__| Not Taken Not Taken Not Taken Not Taken ☐ ☐ ☐ ☐ Is Induration ongoing ? ☐ No ☐ Yes . If Yes then please enter the Largest Diameter observed |__|__|__|

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___|___| To be completed by the investigator or delegate

Pruritis at injection site	☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Functional impairment	Has the swelling episode resulted in functional impairment? ☐ No ☐ Yes -> If yes then: ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Last date when the swelling was still considered a large swelling reaction *:To be completed by the investigator or delegate	|___|___| |___|___|___| |___|___|___|___| day month year Please enter the date in DD/MMM/YYYY format
Outcome of the extensive swelling	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered with ongoing events / Resolved with ongoing events

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___| To be completed by the investigator or delegate

Instructions to complete:

General symptoms

➢ *HOW TO COMPLETE THE DAILY VALUE?*

- Write down a value for each symptom and each day (measure or intensity). **Don't leave any field empty.**
- Write "0" if there is no increase in intensity compared to normal

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing	Worst Intensity	End Date	Did you receive medical attention?*	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Drowsiness → 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	Tick box if still ongoing ↓ ☐	☐ No ☐ Yes	HOSPMD ☐	☐ No ☐ Yes

➢ *GENERAL SYMPTOMS: TEMPERATURE*

- Please use the provided thermometer.
- Take your child's temperature each day from day of vaccination (day 0) until day 3, and write down the values.
- If you took more than once a day your child's temperature, then write down the highest one.
- The preferred route for recording temperature in this study will be Axillary for Booster vaccination.

Example: if on Day 0
- At 8 am: 98.8°F
- At 1 pm: 99.3°F
- At 7 pm: 99.7°F

→ 99.7°F is to be recorded in for Day 0

- Please write down NT (Not Taken) if you did not take the temperature.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing ≥100.4°F by any route	After Day 3: Highest Temperature	After Day 3: End Date (Tick box if still ongoing)	Did your child receive any medical attention?	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Temperature →	98	99	101	100.5	☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes

GENERAL SYMPTOMS

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing ≥100.4°F by any route	After Day 3: Highest Temperature	After Day 3: End Date (Tick box if still ongoing)	Did your child receive any medical attention?	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Temperature →					☐ No ☐ Yes →			☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes

Temperature:	Route of measurement: (The same route must be used for all your measurements.)
☐ Fahrenheit	

Clarification(s) for Investigator or delegate only:

➢ *INTENSITY DEFINITIONS*

- Drowsiness:
  - 0: Behaviour as usual
  - 1: Mild: Drowsiness easily tolerated
  - 2: Moderate: Drowsiness that interferes with normal activity
  - 3: Severe: Drowsiness that prevents normal activity
- Irritability/Fussiness:
  - 0: Behaviour as usual
  - 1: Mild: Crying more than usual/no effect on normal activity
  - 2: Moderate: Crying more than usual/interferes with normal activity
  - 3: Severe: Crying that cannot be comforted/prevents normal activity
- Loss of appetite:
  - 0: Appetite as usual
  - 1: Mild: Eating less than usual/no effect on normal activity
  - 2: Moderate: Eating less than usual/interferes with normal activity
  - 3: Severe: Not eating at all

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

GENERAL SYMPTOMS

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did your child receive medical attention?*	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
					Ongoing	Worst Intensity	End Date Tick box if still ongoing ↓			
Drowsiness → Intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes
Irritability/Fussiness → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes
Loss of appetite → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Instructions to complete:

Adverse Events

- If your child experience(s) any other symptoms than those listed in the local symptoms or general symptoms pages, please write these symptoms down in this section.
- If a symptom appears only after day 3, please write this symptom down in this section.
- If redness, swelling or pain appears on another area than area where your child received the vaccine, please report these symptoms in this section.

INTENSITY DEFINITIONS

- **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 centre and would cause the parents/guardians to seek medical advice).

BOX "STILL ONGOING" IN THE COLUMN "END DATE" – WHEN TO TICK IT?

- Tick the box "Still ongoing" if the illness / sign / symptom is still present at the time you return the diary card to the site.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

DID YOUR CHILD RECEIVE ANY MEDICAL ATTENTION? HOW TO COMPLETE THIS QUESTION?

- Medical attention means hospitalisation, an emergency room visit or a visit to or from medical personnel (medical doctor).
- Tick the box “No” if your child did not visit a doctor or go to the hospital or an emergency room for the symptom.
- Tick the box “Yes” if your child went to the hospital, an emergency room or if your child visited a doctor for the symptom. Keep the type of medical attention (grey column) empty. It will be completed by the study doctor or study staff.

GlaxoSmithKline **DTPA-HBV-IPV-135** **117119**	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

ADVERSE EVENTS – MULTIPLE INJECTIONS

Record any adverse event (= any illness, sign, symptom) other than the local and general symptoms listed on the previous pages, which may have started or any medical condition which may have worsened since the last study vaccination.

Illness/Sign/Symptom	to be filled in case of reaction at vaccine administration site		**Worst Intensity** 1/2/3	**Start Date**	**End Date**		**Did your child receive medical attention?**	**Type of medical attention** To be completed by the investigator or delegate	**Relationship to inv. Product** To be completed by the investigator or delegate
	Site	**Side**				Tick box if still ongoing ↓			
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |_|_|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

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], intradermal [ID], intramuscular [IM], intranasal [IN], intravenous [IV], oral [PO], parenteral [PE], subcutaneous [SC], sublingual [SL], transdermal [TD], other [OTH], unknown [UNK]

Clarification(s) for Investigator or delegate only:

Instructions to complete:
Medication

➢ *DOSE, UNIT AND FREQUENCY*

- Write the amount of the medication your child took.

Dose, unit and frequency
200mg pill 3 times a day
2 coffee spoon 100mg once per day
3 suppositories per day
Nasal drops 4 times per day

- Most of this information can be found on the label of the medication. You may want to bring the medication to your child's next visit with the study doctor or study staff. Then they can help you to fill in the required information.

➢ *BOX "STILL ONGOING" IN THE COLUMN "END DATE" – WHEN TO TICK IT?*

- Tick the box "Still ongoing" if the medication is still taken at the time you return the diary card to the site.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

MEDICATION

Record any medication taken since the last study vaccination.

Medication	Reason	Dose, unit and frequency	Start Date	End Date Tick box if still ongoing↓	**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:

GlaxoSmithKline DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

NOTES

INVESTIGATOR'S OR DELEGATE'S SIGNATURE

Investigator's or delegate's signature: _____ Date: |__|__||__|__|__||__|__|__|__|

Printed Investigator's or delegate's name: _____

CONFIDENTIAL

GlaxoSmithKline

Diary Cards

Subject number

|__|__|__|__|__|__|__|__|

To be completed by the Investigator or delegate

***Protocol* 117119**

(DTPA-HBV-IPV-135)

Penta GROUP- BOOSTER

PLEASE DO NOT FORGET TO BRING BACK THE DIARY CARD AT THE NEXT VISIT

CONFIDENTIAL

General Instructions

Thank you for your child's participation in this clinical trial.

During your child's last study visit, you received a "Diary Card" to fill in every day for a defined period, so that your child's study doctor or the study staff will know your child's general health status after the vaccination.

Here below you will find general instructions on how to complete the "Diary Card". There are also other specific instructions relative to each part of the "Diary Card" that you will need to fill in.

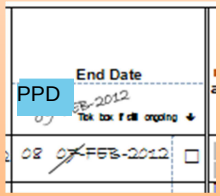
INSTRUCTIONS TO COMPLETE THE "DIARY CARD"

- Write in clearly, use a pen (never pencil).
- The grey areas are dedicated to the investigator or delegate only. Do not write in these areas.

Illness/Sign/Symptom ☑ if at vaccine injection site ↓	Worst Intensity 1/2/3	Start Date	End Date Tick box if still ongoing ↓	Did you receive medical attention?	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
Tendinitis ☐	2	04-FEB-2012	08-FEB-2012 ☐	☐ No ☒ Yes	HOER/MD ☐☐	☐ No ☐ Yes

➢ *HOW TO CORRECT MISTAKES?*

- Cross out the mistake with a single line.
- Don't hide the mistake. Don't use correction fluid or don't make inkblots.
- Write the correct response close to the mistaken one.
- If the correct response is written outside of the box, circle it and point to it with an arrow towards the box.
- **Put your initials near the correction.**
- **Date the correction**



➢ *WHO TO CONTACT IN CASE OF QUESTIONS?*

If you have any questions, please contact your child's study doctor or the study staff on the following phone number:

[insert phone n° of the study doctor or study staff]

Please contact your child's study doctor or the study staff immediately if your child has any symptoms you think are serious.

Instructions to complete:
Local and general symptoms

- If your child experience(s) any other symptoms than those listed in the local symptoms or general symptoms pages, please write these symptoms down in the Adverse Event section.
- If a symptom <u>appears only after</u> day 3, please write this symptom down in the Adverse Event section.

➢ *<u>HOW TO COMPLETE DIARY CARD FOR ANY SYMPTOM "AFTER DAY 3"?</u>*

- In the columns "After day 3", if the symptom is still ongoing* after day 3, tick "Yes". Otherwise, tick "No".

* The symptom is ongoing if after day 3:
- The intensity of the symptom is 1 or higher
- The oral (in the mouth), axillary (under the armpit), tympanic (in the ear) or rectal (in the anus) temperature is higher or equal to 100.4°F.

- If Yes,
  - Please write the worst intensity for pain, the highest temperature or the greatest measurement of Redness or swelling recorded for the respective symptom during this follow-up period, after day 3.
  - And note the date when the symptom has disappeared or tick the box "still ongoing".
- If No, then leave empty the columns "Worst intensity/ greatest size/ highest temperature" and "End Date".

➢ *<u>BOX "STILL ONGOING" IN COLUMN "END DATE" – WHEN TO TICK IT?</u>*

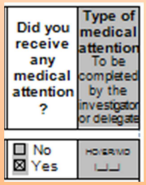
- Tick the box "Still ongoing" if the illness /sign /symptom is still present at the time you return the diary card to the site

	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	Worst Intensity/ Greatest size	End Date Tick box if still ongoing ↓		
Injection site **Redness** → size (mm)	mm 10	mm 8	mm 5	mm 3	☐ No ☒ Yes →	mm 2	☒	☐ No ☒ Yes	HO/ERMD ___

➢ *DID YOUR CHILD RECEIVE ANY MEDICAL ATTENTION? HOW TO COMPLETE THIS QUESTION?*

- Medical attention means hospitalisation, an emergency room visit or a visit to or from medical personnel.
- Tick the box "No" if your child did not visit medical personnel or was not visited by medical personnel or did not go to the hospital or an emergency room for the symptom.
- Tick the box "Yes" if your child went to the hospital, an emergency room, if your child visited medical personnel or was visited by medical personnel for the symptom.

  Keep the type of medical attention (grey column) empty. It will be completed by the study doctor or study staff.



Instructions to complete:
Local symptoms

- If your child receive(s) more than one vaccine, you will have to fill in one section for each administered vaccine.

- Redness, swelling and pain may appear around the area where your child received the vaccine (administration site(s)). These are called LOCAL symptoms.
- If similar symptoms appear on another part of your child's body than this/those corresponding to the administration site(s), please report them in the Adverse Event section.

  [The study doctor or study staff should show in the drawing where is/are the administration site(s).]

For Pentacel

- Write down the size of the redness and swelling in millimetres (mm) only. Use the ruler given to you by the site staff.

  Please note that in case a swelling greater than 50 mm is observed please describe the swelling on the page titled the Large Swelling Reaction

➢ *HOW TO COMPLETE THE DAILY VALUE?*

- Write down a value for each symptom and each day (measure or intensity). **Don't leave any field empty.**
- If there is no symptom, please write "0".

Injection site **Swelling** → size (mm)	mm 2	mm 0	mm 0	mm 0	☒ No ☐ Yes →	mm		☐	☒ No ☐ Yes	HOERMD __
Measure and record the greatest surface diameter (in mm).										

Daily measurement of circumference: Every day, using the tape provided to you, please measure around the vaccinated arm or leg.

INTENSITY DEFINITIONS

- Redness and swelling:

  Measure and record the greatest surface diameter in millimetres (mm).
- Pain:

  0: Absent

  1: Minor reaction to touch

  2: Cries/protests on touch

  3: Cries when limb is moved / spontaneously painful

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

LOCAL SYMPTOMS (*PENTA GROUP-Booster*)

Pentacel

To be completed by the investigator or delegate:

Date of vaccination = Day 0: _____ **Injection Site**: _____ **Side**: _____

Baseline Circumference of injected limb (In mm) = _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did your child receive any medical attention ?	Type of medical attention To be completed by the investigator or delegate
					Ongoing	Worst Intensity/ Greatest size	End Date Tick box if still ongoing ↓		
Injection site **Redness** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘
Injection site **Swelling** → size (mm)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘
Injection site **Pain** → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┘└┘

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Daily Circumferential measurement- Pentacel

* Please measure the circumference using the tape provided to you, around the vaccinated arm or leg.

	Day 0	Day 1	Day 2	Day 3	After Day 3		
					Is large swelling reaction ongoing	**If Yes then please enter the maximum circumference observed**	**End Date** **Tick box if still ongoing ↓**
Daily measurement of Injection site **Circumference→** size (mm)					☐ No ☐ Yes →		☐

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

➢ *LARGE SWELLING REACTION*

- A large swelling reaction is a swelling at the place where your child received the vaccination that has a diameter greater than 50 mm, or a large swelling that is very spread out and cannot be measured or a noticeable swelling of the vaccinated arm or thigh circumference.
- If your child has a large swelling please call the study doctor immediately.
- Please fill in the data in the large swelling reaction section. In the section below, please enter the day, month and year when the large swelling reaction was first observed.

➢ *DESCRIBE THE TYPE OF SWELLING*.

- If the swelling occurred only around the place where the vaccination shot was given and did not spread to the adjacent joint, check the first box. Adjacent joint means the shoulder or elbow (in cases where the vaccination was given in the arm) or the knee or hip joint (in cases where the vaccination was given in the thigh)
- If the swelling was spread out over a large area, but did not spread to adjacent joint, check the middle box.
- If the swelling spread to the adjacent joint

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

INDURATION

- If the large swelling is hard to the touch, measure and record daily the greatest surface diameter in millimetres (mm) of the hard area.

  If the swelling is not hard, check the "No" box.

PRURITIS MEANS ITCHING

- If you notice your child has itching at the large injection site (e.g. your child is scratching or vigorously rubbing the swelling), please check "Yes" and the type of Grade it is. If there is no itch check the "No" box

FUNCTIONAL IMPAIRMENT

- If the large swelling changes the way your child moves or uses the swollen arm or leg as they normally would, please check "Yes" and the type of Grade it is. If there is no change to your child's use of the swollen arm or leg, check the "No" box.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Large Swelling Reaction (*PENTA GROUP-Booster*)

Pentacel

Date when the swelling was first considered to be a large swelling reaction*: *:To be completed by the investigator or delegate	|__|__| |__|__|__| |__|__|__|__| day month year Please enter the date in DD/MMM/YYYY format Was the examination performed by a member of study personnel during the large swelling reaction period? ☐ No ☐ Yes
Type of swelling and Location of swelling	☐ Local swelling only around the injection site, not involving adjacent joint ☐ Diffuse swelling, not involving adjacent joint ☐ Swelling involving adjacent joint
Induration at injection site (in mm)	☐ No ☐ Yes → If Yes then, Day 0 Day 1 Day 2 Day 3 |__|__|__| |__|__|__| |__|__|__| |__|__|__| Not Taken Not Taken Not Taken Not Taken ☐ ☐ ☐ ☐ Is Induration ongoing ? ☐ No ☐ Yes . If Yes then please enter the Largest Diameter observed |__|__|__|

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |___|___|___|___|___|___|___| To be completed by the investigator or delegate

Pruritis at injection site	☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Functional impairment	Has the swelling episode resulted in functional impairment? ☐ No ☐ Yes -> If yes then : ☐ Grade 1 (An AE which is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.) ☐ Grade 2 (An AE which is sufficiently discomforting to interfere with normal everyday activities.) ☐ Grade 3 (An AE which prevents normal, everyday activities. In a young child, such an AE would, for example, prevent attendance at school/kindergarten/a day-care center and would cause the parent(s)/LAR(s) to seek medical advice)
Last date when the swelling was still considered a large swelling reaction * *:To be completed by the investigator or delegate	|___|___| |___|___|___| |___|___|___|___| day month year Please enter the date in DD/MMM/YYYY format
Outcome of the extensive swelling	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered with ongoing events / Resolved with ongoing events

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |_____| To be completed by the investigator or delegate

Instructions to complete:

General symptoms

➢ *HOW TO COMPLETE THE DAILY VALUE?*

- Write down a value for each symptom and each day (measure or intensity). **Don't leave any field empty.**
- Write "0" if there is no increase in intensity compared to normal

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing	After Day 3: Worst Intensity	After Day 3: End Date	Did you receive medical attention?*	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Drowsiness → 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	Tick box if still ongoing ↓ ☐	☐ No ☐ Yes	HOSPMED ☐☐	☐ No ☐ Yes

➢ *GENERAL SYMPTOMS: TEMPERATURE*

- Please use the provided thermometer.
- Take your child's temperature each day from day of vaccination (day 0) until day 3, and write down the values.
- If you took more than once a day your child's temperature, then write down the highest one.
- The preferred route for recording temperature in this study will be Axillary for Booster vaccination.

Example: if on Day 0
- At 8 am: 98.8°F
- At 1 pm: 99.3°F
- At 7 pm: 99.7°F

→ 99.7°F is to be recorded in for Day 0

- Please write down NT (Not Taken) if you did not take the temperature.

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing ≥100.4°F by any route	After Day 3: Highest Temperature	After Day 3: End Date	Did your child receive any medical attention?	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Temperature →	98	99	101	100.5	☐ No ☐ Yes →		Tick box if still ongoing ↓ ☐	☐ No ☐ Yes	HOSPMED ☐☐	☐ No ☐ Yes

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

GENERAL SYMPTOMS

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3: Ongoing ≥100.4°F by any route	After Day 3: Highest Temperature	After Day 3: End Date (Tick box if still ongoing)	Did your child receive any medical attention?	Type of medical attention (To be completed by the investigator or delegate)	Relationship to inv. Product (To be completed by the investigator or delegate)
Temperature →					☐ No ☐ Yes →			☐ No ☐ Yes	HO/ER/MD |_|_|	☐ No ☐ Yes

Temperature:	Route of measurement: (The same route must be used for all your measurements.)
☐ Fahrenheit	

Clarification(s) for Investigator or delegate only:

➢ *INTENSITY DEFINITIONS*

- Drowsiness:
  - 0: Behaviour as usual
  - 1: Mild: Drowsiness easily tolerated
  - 2: Moderate: Drowsiness that interferes with normal activity
  - 3: Severe: Drowsiness that prevents normal activity
- Irritability/Fussiness:
  - 0: Behaviour as usual
  - 1: Mild: Crying more than usual/no effect on normal activity
  - 2: Moderate: Crying more than usual/interferes with normal activity
  - 3: Severe: Crying that cannot be comforted/prevents normal activity
- Loss of appetite:
  - 0: Appetite as usual
  - 1: Mild: Eating less than usual/no effect on normal activity
  - 2: Moderate: Eating less than usual/interferes with normal activity
  - 3: Severe: Not eating at all

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

GENERAL SYMPTOMS

To be completed by the investigator or delegate: **Date of vaccination = Day 0**: _____

	Day 0	Day 1	Day 2	Day 3	After Day 3			Did your child receive medical attention?*	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
					Ongoing	Worst Intensity	End Date Tick box if still ongoing ↓			
Drowsiness → Intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes
Irritability/Fussiness → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes
Loss of appetite → intensity (0/1/2/3)					☐ No ☐ Yes →		☐	☐ No ☐ Yes	HO/ER/MD └┴┘	☐ No ☐ Yes

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

Instructions to complete:

Adverse Events

- If your child experience(s) any other symptoms than those listed in the local symptoms or general symptoms pages, please write these symptoms down in this section.
- If a symptom appears only after day 3, please write this symptom down in this section.
- If redness, swelling or pain appears on another area than area where your child received the vaccine, please report these symptoms in this section.

INTENSITY DEFINITIONS

- **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 centre and would cause the parents/guardians to seek medical advice).

BOX "STILL ONGOING" IN THE COLUMN "END DATE" – WHEN TO TICK IT?

- Tick the box "Still ongoing" if the illness / sign / symptom is still present at the time you return the diary card to the site.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

DID YOUR CHILD RECEIVE ANY MEDICAL ATTENTION? HOW TO COMPLETE THIS QUESTION?

- Medical attention means hospitalisation, an emergency room visit or a visit to or from medical personnel (medical doctor).
- Tick the box “No” if your child did not visit a doctor or go to the hospital or an emergency room for the symptom.
- Tick the box “Yes” if your child went to the hospital, an emergency room or if your child visited a doctor for the symptom. Keep the type of medical attention (grey column) empty. It will be completed by the study doctor or study staff.

GlaxoSmithKline **DTPA-HBV-IPV-135** **117119**	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

ADVERSE EVENTS – MULTIPLE INJECTIONS

Record any adverse event (= any illness, sign, symptom) other than the local and general symptoms listed on the previous pages, which may have started or any medical condition which may have worsened since the last study vaccination.

Illness/Sign/Symptom	to be filled in case of reaction at vaccine administration site		Worst Intensity 1/2/3	Start Date	End Date	Tick box if still ongoing ↓	Did your child receive medical attention?	Type of medical attention To be completed by the investigator or delegate	Relationship to inv. Product To be completed by the investigator or delegate
	Site	Side							
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes
	☐ Thigh ☐ Deltoid	☐ Left ☐ Right				☐	☐ No ☐ Yes	HO/ER/MD |__|__|	☐ No ☐ Yes

Clarification(s) for Investigator or delegate only:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

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], intradermal [ID], intramuscular [IM], intranasal [IN], intravenous [IV], oral [PO], parenteral [PE], subcutaneous [SC], sublingual [SL], transdermal [TD], other [OTH], unknown [UNK]

Clarification(s) for Investigator or delegate only:

Instructions to complete:
Medication

➢ *DOSE, UNIT AND FREQUENCY*

- Write the amount of the medication your child took.

Dose, unit and frequency
200mg pill 3 times a day
2 coffee spoon 100mg once per day
3 suppositories per day
Nasal drops 4 times per day

- Most of this information can be found on the label of the medication. You may want to bring the medication to your child's next visit with the study doctor or study staff. Then they can help you to fill in the required information.

➢ *BOX "STILL ONGOING" IN THE COLUMN "END DATE" – WHEN TO TICK IT?*

- Tick the box "Still ongoing" if the medication is still taken at the time you return the diary card to the site.

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__|__| To be completed by the investigator or delegate

MEDICATION

Record any medication taken since the last study vaccination.

Medication	Reason	Dose, unit and frequency	Start Date	End Date Tick box if still ongoing↓	**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:

DTPA-HBV-IPV-135 117119	**DIARY CARDS** **Vaccine Dose Number 4**	**Subject Number** |__|__|__|__|__|__| To be completed by the investigator or delegate

NOTES

INVESTIGATOR'S OR DELEGATE'S SIGNATURE

Investigator's or delegate's signature: _____

Date: |__|__||__|__||__|__|__|

Printed Investigator's or delegate's name: _____

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
United States					585	100
Aguilar, Richard	Charlesworth, Cynthia Cihigoyenetche, Jennie Crook, Teresa Earl, Lisa Rose, Vicki	PPD	Saltzer Medical Group, 215 E Hawaii Ave,Nampa,Idaho,United States,83686	St. Luke's Health System Institutional Review Board, 190 E. Bannock Street Boise, ID 83712 St. Luke's Health System Institutional Review Board, 3000 S. Denver Way Boise, ID 83705	11	1.9
Andrews, Wilson	Anderson, Dana Bien, Richard Chernik, Christine Fearing, Donna Fernandez, Carole Fleming, Debra Hassel, Stephanie King, Deborah King, Stephen Morgan, Bakari Nevius, Patricia Nix, Tamara Royal, Dina Scheffer, Elizabeth Smail, Nicole Turlapaty, Neelima Worly, Julia		Pediatric and Adolescent Medicine PA, 2155 Post Oak Tritt Road, Marietta, Georgia, United States,30062	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	10	1.7

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects	% of Subjects
Andrews, Wilson	Anderson, Dana Bien, Richard Chernik, Christine Fearing, Donna Fernandez, Carole Fleming, Debra Hassel, Stephanie King, Deborah King, Stephen Morgan, Bakari Nevius, Patricia Nix, Tamara Royal, Dina Scheffer, Elizabeth Smail, Nicole Turlapaty, Neelima Worly, Julia	PPD	Pediatrics and Adolescent Medicine, 120 Stonebridge Parkway, Woodstock, Georgia, United States,30189	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	11	1.9
Concannon, Kevin	Davis, Eileen McHorney, David Patton, Robert Typlin, Bonnie Valdes de-la-Cruz, Monica		Cholla Pediatrics, 2167 West Orange Grove Rd,Tucson,Arizona,United States,85741	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	14	2.4
Daly, Wendy	Becherer, Rebecca Cornett, Denver III Heustis, Renee		Bluegrass Clinical Research, INC, 5512 Bardstown Road, Louisville,Kentucky, United States,40291	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	5	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
Garscadden, Alan	Burke, Charles Finck, Lani Freson, Brandon Hill, Stephanie Karaboitis, Krisoula Lundy, Samantha Nevarez, Max Pink, Cyndi Southern, Patryce Weiss, Sarah	PPD	Colorado Springs Heath Partner - East, 6340 Barnes Road, Colorado Springs, Colorado,United States,80922	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	11	1.9
Haney, Byron	Beachy, Ryan Bowman, Diane Brower, Stephanie Izzi, Tami Kelly, Kate Long, Aaron McHargue, Jenny Miller, Heidi Mongrain, Chad Sackett, Stephanie Vaughan, Rick Walters, John		Family Health Care of Ellensburg,107 East Mountain View Ave, Ellensburg, Washington,United States,98926	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	7	1.2
Harris, JoAnn	Cabrilo, Nadia Cotter, Michael Noruzian, Masoud Parr, Harold Schumacher, Randall		Cotton O'Neill Research Center, 4100 SW 15th St,Topeka,Kansas,United States,66604	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	12	2.1

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects	% of Subjects
Harrison, Christopher	Buford, Terry Hobbs, Kristie Pahud, Barbara Seybert, Missy Weltmer, Kristen	PPD	Children's Mercy Hospitals and Clinics - Pediatric Clinical Pharmacology & Medical Toxicology, 2401 Gillham Road,Kansas City, Missouri, United States,64108	Children's Mercy Hospitals Pediatric Institutional Review Board 2401 Gillham Road Kansas City, MO 64108	6	1.0
Hartvickson, Robyn	Allen, Michele Barnes, Adriene Craig, Abigail Holdeman, Troy King, Jeri Lindholm, Gerald Oubre, Sarah Phillips, Justin Shuman, Bobbie Slechta, Stacy Thomas, Shannon Thompson, Jackie Watts, Hannah Wiens, Terra		Heartland Research Associates,700 Medical Center Drive, Newton, Kansas,United States,67114	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	10	1.7
Heise, John	Backus, Kathryn Bays, Anna Lewis, Donald Reinhardt, Diana Ress, Diane Shook, Josh Smith, Ashley Sturm, Donna Taylor, Peggy		Holston Medical Group, 2033 Meadowview Lane, Kingsport, Tennessee, United States,37660	Quorum Review IRB, 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	3	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
Klein, Nicola	Baxter, Roger Hempstead, Kenneth Rossi, LaVonne	PPD	Kaiser Permanente Roseville 1840 Sierra Gardens Dr RosevilleOakland, California, United States,95661	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	45	7.7
Klein, Nicola	Bailon, Eileen Baxter, Roger Pelliccione, Linda Purdy, Kenneth Upadhyaya, Sally		Kaiser Permanente - Santa Clara,186 710 Expressway,Santa Clara, California, United States,95051	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	34	5.8
Klein, Nicola	Baxter, Roger Huynh, Tuan Mullen, Shannon		Kaiser Permanente - San Jose,Unit B1 276 International Circle,San Jose, California,United States,95119	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	42	7.2
Klein, Nicola	Baguinguito, Michelle Baxter, Roger Enochian, Karen Latimer, Manya Lepejian, Garine		Kaiser Permanente Fresno 4785 North First Street Fresno,California,United States,93726	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	18	3.1
Klein, Nicola	Backs, Julia Baires, Janelle Baxter, Roger Chan-Werner, Siew		Kaiser Permanente Oakland, 3505 Broadway,Oakland,California,United States,94611	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	29	5.0
Klein, Nicola	Anand, Lei Baxter, Roger Duenas-Fernandez, Therese Kaneko, Jennifer		Kaiser Permanente Clinic - Pleasanton, 2nd Floor 7601 Stoneridge Mall Road, Pleasanton, California, United States,94588	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	8	1.4

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects	% of Subjects
Klein, Nicola	Baxter, Roger Lee, Sandra Minetto, Margaret Owen, Susie Takahashi, Irene	PPD	Kaiser Permanente Daly City 395 Hickey Blvd,Daly City, California, United States,94015	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	48	8.2
Klein, Nicola	Baxter, Roger Carlson, Linda Chan, Eva Duenas-Fernandez, Therese Phelan, Michael Tichenor, Thorston		Kaiser Permanente Hayward, 27303 Sleepy Hollow Ave, Hayward, California, United States,94545	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	20	3.4
Klein, Nicola	Baxter, Roger Cook, Gail Cooper, David Hansen, Gabriel Henson, Linda		Kaiser Permanente Sacramento, 1650 Response Road, Sacramento, California, United States, 95815	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	23	3.9
Klein, Nicola	Baxter, Roger Burun, Latisha Hansen, Gabriel Jordan, Weldon Theisen, Susan		Kaiser Permanente South Sacramento, 6600 Bruceville Rd,Sacramento, California, United States,95823	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	13	2.2
Klein, Nicola	Angel, Valerie Baxter, Roger Bergen, Randy Encarnacion, Jolynne		Kaiser Permanente Walnut Creek, 1425 South Main Street,Walnut Creek, California, United States,94596	Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB). 1800 Harrison Street Oakland, CA 94612	11	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
Kratz, Richard	Bartholomew, Susan Bolanowski, Deborah Couper, Rebecca Dickinson, Normajean Dolha, Anuta Faccenda, Deborah Flaherty, Betty Jo Hipp, Thomas Kivela, Ursula Lamberth, Erik Leatherman, Tammy Moretski, Kelly Moyer, Margery Ozeck, Deborah Pforter, Bonnie Schafer, Katelyn Sims, Audrey Souder, Ronald Velasquez, Ivania Vogl, Jeffery	PPD	Pennridge Pediatric Associates, 711 Lawn Ave,Sellersville, Pennsylvania, United States,18960	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	7	1.2
Landis, Miles	Alber, Thomas Hillock, Karen Kornegay, Jill Roque, Mark Walker, Cynthia		Miles M. Landis, MD 2505 Junior Street Orange City Florida United States 32763	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	2	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
Livingston, Sean	Ball, Charles Benafield, Laureen Davis, Orrin Denton, Meredith Furlow, Stacy Grear, Tim Jackson, Charles Koehler, Andrew Mahan, Meredith McCord, Virginia Park, Josephine Payton, Terry Rasmussen, Daniel Robinson, Joe Silvey, Brentley Simmons, John Swindle, James	PPD	Northwest Arkansas Pediatric, 3383 N. MANA Court, Fayetteville, Arkansas, United States,72703	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	19	3.3
Marshall, Gary	Bryant, Kristina Carothers, Becky Chaney, Elizabeth Espinosa, Claudia Franck, Emily Franco, Sofia Frazier, Erin Jones, Veronnie Kurbasic, Mirzada Nota, Maria Fernanda Pasquenza, Natalie		University of Louisville Hospital, 555 South Floyd Street, Louisville, Kentucky, United States,40202	University of Louisville Human Subjects Protection Program Office MedCenter One – Suite 200 501 E. Broadway Louisville, KY 40202-1798	15	2.6

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects	% of Subjects
	Patel, Pradip Pendleton, Amber Sayat, Gena Sayat, Jonathan Scott, Penny Smith, Michael Statler, Victoria Theriot, Judith Thompson, Jennifer Woods, Charles Wortham, Laura					
Mehta, Praful	Duncan, Sheri Entriken, Leslie Goering, Tana Hardy, Chelsey Hastings, Amber Hook, Kristen Koehler, Timothy Neuberger, Cari Reheis, Jordan Schmidt, Holli Thomas, Shannon Zinkovsky, Sophia	PPD	Heartland Research Associates, LLC, 3730 N Ridge Road, Wichita,Kansas, United States, 67205	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	9	1.5

Investigator	Sub-Investigator	Center no.	Description of Research Facility, Hospital/ Institution, and Address	Name of IEC/IRB Committee, Address	Number of Subjects	% of Subjects
Miller, Garron	Goodrich, Diane Hellyer, Jeanie Lauritzen, Benjamin Murphy, Annette Peterson, Jonathan Yacolca, Ischia	PPD	Utah Valley Pediatrics - Payson, 15 S 1000 East, Payson, Utah, United States,84651	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	20	3.4
Moore, Susan	Zomcik, Anne		Childrens Health Care - West, 2501 West 12th Street, Erie, Pennsylvania, United States,16505	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	21	3.6
Peterson, James	Clark, Alexander Clyde, Jennifer Eborn, Shana Edwards, Susan Henry, Dan Iwasaki, Pamela Ann Jackson, Heather John, Whitney Kelty, Gerald Lewis, Janet C Mickelson, Christopher Pace, Laura Rohrer, Jacqueline Taylor, Jack Wagner, Gintare Wilkerson, Jeanna		J. Lewis Research, Inc., Foothill Family Clinic, 2295 Foothill Drive,Salt Lake City,Utah,United States,84109	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	3	0.5
Ramsey, Keith			Jordan Ridge Kids and Teens, 8822 S Redwood Road,West Jordan, Utah, United States,84088	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	6	1.0
Rausch, Michael	Allen, Michele		Heartland Research Associates, LLC,	Quorum Review IRB 1501 Fourth	3	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
Naccarato, Teran (FPI)	Babb, Andrea Cerullo, Janis Cowgill, Stephanie Hiebert, Jill Phan, Linda Phillips, Justin Regehr, Emily Stackhouse, Johnny Warman, Elizabeth Wilson, Dorothy		1601 State Street, Augusta, Kansas, United States,67010	Avenue, Suite 800| Seattle, WA 98101		
Reyes, Elizabeth	Reyes, Antonio	PPD	Emmaus Research Center Inc, 408 South Beach Blvd, Anaheim, California, United States,92804	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	10	1.7
Shepard, Julie	Byers, Matthew Goodfellow, Jessica Mergler, Kristin		Ohio Pediatric Research Association, 7200 Poe Avenue,Dayton,Ohio,United States,45414	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	11	1.9
Sigg, Laurent	Cook, Kimberly Downs, Kandy Hunt, Vickie Silas, Peter		Wee Care Pediatrics II, 934 South Main Street, Layton, Utah, United States,84041	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	2	0.3
Simon, Michael	Hippe, Sandra Rush, Carol Sutherland, Teresa Wilson, Erin		Michael W Simon MD, 610 East Brannon Road, Nicholasville, Kentucky, United States, 40356	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	2	0.3
Strahlman, R Scott	Kari, Manjula Zapata, Graciela		Columbia Medical Practice, 5450 Knoll Drive North, Columbia, Maryland, United States,21045	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	2	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
Tipton, Mary	Andrews, Curtis Cook, Kimberly Cottle, Kevin Garcia, Kathy Goodrich, Diane Hellyer, Jeanie Hollingsworth, Martin Hunt, Vickie Nakata, Thanh Perkins, Janene Thur, Vilate	PPD	Copperview Medical Center, 3556 West 9800 South, South Jordon,U tah, United States,84095	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	7	1.2
Twiggs, Jerry	Lee, Russell McMullin, Karl		Dixie Pediatrics, 1240 East 100 South, #14,St. George, Utah, United States,84790	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	14	2.4
Weiner, Leonard	Butler, Maureen Ferguson, Lori Fluno, Kristen Halczyn, Jodi Joseph, Kristine Losito, Vito Massa, Tracy Odin, Rosalind O'Malley, Sean Potter, Rebecca Remillard, Phillip Shaw, Jana Sisskind, Jaclyn Skeval, Sandra Stoeckel, Kathleen		SUNY Upstate Medical University, 750 E. Adams Street, Syracuse, New York, United States,13210	Upstate Medical University Institutional Review Board for the Protection of Human Subjects SUNY Upstate Medical University Institutional Review Board 750 East Adams Street, WSK Hall Syracuse NY USA 13210	11	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
Wisman, Paul	Aderholt, Christie Armengol, Carlos Bouber, Gemilla Brown, Alaina Davis, Sheila Harper, Lorna Knight, Sarah Perriello, L. Paige Sauer, Paul Wisman, Claudia	PPD	Pediatric Associates of Charlottesville LLC, 1011 East Jefferson Street, Charlottesville, Virginia, United States,22902	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	9	1.5
Zissman, Edward	Belton, Janet Candelori, Jaime Harris, Brian Mullen, Kerry Powell, Kristin Soven, Wayne		Advanced Investigation Research, 475 Osceola Street, Altamonte Springs, Florida, United States,32701	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	10	1.7
Zollo, Kenneth	Fuller, Joshua Goodrich, Diane Meyer, Marie Murphy, Annette Wright, Aubrey Yacolca, Ischia		Pediatric Care, 1675 North Freedom Boulevard, Provo, Utah, United States, 84604	Quorum Review IRB 1501 Fourth Avenue, Suite 800| Seattle, WA 98101	11	1.9

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.

When developing a Local ICF, all changes to the content that affect the meaning of the Model ICF should be justified and documented locally. Any **black bold** text in the final Model ICF is GSK Vaccines' **mandatory** wording and should be retained, any alterations or additions to this text must be communicated to the central team prior to the finalization of the local ICF.

Refer to Appendix A Best Practices document for the development of the Local ICF.

Significant changes in the local ICF compared to the model ICF related to the processing and use of human biological samples and data need to be tracked in the Informed Consent Significant Changes Tracking Form. For example changes in the sample use and/or future research; sample retention period; what happens to samples or data if a subject withdraws consent; any restriction in sharing samples or data with other researchers; any changes to what data can be collected. These changes are tracked to ensure that GSK and other third parties collecting and using samples and data from GSK clinical trials are informed of and can comply with what was agreed to by the subject in the informed consent he/she signed.

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 SOP_54823, GUI_51905 and GUI-BIO-CLIN-0014 for more information.
(Delete the instructions above from the Final Local ICF).

INFORMED CONSENT FORM

Study Identification: 117119 (DTPA-HBV-IPV-135)

Study Title: Immunogenicity and safety study of GSK Biologicals' Infanrix hexa™ at 2, 4 and 6 months of age in healthy infants.

Model ICF Version Number: Final Version 03 **(replace with Version of Local ICF)**

Date: 08/APR/2014 **(replace with Date of Local ICF)**

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: _____

Insert subject ID here

What is consent?

Consent means that you allow your child/ward to take part in this research study. You can decide if you want your child/ward to take part in this study or not. Please take time to read the following information and ask us if you have any questions. You can talk in confidence with your family and family doctor to help you make a decision. You must sign the consent pages at the end of this form if you decide to let your child/ward join this research study. You will receive a copy of this form.

Why is this study being done?

This research study is looking at the safety and effectiveness of *Infanrix hexa* in infants in the United States of America (USA). *Infanrix hexa* is a combination vaccine (a vaccine against more than one disease combined into one shot) that protects children against the following six diseases in a single injection: diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b (Hib) and hepatitis B. Some of the effects of these diseases are explained below:

- Diphtheria is an infection of the throat. Children with diphtheria may stop breathing, have permanent damage to the heart and brain, or even die.
- Tetanus is an infection of the blood. It causes strong cramps that prevent breathing and can lead to death.
- Pertussis (whooping cough) is a highly infectious disease which causes severe coughing during which children are unable to breathe. The disease can lead to death. Recently there have been outbreaks of pertussis in several states in the US.
- Poliomyelitis is a severe disease that is highly contagious amongst children and can cause paralysis (loss or inability to move a body part) and death.
- Hib causes bacterial meningitis (an infection of the fluid and cover surrounding the brain) and infections of the blood, lungs, joints or bones. Most cases occur in children less than five years old. About a quarter of the children who survive Hib

meningitis suffer permanent damage to the brain and/or nerves ranging from mild hearing loss to mental retardation.

- Hepatitis B is a viral infection that attacks the liver and can causes life threatening liver infection. It is also a major cause of liver cancer worldwide.

In the USA, vaccination against all of these diseases is routinely recommended.

Combination vaccines are easier and more cost-effective to administer as they reduce the number of injections needed to vaccinate a child. *Infanrix hexa* is licensed in more than 98 countries around the world, including the European Union, but not in the USA. This vaccine is an investigational vaccine in the USA, which means it is still being tested and it is not approved by the government for sale.

Vaccines work by causing the body to make substances in the blood called antibodies that protect against disease. The present study will compare how *Infanrix hexa* causes the body to produce antibodies as compared to vaccines that are already approved by the government in the USA.

How is GSK involved?

GlaxoSmithKline (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 use the information from this study to get patents, sell the vaccine in the future or make profits in other ways. 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. You can share this information with your doctor, family or friends when discussing about your child's/ward's participation in this study and your child's/ward's healthcare.

Who can join this study?

Your child/ ward can only be in this study if:

– He/she is between, and including, 6 and 12 weeks of age at the time of the first vaccination,

– He/she is healthy,

– He/she has not had a history of diphtheria, tetanus, pertussis, pneumococcal, rotavirus, poliovirus, hepatitis B and Hib disease.

– He/she has not had previous vaccinations against diphtheria, tetanus, pertussis, poliomyelitis, pneumococcal, rotavirus and Hib diseases; and has received no more than one previous dose of hepatitis B vaccine,

– You, as the parent(s)/legally acceptable representative [LAR(s)] of the child/ward provide written informed consent for your child/ward to participate in this study.

The study doctor will also check details about your child's/ward's medical history before your child/ ward can join this study. If the mother agrees by signing a separate informed consent, the study doctor will ask if the mother received vaccination against pertussis during her pregnancy. However, even if the mother does not sign the separate informed consent, the child can still be allowed to enroll and to participate in this study if he/she is eligible.

You can ask your study doctor for more details.

What does this study involve?

About 585 children will take part in this study. When we have enough children taking part in this study, we will not allow any more to join.

The study will be done in multiple locations in the USA.

Your doctor will evaluate whether your child/ward can take part in this study by asking you questions about your child's/ward's health and doing a physical examination.

The children participating in this study will be divided into three vaccination groups (the Hexa group, the Pedia group and the Penta group). Upon your consent to have your child/ward participate in the study, a computer will be used to place the children into groups. Your child/ward has a one in three chance of being placed in any one group. Neither you nor the study doctor can choose a group. You will know what vaccines your child/ward will be receiving.

All children in the study will receive vaccines at four visits. Children who are not assigned to receive the *Infanrix Hexa* vaccine will instead receive two other vaccination regimens that are standard of care in the USA. All the children will be vaccinated against the same diseases in this study.

At the first three visits (at approximately 2, 4 and 6 months of age), the following vaccines will be given by injection into the thigh muscle:

- **Hexa Group:** Children in this group will receive a single dose of *Infanrix hexa* at each of the first three visits.
- **Pedia Group:** Children in this group will receive a single dose of *Pediarix* and a single dose of *ActHib* at each of the first three visits.
- **Penta Group**: Children in this group will receive a single dose of *Pentacel* at each of the first three visits and a single dose of *Engerix-B* at either two or three visits, depending on whether your child/ward has been vaccinated against hepatitis B in the past.

In addition, all the children will receive a dose of *Prevnar13* at approximately 2, 4, and 6 months of age by injection into the thigh muscle and a dose of *Rotarix* vaccine at approximately 2 and 4 months of age orally as per US national recommendations.

At the fourth vaccination visit (at approximately 15 to 18 months of age), the following vaccines will be given by injection into the thigh or arm muscle:

- **Hexa Group**: Children in this group will receive a dose of *Infanrix* and *Hiberix* vaccines.
- **Pedia Group**: Children in this group will receive a dose of *Infanrix* and *ActHIB* vaccines.
- **Penta Group**: Children in this group will receive a dose of *Pentacel* vaccine.

Besides the vaccines given in this study, your child could receive the influenza, measles, mumps, rubella, varicella, hepatitis A, and a fourth dose of pneumococcal vaccine (*Prevnar 13*) as per US national recommendations. Talk to your doctor for more information about these.

If your child/ward is sick on the day of vaccination visit, the visit will be rescheduled during the period permitted by the study.

After each vaccination, you and your child/ward will have to stay at the study center for at least 30 minutes to make sure your child/ward does not have any immediate adverse reactions to any of the vaccinations before going home.

After your child/ward receives the vaccines, the study staff will give you a card (called a diary card) to write down information about how your child/ward feels on the day of each vaccination and for the following three days (for a total of four days). You will need to write down:

- if there was any pain, redness or swelling and the size of any redness and/or swelling where the vaccines were given. The doctor will instruct you how to measure the redness and swelling,
- any drowsiness, irritability, or loss of appetite that your child/ward experiences.
- your child's/ward's temperature and how you measured it.

You will also be asked to write down any changes in your child's/ward's health and any medications and vaccines your child/ward got besides those that are part of the study for a month after each vaccination visit.

Information about the effect of the vaccines on your child's/ward's body and health will be collected by taking a blood sample and asking you questions. Approximately 5 mL (for Visit 4 and 5) and 3.5 mL (for Visit 6) of blood will be taken from your child/ward at three separate visits to measure the amount of antibodies your child's/ ward's body made to the vaccines which were given. At the end of the study, the study doctor will be informed of your child's/ward's response to the vaccinations.

The study will last for a period of about 14-17 months. Your child/ward will need to visit the study site six times.

If you allow your child/ward to take part in this study then it is important that you follow all study activities as described here:

Day	What will happen at this visit
First phase of the study	
Day 0 (Visit 1) – your child/ward is 6 to 12 weeks of age	You will have the study purpose and procedures explained to you and you will be asked to sign the informed consent form. The doctor will ask you about your child's/ward's medical history. Your child/ward will undergo: – Physical examination – Measurement of body temperature – Administration of vaccines according to the group your child/ward is in. You will receive a diary card for Visit 1 and will be asked to use it to write down any symptom/illness your child/ward may get and medications or vaccines your child/ward may receive for a month after the study vaccination.
Month 2 (Visit 2) – your child/ward is about 4 months of age	You will return the completed diary card from Visit 1 and the study doctor will review it with you. Your child/ward will undergo: – Measurement of body temperature – Administration of vaccines according to the group your child/ward is in You will receive a diary card for Visit 2 and will be asked to write down any symptom/illness your child/ward may get and medications or vaccines your child/ward may receive for a month after the study vaccination.
Month 4 (Visit 3) – your child/ward is about 6 months of age	You will return the completed diary card from Visit 2 and the study doctor will review it with you. Your child/ward will undergo: – Measurement of body temperature – Administration of vaccines according to the group your child/ward is in You will receive a diary card for Visit 3 and will be asked to write down any symptom/illness your child/ward may get and medications or vaccines your child/ward may receive for a month after the study vaccination.
Month 5 (Visit 4) – your child/ward is about 7 months of age	You will return the completed diary card for Visit 3 and the study doctor will review it with you. Your child/ward will undergo: – Blood sampling (approximately 1 teaspoon of blood)
Month 10 (Phone-contact)- your child/ward is about 12 months of age	You will receive a phone call by the study staff asking about your child's/ward's health and about any other vaccines or medicines given during Month 5 to Month 10 of the study period.
Important non study activity: A fourth dose of *Prevnar13* is required at 12-15 months of age as part of your child's/ward's routine health care, but only the first three doses are given as part of this study. Your primary health care provider will provide the fourth dose of *Prevnar13* vaccine at 12-15 months of age. Please make sure you schedule an appointment with your primary health care provider to receive *Prevnar 13* and any other non-study vaccines as per US national recommendation at least 30 days before and/or after your child receives a study vaccine. The study doctor will ask you about the other vaccines your child might have received as per the US	

Day	What will happen at this visit
national recommendation.	
Second phase of the study	
Month 13-16 (Visit 5) – your child/ward is about 15 to 18 months of age	Your child/ward will undergo: – Physical examination – Measurement of body temperature – Blood sampling (approximately 1 teaspoon of blood) Administration of vaccines according to the group your child is in. You will receive a diary card for Visit 5 and will be asked to use it to write down any symptom/illness your child/ward may get and medications or vaccines your child/ward may receive for a month after the study vaccination.
Month 14-17 (Visit 6) – your child/ward is about 16 to 19 months of age	You will return the completed diary card for Visit 5 and the study doctor will review it with you. Your child/ward will undergo: – Blood sampling (approximately 1 teaspoon of blood) The study will then be completed.

Throughout the study, you will be asked to contact the study doctor immediately if your child/ward has any reactions or changes to his/her health, went to emergency care for a medical condition or has to be hospitalized.

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/ ward 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/ ward received.

What will happen to samples taken in this study?

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, samples of your child's/ward's blood will be collected. **Your** child's/ward's blood **samples may be sent to GSK or other laboratories working with GSK including those outside the United States to**:

- measure how your child's/ward's body reacts to the study vaccines,
- **ensure the quality of the tests used for the study vaccines and/ or diseases,**
- **improve tests and develop new tests linked to the study vaccines and/or diseases. These tests will never include testing related to your child's/ward's genes or hereditary characteristics.**

Your child's/ward's samples will be given a code so that it does not directly identify to your child/ward.

Your child's/ward'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/ward's sample(s) may also be used for future research. GSK will always ask permission for this research to an independent ethics committee or independent review board.

You can choose not to allow these optional tests and your child/ward will still be in the study.

What side effects or risks can you expect in this study?

If your child/ward is allergic to latex, he/she should not receive the vaccines. The study staff will ask you about this.

Most children who receive vaccines remain healthy. There are some common reactions that might be observed after vaccination with *Infanrix hexa,* which can be divided into local (at the place where shot was given) and general (not local) reactions, and are described below. These reactions are usually seen within three days following vaccination.

- Local side effects (at the place where shot was given):
  - very common (reported in more than 1 in 10 children): pain, redness, swelling smaller than 50 mm (about 2 inches);
  - common (reported in more than 1 in 100 children): swelling larger than 50 mm, hard lump where the injection was given;
  - uncommon (reported in more than 1 in 1000 children): large swelling of the vaccinated limb;
  - very rare (reported in less than 1 in 10,000 children): swelling of the whole injected limb and blister where the injection was given;
- General (not local) side effects after vaccination are:
  - very common (reported in more than 1 in 10 children): fever of 100.4°F or more, loss of appetite, tiredness, irritability, restlessness and abnormal crying.
  - common (reported in more than 1 in 100 children): nervousness, vomiting, diarrhea, itching, fever of 103.1°F or more.
  - uncommon (reported in more than 1 in 1,000 children): infection of the nose, throat or windpipe, cough and feeling sleepy.
  - rare (reported in more than 1 in 10,000 children): bronchitis and rash.
  - very rare (reported in less than 1 in 10,000 children): uncontrollable shaking of the body with or without fever, skin rash (also known as hives which is an outbreak of swollen, pale red bumps, patches on the skin that appear suddenly),

swollen glands in the neck, armpit or groin, bleeding or bruising more easily than normal, temporarily stopping breathing, in babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, allergic reactions including anaphylactic (extreme sensitivity) reactions. These extreme sensitivity reactions can be recognized by symptoms such as an itchy rash of the hands and feet, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness.

When *Infanrix hexa* and *Prevnar* are administered on the same day, higher incidence of fever > 103.1°F (1.7%) was reported as compared *to Infanrix hexa* given alone (0.6%).

It has been noted that when *Infanrix hexa* was given with *Prevnar 13* compared to *Infanrix hexa* given alone, the following events were reported more often:

Fits (with or without fever), collapse (sudden onset of muscle floppiness), periods of unconsciousness or lack of awareness and paleness or bluish skin discoloration were observed. However, all events were still rare.

Hepatitis B vaccine is included in the *Infanrix hexa*, *Pediarix*, and *Engerix-B* vaccines. During the routine use of hepatitis B vaccines, very rare events (reported in less than 1 in 10,000 children) were reported which included loss of skin sensitivity to pain or touch, swelling or infection of the brain (meningitis), numbness or weakness of the arms and legs, inflammation of nerves, blood vessels or joints; low blood pressure (hypotension) paralysis, convulsions, fits or seizures and severe allergic reactions like itchy rash of the hands and feet, swelling of eyes and feet and difficulty in breathing or swallowing.

After your child receives *Infanrix hexa*, contact the study doctor right away if your child has any of the following serious side effects:

- collapse,
- times when they lose consciousness or have a lack of awareness,
- fits – this may be when they have a fever.

These side effects have happened very rarely with other vaccines against whooping cough. They usually happen within 2 to 3 days after vaccination.

After your child/ward has received *Rotarix*, contact the study doctor right away if your child/ward has the following:

- **severe stomach pain,**
- **keeps on vomiting,**
- **has blood in his or her stools,**
- **has a swollen belly, or**
- **high fever.**

These signs may show that your child/ward has a blockage or twisting of part of his or her intestine.

GSK found in one study that this blockage or twisting happened more often, although still very rarely, in the first week after the first dose.

Pieces from a virus that is commonly seen in animals (called "PCV-1") were found in *Rotarix* vaccine. This virus does not make animals or people sick.

Please refer to the vaccines information sheet for the side effects/risks expected due to administration of the other vaccines used in this study- *Prevnar13, Pediarix, ActHIB, Pentacel, Engerix-B, Infanrix and Hiberix* vaccines. The study doctor can provide you with more information.

When a blood sample is taken from your child/ward there is the possibility that some temporary bruising and infection may occur at the site where the blood was drawn.

The vaccines in this study may not protect all children who get them. In some cases, tests may show that your child's/ward's response to the vaccination was not strong enough to protect against the diseases. If the study doctor believes your child/ward would benefit from another vaccination, he or she will contact you.

What benefits can you expect in this study?

This study may be beneficial/ useful in the following ways:

- The potential to protect your child/ward against the following major diseases: diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, Hib, pneumococcal and rotavirus diseases. However, there is no guarantee your child/ward will be protected against these diseases.
- Your child/ward will be closely watched and followed-up by the physician and his staff. Also, tests will be done on the blood samples taken from your child/ward to assess if your child/ward is protected. Such tests are not done during routine vaccination and are a benefit of study participation.
- Information from this study may help to learn more about the vaccine or disease. This will help to make new vaccines to protect people against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Hib diseases.

Are there other products or treatment?

This section should be completed locally using the most current information regarding the vaccines that are available in the country and their important potential benefits and risks. State if there are no alternate treatments.

There are other vaccines approved in the US that provide protection against the same diseases (although you may need to receive two shots instead of one at each visit). Your doctor can provide you with more information.

In addition, *Pedarix, ActHIB, Hiberix, Infanrix, Pentacel, Prevnar-13* and *Rotarix* are all approved in the US and your child/ward can get them from your doctor without having to participate in this study.

Talk with your doctor about your child's/ ward's options, before you decide if your child/ward should take part in this study. The study doctor can advise you if you need more information.

Does your child/ward have to stay in the study?

You may choose to withdraw your child/ward from 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 the child/ward will receive outside of this study.

We will share with you as soon as possible any new information that may change your choice to let your child/ward stay in the study.

Tell the study doctor if you no longer want your child/ward to take part in this study.

GSK may choose to stop the study or the study doctor may choose to stop your child's/ward's participation in the study at any time. We will then tell you why. We may ask you to withdraw your child/ward from the study if:

- Test results show that this study is not right for your child/ward
- You do not follow study instructions
- The study doctor thinks it is in your child/ward's best interest to stop, e.g. if your child/ward develops specific health problems.

What happens if your child/ward leaves the study?

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 Vaccines' ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for database collection can be taken into account. Significant changes to this section must be documented in the Tracking Form.

You may choose to stop your child/ward from being in this study at any time, without giving a reason. **We will keep and use the data and samples collected before your child/ward left the study. The study doctor may find out information about your child's/ward's health after your child/ward has left the study. The study doctor will send this information to GSK if it involves the safety profile of the vaccine.**

What about your personal and medical information?

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. These changes must be discussed with the central study team and GSK Vaccines' ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for data sharing can be taken into account. Significant changes to this section must be documented in the Tracking Form.

It is very important that your child's/ward's personal and medical information stay confidential and secure. Your child's/ward's personal and medical information will be protected in accordance with current law.

When you sign this consent form you agree that your child/ward's personal and medical information can be used as described here.

- Your child's/ward's personal and medical information may be checked by GSK and others [like agencies that approve and monitor studies, for example the Food and Drug administration (FDA)]. This is to make sure that the study is being run properly.
- Besides that, only the researchers at this study site can use information that identifies your child/ward (such as name and address) and only for the purpose of the study.
- Your child's/ward's information collected during the study will be labelled with a code number (for example, PPD It will not include your child/ward's name or address. The study doctor will have the link between your child/ward's name and the code number.
- The link between your child's/ward's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
- GSK will use your child's/ward's coded information for research only, including research looking at improving the quality and efficiency in conducting clinical research trials in general.
- GSK may do the following with your child's/ward's coded study information:
  - keep it electronically, and analyze it by computer to find out what the study is telling us. This may be done by GSK or a third party, in which case GSK will ensure that the third party is required to keep your data secure.
  - 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 and this disease and related diseases. 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. Your child's/ward's name will not appear in any publication.
  - share coded information with other companies, organizations or universities to carry out research, including research looking at improving the quality and efficiency in conducting clinical research trials in general.

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or another 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 where you live. GSK will make sure that if your child/ward's data are 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 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.

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/ward. At most, the web site will include a summary of the results. You can search this web site at any time.

If you withdraw your consent for us to use your child's/ward's personal information your child/ward will no longer be able to continue in the study.

At any time, you may ask to see your child's/ward's personal information and correct it if necessary.

In some circumstances you may not be able to access your child/ward's study information while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your child/ward's health during the course of the study.

You should know that once identifiable medical information about your child/ward 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/ward gets hurt while taking part in this study?

GSK will help pay for your child/ward's care if your child/ward is hurt by the study vaccines or a procedure done to your child/ward 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/ward like your child/ward'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/ward receives Medicare and if your child/ward does, 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 your child/ward may have.

Will you be paid for your child/ward being in the study?

This section should be completed locally.

You will be paid for the cost of travelling to your child's/ward's study visits. You may receive up to **[amount]** for travel / per visit.

Do you have to pay anything to allow your child/ward to be in the study?

Authors note that this section is optional. This section should be completed locally.

Your child/ward will get all the study vaccines and study tests and procedures for free **[or indicate if there is a cost]**.

Who should you contact if you have questions?

Identify who the legally acceptable representative should contact for information about the study, the subject's rights or study-related injuries. This section may be completed at Country Level.

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.**

Informed Consent Form Subject ID_____

CONFIDENTIAL
Study Identification 117119 (DTPA-HBV-IPV-135)

Consent statement

I,

_____
(Printed name of Parent/ Legally acceptable representative)

Parent/ Legally acceptable representative of

_____
Subject's name

- confirm that I have read the written information (or have had the information read to me) for study 117119 (DTPA-HBV-IPV-135) Final Version 03 08/APR/2014 15 Pages **(to be updated locally)**, 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 of my child/ward to authorized persons described in this information sheet.
- I know what will happen to my child's/ward's blood samples.
- understand that by signing this form any of my child's/ward's 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/ward to take part in this study.

Tick as appropriate (this decision will not affect your child's/ward's ability to enter the study):

I agree that the study doctor tells my family doctor of my child/ward taking part in the study.

☐ **Yes** ☐ **No** ☐ **NA**

Tick as appropriate

I agree that my child'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 child/ ward **can still take part in the study.**

☐ **Yes** ☐ **No**

Informed Consent Form Subject ID_____

CONFIDENTIAL

Study Identification 117119 (DTPA-HBV-IPV-135)

I agree to let my child/ward to take part in this study.

Relationship of legally acceptable representative to 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 _____

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.

*Printed name of Witness _____

Signature of Witness _____ Date: _____ day/ month/ year

* Witness is only required if the subject/ legally acceptable representative is unable to read.

Delete the following Appendix in the Final local ICF.

Appendix A GlaxoSmithKline Vaccines Best Practices Document for the Development of the Local ICF

Introduction

The local informed consent form (ICF) is created based on the GSK Vaccines 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/patient 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 study team and GSK Vaccines' central ICF taskforce for alignment prior to the finalization of the local ICF.

Significant changes to this section must be documented in the Tracking Form.

Subject/patient 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/patient 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 study team and GSK Vaccines' 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.

Significant changes to this section must be documented in the Tracking Form.

What about your personal and medical information?

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/patient and could have legal implications. If any changes are made to this section in response to a request from any source, these changes must be discussed with the central study team and GSK Vaccines' central ICF taskforce for alignment prior to the finalization of the local ICF, so that the impact for data sharing can be taken into account.

Significant changes to this section must be documented in the Tracking Form.

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/patient 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/patient is linked to the correct study.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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 by local regulations.	Justified	A change to this section is permitted if it is justified by local regulations. For some countries, the local GSK affiliate should be indicated as Company Name.
Subject/Patient Identification		
Check whether there is space foreseen to insert the subject ID.	Required	The subject/patient ID should be mentioned on the ICF to be able to link the subject/patient 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/patient is linked to the correct study.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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/patient 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/patient/LAR prior to study participation. Informed consent involves an education and information exchange that takes place between the researcher and the potential subject/patient. 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/patient may not receive the complete information required to make an informed consent. Text can be simplified if necessary.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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/patient 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/patients 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/patient 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 the subject/patient 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/patient.
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/patient may not receive the complete information required to make an informed consent. Text can be simplified if necessary.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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/patient's consent. This has major ethical implications and can lead to a loss of company reputation, lack of confidence, invalid study data etc… . Significant changes to this section must be documented in the Tracking Form
Check if the QA (Quality Assurance), test improvement and new test method development in the scope of the study protocol is reported in the Local ICF.	Not permitted	This testing will be done at <u>all times</u>, assuming it is allowed as per individual subject's/patient's consent. If this 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. Also refer to the Clarification Paper on the future use of biospecimens.
Check Local regulations regarding storage duration. Check if the wording "for a maximum of 20 years" is not changed into "for 20 years". [If there are concerns regarding this text then this should be discussed with the central project team and GSK Vaccines' 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 "for a maximum of"20 years. Attention should be paid to the used wording "**for a maximum of**" 20 years. This wording allows GSK to cover different situations (e.g. to keep samples for maximum 20 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 Sample Retention Period Form. This will allow the laboratory to take the appropriate measures for sample storage, "for a maximum of 20"

ICF section	Type of changes	Rationale/Impact
		years or as defined in the ICF and documented in the section called "other". Significant changes to this section must be documented in the Tracking Form
Check local regulations regarding future research. [If there are concerns regarding this text then this should be discussed with the central study team and GSK Vaccines' 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, the wording of the text itself, should not be changed and nothing should be added! We capture this info in the CRF/eCRF, which contains standard wording so if the wording in the ICF is changed, this will not be matching. This form allows the central study team to track the actual testing at GSK (or laboratories used for GSK-sponsored studies) with the individual subject's/patient'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…. Also refer to the Clarification Paper on the future use of biospecimens.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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. Refer to the GSK Position Paper on 'Communication of Individual Immunological Assay Results to Study Sites' for additional information.
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/Patients/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/patients 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/patient 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/patient to freely participate to the study and would be putting the company reputation at risk. Text can be simplified if necessary.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
What happens if you leave the study?		
Check if the text on the use of data after subject/patient withdrawal is identical to the Model ICF. [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 Vaccines' central ICF taskforce for alignment prior to the finalization of the local ICF].	Justified	The bold text in this section has been approved by Medical Governance. Changes to this 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. Also refer to the Clarification Paper on the Handling of Data after Subject Withdrawal. Significant changes to this section must be documented in the Tracking Form.
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]. [If the text needs to be changed it should be discussed with the central study team and GSK Vaccines' central ICF taskforce for alignment prior to the finalization of the local ICF].	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/patient and could have legal implications. Text can be simplified if necessary. Significant changes to this section must be documented in the Tracking Form.

GlaxoSmithKline Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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/patients 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/patient is well informed before consenting to participation.
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/patient 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.

Best Practices Document for the Development of the Local ICF

ICF section	Type of changes	Rationale/Impact
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/patient will have to bear for taking part in the study i.e., whether the subject/patient or the subject's/patient's insurance will be charged for any study item or procedure. According to ICH-GCP, the anticipated expenses, if any, to the subject/patient 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/patient 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
Check local regulations regarding future 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 Vaccines' 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/patient, meaning that if this testing is mentioned in the body of the ICF, a tick box 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

ICF section	Type of changes	Rationale/Impact
		changed, this will not be matching with the UHSF.
Check local regulations for the legal of age of consent, the use of LARs, witnesses and any documentation requirements.	Justified	An additional line can be added if two LARs or two witnesses are needed as per local law. Refer to SOP_54823 and local regulations.

References

SOP_54823, Development and implementation of Informed Consent Forms for R&D and GSK Vaccines-Sponsored Studies.

GUI_51905, Guidance for Informed Consent documents.

GUI-BIO-CLIN-0014, Guidance for the development of Informed Consent-related documents.

GSK's Position Paper on Communication of Individual Immunological Assay Results To Study Sites.

GSK's Clarification Paper on Handling Data after Subject withdrawal.

GSK's Clarification Paper on Future Use of Biospecimens.

ADDENDUM 1 TO THE INFORMED CONSENT FORM FOR THE SUBJECT'S MOTHER

[Country to be inserted]

Study Identification: 117119 (DTPA-HBV-IPV-135)

Study Title: Immunogenicity and safety study of GSK Biologicals' Infanrix hexa™ at 2, 4 and 6 months of age in healthy infants.

Version and Date: Addendum 1 to the Model ICF Version 03 16/APR/2014

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: _____

This document should be presented to the subject's mother in full; no pages or sections should be omitted. The document contents should be explained verbally to the subject's mother.

Purpose of this document

You have already signed an informed consent form to allow your child's participation in a research study of the safety and effectiveness of GSK Biologicals' *Infanrix hexa* vaccine in infants in the United States of America (USA).

One of the diseases that the vaccines in the study will vaccinate the infants against is pertussis (whooping cough). There have been recent outbreaks of pertussis in the US, and infants too young to be fully vaccinated against pertussis are at greatest risk for severe disease and even death due to pertussis. In order to protect newborns, the Advisory Committee on Immunization Practices (the group that sets the immunization schedule for the USA) recommended in October 2012 that all women receive a vaccine against pertussis in their third trimester of pregnancy, so that antibodies (what the body makes to protect against disease) transferred from their blood into their infants blood during pregnancy would protect both mothers and their infants. The pertussis vaccine that will be given to the mother is a tetanus, diphtheria toxoid and pertussis vaccine called Tdap.

Since the recommendation to vaccinate the mothers is quite recent, not all mothers of the children in this study will have been vaccinated with Tdap during pregnancy. It is not known whether the mother's antibodies in their infant's bloodstream will affect the infants' ability to make their own antibodies to the study vaccines, so we want to study the responses of the infants enrolled in this study based on whether their mothers received the Tdap vaccine during pregnancy.

This document is intended to obtain your consent in order to collect information about any Tdap vaccination that you might have received during your pregnancy.

Addendum 1 to the Informed Consent Form

CONFIDENTIAL
117119 (DTPA-HBV-IPV-135)

What about your personal and medical information?

It is very important that your personal and medical information stay confidential and secure. Your personal and medical information will be protected in accordance with current law.

When you sign this consent form you agree that your personal and medical information can be used as described here.

- Your personal and medical information may be checked by GSK and others [like agencies that approve and monitor studies, for example the Food and Drug administration (FDA)]. This is to make sure that the study is being run properly.
- Besides that, only the researchers at this study site can use information that identifies you (such as name and address) and only for the purpose of the study.
- Your information collected during the study will be labelled with a code number (for example, PPD It will not include your name or address. The study doctor will have the link between your/your child's name and the code number. The code number assigned to you will be your child's code number.
- The link between your/your child's name and the code number will not be shared. Only the code number and coded information will be sent to GSK.
- GSK will use your/your child's coded information for research only, including research looking at improving the quality and efficiency in conducting clinical research trials in general.
- GSK may do the following with your/your child's coded study information:
  - keep it electronically, and analyze it by computer to find out what the study is telling us. This may be done by GSK or a third party, in which case GSK will ensure that the third party is required to keep your data secure.
  - 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 and this disease and related diseases. 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. Your name will not appear in any publication.
  - share coded information with other companies, organizations or universities to carry out research, including research looking at improving the quality and efficiency in conducting clinical research trials in general.

Addendum 1 to the Informed Consent Form

CONFIDENTIAL

117119 (DTPA-HBV-IPV-135)

Personal and medical data collected during the trial may be moved to, stored and used in the country where you live or another 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 where you live. GSK will make sure that if your data are 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 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.

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 you. At most, the web site will include a summary of the results. You can search this web site at any time.

At any time, you may ask to see your personal information and correct it if necessary.

In some circumstances you may not be able to access your study information while the study is ongoing. However the study doctor will share any important medical information if it is relevant to your health during the course of the study.

You should know that once identifiable medical information about you 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.

Your consent is voluntary. Refusal will involve no penalty or loss of benefits or attention that your child is otherwise entitled to receive from your healthcare provider. Refusal will also not hamper your child's participation in this study.

You should not sign this document unless you have received satisfactory answers to all of your questions. You will receive a signed copy of this form to take home.

Do you agree that we will collect your Tdap vaccination history during pregnancy?

☐ **Yes** ☐ **No**

Addendum 1 to the Informed Consent Form Subject ID_____

CONFIDENTIAL
117119 (DTPA-HBV-IPV-135)

Consent statement

I,

the mother of _____
Printed name of Subject's mother

_____
Subject's name

- confirm that I have read the written information (or have had the information read to me) for 117119 (DTPA-HBV-IPV-135) Addendum 1 to the Model ICF Version 03, dated 16 April 2014, pages 1-5 **[to be updated locally]**), and the changes have been explained to me by study staff during the consent process for this study.
- confirm that I have had the opportunity to ask questions about this addendum and the answers and explanations that have been provided were satisfactory.
- have been given the time and opportunity to consider allowing my child to continue participating in this study.

I agree to let the study doctor collect my Tdap vaccination history including collecting medical history by my obstetrician in this study

_____ _____
Signature of subject's mother Date: dd/mmm/yyyy

_____
Printed name of subject's mother

I confirm that I have conducted the consent process according to applicable regulations

_____ _____
Signature of person explaining the addendum Date: dd/mmm/yyyy

_____
Printed name of person explaining the addendum

Addendum 1 to the Informed Consent Form Subject ID_____

CONFIDENTIAL
117119 (DTPA-HBV-IPV-135)

If the mother of the subject is illiterate, an impartial witness must also sign this form

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

_____ _____

Signature of Witness Date: dd/mmm/yyyy

_____

Printed name of Witness

ADDENDUM 2 TO THE INFORMED CONSENT FORM

[Country to be inserted]

Study Identification: 117119 (DTPA-HBV-IPV-135)

Study Title: Immunogenicity and safety study of GSK Biologicals' Infanrix hexa™ at 2, 4 and 6 months of age in healthy infants.

Version and Date: Addendum 2 to the Model ICF Version 03 28/OCT/2014

Company Name: GlaxoSmithKline (GSK) Biologicals S.A.

Subject Identification: _____

This document should be presented to the subject's parent(s)/legally acceptable representative(s) [LAR(s)] in full; no pages or sections should be omitted. The document contents should be explained verbally to the subject's parent(s)/LAR(s).

Purpose of this document

You have already signed an informed consent form to allow your child's/ward's participation in a research study of the safety and effectiveness of GSK Biologicals' *Infanrix hexa* vaccine in infants in the United States of America (USA).

By means of this document, we would like to provide you with some new information regarding the collection of information on any injection site swelling that your child/ward may experience after vaccination and new information that recently became available about GSK Biologicals' rotavirus vaccine, *Rotarix* which is one of the vaccines that is given in the study your child/ward is taking part.

Please note that your child/ward would have already received the first and second dose of the *Rotarix* vaccine in this study and intussusceptions (twisting or blockage of a part of the intestine) is more often seen during seven days after the first dose and to a lesser extent after the second dose of *Rotarix* vaccine. The updated text regarding intussusceptions provided below is for your information.

The following section of the informed consent which you signed at the start of the study has been updated and the new text is indicated in ***bold italics***.

What does this study involve?

The informed consent that you have signed mentioned the following:

After your child/ward receives the vaccines, the study staff will give you a card (called a diary card) to write down information about how your child/ward feels on the day of each vaccination and for the following three days (for a total of four days). You will need to write down:

- if there was any pain, redness or swelling and the size of any redness and/or swelling where the vaccines were given. The doctor will instruct you how to measure the redness and swelling.
- any drowsiness, irritability, or loss of appetite that your child/ward experiences.
- your child's/ward's temperature and how you measured it.

Please read carefully the following new information:

After your child/ward receives the vaccines, the study staff will give you a card (called a diary card) to write down information about how your child/ward feels on the day of each vaccination and for the following three days (for a total of four days). You will need to write down:

- if there was any pain, redness or swelling and the size of any redness and/or swelling where the vaccines were given. The doctor will instruct you how to measure the redness and swelling.
- any drowsiness, irritability, or loss of appetite that your child/ward experiences.
- your child's/ward's temperature and how you measured it.
- ***After the fourth vaccination, when your child/ward is 15-18 months of age, you will also have to measure the circumference (length around) the arm or leg where your child/ward received a vaccine. The doctor will instruct you how to measure this length.***
- ***If after the fourth vaccination, the swelling where the vaccine was given is greater than 50 mm and/or you feel the swelling is quite noticeable, you will also have to write down additional symptoms such as itching, hardness and whether the swelling interferes with the use of the injected arm or leg. You will also have to call the study doctor and come in right away for examination of the swelling.***

What side effects or risks can you expect in this study?

The informed consent that you have signed mentioned the following:

After your child/ward has received *Rotarix*, contact the study doctor right away if your child/ward has the following:

- severe stomach pain,
- keeps on vomiting,

- has blood in his or her stools,
- has a swollen belly, or
- high fever.

These signs may show that your child/ward has a blockage or twisting of part of his or her intestine.

GSK found in one study that this blockage or twisting happened more often, although still very rarely, in the first week after the first dose.

Pieces from a virus that is commonly seen in animals (called "PCV-1") were found in *Rotarix* vaccine. This virus does not make animals or people sick.

Please read carefully the following new information:

After your child/ward has received *Rotarix*, contact the study doctor right away if your child/ward has the following:

- severe stomach pain,
- keeps on vomiting,
- has blood in his or her stools,
- has a swollen belly, or
- high fever.

These signs may show that your child/ward has a blockage or twisting of part of his or her intestine.

Large post-marketing safety studies indicate a transient increased incidence of intussusception after vaccination, mostly within 7 days of the first dose and, to a lesser extent, the second dose.

The overall incidence of intussusception remains rare.

Pieces from a virus that is commonly seen in animals (called "PCV-1") were found in *Rotarix* vaccine. This virus does not make animals or people sick.

Addendum 2 to the Informed Consent Form Subject ID_____

CONFIDENTIAL
117119 (DTPA-HBV-IPV-135)

Your consent is voluntary. Refusal will involve no penalty or loss of benefits or attention that your child/ward is otherwise entitled to receive from your healthcare provider.

You should not sign this document unless you have received satisfactory answers to all of your questions. You will receive a signed copy of this form to take home.

Consent statement

I,

_____
Printed name of Subject's parent/LAR

the Parent/ Legally acceptable representative of

_____
Subject's name

- confirm that I have read the written information (or have had the information read to me) for 117119 (DTPA-HBV-IPV-135) Addendum 2 to the Model ICF Version 03, dated 28 October 2014, pages 1-5 **[to be updated locally]**), and the changes have been explained to me by study staff during the consent process for this study.
- confirm that I have had the opportunity to ask questions about this addendum and the answers and explanations that have been provided were satisfactory.
- have been given the time and opportunity to consider allowing my child/ward to continue participating in this study.
- agree to let my child/ward continue to participate in the study

I confirm that I have conducted the consent process according to applicable regulations

_____ _____
Signature of person explaining the addendum Date: dd/mmm/yyyy

_____
Printed name of person explaining the addendum

Addendum 2 to the Informed Consent Form Subject ID_____

CONFIDENTIAL
117119 (DTPA-HBV-IPV-135)

If the Parent/ Legally acceptable representative of the subject is illiterate, an impartial witness must also sign this form

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

_____ _____

Signature of Witness Date: dd/mmm/yyyy

_____

Printed name of Witness

Investigator CVs or equivalent summaries of training and experience relevant to the performance of the clinical study

Page(s) 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 III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age.

Study: 117119 (DTPA-HBV-IPV-135) Development Phase: III

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:	Dr. Nicola Klein
Affiliation /investigational centre:	Kaiser Permanente Oakland, One Kaiser Plaza, Oakland, CA, USA
Signature of Investigator:	_____
Date:	_____

For internal use only

- ----------Checksum----------!Ver.!Created On - -
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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 III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age.

Study: 117119 (DTPA-HBV-IPV-135) Development Phase: III

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:	Narcisa Elena Mesaros
Title of Sponsor Signatory:	MD, Clinical and Epidemiology R&D Project Leader, DTP, Polio and Hib containing vaccines – R&D Centre Belgium, GlaxoSmithKline Biologicals
Signature:	_____
Date:	_____

For internal use only

- ----------Checksum----------!Ver.!Created On - -
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622d4ec61abc0524d85a0f1af3968a4c1306b198 1.0 7/12/2018 1:55:22 PM - -
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4138e5e7efd1f15bf35572227c1d9fd9bd7066e8 1.0 7/12/2018 1:53:54 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

Batch (Lot) number	Treatement group
DLOCA102AY@DLOCA102AZ@	Penta
AD05VA833A@AROTVA291D@	Rotarix
DLOCA107A@	Prevnar 13
AHBVC253A@	Engerix B
DLOCA144AY@DLOCA144AZ@	Pentacel
AHIBC950C@	Hexa_1
AC14B195A@	Infanrix
AHIBC875A@DEXTA517AZ@	Hiberix
DLOCA106AY@DLOCA106AZ@	ActHIB
AC21VB448C@	Pedia
DLOCA150AY@DLOCA150AZ@	ActHIB-Epoch2
AC21B514A@AHIBC907D@	Hexa_2
DLOCA108AY@DLOCA108AZ@	Penta
AC21B510B@AHIBC954A@	Hexa_3

Randomisation list

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot A

Trt.	Bl. No	nb
PPD	1	1
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Trt.	Bl. No	nb
PPD	42	42
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Trt.	Bl. No	nb
PPD	83	83
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Trt.	Bl. No	nb
PPD	124	124
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Trt.	Bl. No	nb
PPD	165	165
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Trt.	Bl. No	nb
PPD	206	206
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Trt.	Bl. No	nb
PPD	247	247
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot A

Trt.	Bl. No	nb
PPD	1	288
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	39	326
	40	327
	41	328
PPD	1	329
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	3	331
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PPD	1	370
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PPD	1	411
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PPD	1	493
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	41	574

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot A

Trt.	Bl. No	nb
PPD	1	575
	2	576
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	4	578
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	35	609
	36	610
	37	611
	38	612
	39	613
	40	614
	41	615

Trt.	Bl. No	nb
PPD	1	616
	2	617
	3	618
	4	619
	5	620
	6	621
	7	622
	8	623
	9	624
	10	625
	11	626
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	38	653
	39	654
	40	655
	41	656

Trt.	Bl. No	nb
PPD	1	657
	2	658
	3	659
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	38	694
	39	695
	40	696
	41	697

Trt.	Bl. No	nb
PPD	1	698
	2	699
	3	700
	4	701
	5	702
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	39	736
	40	737
	41	738

Trt.	Bl. No	nb
PPD	1	739
	2	740
	3	741
	4	742
	5	743
	6	744
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	34	772
	35	773
	36	774
	37	775
	38	776
	39	777
	40	778
	41	779

Trt.	Bl. No	nb
PPD	1	780
	2	781
	3	782
	4	783
	5	784
	6	785
	7	786
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	33	812
	34	813
	35	814
	36	815
	37	816
	38	817
	39	818
	40	819
	41	820

Trt.	Bl. No	nb
PPD	1	821
	2	822
	3	823
	4	824
	5	825
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	26	846
	27	847
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	30	850
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	36	856
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot A

Trt.	Bl. No	nb
PPD		862
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Trt.	Bl. No	nb
PPD		903
		904
		905
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot C

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	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

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot C

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

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot C

Trt.	Bl. No	nb
PPD	1	575
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	41	615

Trt.	Bl. No	nb
PPD	1	616
	2	617
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Trt.	Bl. No	nb
PPD	1	657
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Trt.	Bl. No	nb
PPD	1	698
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	15	712
	16	713
	17	714
	18	715
	19	716
	20	717
	21	718
	22	719
	23	720
	24	721
	25	722
	26	723
	27	724
	28	725
	29	726
	30	727
	31	728
	32	729
	33	730
	34	731
	35	732
	36	733
	37	734
	38	735
	39	736
	40	737
	41	738

Trt.	Bl. No	nb
PPD	1	739
	2	740
	3	741
	4	742
	5	743
	6	744
	7	745
	8	746
	9	747
	10	748
	11	749
	12	750
	13	751
	14	752
	15	753
	16	754
	17	755
	18	756
	19	757
	20	758
	21	759
	22	760
	23	761
	24	762
	25	763
	26	764
	27	765
	28	766
	29	767
	30	768
	31	769
	32	770
	33	771
	34	772
	35	773
	36	774
	37	775
	38	776
	39	777
	40	778
	41	779

Trt.	Bl. No	nb
PPD	1	780
	2	781
	3	782
	4	783
	5	784
	6	785
	7	786
	8	787
	9	788
	10	789
	11	790
	12	791
	13	792
	14	793
	15	794
	16	795
	17	796
	18	797
	19	798
	20	799
	21	800
	22	801
	23	802
	24	803
	25	804
	26	805
	27	806
	28	807
	29	808
	30	809
	31	810
	32	811
	33	812
	34	813
	35	814
	36	815
	37	816
	38	817
	39	818
	40	819
	41	820

Trt.	Bl. No	nb
PPD	1	821
	2	822
	3	823
	4	824
	5	825
	6	826
	7	827
	8	828
	9	829
	10	830
	11	831
	12	832
	13	833
	14	834
	15	835
	16	836
	17	837
	18	838
	19	839
	20	840
	21	841
	22	842
	23	843
	24	844
	25	845
	26	846
	27	847
	28	848
	29	849
	30	850
	31	851
	32	852
	33	853
	34	854
	35	855
	36	856
	37	857
	38	858
	39	859
	40	860
	41	861

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot C

Trt. No	Bl. nb
PPD	862
	863
	864
	865
	866
	867
	868
	869
	870
	871
	872
	873
	874
	875
	876
	877
	878
	879
	880
	881
	882
	883
	884
	885
	886
	887
	888
	889
	890
	891
	892
	893
	894
	895
	896
	897
	898
	899
	900
	901
	902

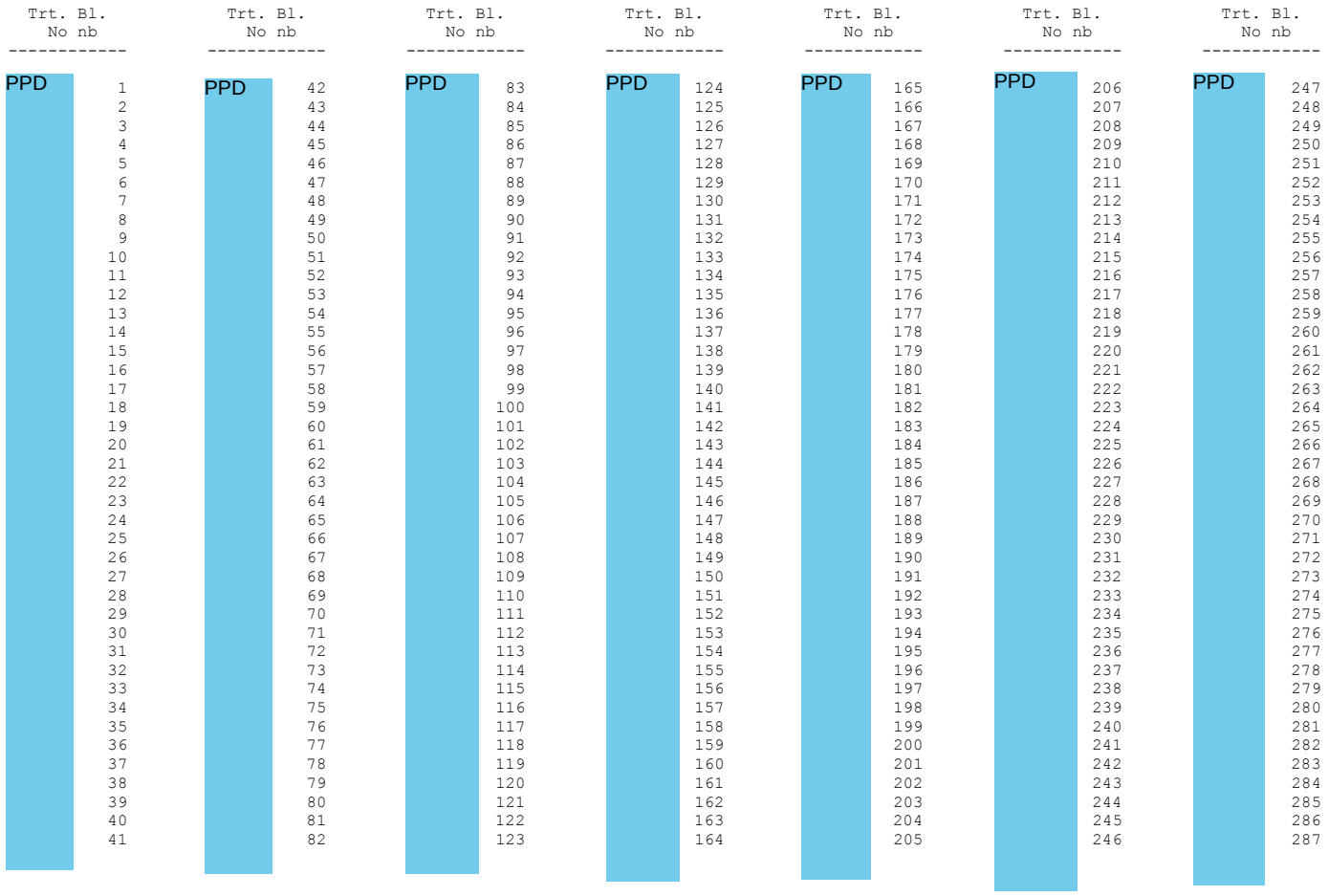
Trt. No	Bl. nb
PPD	903
	904
	905
	906

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot B



SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot B

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

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot B

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

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hexa lot B

Trt. No	Bl. nb
PPD	862
	863
	864
	865
	866
	867
	868
	869
	870
	871
	872
	873
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	875
	876
	877
	878
	879
	880
	881
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	902

Trt. No	Bl. nb
PPD	903
	904
	905
	906

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

Trt.	Bl. No	nb
PPD	1	1
PPD	1	2
PPD	2	3
PPD	2	4
PPD	3	5
PPD	3	6
PPD	4	7
PPD	4	8
PPD	5	9
PPD	5	10
PPD	6	11
PPD	6	12
PPD	7	13
PPD	7	14
PPD	8	15
PPD	8	16
PPD	9	17
PPD	9	18
PPD	10	19
PPD	10	20
PPD	11	21
PPD	11	22
PPD	12	23
PPD	12	24
PPD	13	25
PPD	13	26
PPD	14	27
PPD	14	28

Trt.	Bl. No	nb
PPD	14	29
PPD	15	30
PPD	15	31
PPD	15	32
PPD	16	33
PPD	16	34
PPD	16	35
PPD	17	36
PPD	17	37
PPD	18	38
PPD	18	39
PPD	18	40
PPD	19	41
PPD	19	42
PPD	20	43
PPD	20	44
PPD	21	45
PPD	21	46
PPD	21	47
PPD	22	48
PPD	22	49
PPD	22	50
PPD	23	51
PPD	23	52
PPD	24	53
PPD	24	54
PPD	25	55
PPD	25	56

Trt.	Bl. No	nb
PPD	28	57
PPD	28	58
PPD	29	59
PPD	29	60
PPD	30	61
PPD	30	62
PPD	31	63
PPD	31	64
PPD	31	65
PPD	32	66
PPD	32	67
PPD	32	68
PPD	33	69
PPD	33	70
PPD	33	71
PPD	34	72
PPD	34	73
PPD	34	74
PPD	35	75
PPD	35	76
PPD	36	77
PPD	36	78
PPD	36	79
PPD	37	80
PPD	37	81
PPD	37	82
PPD	38	83
PPD	38	84
PPD	38	85
PPD	39	86
PPD	39	87
PPD	39	88
PPD	40	89
PPD	40	90
PPD	41	91
PPD	41	92
PPD	41	93

Trt.	Bl. No	nb
PPD	42	94
PPD	42	95
PPD	42	96
PPD	43	97
PPD	43	98
PPD	43	99
PPD	44	100
PPD	44	101
PPD	44	102
PPD	45	103
PPD	45	104
PPD	45	105
PPD	46	106
PPD	46	107
PPD	46	108
PPD	47	109
PPD	47	110
PPD	47	111
PPD	48	112
PPD	48	113
PPD	48	114
PPD	49	115
PPD	49	116
PPD	49	117
PPD	50	118
PPD	50	119
PPD	50	120
PPD	51	121
PPD	51	122
PPD	51	123
PPD	52	124
PPD	52	125
PPD	52	126
PPD	53	127
PPD	53	128
PPD	53	129
PPD	54	130
PPD	54	131
PPD	54	132
PPD	55	133
PPD	55	134
PPD	55	135

Trt.	Bl. No	nb
PPD	55	136
PPD	56	137
PPD	56	138
PPD	56	139
PPD	56	140
PPD	57	141
PPD	57	142
PPD	57	143
PPD	58	144
PPD	58	145
PPD	58	146
PPD	59	147
PPD	59	148
PPD	59	149
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PPD	60	151
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PPD	65	165
PPD	65	166
PPD	65	167
PPD	66	168
PPD	66	169
PPD	66	170
PPD	67	171
PPD	67	172
PPD	67	173
PPD	68	174
PPD	68	175
PPD	68	176
PPD	69	177
PPD	69	178
PPD	69	179

Trt.	Bl. No	nb
PPD	69	180
PPD	70	181
PPD	70	182
PPD	70	183
PPD	71	184
PPD	71	185
PPD	71	186
PPD	72	187
PPD	72	188
PPD	72	189
PPD	73	190
PPD	73	191
PPD	73	192
PPD	74	193
PPD	74	194
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PPD	77	203
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PPD	78	205
PPD	78	206
PPD	78	207
PPD	79	208
PPD	79	209
PPD	79	210
PPD	80	211
PPD	80	212
PPD	80	213
PPD	81	214
PPD	81	215
PPD	81	216
PPD	82	217
PPD	82	218
PPD	82	219

Trt.	Bl. No	nb
PPD	83	220
PPD	83	221
PPD	83	222
PPD	84	223
PPD	84	224
PPD	84	225
PPD	85	226
PPD	85	227
PPD	85	228
PPD	86	229
PPD	86	230
PPD	86	231
PPD	87	232
PPD	87	233
PPD	87	234
PPD	88	235
PPD	88	236
PPD	88	237
PPD	89	238
PPD	89	239
PPD	89	240
PPD	90	241
PPD	90	242
PPD	90	243
PPD	91	244
PPD	91	245
PPD	91	246
PPD	92	247
PPD	92	248
PPD	92	249
PPD	93	250
PPD	93	251
PPD	93	252
PPD	94	253
PPD	94	254
PPD	94	255
PPD	95	256
PPD	95	257
PPD	95	258
PPD	96	259
PPD	96	260
PPD	96	261

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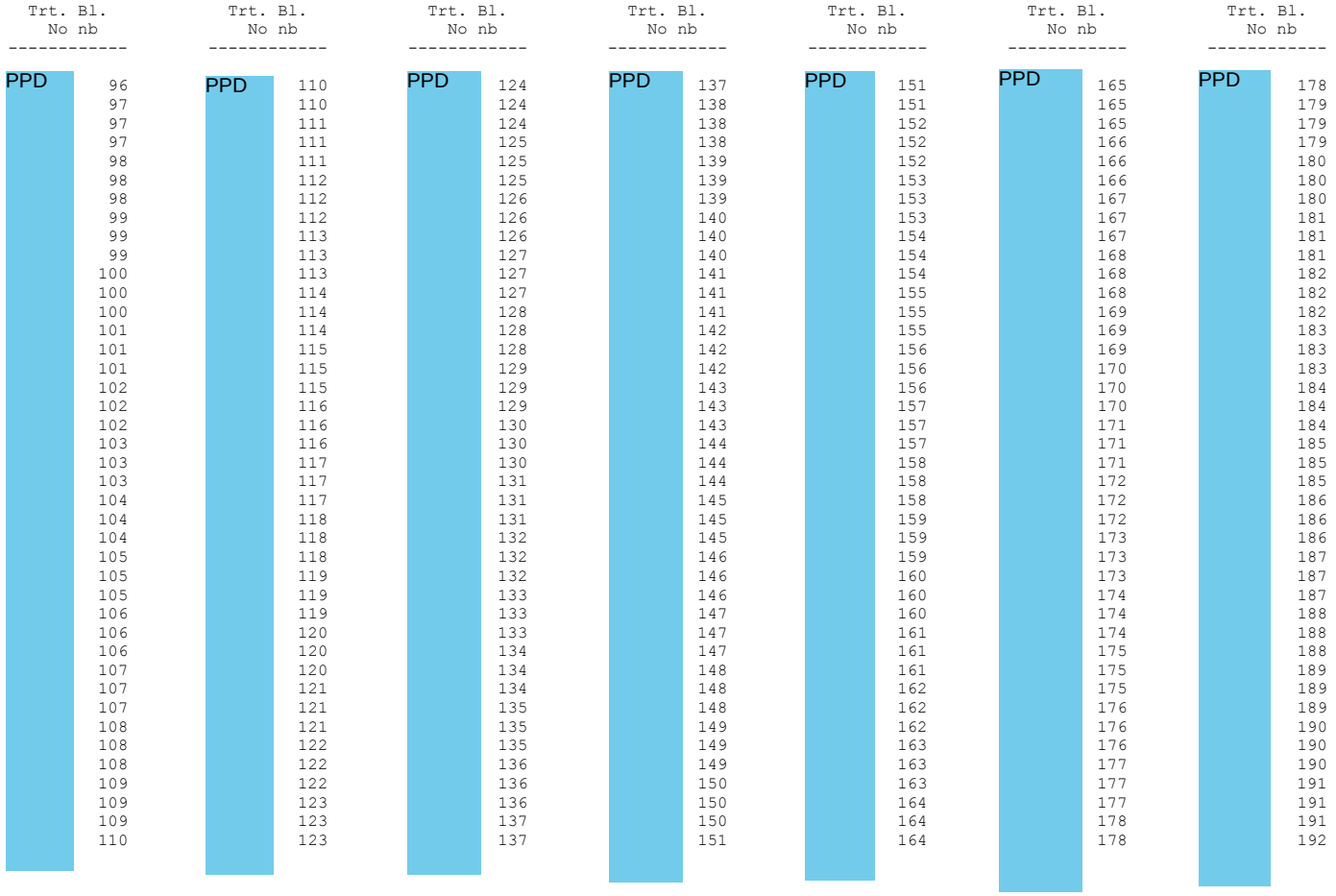
Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

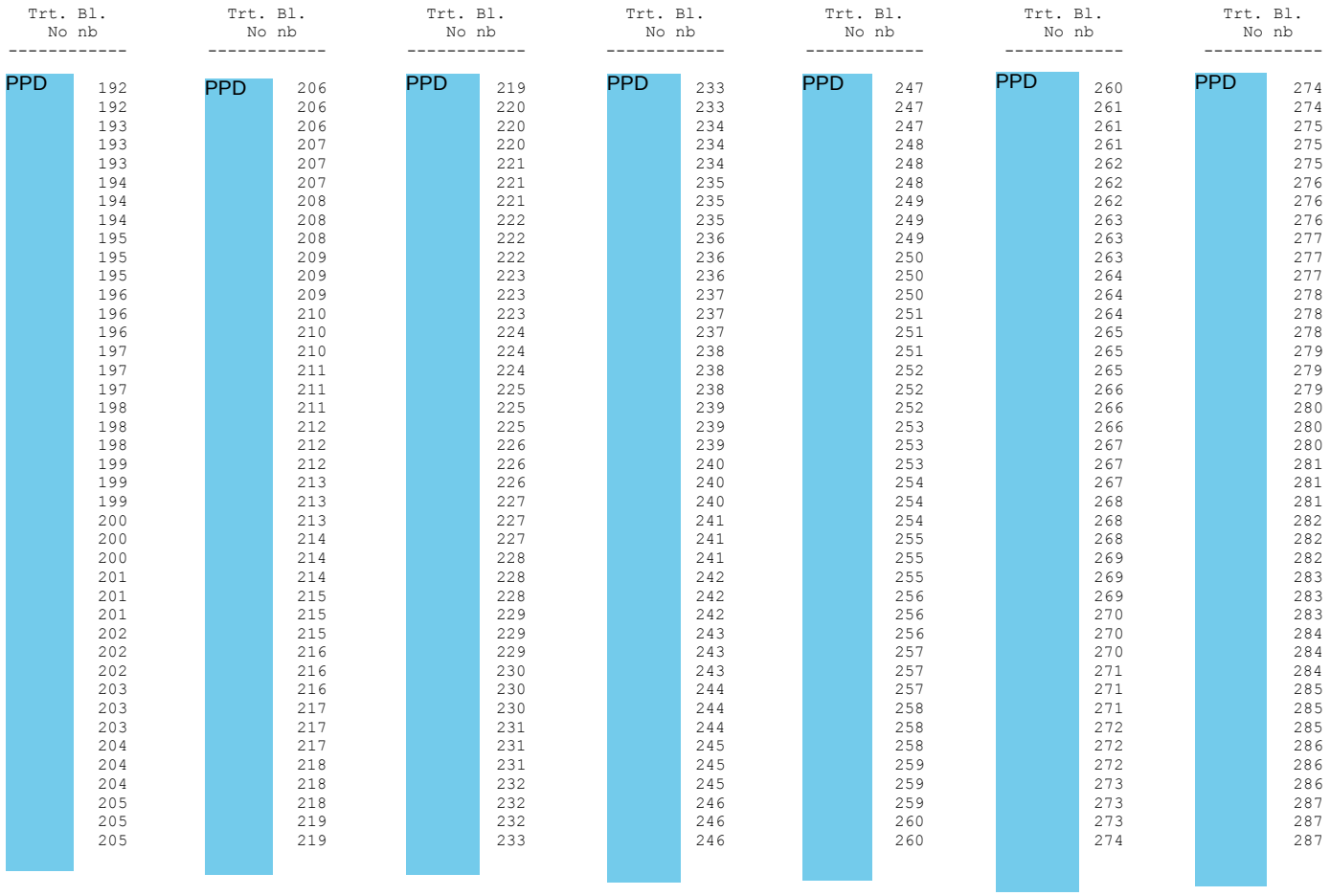


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

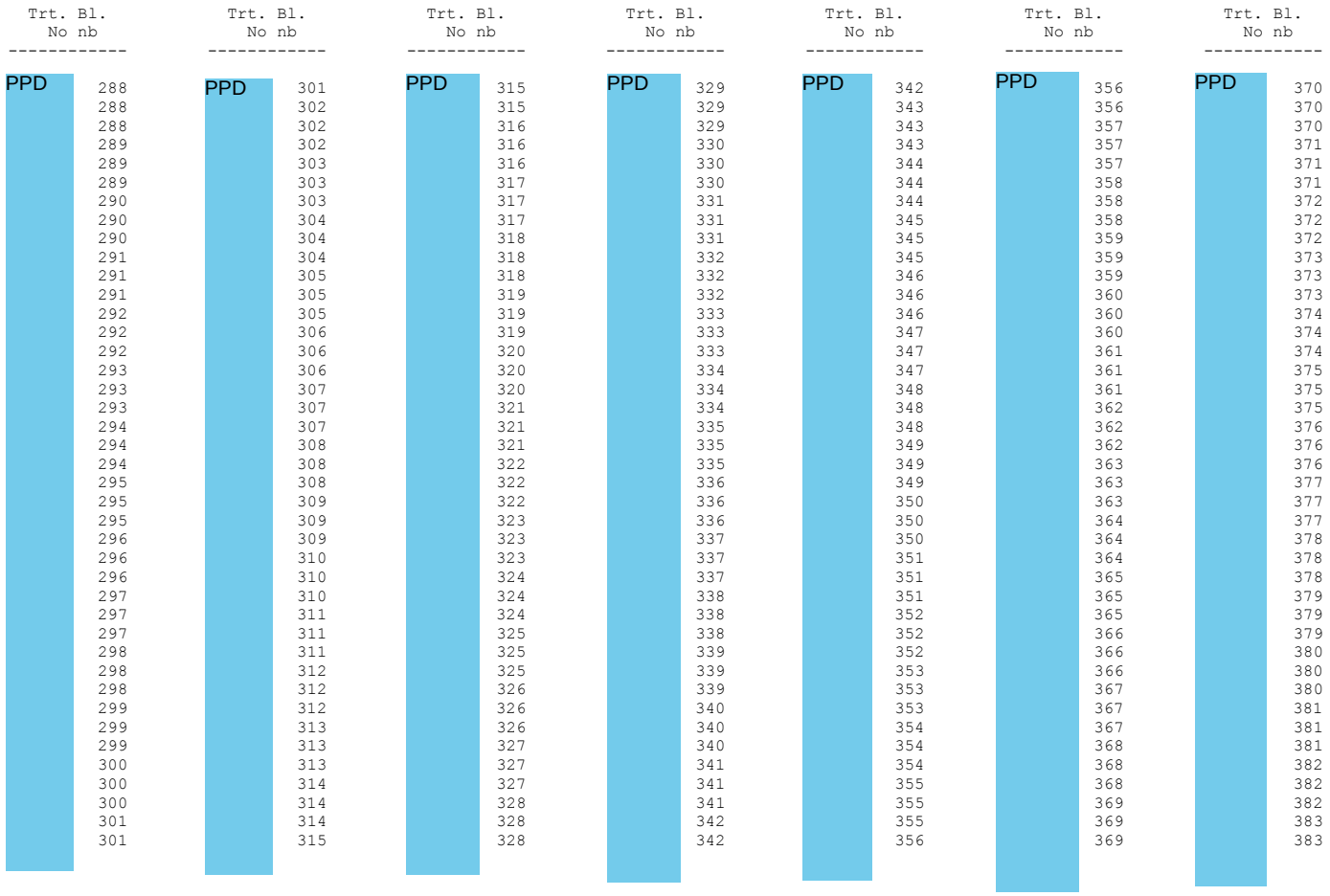


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix



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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

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	383	PPD	397	PPD	411	PPD	424	PPD	438	PPD	452	PPD	465
	384		397		411		425		438		452		466
	384		398		411		425		439		452		466
	384		398		412		425		439		453		466
	385		398		412		426		439		453		467
	385		399		412		426		440		453		467
	385		399		413		426		440		454		467
	386		399		413		427		440		454		468
	386		400		413		427		441		454		468
	386		400		414		427		441		455		468
	387		400		414		428		441		455		469
	387		401		414		428		442		455		469
	387		401		415		428		442		456		469
	388		401		415		429		442		456		470
	388		402		415		429		443		456		470
	388		402		416		429		443		457		470
	389		402		416		430		443		457		471
	389		403		416		430		444		457		471
	389		403		417		430		444		458		471
	390		403		417		431		444		458		472
	390		404		417		431		445		458		472
	390		404		418		431		445		459		472
	391		404		418		432		445		459		473
	391		405		418		432		446		459		473
	391		405		419		432		446		460		473
	392		405		419		433		446		460		474
	392		406		419		433		447		460		474
	392		406		420		433		447		461		474
	393		406		420		434		447		461		475
	393		407		420		434		448		461		475
	393		407		421		434		448		462		475
	394		407		421		435		448		462		476
	394		408		421		435		449		462		476
	394		408		422		435		449		463		476
	395		408		422		436		449		463		477
	395		409		422		436		450		463		477
	395		409		423		436		450		464		477
	396		409		423		437		450		464		478
	396		410		423		437		451		464		478
	396		410		424		437		451		465		478
	397		410		424		438		451		465		479

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

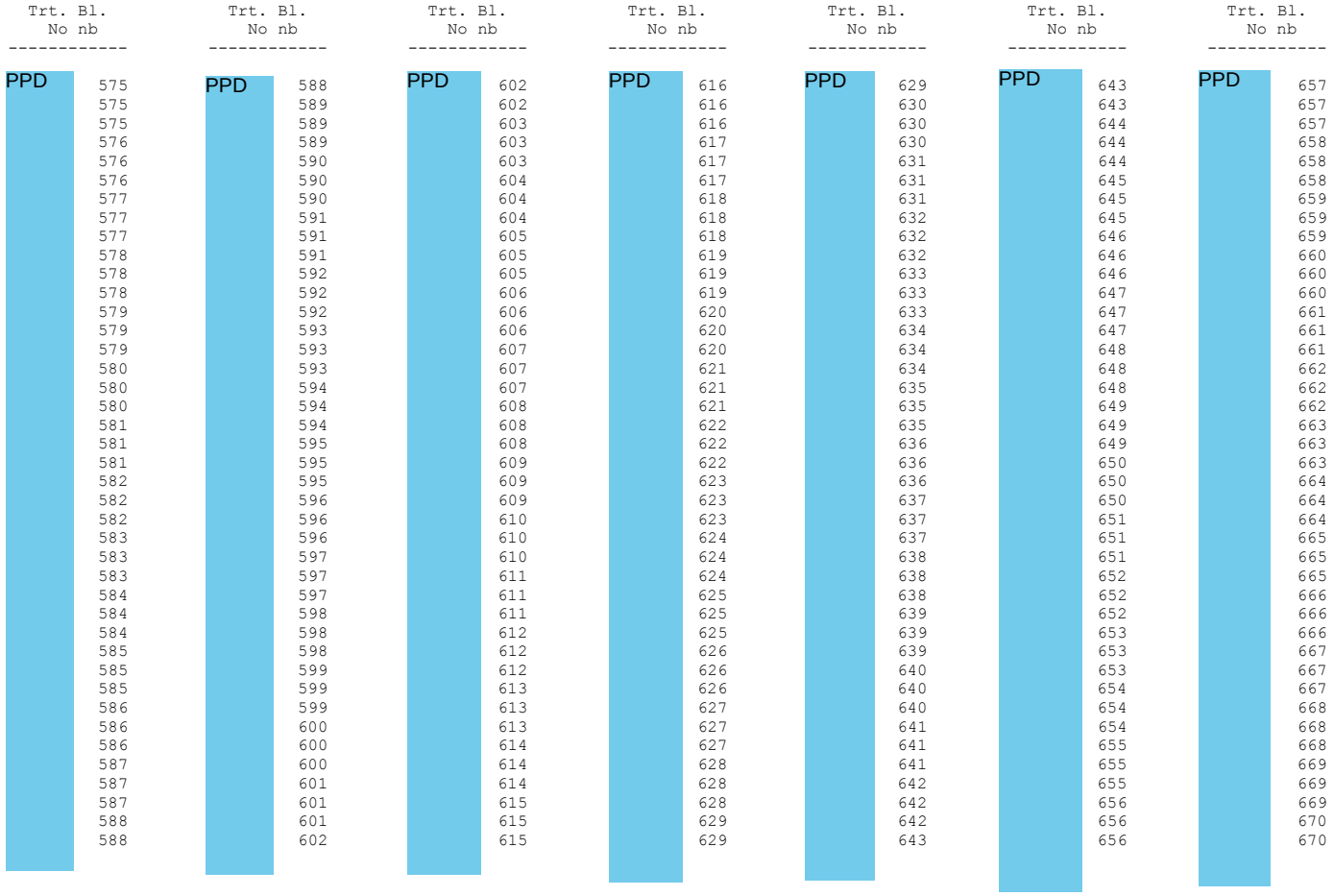
Trt. Bl. No nb		Trt. Bl. No nb		Trt. Bl. No nb		Trt. Bl. No nb		Trt. Bl. No nb		Trt. Bl. No nb		Trt. Bl. No nb	
PPD	479	PPD	493	PPD	506	PPD	520	PPD	534	PPD	547	PPD	561
	479		493		507		520		534		548		561
	480		493		507		521		534		548		562
	480		494		507		521		535		548		562
	480		494		508		521		535		549		562
	481		494		508		522		535		549		563
	481		495		508		522		536		549		563
	481		495		509		522		536		550		563
	482		495		509		523		536		550		564
	482		496		509		523		537		550		564
	482		496		510		523		537		551		564
	483		496		510		524		537		551		565
	483		497		510		524		538		551		565
	483		497		511		524		538		552		565
	484		497		511		525		538		552		566
	484		498		511		525		539		552		566
	484		498		512		525		539		553		566
	485		498		512		526		539		553		567
	485		499		512		526		540		553		567
	485		499		513		526		540		554		567
	486		499		513		527		540		554		568
	486		500		513		527		541		554		568
	486		500		514		527		541		555		568
	487		500		514		528		541		555		569
	487		501		514		528		542		555		569
	487		501		515		528		542		556		569
	488		501		515		529		542		556		570
	488		502		515		529		543		556		570
	488		502		516		529		543		557		570
	489		502		516		530		543		557		571
	489		503		516		530		544		557		571
	489		503		517		530		544		558		571
	490		503		517		531		544		558		572
	490		504		517		531		545		558		572
	490		504		518		531		545		559		572
	491		504		518		532		545		559		573
	491		505		518		532		546		559		573
	491		505		519		532		546		560		573
	492		505		519		533		546		560		574
	492		506		519		533		547		560		574
	492		506		520		533		547		561		574

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

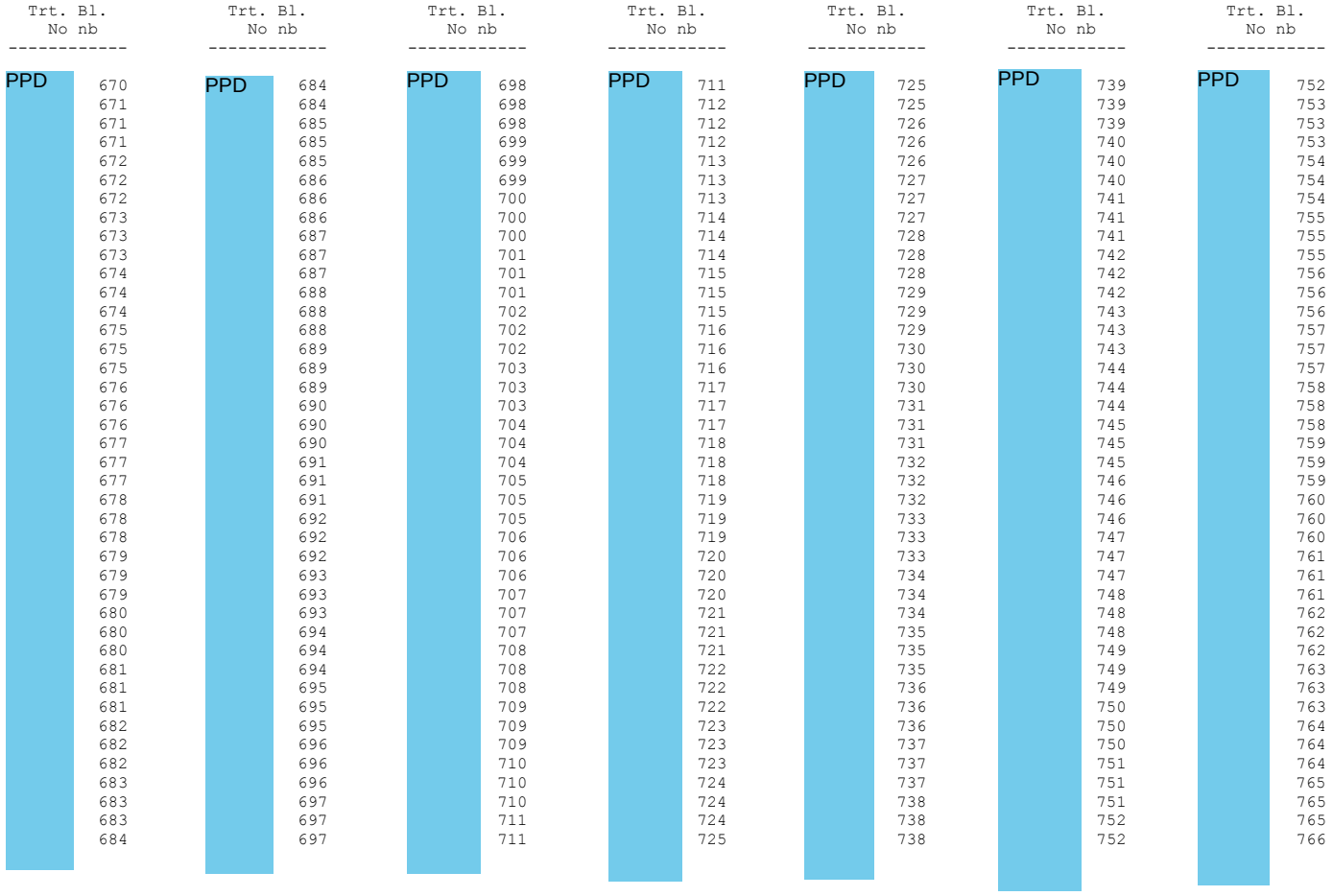


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix



SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

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	766	PPD	780	PPD	793	PPD	807	PPD	821	PPD	834	PPD	848
	766		780		794		807		821		835		848
	767		780		794		808		821		835		849
	767		781		794		808		822		835		849
	767		781		795		808		822		836		849
	768		781		795		809		822		836		850
	768		782		795		809		823		836		850
	768		782		796		809		823		837		850
	769		782		796		810		823		837		851
	769		783		796		810		824		837		851
	769		783		797		810		824		838		851
	770		783		797		811		824		838		852
	770		784		797		811		825		838		852
	770		784		798		811		825		839		852
	771		784		798		812		825		839		853
	771		785		798		812		826		839		853
	771		785		799		812		826		840		853
	772		785		799		813		826		840		854
	772		786		799		813		827		840		854
	772		786		800		813		827		841		854
	773		786		800		814		827		841		855
	773		787		800		814		828		841		855
	773		787		801		814		828		842		855
	774		787		801		815		828		842		856
	774		788		801		815		829		842		856
	774		788		802		815		829		843		856
	775		788		802		816		829		843		857
	775		789		802		816		830		843		857
	775		789		803		816		830		844		857
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	776		790		804		817		831		845		858
	777		790		804		818		831		845		859
	777		791		804		818		832		845		859
	777		791		805		818		832		846		859
	778		791		805		819		832		846		860
	778		792		805		819		833		846		860
	778		792		806		819		833		847		860
	779		792		806		820		833		847		861
	779		793		806		820		834		847		861
	779		793		807		820		834		848		861

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pediarix

Trt.	Bl. No	nb
PPD	862	862
	862	863
	862	863
	863	863
	863	864
	864	864
	864	865
	865	865
	865	866
	866	866
	866	867
	867	867
	867	868
	868	868
	868	869
	869	869
	869	870
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	870	871
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	871	872
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	872	873
	873	873
	873	874
	874	874
	874	875
	875	875

Trt.	Bl. No	nb
PPD	875	876
	876	876
	876	876
	876	877
	877	877
	877	878
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	885	886
	886	886
	886	887
	887	887
	887	888
	888	888
	888	889
	889	889

Trt.	Bl. No	nb
PPD	889	890
	890	890
	890	890
	891	891
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	891	892
	892	892
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	898	899
	899	899
	899	900
	900	900
	900	901
	901	901
	901	902
	902	902
	902	903

Trt.	Bl. No	nb
PPD	903	903
	903	904
	904	904
	904	905
	905	905
	905	906
	906	906
	906	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	1
	1	2
	1	3
	2	4
	2	4
	2	5
	3	5
	3	6
	3	6
	4	7
	4	7
	4	8
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	11	17
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	11	18
	12	19
	12	19
	12	20
	13	20
	13	21
	13	21
	14	22
	14	22

Trt.	Bl. No	nb
PPD	14	23
	15	23
	15	24
	15	24
	16	25
	16	25
	16	26
	17	26
	17	27
	18	27
	18	28
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	25	37
	25	37
	26	38
	26	38
	26	39
	27	39
	27	40
	27	40
	28	41
	28	41

Trt.	Bl. No	nb
PPD	28	42
	28	42
	29	42
	29	43
	29	43
	30	43
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	30	44
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	41	54
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	41	55

Trt.	Bl. No	nb
PPD	42	55
	42	56
	42	56
	43	56
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	54	68
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	55	69

Trt.	Bl. No	nb
PPD	55	69
	56	69
	56	70
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	69	82

Trt.	Bl. No	nb
PPD	69	83
	69	83
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	81	95
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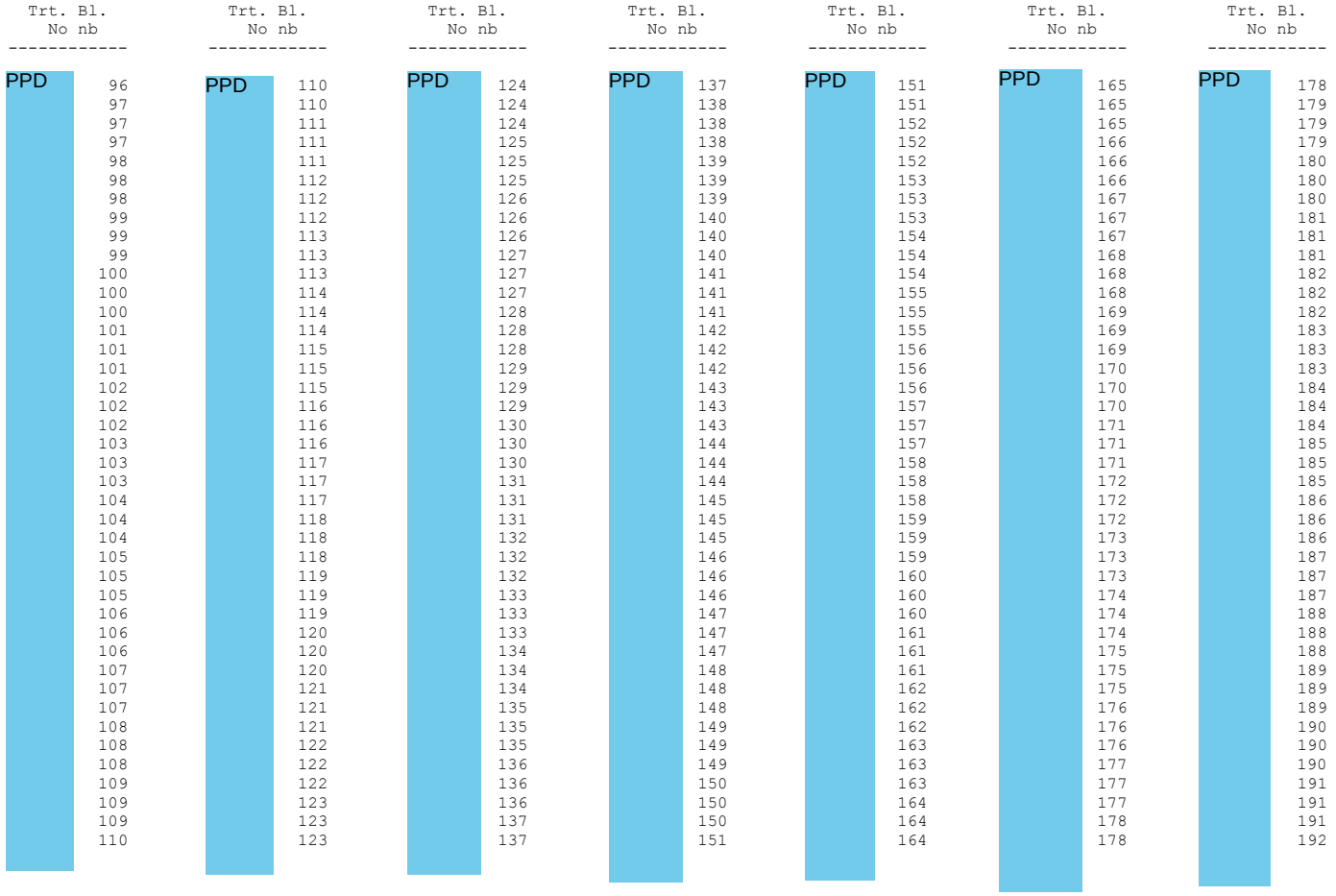
SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

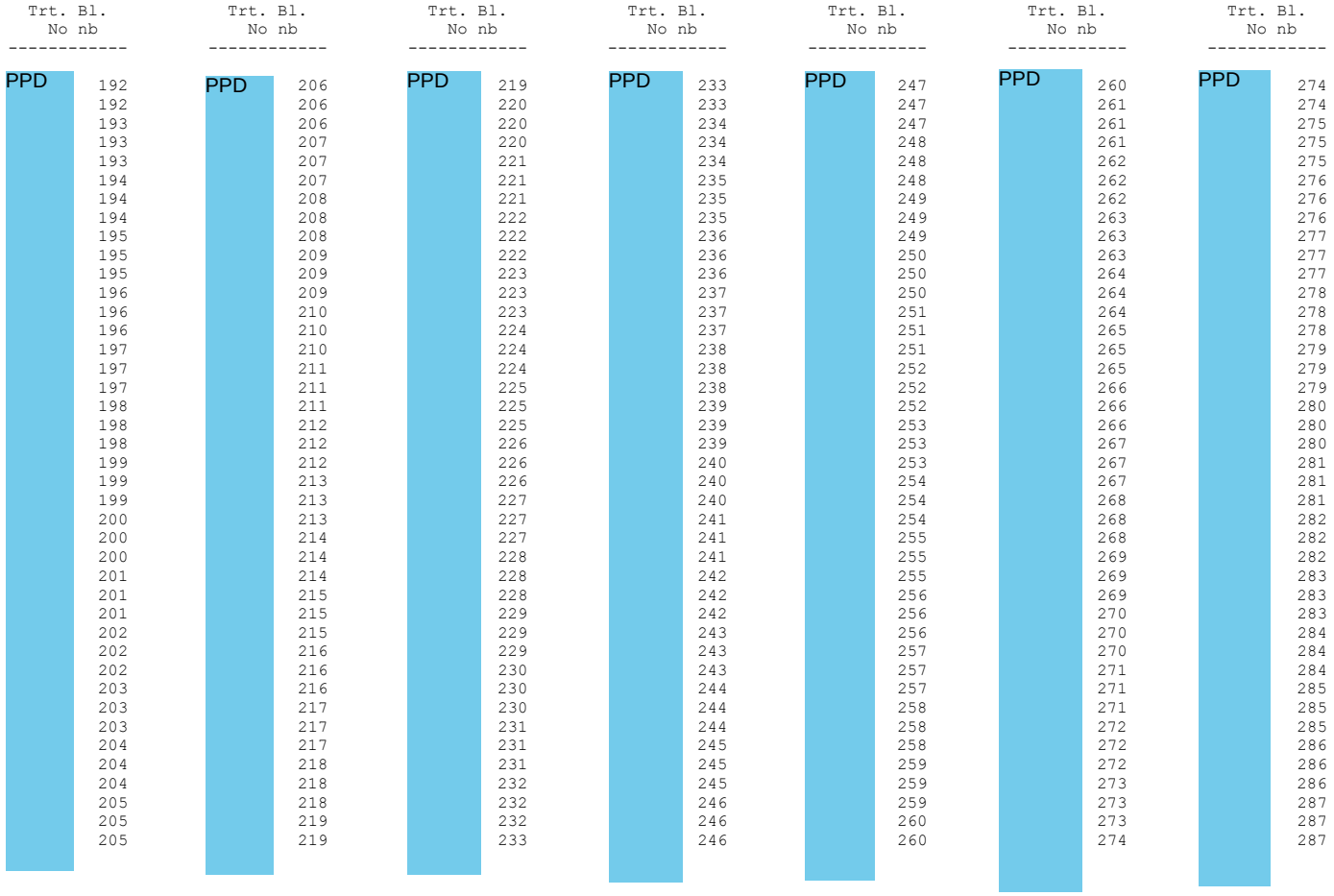


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

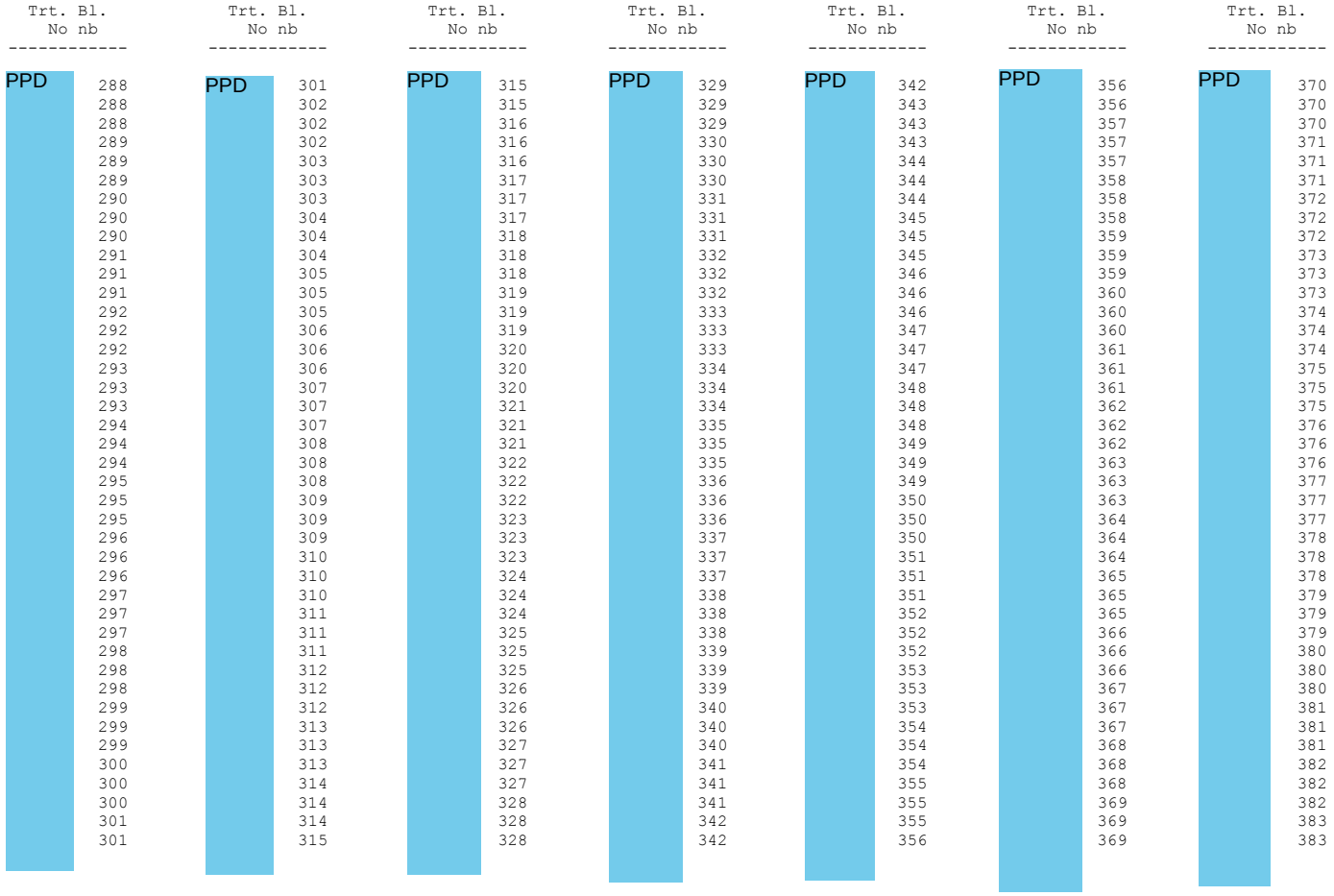


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel



SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	588	PPD	602	PPD	616	PPD	629	PPD	643	PPD	657
	575		589		602		616		630		643		657
	575		589		603		616		630		644		657
	576		589		603		617		630		644		658
	576		590		603		617		631		644		658
	576		590		604		617		631		645		658
	577		590		604		618		631		645		659
	577		591		604		618		632		645		659
	577		591		605		618		632		646		659
	578		591		605		619		632		646		660
	578		592		605		619		633		646		660
	578		592		606		619		633		647		660
	579		592		606		620		633		647		661
	579		593		606		620		634		647		661
	579		593		607		620		634		648		661
	580		593		607		621		634		648		662
	580		594		607		621		635		648		662
	580		594		608		621		635		649		662
	581		594		608		622		635		649		663
	581		595		608		622		636		649		663
	581		595		609		622		636		650		663
	582		595		609		623		636		650		664
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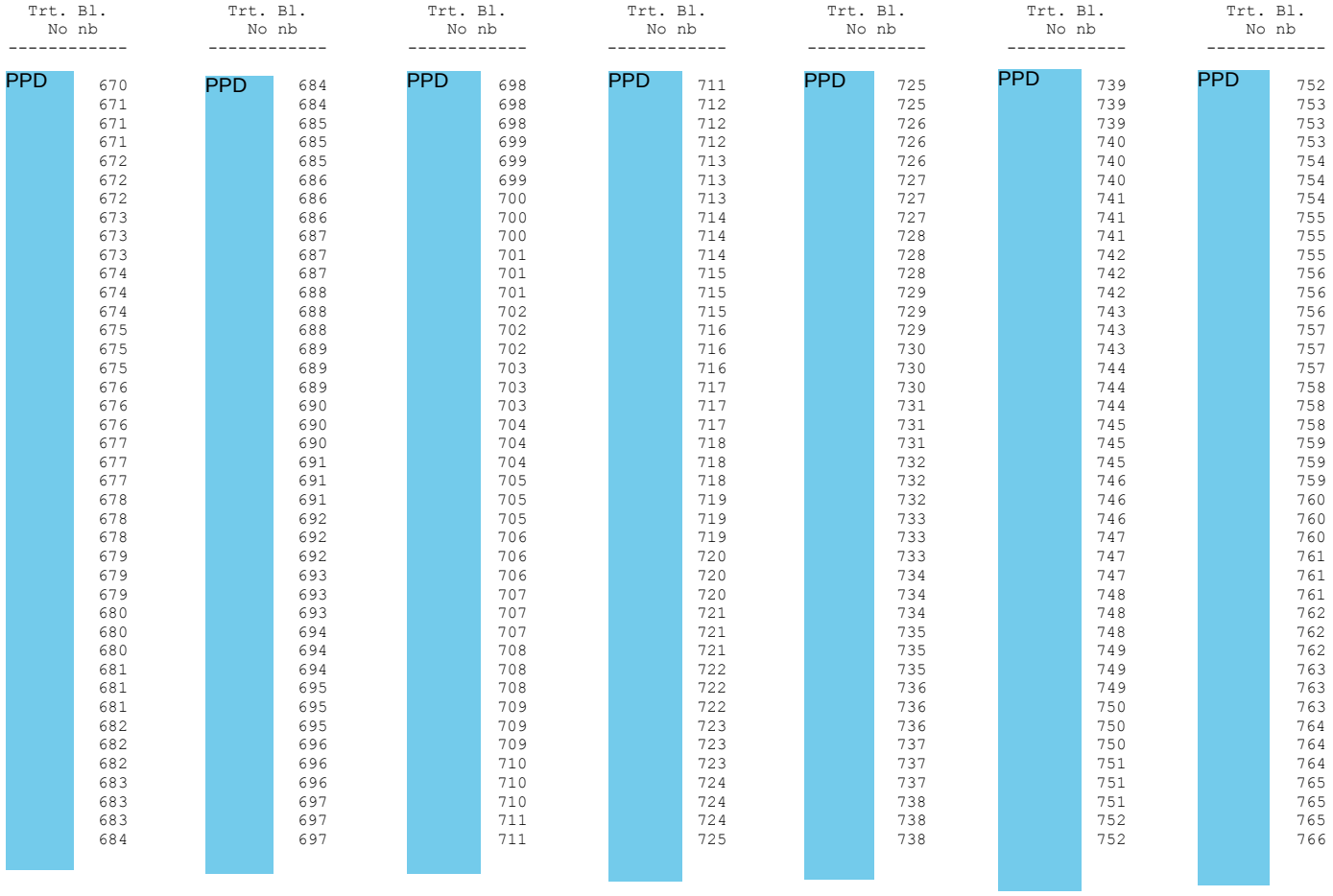
	586		600		614		627		641		655		668
	587		600		614		628		641		655		669
	587		601		614		628		642		655		669
	587		601		615		628		642		656		669
	588		601		615		629		642		656		670
	588		602		615		629		643		656		670

SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

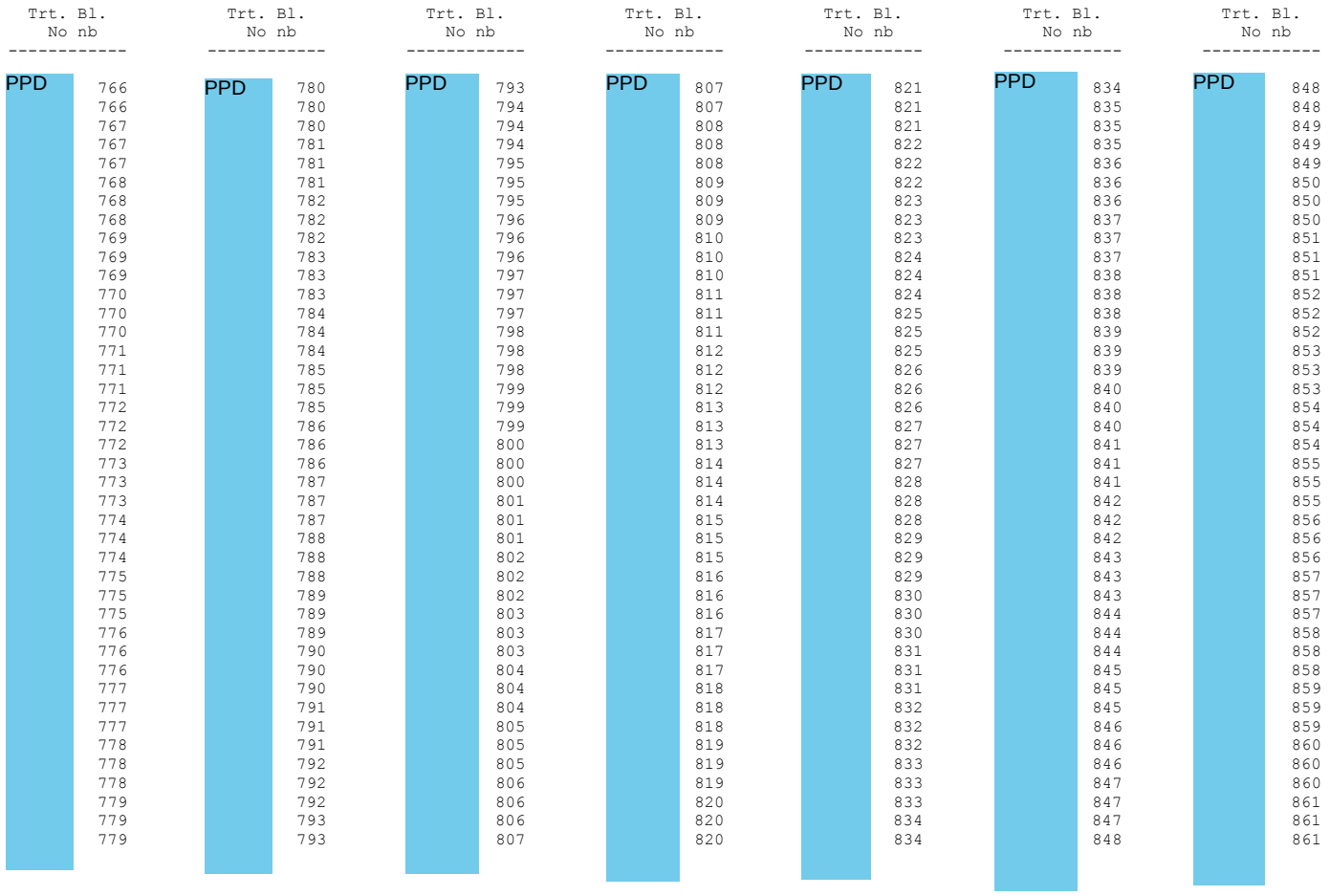


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

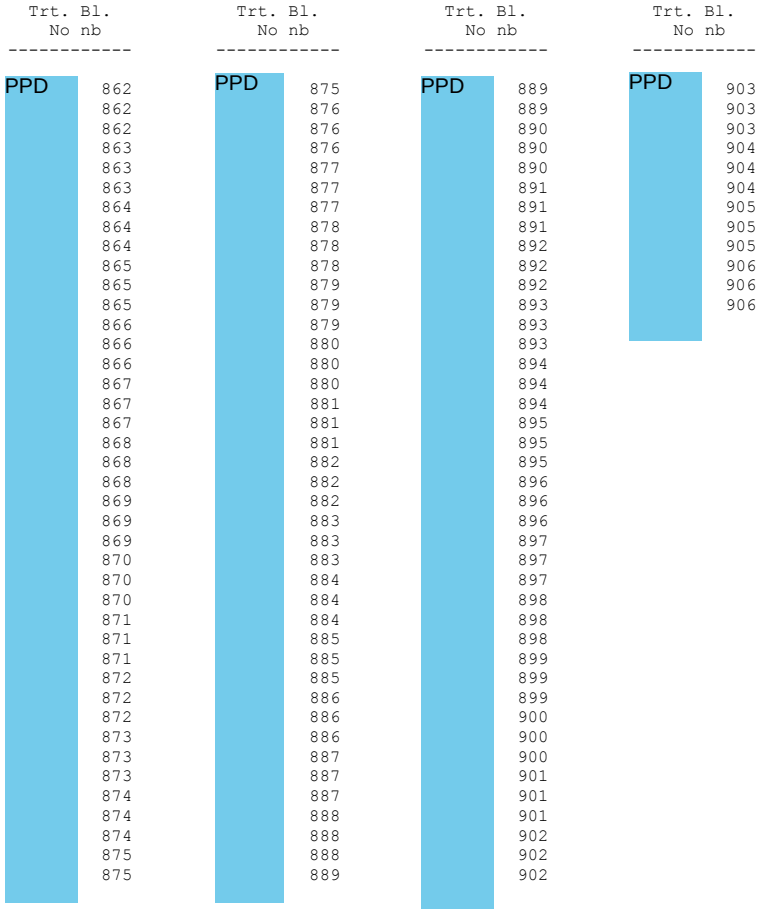


SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel



SD4\0\INFORM

Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	70907	PPD	70948	PPD	70989	PPD	71030	PPD	71071	PPD	71112	PPD	71153
	70908		70949		70990		71031		71072		71113		71154
	70909		70950		70991		71032		71073		71114		71155
	70910		70951		70992		71033		71074		71115		71156
	70911		70952		70993		71034		71075		71116		71157
	70912		70953		70994		71035		71076		71117		71158
	70913		70954		70995		71036		71077		71118		71159
	70914		70955		70996		71037		71078		71119		71160
	70915		70956		70997		71038		71079		71120		71161
	70916		70957		70998		71039		71080		71121		71162
	70917		70958		70999		71040		71081		71122		71163
	70918		70959		71000		71041		71082		71123		71164
	70919		70960		71001		71042		71083		71124		71165
	70920		70961		71002		71043		71084		71125		71166
	70921		70962		71003		71044		71085		71126		71167
	70922		70963		71004		71045		71086		71127		71168
	70923		70964		71005		71046		71087		71128		71169
	70924		70965		71006		71047		71088		71129		71170
	70925		70966		71007		71048		71089		71130		71171
	70926		70967		71008		71049		71090		71131		71172
	70927		70968		71009		71050		71091		71132		71173
	70928		70969		71010		71051		71092		71133		71174
	70929		70970		71011		71052		71093		71134		71175
	70930		70971		71012		71053		71094		71135		71176
	70931		70972		71013		71054		71095		71136		71177
	70932		70973		71014		71055		71096		71137		71178
	70933		70974		71015		71056		71097		71138		71179
	70934		70975		71016		71057		71098		71139		71180
	70935		70976		71017		71058		71099		71140		71181
	70936		70977		71018		71059		71100		71141		71182
	70937		70978		71019		71060		71101		71142		71183
	70938		70979		71020		71061		71102		71143		71184
	70939		70980		71021		71062		71103		71144		71185
	70940		70981		71022		71063		71104		71145		71186
	70941		70982		71023		71064		71105		71146		71187
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	70946		70987		71028		71069		71110		71151		71192
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	71194
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	3	71196
	4	71197
	5	71198
	6	71199
	7	71200
	8	71201
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	10	71203
	11	71204
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	287	71480

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
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	41	71521
PPD	1	71522
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PPD	1	71563
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PPD	1	71645
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PPD	1	71686
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Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	71768	71808
PPD	71809	71849
PPD	71850	71890
PPD	71891	71931
PPD	71932	71972
PPD	71973	72013
PPD	72014	72054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
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	39	72093
	40	72094
	41	72095

Trt.	Bl. No	nb
PPD	1	72096
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	5	72100
	6	72101
	7	72102
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	40	72135
	41	72136

Trt.	Bl. No	nb
PPD	1	72137
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	39	72175
	40	72176
	41	72177

Trt.	Bl. No	nb
PPD	1	72178
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	3	72180
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Trt.	Bl. No	nb
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	36	72254
	37	72255
	38	72256
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	41	72259

Trt.	Bl. No	nb
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	3	72262
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	39	72298
	40	72299
	41	72300

Trt.	Bl. No	nb
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Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
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	37	72378
	38	72379
	39	72380
	40	72381
	41	72382

Trt.	Bl. No	nb
PPD	1	72383
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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	1	72588
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	72629	72669
PPD	72670	72710
PPD	72711	72751
PPD	72752	72792
PPD	72793	72833
PPD	72834	72874
PPD	72875	72915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	72916	PPD	72957	PPD	72998	PPD	73039	PPD	73080	PPD	73121	PPD	73162
	72917		72958		72999		73040		73081		73122		73163
	72918		72959		73000		73041		73082		73123		73164
	72919		72960		73001		73042		73083		73124		73165
	72920		72961		73002		73043		73084		73125		73166
	72921		72962		73003		73044		73085		73126		73167
	72922		72963		73004		73045		73086		73127		73168
	72923		72964		73005		73046		73087		73128		73169
	72924		72965		73006		73047		73088		73129		73170
	72925		72966		73007		73048		73089		73130		73171
	72926		72967		73008		73049		73090		73131		73172
	72927		72968		73009		73050		73091		73132		73173
	72928		72969		73010		73051		73092		73133		73174
	72929		72970		73011		73052		73093		73134		73175
	72930		72971		73012		73053		73094		73135		73176
	72931		72972		73013		73054		73095		73136		73177
	72932		72973		73014		73055		73096		73137		73178
	72933		72974		73015		73056		73097		73138		73179
	72934		72975		73016		73057		73098		73139		73180
	72935		72976		73017		73058		73099		73140		73181
	72936		72977		73018		73059		73100		73141		73182
	72937		72978		73019		73060		73101		73142		73183
	72938		72979		73020		73061		73102		73143		73184
	72939		72980		73021		73062		73103		73144		73185
	72940		72981		73022		73063		73104		73145		73186
	72941		72982		73023		73064		73105		73146		73187
	72942		72983		73024		73065		73106		73147		73188
	72943		72984		73025		73066		73107		73148		73189
	72944		72985		73026		73067		73108		73149		73190
	72945		72986		73027		73068		73109		73150		73191
	72946		72987		73028		73069		73110		73151		73192
	72947		72988		73029		73070		73111		73152		73193
	72948		72989		73030		73071		73112		73153		73194
	72949		72990		73031		73072		73113		73154		73195
	72950		72991		73032		73073		73114		73155		73196
	72951		72992		73033		73074		73115		73156		73197
	72952		72993		73034		73075		73116		73157		73198
	72953		72994		73035		73076		73117		73158		73199
	72954		72995		73036		73077		73118		73159		73200
	72955		72996		73037		73078		73119		73160		73201
	72956		72997		73038		73079		73120		73161		73202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt. Bl.	No nb
PPD	73203
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Trt. Bl.	No nb
PPD	73244
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Trt. Bl.	No nb
PPD	73285
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Trt. Bl.	No nb
PPD	73326
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Trt. Bl.	No nb
PPD	73367
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Trt. Bl.	No nb
PPD	73408
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Trt. Bl.	No nb
PPD	73449
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	73490	PPD	73531	PPD	73572	PPD	73613	PPD	73654	PPD	73695	PPD	73736
	73491		73532		73573		73614		73655		73696		73737
	73492		73533		73574		73615		73656		73697		73738
	73493		73534		73575		73616		73657		73698		73739
	73494		73535		73576		73617		73658		73699		73740
	73495		73536		73577		73618		73659		73700		73741
	73496		73537		73578		73619		73660		73701		73742
	73497		73538		73579		73620		73661		73702		73743
	73498		73539		73580		73621		73662		73703		73744
	73499		73540		73581		73622		73663		73704		73745
	73500		73541		73582		73623		73664		73705		73746
	73501		73542		73583		73624		73665		73706		73747
	73502		73543		73584		73625		73666		73707		73748
	73503		73544		73585		73626		73667		73708		73749
	73504		73545		73586		73627		73668		73709		73750
	73505		73546		73587		73628		73669		73710		73751
	73506		73547		73588		73629		73670		73711		73752
	73507		73548		73589		73630		73671		73712		73753
	73508		73549		73590		73631		73672		73713		73754
	73509		73550		73591		73632		73673		73714		73755
	73510		73551		73592		73633		73674		73715		73756
	73511		73552		73593		73634		73675		73716		73757
	73512		73553		73594		73635		73676		73717		73758
	73513		73554		73595		73636		73677		73718		73759
	73514		73555		73596		73637		73678		73719		73760
	73515		73556		73597		73638		73679		73720		73761
	73516		73557		73598		73639		73680		73721		73762
	73517		73558		73599		73640		73681		73722		73763
	73518		73559		73600		73641		73682		73723		73764
	73519		73560		73601		73642		73683		73724		73765
	73520		73561		73602		73643		73684		73725		73766
	73521		73562		73603		73644		73685		73726		73767
	73522		73563		73604		73645		73686		73727		73768
	73523		73564		73605		73646		73687		73728		73769
	73524		73565		73606		73647		73688		73729		73770
	73525		73566		73607		73648		73689		73730		73771
	73526		73567		73608		73649		73690		73731		73772
	73527		73568		73609		73650		73691		73732		73773
	73528		73569		73610		73651		73692		73733		73774
	73529		73570		73611		73652		73693		73734		73775
	73530		73571		73612		73653		73694		73735		73776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	73777	
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Trt.	Bl. No	nb
PPD	73818	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	73900	
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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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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	74064	
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Trt.	Bl. No	nb
PPD	74105	
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Trt.	Bl. No	nb
PPD	74146	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	74228	
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Trt.	Bl. No	nb
PPD	74269	
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Trt.	Bl. No	nb
PPD	74310	
	74311	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
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	39	74389
	40	74390
	41	74391
PPD	1	74392
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	7	74398
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PPD	1	74433
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PPD	1	74515
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PPD	1	74556
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PPD	1	74597
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	41	74637

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	74638	PPD	74679	PPD	74720	PPD	74761	PPD	74802	PPD	74843	PPD	74884
	74639		74680		74721		74762		74803		74844		74885
	74640		74681		74722		74763		74804		74845		74886
	74641		74682		74723		74764		74805		74846		74887
	74642		74683		74724		74765		74806		74847		74888
	74643		74684		74725		74766		74807		74848		74889
	74644		74685		74726		74767		74808		74849		74890
	74645		74686		74727		74768		74809		74850		74891
	74646		74687		74728		74769		74810		74851		74892
	74647		74688		74729		74770		74811		74852		74893
	74648		74689		74730		74771		74812		74853		74894
	74649		74690		74731		74772		74813		74854		74895
	74650		74691		74732		74773		74814		74855		74896
	74651		74692		74733		74774		74815		74856		74897
	74652		74693		74734		74775		74816		74857		74898
	74653		74694		74735		74776		74817		74858		74899
	74654		74695		74736		74777		74818		74859		74900
	74655		74696		74737		74778		74819		74860		74901
	74656		74697		74738		74779		74820		74861		74902
	74657		74698		74739		74780		74821		74862		74903
	74658		74699		74740		74781		74822		74863		74904
	74659		74700		74741		74782		74823		74864		74905
	74660		74701		74742		74783		74824		74865		74906
	74661		74702		74743		74784		74825		74866		74907
	74662		74703		74744		74785		74826		74867		74908
	74663		74704		74745		74786		74827		74868		74909
	74664		74705		74746		74787		74828		74869		74910
	74665		74706		74747		74788		74829		74870		74911
	74666		74707		74748		74789		74830		74871		74912
	74667		74708		74749		74790		74831		74872		74913
	74668		74709		74750		74791		74832		74873		74914
	74669		74710		74751		74792		74833		74874		74915
	74670		74711		74752		74793		74834		74875		74916
	74671		74712		74753		74794		74835		74876		74917
	74672		74713		74754		74795		74836		74877		74918
	74673		74714		74755		74796		74837		74878		74919
	74674		74715		74756		74797		74838		74879		74920
	74675		74716		74757		74798		74839		74880		74921
	74676		74717		74758		74799		74840		74881		74922
	74677		74718		74759		74800		74841		74882		74923
	74678		74719		74760		74801		74842		74883		74924

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	74925	
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Trt.	Bl. No	nb
PPD	74966	
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Trt.	Bl. No	nb
PPD	75007	
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Trt.	Bl. No	nb
PPD	75048	
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Trt.	Bl. No	nb
PPD	75089	
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Trt.	Bl. No	nb
PPD	75130	
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Trt.	Bl. No	nb
PPD	75171	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	75212	PPD	75253	PPD	75294	PPD	75335	PPD	75376	PPD	75417	PPD	75458
	75213		75254		75295		75336		75377		75418		75459
	75214		75255		75296		75337		75378		75419		75460
	75215		75256		75297		75338		75379		75420		75461
	75216		75257		75298		75339		75380		75421		75462
	75217		75258		75299		75340		75381		75422		75463
	75218		75259		75300		75341		75382		75423		75464
	75219		75260		75301		75342		75383		75424		75465
	75220		75261		75302		75343		75384		75425		75466
	75221		75262		75303		75344		75385		75426		75467
	75222		75263		75304		75345		75386		75427		75468
	75223		75264		75305		75346		75387		75428		75469
	75224		75265		75306		75347		75388		75429		75470
	75225		75266		75307		75348		75389		75430		75471
	75226		75267		75308		75349		75390		75431		75472
	75227		75268		75309		75350		75391		75432		75473
	75228		75269		75310		75351		75392		75433		75474
	75229		75270		75311		75352		75393		75434		75475
	75230		75271		75312		75353		75394		75435		75476
	75231		75272		75313		75354		75395		75436		75477
	75232		75273		75314		75355		75396		75437		75478
	75233		75274		75315		75356		75397		75438		75479
	75234		75275		75316		75357		75398		75439		75480
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	75237		75278		75319		75360		75401		75442		75483
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	75239		75280		75321		75362		75403		75444		75485
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	75241		75282		75323		75364		75405		75446		75487
	75242		75283		75324		75365		75406		75447		75488
	75243		75284		75325		75366		75407		75448		75489
	75244		75285		75326		75367		75408		75449		75490
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	75246		75287		75328		75369		75410		75451		75492
	75247		75288		75329		75370		75411		75452		75493
	75248		75289		75330		75371		75412		75453		75494
	75249		75290		75331		75372		75413		75454		75495
	75250		75291		75332		75373		75414		75455		75496
	75251		75292		75333		75374		75415		75456		75497
	75252		75293		75334		75375		75416		75457		75498

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	75499	PPD	75540	PPD	75581	PPD	75622	PPD	75663	PPD	75704	PPD	75745
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	75501		75542		75583		75624		75665		75706		75747
	75502		75543		75584		75625		75666		75707		75748
	75503		75544		75585		75626		75667		75708		75749
	75504		75545		75586		75627		75668		75709		75750
	75505		75546		75587		75628		75669		75710		75751
	75506		75547		75588		75629		75670		75711		75752
	75507		75548		75589		75630		75671		75712		75753
	75508		75549		75590		75631		75672		75713		75754
	75509		75550		75591		75632		75673		75714		75755
	75510		75551		75592		75633		75674		75715		75756
	75511		75552		75593		75634		75675		75716		75757
	75512		75553		75594		75635		75676		75717		75758
	75513		75554		75595		75636		75677		75718		75759
	75514		75555		75596		75637		75678		75719		75760
	75515		75556		75597		75638		75679		75720		75761
	75516		75557		75598		75639		75680		75721		75762
	75517		75558		75599		75640		75681		75722		75763
	75518		75559		75600		75641		75682		75723		75764
	75519		75560		75601		75642		75683		75724		75765
	75520		75561		75602		75643		75684		75725		75766
	75521		75562		75603		75644		75685		75726		75767
	75522		75563		75604		75645		75686		75727		75768
	75523		75564		75605		75646		75687		75728		75769
	75524		75565		75606		75647		75688		75729		75770
	75525		75566		75607		75648		75689		75730		75771
	75526		75567		75608		75649		75690		75731		75772
	75527		75568		75609		75650		75691		75732		75773
	75528		75569		75610		75651		75692		75733		75774
	75529		75570		75611		75652		75693		75734		75775
	75530		75571		75612		75653		75694		75735		75776
	75531		75572		75613		75654		75695		75736		75777
	75532		75573		75614		75655		75696		75737		75778
	75533		75574		75615		75656		75697		75738		75779
	75534		75575		75616		75657		75698		75739		75780
	75535		75576		75617		75658		75699		75740		75781
	75536		75577		75618		75659		75700		75741		75782
	75537		75578		75619		75660		75701		75742		75783
	75538		75579		75620		75661		75702		75743		75784
	75539		75580		75621		75662		75703		75744		75785

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	75786
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	41	75826

Trt.	Bl. No	nb
PPD	1	75827
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	31	75857
	32	75858
	33	75859
	34	75860
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	36	75862
	37	75863
	38	75864
	39	75865
	40	75866
	41	75867

Trt.	Bl. No	nb
PPD	1	75868
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	32	75899
	33	75900
	34	75901
	35	75902
	36	75903
	37	75904
	38	75905
	39	75906
	40	75907
	41	75908

Trt.	Bl. No	nb
PPD	1	75909
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	41	75949

Trt.	Bl. No	nb
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	39	75988
	40	75989
	41	75990

Trt.	Bl. No	nb
PPD	1	75991
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	4	75994
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	21	76011
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	23	76013
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	40	76030
	41	76031

Trt.	Bl. No	nb
PPD	1	76032
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	41	76072

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	76073
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	33	76105
	34	76106
	35	76107
	36	76108
	37	76109
	38	76110
	39	76111
	40	76112
	41	76113
PPD	1	76114
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	3	76116
	4	76117
	5	76118
	6	76119
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	38	76151
	39	76152
	40	76153
	41	76154
PPD	1	76155
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	38	76192
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	41	76236
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	40	76317
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PPD	1	76319
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	40	76358
	41	76359

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	76360
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	37	76396
	38	76397
	39	76398
	40	76399
	41	76400
PPD	42	76401
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	245	76604
	246	76605
PPD	247	76606
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	287	76646

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	76647
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	13	76659
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	16	76662
	17	76663
	18	76664
	19	76665
	20	76666
	21	76667
	22	76668
	23	76669
	24	76670
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	32	76678
	33	76679
	34	76680
	35	76681
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	37	76683
	38	76684
	39	76685
	40	76686
	41	76687

Trt.	Bl. No	nb
PPD	1	76688
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	41	76728

Trt.	Bl. No	nb
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	40	76768
	41	76769

Trt.	Bl. No	nb
PPD	1	76770
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	36	76805
	37	76806
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	39	76808
	40	76809
	41	76810

Trt.	Bl. No	nb
PPD	1	76811
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	39	76849
	40	76850
	41	76851

Trt.	Bl. No	nb
PPD	1	76852
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	5	76856
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	32	76883
	33	76884
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	35	76886
	36	76887
	37	76888
	38	76889
	39	76890
	40	76891
	41	76892

Trt.	Bl. No	nb
PPD	1	76893
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	3	76895
	4	76896
	5	76897
	6	76898
	7	76899
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	41	76933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	76934	PPD	76975	PPD	77016	PPD	77057	PPD	77098	PPD	77139	PPD	77180
	76935		76976		77017		77058		77099		77140		77181
	76936		76977		77018		77059		77100		77141		77182
	76937		76978		77019		77060		77101		77142		77183
	76938		76979		77020		77061		77102		77143		77184
	76939		76980		77021		77062		77103		77144		77185
	76940		76981		77022		77063		77104		77145		77186
	76941		76982		77023		77064		77105		77146		77187
	76942		76983		77024		77065		77106		77147		77188
	76943		76984		77025		77066		77107		77148		77189
	76944		76985		77026		77067		77108		77149		77190
	76945		76986		77027		77068		77109		77150		77191
	76946		76987		77028		77069		77110		77151		77192
	76947		76988		77029		77070		77111		77152		77193
	76948		76989		77030		77071		77112		77153		77194
	76949		76990		77031		77072		77113		77154		77195
	76950		76991		77032		77073		77114		77155		77196
	76951		76992		77033		77074		77115		77156		77197
	76952		76993		77034		77075		77116		77157		77198
	76953		76994		77035		77076		77117		77158		77199
	76954		76995		77036		77077		77118		77159		77200
	76955		76996		77037		77078		77119		77160		77201
	76956		76997		77038		77079		77120		77161		77202
	76957		76998		77039		77080		77121		77162		77203
	76958		76999		77040		77081		77122		77163		77204
	76959		77000		77041		77082		77123		77164		77205
	76960		77001		77042		77083		77124		77165		77206
	76961		77002		77043		77084		77125		77166		77207
	76962		77003		77044		77085		77126		77167		77208
	76963		77004		77045		77086		77127		77168		77209
	76964		77005		77046		77087		77128		77169		77210
	76965		77006		77047		77088		77129		77170		77211
	76966		77007		77048		77089		77130		77171		77212
	76967		77008		77049		77090		77131		77172		77213
	76968		77009		77050		77091		77132		77173		77214
	76969		77010		77051		77092		77133		77174		77215
	76970		77011		77052		77093		77134		77175		77216
	76971		77012		77053		77094		77135		77176		77217
	76972		77013		77054		77095		77136		77177		77218
	76973		77014		77055		77096		77137		77178		77219
	76974		77015		77056		77097		77138		77179		77220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	77221
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	34	77254
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	36	77256
	37	77257
	38	77258
	39	77259
	40	77260
	41	77261
PPD	42	77262
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	81	77301
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PPD	83	77303
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	122	77342
	123	77343
PPD	124	77344
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	163	77383
	164	77384
PPD	165	77385
	166	77386
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PPD	206	77426
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	240	77460
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	243	77463
	244	77464
	245	77465
	246	77466
PPD	247	77467
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	250	77470
	251	77471
	252	77472
	253	77473
	254	77474
	255	77475
	256	77476
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	281	77501
	282	77502
	283	77503
	284	77504
	285	77505
	286	77506
	287	77507

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	77508	77547
PPD	77549	77588
PPD	77590	77629
PPD	77631	77670
PPD	77672	77712
PPD	77713	77753
PPD	77754	77794

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	77795	
	77796	
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Trt.	Bl. No	nb
PPD	77836	
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	77838	
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Trt.	Bl. No	nb
PPD	77877	
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Trt.	Bl. No	nb
PPD	77918	
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Trt.	Bl. No	nb
PPD	77959	
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Trt.	Bl. No	nb
PPD	78000	
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Trt.	Bl. No	nb
PPD	78041	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	78082	78083
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	78088	78089
	78090	78091
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	78108	78109
	78110	78111
	78112	78113
	78114	78115
	78116	78117
	78118	78119
	78120	78121
	78122	

Trt.	Bl. No	nb
PPD	78123	78124
	78125	78126
	78127	78128
	78129	78130
	78131	78132
	78133	78134
	78135	78136
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	78153	78154
	78155	78156
	78157	78158
	78159	78160
	78161	78162
	78163	

Trt.	Bl. No	nb
PPD	78164	78165
	78166	78167
	78168	78169
	78170	78171
	78172	78173
	78174	78175
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	78180	78181
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	78188	78189
	78190	78191
	78192	78193
	78194	78195
	78196	78197
	78198	78199
	78200	78201
	78202	78203
	78204	

Trt.	Bl. No	nb
PPD	78205	78206
	78207	78208
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	78211	78212
	78213	78214
	78215	78216
	78217	78218
	78219	78220
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	78229	78230
	78231	78232
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	78235	78236
	78237	78238
	78239	78240
	78241	78242
	78243	78244
	78245	

Trt.	Bl. No	nb
PPD	78246	78247
	78248	78249
	78250	78251
	78252	78253
	78254	78255
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	78284	78285
	78286	

Trt.	Bl. No	nb
PPD	78287	78288
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	78319	78320
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	78323	78324
	78325	78326
	78327	

Trt.	Bl. No	nb
PPD	78328	78329
	78330	78331
	78332	78333
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	78364	78365
	78366	78367
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	1	78369
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	4	78372
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PPD	1	78615
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	41	78655

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	78697	
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Trt.	Bl. No	nb
PPD	78738	
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Trt.	Bl. No	nb
PPD	78779	
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Trt.	Bl. No	nb
PPD	78820	
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Trt.	Bl. No	nb
PPD	78861	
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	78901	

Trt.	Bl. No	nb
PPD	78902	
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	78905	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
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	36	78978
	37	78979
	38	78980
	39	78981
	40	78982
	41	78983

Trt.	Bl. No	nb
PPD	1	78984
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	3	78986
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	7	78990
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	41	79024

Trt.	Bl. No	nb
PPD	1	79025
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	35	79059
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	39	79063
	40	79064
	41	79065

Trt.	Bl. No	nb
PPD	1	79066
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	40	79105
	41	79106

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	1	79148
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	41	79188

Trt.	Bl. No	nb
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	79230	79270
PPD	79271	79311
PPD	79312	79352
PPD	79353	79393
PPD	79394	79434
PPD	79435	79475
PPD	79476	79516

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

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	33	79754
	34	79755
	35	79756
	36	79757
	37	79758
	38	79759
	39	79760
	40	79761
	41	79762
PPD	1	79763
	2	79764
	3	79765
	4	79766
	5	79767
	6	79768
	7	79769
	8	79770
	9	79771
	10	79772
	11	79773
	12	79774
	13	79775
	14	79776
	15	79777
	16	79778
	17	79779
	18	79780
	19	79781
	20	79782
	21	79783
	22	79784
	23	79785
	24	79786
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	26	79788
	27	79789
	28	79790
	29	79791
	30	79792
	31	79793
	32	79794
	33	79795
	34	79796
	35	79797
	36	79798
	37	79799
	38	79800
	39	79801
	40	79802
	41	79803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	79804	79844
PPD	79845	79885
PPD	79886	79926
PPD	79927	79967
PPD	79968	80008
PPD	80009	80049
PPD	80050	80090

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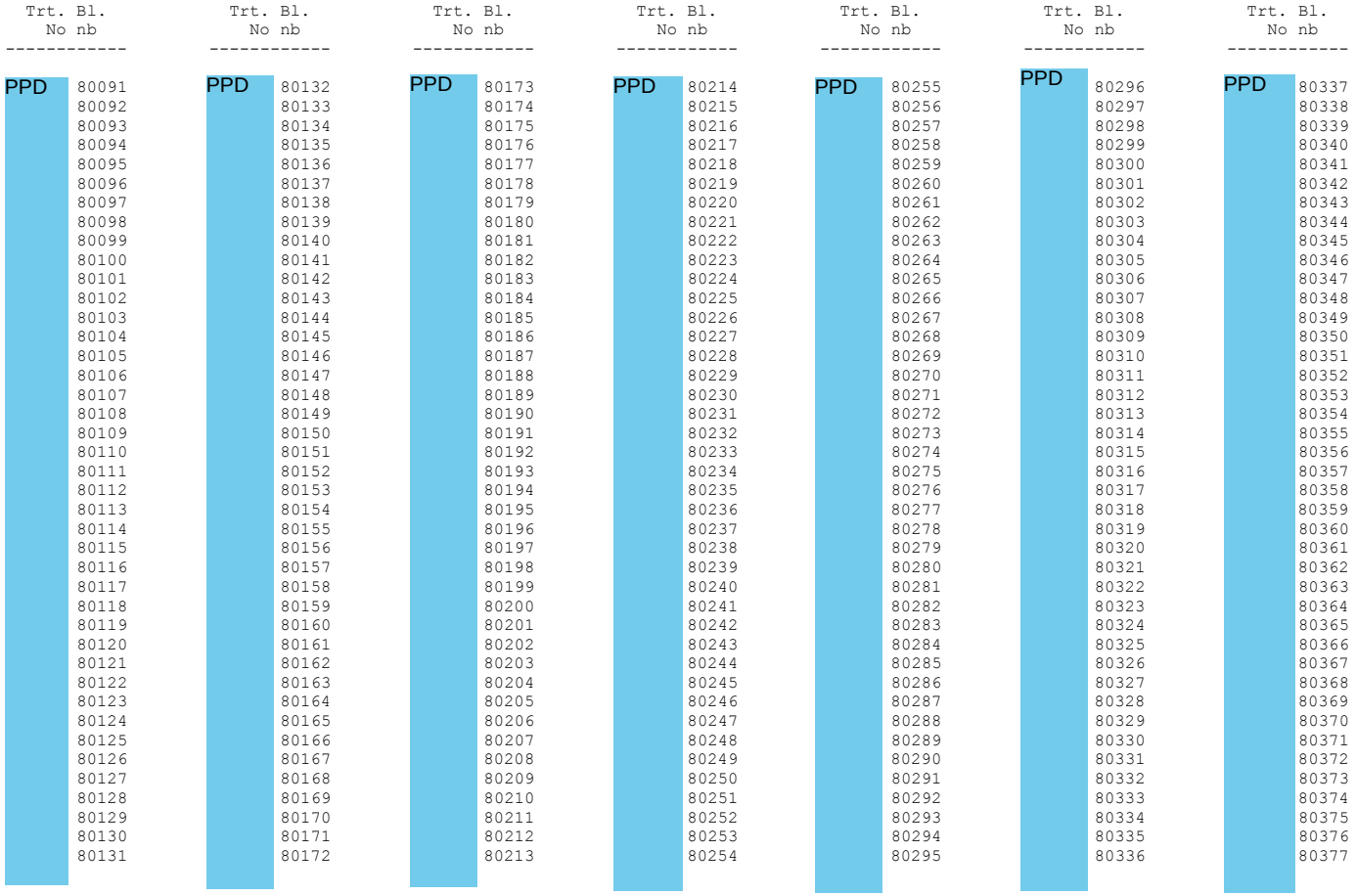
Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel



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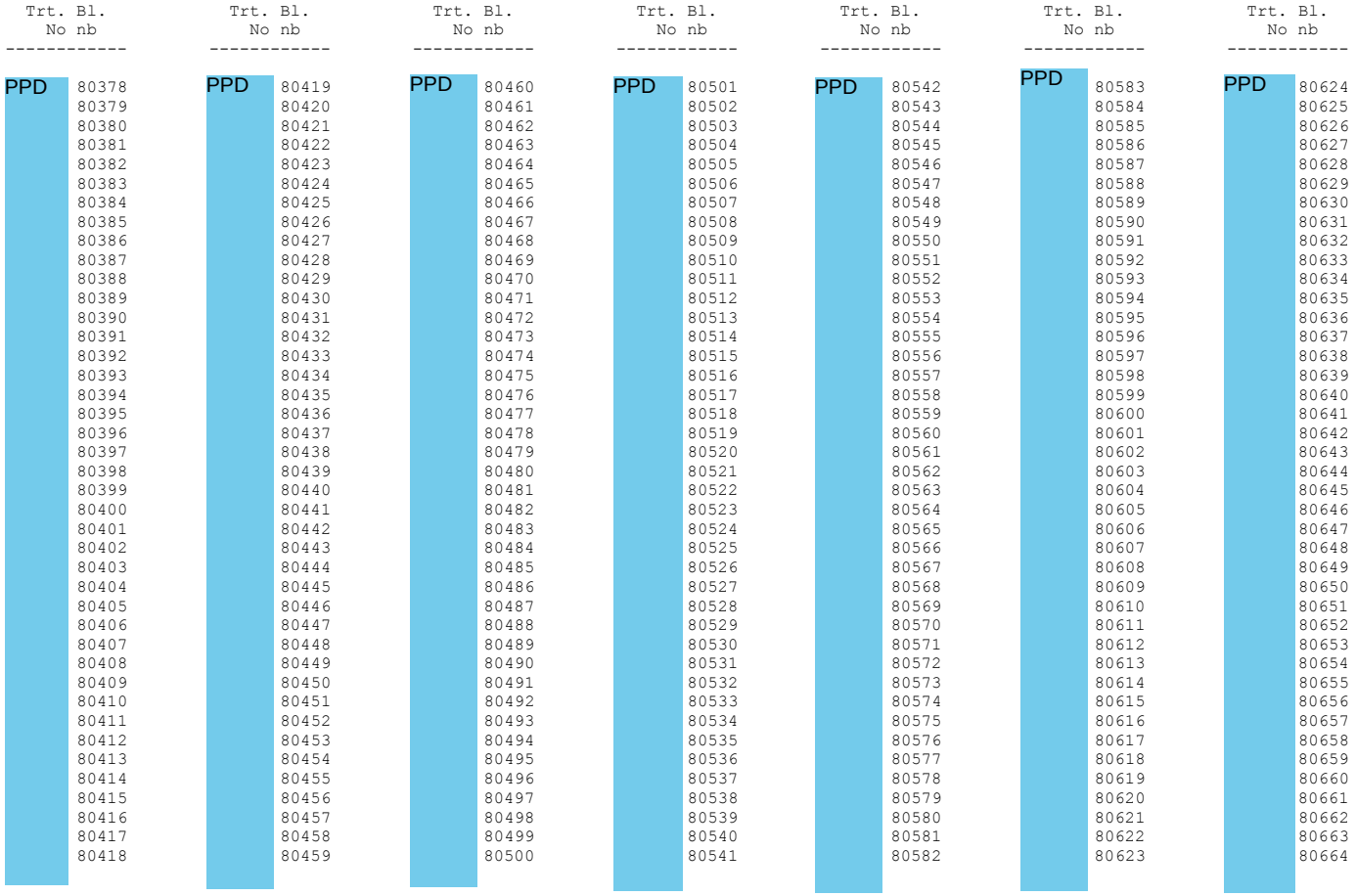
Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel



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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Pentacel

Trt.	Bl. No	nb
PPD	80665	
	80666	
	80667	
	80668	
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	80675	
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	80699	
	80700	
	80701	
	80702	
	80703	
	80704	
	80705	

Trt.	Bl. No	nb
PPD	80706	
	80707	
	80708	
	80709	
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	80714	
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Trt.	Bl. No	nb
PPD	80747	
	80748	
	80749	
	80750	
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Trt.	Bl. No	nb
PPD	80788	
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Trt.	Bl. No	nb
PPD	80829	
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	80862	
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	80864	
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Trt.	Bl. No	nb
PPD	80870	
	80871	
	80872	
	80873	
	80874	
	80875	
	80876	
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	80878	
	80879	
	80880	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

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	10907		PPD	10948		PPD	10989		PPD	11030		PPD	11071		PPD	11112		PPD	11153	
	10908			10949			10990			11031			11072			11113			11154	
	10909			10950			10991			11032			11073			11114			11155	
	10910			10951			10992			11033			11074			11115			11156	
	10911			10952			10993			11034			11075			11116			11157	
	10912			10953			10994			11035			11076			11117			11158	
	10913			10954			10995			11036			11077			11118			11159	
	10914			10955			10996			11037			11078			11119			11160	
	10915			10956			10997			11038			11079			11120			11161	
	10916			10957			10998			11039			11080			11121			11162	
	10917			10958			10999			11040			11081			11122			11163	
	10918			10959			11000			11041			11082			11123			11164	
	10919			10960			11001			11042			11083			11124			11165	
	10920			10961			11002			11043			11084			11125			11166	
	10921			10962			11003			11044			11085			11126			11167	
	10922			10963			11004			11045			11086			11127			11168	
	10923			10964			11005			11046			11087			11128			11169	
	10924			10965			11006			11047			11088			11129			11170	
	10925			10966			11007			11048			11089			11130			11171	
	10926			10967			11008			11049			11090			11131			11172	
	10927			10968			11009			11050			11091			11132			11173	
	10928			10969			11010			11051			11092			11133			11174	
	10929			10970			11011			11052			11093			11134			11175	
	10930			10971			11012			11053			11094			11135			11176	
	10931			10972			11013			11054			11095			11136			11177	
	10932			10973			11014			11055			11096			11137			11178	
	10933			10974			11015			11056			11097			11138			11179	
	10934			10975			11016			11057			11098			11139			11180	
	10935			10976			11017			11058			11099			11140			11181	
	10936			10977			11018			11059			11100			11141			11182	
	10937			10978			11019			11060			11101			11142			11183	
	10938			10979			11020			11061			11102			11143			11184	
	10939			10980			11021			11062			11103			11144			11185	
	10940			10981			11022			11063			11104			11145			11186	
	10941			10982			11023			11064			11105			11146			11187	
	10942			10983			11024			11065			11106			11147			11188	
	10943			10984			11025			11066			11107			11148			11189	
	10944			10985			11026			11067			11108			11149			11190	
	10945			10986			11027			11068			11109			11150			11191	
	10946			10987			11028			11069			11110			11151			11192	
	10947			10988			11029			11070			11111			11152			11193	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	11194	11234
PPD	11235	11275
PPD	11276	11316
PPD	11317	11357
PPD	11358	11398
PPD	11399	11439
PPD	11440	11480

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	11481	11521
PPD	11522	11562
PPD	11563	11603
PPD	11604	11644
PPD	11645	11685
PPD	11686	11726
PPD	11727	11767

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	11768	11808
PPD	11809	11849
PPD	11850	11890
PPD	11891	11931
PPD	11932	11972
PPD	11973	12013
PPD	12014	12054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	12055	12095
PPD	12096	12136
PPD	12137	12177
PPD	12178	12218
PPD	12219	12259
PPD	12260	12300
PPD	12301	12341

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	12342	
	12343	
	12344	
	12345	
	12346	
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	12364	
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	12380	
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Trt.	Bl. No	nb
PPD	12383	
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Trt.	Bl. No	nb
PPD	12424	
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Trt.	Bl. No	nb
PPD	12465	
	12466	
	12467	
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	12471	
	12472	
	12473	
	12474	
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	12499	
	12500	
	12501	
	12502	
	12503	
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	12505	

Trt.	Bl. No	nb
PPD	12506	
	12507	
	12508	
	12509	
	12510	
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	12514	
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Trt.	Bl. No	nb
PPD	12547	
	12548	
	12549	
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	12551	
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Trt.	Bl. No	nb
PPD	12588	
	12589	
	12590	
	12591	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	12629	12669
PPD	12670	12710
PPD	12711	12751
PPD	12752	12792
PPD	12793	12833
PPD	12834	12874
PPD	12875	12915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	12916	12956
PPD	12957	12997
PPD	12998	13038
PPD	13039	13079
PPD	13080	13120
PPD	13121	13161
PPD	13162	13202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

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	13203	PPD	13244	PPD	13285	PPD	13326	PPD	13367	PPD	13408	PPD	13449
	13204		13245		13286		13327		13368		13409		13450
	13205		13246		13287		13328		13369		13410		13451
	13206		13247		13288		13329		13370		13411		13452
	13207		13248		13289		13330		13371		13412		13453
	13208		13249		13290		13331		13372		13413		13454
	13209		13250		13291		13332		13373		13414		13455
	13210		13251		13292		13333		13374		13415		13456
	13211		13252		13293		13334		13375		13416		13457
	13212		13253		13294		13335		13376		13417		13458
	13213		13254		13295		13336		13377		13418		13459
	13214		13255		13296		13337		13378		13419		13460
	13215		13256		13297		13338		13379		13420		13461
	13216		13257		13298		13339		13380		13421		13462
	13217		13258		13299		13340		13381		13422		13463
	13218		13259		13300		13341		13382		13423		13464
	13219		13260		13301		13342		13383		13424		13465
	13220		13261		13302		13343		13384		13425		13466
	13221		13262		13303		13344		13385		13426		13467
	13222		13263		13304		13345		13386		13427		13468
	13223		13264		13305		13346		13387		13428		13469
	13224		13265		13306		13347		13388		13429		13470
	13225		13266		13307		13348		13389		13430		13471
	13226		13267		13308		13349		13390		13431		13472
	13227		13268		13309		13350		13391		13432		13473
	13228		13269		13310		13351		13392		13433		13474
	13229		13270		13311		13352		13393		13434		13475
	13230		13271		13312		13353		13394		13435		13476
	13231		13272		13313		13354		13395		13436		13477
	13232		13273		13314		13355		13396		13437		13478
	13233		13274		13315		13356		13397		13438		13479
	13234		13275		13316		13357		13398		13439		13480
	13235		13276		13317		13358		13399		13440		13481
	13236		13277		13318		13359		13400		13441		13482
	13237		13278		13319		13360		13401		13442		13483
	13238		13279		13320		13361		13402		13443		13484
	13239		13280		13321		13362		13403		13444		13485
	13240		13281		13322		13363		13404		13445		13486
	13241		13282		13323		13364		13405		13446		13487
	13242		13283		13324		13365		13406		13447		13488
	13243		13284		13325		13366		13407		13448		13489

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	13490	13530
PPD	13531	13571
PPD	13572	13612
PPD	13613	13653
PPD	13654	13694
PPD	13695	13735
PPD	13736	13776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	13777	13817
PPD	13818	13858
PPD	13859	13899
PPD	13900	13940
PPD	13941	13981
PPD	13982	14022
PPD	14023	14063

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	14064	14105
	14065	14106
	14066	14107
	14067	14108
	14068	14109
	14069	14110
	14070	14111
	14071	14112
	14072	14113
	14073	14114
	14074	14115
	14075	14116
	14076	14117
	14077	14118
	14078	14119
	14079	14120
	14080	14121
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Trt.	Bl. No	nb
PPD	14146	14187
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	14183	14224
	14184	14225
	14185	14226
	14186	14227

Trt.	Bl. No	nb
PPD	14228	14269
	14229	14270
	14230	14271
	14231	14272
	14232	14273
	14233	14274
	14234	14275
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	14239	14280
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	14268	14309

Trt.	Bl. No	nb
PPD	14310	14350
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	14392	
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Trt.	Bl. No	nb
PPD	14433	
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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	14556	
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Trt.	Bl. No	nb
PPD	14597	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	14638	14678
PPD	14679	14719
PPD	14720	14760
PPD	14761	14801
PPD	14802	14842
PPD	14843	14883
PPD	14884	14924

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	14925	
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Trt.	Bl. No	nb
PPD	14966	
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Trt.	Bl. No	nb
PPD	15007	
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Trt.	Bl. No	nb
PPD	15048	
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Trt.	Bl. No	nb
PPD	15089	
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Trt.	Bl. No	nb
PPD	15130	
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Trt.	Bl. No	nb
PPD	15171	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	1	15212
	2	15213
	3	15214
	4	15215
	5	15216
	6	15217
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	8	15219
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	12	15223
	13	15224
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	15	15226
	16	15227
	17	15228
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	19	15230
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	35	15246
	36	15247
	37	15248
	38	15249
	39	15250
	40	15251
	41	15252

Trt.	Bl. No	nb
PPD	1	15253
	2	15254
	3	15255
	4	15256
	5	15257
	6	15258
	7	15259
	8	15260
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	10	15262
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	12	15264
	13	15265
	14	15266
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	16	15268
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	32	15284
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	37	15289
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	39	15291
	40	15292
	41	15293

Trt.	Bl. No	nb
PPD	1	15294
	2	15295
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	4	15297
	5	15298
	6	15299
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	39	15332
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	41	15334

Trt.	Bl. No	nb
PPD	1	15335
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	41	15375

Trt.	Bl. No	nb
PPD	1	15376
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	41	15416

Trt.	Bl. No	nb
PPD	1	15417
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Trt.	Bl. No	nb
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Treatment number associated to material : Prevnar 13

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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	15663	
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Trt.	Bl. No	nb
PPD	15704	
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Trt.	Bl. No	nb
PPD	15745	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	15827	
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Trt.	Bl. No	nb
PPD	15868	
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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

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	16073	16113
PPD	16114	16154
PPD	16155	16195
PPD	16196	16236
PPD	16237	16277
PPD	16278	16318
PPD	16319	16359

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	16360	16400
PPD	16401	16441
PPD	16442	16482
PPD	16483	16523
PPD	16524	16564
PPD	16565	16605
PPD	16606	16646

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	16647	
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Trt.	Bl. No	nb
PPD	16688	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	16770	
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Trt.	Bl. No	nb
PPD	16811	
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Trt.	Bl. No	nb
PPD	16852	
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Trt.	Bl. No	nb
PPD	16893	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	16934	16974
PPD	16975	17015
PPD	17016	17056
PPD	17057	17097
PPD	17098	17138
PPD	17139	17179
PPD	17180	17220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	1	17221
	2	17222
	3	17223
	4	17224
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	36	17256
	37	17257
	38	17258
	39	17259
	40	17260
	41	17261
PPD	42	17262
	43	17263
	44	17264
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	46	17266
	47	17267
	48	17268
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	78	17298
	79	17299
	80	17300
	81	17301
	82	17302
PPD	83	17303
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	120	17340
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	123	17343
PPD	124	17344
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	164	17384
PPD	165	17385
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PPD	206	17426
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PPD	247	17467
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	17508	17548
PPD	17549	17589
PPD	17590	17630
PPD	17631	17671
PPD	17672	17712
PPD	17713	17753
PPD	17754	17794

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

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	17959	
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Trt.	Bl. No	nb
PPD	18000	
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Trt.	Bl. No	nb
PPD	18041	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	18082	18123
	18083	18124
	18084	18125
	18085	18126
	18086	18127
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	18122	18163

Trt.	Bl. No	nb
PPD	18164	18205
	18165	18206
	18166	18207
	18167	18208
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	18169	18210
	18170	18211
	18171	18212
	18172	18213
	18173	18214
	18174	18215
	18175	18216
	18176	18217
	18177	18218
	18178	18219
	18179	18220
	18180	18221
	18181	18222
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	18204	18245

Trt.	Bl. No	nb
PPD	18246	18287
	18247	18288
	18248	18289
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	18273	18314
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	18279	18320
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	18285	18326
	18286	18327

Trt.	Bl. No	nb
PPD	18328	18368
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Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	18410	
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Trt.	Bl. No	nb
PPD	18451	
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Trt.	Bl. No	nb
PPD	18492	
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Trt.	Bl. No	nb
PPD	18533	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	18615	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

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	18656	PPD	18697	PPD	18738	PPD	18779	PPD	18820	PPD	18861	PPD	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
	18685		18726		18767		18808		18849		18890		18931
	18686		18727		18768		18809		18850		18891		18932
	18687		18728		18769		18810		18851		18892		18933
	18688		18729		18770		18811		18852		18893		18934
	18689		18730		18771		18812		18853		18894		18935
	18690		18731		18772		18813		18854		18895		18936
	18691		18732		18773		18814		18855		18896		18937
	18692		18733		18774		18815		18856		18897		18938
	18693		18734		18775		18816		18857		18898		18939
	18694		18735		18776		18817		18858		18899		18940
	18695		18736		18777		18818		18859		18900		18941
	18696		18737		18778		18819		18860		18901		18942

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	18943	18983
PPD	18984	19024
PPD	19025	19065
PPD	19066	19106
PPD	19107	19147
PPD	19148	19188
PPD	19189	19229

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	19230	
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	19232	
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Trt.	Bl. No	nb
PPD	19271	
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Trt.	Bl. No	nb
PPD	19312	
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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	19476	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	19517	19557
PPD	19558	19598
PPD	19599	19639
PPD	19640	19680
PPD	19681	19721
PPD	19722	19762
PPD	19763	19803

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	19804	19844
PPD	19845	19885
PPD	19886	19926
PPD	19927	19967
PPD	19968	20008
PPD	20009	20049
PPD	20050	20090

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
PPD	1	20091
	2	20092
	3	20093
	4	20094
	5	20095
	6	20096
	7	20097
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	40	20130
	41	20131
PPD	1	20132
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	3	20134
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	40	20171
	41	20172
PPD	1	20173
	2	20174
	3	20175
	4	20176
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PPD	1	20255
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	39	20293
	40	20294
	41	20295
PPD	1	20296
	2	20297
	3	20298
	4	20299
	5	20300
	6	20301
	7	20302
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PPD	1	20337
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	20419	
	20420	
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Trt.	Bl. No	nb
PPD	20460	
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Trt.	Bl. No	nb
PPD	20501	
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Trt.	Bl. No	nb
PPD	20542	
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Trt.	Bl. No	nb
PPD	20583	
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Trt.	Bl. No	nb
PPD	20624	
	20625	
	20626	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Prevnar 13

Trt.	Bl. No	nb
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PPD	42	20706
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PPD	124	20788
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	205	20869
PPD	206	20870
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	208	20872
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	210	20874
	211	20875
	212	20876
	213	20877
	214	20878
	215	20879
	216	20880
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	219	20883
	220	20884
	221	20885
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	225	20889
	226	20890
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	239	20903
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	241	20905
	242	20906

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

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	907		PPD	948		PPD	989		PPD	1030		PPD	1071		PPD	1112		PPD	1153	
	908			949			990			1031			1072			1113			1154	
	909			950			991			1032			1073			1114			1155	
	910			951			992			1033			1074			1115			1156	
	911			952			993			1034			1075			1116			1157	
	912			953			994			1035			1076			1117			1158	
	913			954			995			1036			1077			1118			1159	
	914			955			996			1037			1078			1119			1160	
	915			956			997			1038			1079			1120			1161	
	916			957			998			1039			1080			1121			1162	
	917			958			999			1040			1081			1122			1163	
	918			959			1000			1041			1082			1123			1164	
	919			960			1001			1042			1083			1124			1165	
	920			961			1002			1043			1084			1125			1166	
	921			962			1003			1044			1085			1126			1167	
	922			963			1004			1045			1086			1127			1168	
	923			964			1005			1046			1087			1128			1169	
	924			965			1006			1047			1088			1129			1170	
	925			966			1007			1048			1089			1130			1171	
	926			967			1008			1049			1090			1131			1172	
	927			968			1009			1050			1091			1132			1173	
	928			969			1010			1051			1092			1133			1174	
	929			970			1011			1052			1093			1134			1175	
	930			971			1012			1053			1094			1135			1176	
	931			972			1013			1054			1095			1136			1177	
	932			973			1014			1055			1096			1137			1178	
	933			974			1015			1056			1097			1138			1179	
	934			975			1016			1057			1098			1139			1180	
	935			976			1017			1058			1099			1140			1181	
	936			977			1018			1059			1100			1141			1182	
	937			978			1019			1060			1101			1142			1183	
	938			979			1020			1061			1102			1143			1184	
	939			980			1021			1062			1103			1144			1185	
	940			981			1022			1063			1104			1145			1186	
	941			982			1023			1064			1105			1146			1187	
	942			983			1024			1065			1106			1147			1188	
	943			984			1025			1066			1107			1148			1189	
	944			985			1026			1067			1108			1149			1190	
	945			986			1027			1068			1109			1150			1191	
	946			987			1028			1069			1110			1151			1192	
	947			988			1029			1070			1111			1152			1193	

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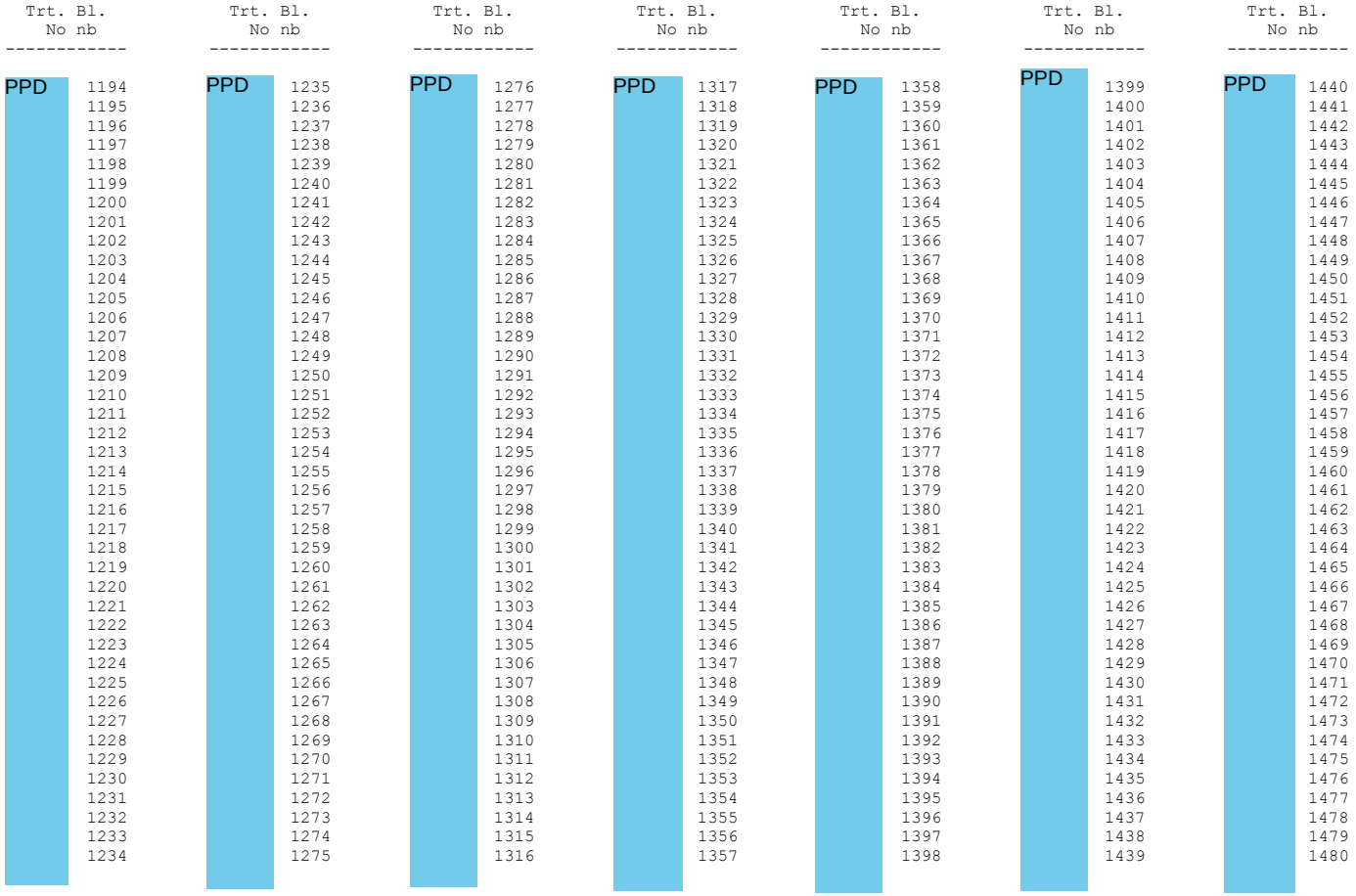
Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix



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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1481	1521
PPD	1522	1562
PPD	1563	1603
PPD	1604	1644
PPD	1645	1685
PPD	1686	1726
PPD	1727	1767

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1768	1808
PPD	1809	1849
PPD	1850	1890
PPD	1891	1931
PPD	1932	1972
PPD	1973	2013
PPD	2014	2054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt. Bl.	No nb
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Trt. Bl.	No nb
PPD	2096
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Trt. Bl.	No nb
PPD	2137
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Trt. Bl.	No nb
PPD	2178
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Trt. Bl.	No nb
PPD	2219
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	2257
	2258
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Trt. Bl.	No nb
PPD	2260
	2261
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	2300

Trt. Bl.	No nb
PPD	2301
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1	2342
	2	2343
	3	2344
	4	2345
	5	2346
	6	2347
	7	2348
	8	2349
	9	2350
	10	2351
	11	2352
	12	2353
	13	2354
	14	2355
	15	2356
	16	2357
	17	2358
	18	2359
	19	2360
	20	2361
	21	2362
	22	2363
	23	2364
	24	2365
	25	2366
	26	2367
	27	2368
	28	2369
	29	2370
	30	2371
	31	2372
	32	2373
	33	2374
	34	2375
	35	2376
	36	2377
	37	2378
	38	2379
	39	2380
	40	2381
	41	2382

Trt.	Bl. No	nb
PPD	1	2383
	2	2384
	3	2385
	4	2386
	5	2387
	6	2388
	7	2389
	8	2390
	9	2391
	10	2392
	11	2393
	12	2394
	13	2395
	14	2396
	15	2397
	16	2398
	17	2399
	18	2400
	19	2401
	20	2402
	21	2403
	22	2404
	23	2405
	24	2406
	25	2407
	26	2408
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	29	2411
	30	2412
	31	2413
	32	2414
	33	2415
	34	2416
	35	2417
	36	2418
	37	2419
	38	2420
	39	2421
	40	2422
	41	2423

Trt.	Bl. No	nb
PPD	1	2424
	2	2425
	3	2426
	4	2427
	5	2428
	6	2429
	7	2430
	8	2431
	9	2432
	10	2433
	11	2434
	12	2435
	13	2436
	14	2437
	15	2438
	16	2439
	17	2440
	18	2441
	19	2442
	20	2443
	21	2444
	22	2445
	23	2446
	24	2447
	25	2448
	26	2449
	27	2450
	28	2451
	29	2452
	30	2453
	31	2454
	32	2455
	33	2456
	34	2457
	35	2458
	36	2459
	37	2460
	38	2461
	39	2462
	40	2463
	41	2464

Trt.	Bl. No	nb
PPD	1	2465
	2	2466
	3	2467
	4	2468
	5	2469
	6	2470
	7	2471
	8	2472
	9	2473
	10	2474
	11	2475
	12	2476
	13	2477
	14	2478
	15	2479
	16	2480
	17	2481
	18	2482
	19	2483
	20	2484
	21	2485
	22	2486
	23	2487
	24	2488
	25	2489
	26	2490
	27	2491
	28	2492
	29	2493
	30	2494
	31	2495
	32	2496
	33	2497
	34	2498
	35	2499
	36	2500
	37	2501
	38	2502
	39	2503
	40	2504
	41	2505

Trt.	Bl. No	nb
PPD	1	2506
	2	2507
	3	2508
	4	2509
	5	2510
	6	2511
	7	2512
	8	2513
	9	2514
	10	2515
	11	2516
	12	2517
	13	2518
	14	2519
	15	2520
	16	2521
	17	2522
	18	2523
	19	2524
	20	2525
	21	2526
	22	2527
	23	2528
	24	2529
	25	2530
	26	2531
	27	2532
	28	2533
	29	2534
	30	2535
	31	2536
	32	2537
	33	2538
	34	2539
	35	2540
	36	2541
	37	2542
	38	2543
	39	2544
	40	2545
	41	2546

Trt.	Bl. No	nb
PPD	1	2547
	2	2548
	3	2549
	4	2550
	5	2551
	6	2552
	7	2553
	8	2554
	9	2555
	10	2556
	11	2557
	12	2558
	13	2559
	14	2560
	15	2561
	16	2562
	17	2563
	18	2564
	19	2565
	20	2566
	21	2567
	22	2568
	23	2569
	24	2570
	25	2571
	26	2572
	27	2573
	28	2574
	29	2575
	30	2576
	31	2577
	32	2578
	33	2579
	34	2580
	35	2581
	36	2582
	37	2583
	38	2584
	39	2585
	40	2586
	41	2587

Trt.	Bl. No	nb
PPD	1	2588
	2	2589
	3	2590
	4	2591
	5	2592
	6	2593
	7	2594
	8	2595
	9	2596
	10	2597
	11	2598
	12	2599
	13	2600
	14	2601
	15	2602
	16	2603
	17	2604
	18	2605
	19	2606
	20	2607
	21	2608
	22	2609
	23	2610
	24	2611
	25	2612
	26	2613
	27	2614
	28	2615
	29	2616
	30	2617
	31	2618
	32	2619
	33	2620
	34	2621
	35	2622
	36	2623
	37	2624
	38	2625
	39	2626
	40	2627
	41	2628

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1	2629
	2	2630
	3	2631
	4	2632
	5	2633
	6	2634
	7	2635
	8	2636
	9	2637
	10	2638
	11	2639
	12	2640
	13	2641
	14	2642
	15	2643
	16	2644
	17	2645
	18	2646
	19	2647
	20	2648
	21	2649
	22	2650
	23	2651
	24	2652
	25	2653
	26	2654
	27	2655
	28	2656
	29	2657
	30	2658
	31	2659
	32	2660
	33	2661
	34	2662
	35	2663
	36	2664
	37	2665
	38	2666
	39	2667
	40	2668
	41	2669
PPD	1	2670
	2	2671
	3	2672
	4	2673
	5	2674
	6	2675
	7	2676
	8	2677
	9	2678
	10	2679
	11	2680
	12	2681
	13	2682
	14	2683
	15	2684
	16	2685
	17	2686
	18	2687
	19	2688
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	23	2692
	24	2693
	25	2694
	26	2695
	27	2696
	28	2697
	29	2698
	30	2699
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	32	2701
	33	2702
	34	2703
	35	2704
	36	2705
	37	2706
	38	2707
	39	2708
	40	2709
	41	2710
PPD	1	2711
	2	2712
	3	2713
	4	2714
	5	2715
	6	2716
	7	2717
	8	2718
	9	2719
	10	2720
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	30	2740
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	32	2742
	33	2743
	34	2744
	35	2745
	36	2746
	37	2747
	38	2748
	39	2749
	40	2750
	41	2751
PPD	1	2752
	2	2753
	3	2754
	4	2755
	5	2756
	6	2757
	7	2758
	8	2759
	9	2760
	10	2761
	11	2762
	12	2763
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	31	2782
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	33	2784
	34	2785
	35	2786
	36	2787
	37	2788
	38	2789
	39	2790
	40	2791
	41	2792
PPD	1	2793
	2	2794
	3	2795
	4	2796
	5	2797
	6	2798
	7	2799
	8	2800
	9	2801
	10	2802
	11	2803
	12	2804
	13	2805
	14	2806
	15	2807
	16	2808
	17	2809
	18	2810
	19	2811
	20	2812
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	22	2814
	23	2815
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	34	2826
	35	2827
	36	2828
	37	2829
	38	2830
	39	2831
	40	2832
	41	2833
PPD	1	2834
	2	2835
	3	2836
	4	2837
	5	2838
	6	2839
	7	2840
	8	2841
	9	2842
	10	2843
	11	2844
	12	2845
	13	2846
	14	2847
	15	2848
	16	2849
	17	2850
	18	2851
	19	2852
	20	2853
	21	2854
	22	2855
	23	2856
	24	2857
	25	2858
	26	2859
	27	2860
	28	2861
	29	2862
	30	2863
	31	2864
	32	2865
	33	2866
	34	2867
	35	2868
	36	2869
	37	2870
	38	2871
	39	2872
	40	2873
	41	2874
PPD	1	2875
	2	2876
	3	2877
	4	2878
	5	2879
	6	2880
	7	2881
	8	2882
	9	2883
	10	2884
	11	2885
	12	2886
	13	2887
	14	2888
	15	2889
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	19	2893
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	23	2897
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	27	2901
	28	2902
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	36	2910
	37	2911
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	41	2915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	2916	2956
PPD	2957	2997
PPD	2998	3038
PPD	3039	3079
PPD	3080	3120
PPD	3121	3161
PPD	3162	3202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	3203	
	3204	
	3205	
	3206	
	3207	
	3208	
	3209	
	3210	
	3211	
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	3213	
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	3240	
	3241	
	3242	
	3243	

Trt.	Bl. No	nb
PPD	3244	
	3245	
	3246	
	3247	
	3248	
	3249	
	3250	
	3251	
	3252	
	3253	
	3254	
	3255	
	3256	
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	3259	
	3260	
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	3284	

Trt.	Bl. No	nb
PPD	3285	
	3286	
	3287	
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	3293	
	3294	
	3295	
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	3299	
	3300	
	3301	
	3302	
	3303	
	3304	
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	3323	
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Trt.	Bl. No	nb
PPD	3326	
	3327	
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Trt.	Bl. No	nb
PPD	3367	
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	3400	
	3401	
	3402	
	3403	
	3404	
	3405	
	3406	
	3407	

Trt.	Bl. No	nb
PPD	3408	
	3409	
	3410	
	3411	
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Trt.	Bl. No	nb
PPD	3449	
	3450	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	3490	3530
PPD	3531	3571
PPD	3572	3612
PPD	3613	3653
PPD	3654	3694
PPD	3695	3735
PPD	3736	3776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	3777	3817
PPD	3818	3858
PPD	3859	3899
PPD	3900	3940
PPD	3941	3981
PPD	3982	4022
PPD	4023	4063

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	4064	4065
	4066	4067
	4068	4069
	4070	4071
	4072	4073
	4074	4075
	4076	4077
	4078	4079
	4080	4081
	4082	4083
	4084	4085
	4086	4087
	4088	4089
	4090	4091
	4092	4093
	4094	4095
	4096	4097
	4098	4099
	4100	4101
	4102	4103
	4104	

Trt.	Bl. No	nb
PPD	4105	4106
	4107	4108
	4109	4110
	4111	4112
	4113	4114
	4115	4116
	4117	4118
	4119	4120
	4121	4122
	4123	4124
	4125	4126
	4127	4128
	4129	4130
	4131	4132
	4133	4134
	4135	4136
	4137	4138
	4139	4140
	4141	4142
	4143	4144
	4145	

Trt.	Bl. No	nb
PPD	4146	4147
	4148	4149
	4150	4151
	4152	4153
	4154	4155
	4156	4157
	4158	4159
	4160	4161
	4162	4163
	4164	4165
	4166	4167
	4168	4169
	4170	4171
	4172	4173
	4174	4175
	4176	4177
	4178	4179
	4180	4181
	4182	4183
	4184	4185
	4186	

Trt.	Bl. No	nb
PPD	4187	4188
	4189	4190
	4191	4192
	4193	4194
	4195	4196
	4197	4198
	4199	4200
	4201	4202
	4203	4204
	4205	4206
	4207	4208
	4209	4210
	4211	4212
	4213	4214
	4215	4216
	4217	4218
	4219	4220
	4221	4222
	4223	4224
	4225	4226
	4227	

Trt.	Bl. No	nb
PPD	4228	4229
	4230	4231
	4232	4233
	4234	4235
	4236	4237
	4238	4239
	4240	4241
	4242	4243
	4244	4245
	4246	4247
	4248	4249
	4250	4251
	4252	4253
	4254	4255
	4256	4257
	4258	4259
	4260	4261
	4262	4263
	4264	4265
	4266	4267
	4268	

Trt.	Bl. No	nb
PPD	4269	4270
	4271	4272
	4273	4274
	4275	4276
	4277	4278
	4279	4280
	4281	4282
	4283	4284
	4285	4286
	4287	4288
	4289	4290
	4291	4292
	4293	4294
	4295	4296
	4297	4298
	4299	4300
	4301	4302
	4303	4304
	4305	4306
	4307	4308
	4309	

Trt.	Bl. No	nb
PPD	4310	4311
	4312	4313
	4314	4315
	4316	4317
	4318	4319
	4320	4321
	4322	4323
	4324	4325
	4326	4327
	4328	4329
	4330	4331
	4332	4333
	4334	4335
	4336	4337
	4338	4339
	4340	4341
	4342	4343
	4344	4345
	4346	4347
	4348	4349
	4350	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	4351	4391
	4352	
	4353	
	4354	
	4355	
	4356	
	4357	
	4358	
	4359	
	4360	
	4361	
	4362	
	4363	
	4364	
	4365	
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	4369	
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	4371	
	4372	
	4373	
	4374	
	4375	
	4376	
	4377	
	4378	
	4379	
	4380	
	4381	
	4382	
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	4385	
	4386	
	4387	
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Trt.	Bl. No	nb
PPD	4392	4432
	4393	
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	4399	
	4400	
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Trt.	Bl. No	nb
PPD	4433	4473
	4434	
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Trt.	Bl. No	nb
PPD	4474	4514
	4475	
	4476	
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Trt.	Bl. No	nb
PPD	4515	4555
	4516	
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Trt.	Bl. No	nb
PPD	4556	4596
	4557	
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Trt.	Bl. No	nb
PPD	4597	4637
	4598	
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	4600	
	4601	
	4602	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	4638	4678
PPD	4679	4719
PPD	4720	4760
PPD	4761	4801
PPD	4802	4842
PPD	4843	4883
PPD	4884	4924

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	4925	
	4926	
	4927	
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	4951	
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	4955	
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Trt.	Bl. No	nb
PPD	4966	
	4967	
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	4990	
	4991	
	4992	
	4993	
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	4997	
	4998	
	4999	
	5000	
	5001	
	5002	
	5003	
	5004	
	5005	
	5006	

Trt.	Bl. No	nb
PPD	5007	
	5008	
	5009	
	5010	
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Trt.	Bl. No	nb
PPD	5048	
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Trt.	Bl. No	nb
PPD	5089	
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Trt.	Bl. No	nb
PPD	5130	
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Trt.	Bl. No	nb
PPD	5171	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

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	5212		PPD	5253		PPD	5294		PPD	5335		PPD	5376		PPD	5417		PPD	5458	
	5213			5254			5295			5336			5377			5418			5459	
	5214			5255			5296			5337			5378			5419			5460	
	5215			5256			5297			5338			5379			5420			5461	
	5216			5257			5298			5339			5380			5421			5462	
	5217			5258			5299			5340			5381			5422			5463	
	5218			5259			5300			5341			5382			5423			5464	
	5219			5260			5301			5342			5383			5424			5465	
	5220			5261			5302			5343			5384			5425			5466	
	5221			5262			5303			5344			5385			5426			5467	
	5222			5263			5304			5345			5386			5427			5468	
	5223			5264			5305			5346			5387			5428			5469	
	5224			5265			5306			5347			5388			5429			5470	
	5225			5266			5307			5348			5389			5430			5471	
	5226			5267			5308			5349			5390			5431			5472	
	5227			5268			5309			5350			5391			5432			5473	
	5228			5269			5310			5351			5392			5433			5474	
	5229			5270			5311			5352			5393			5434			5475	
	5230			5271			5312			5353			5394			5435			5476	
	5231			5272			5313			5354			5395			5436			5477	
	5232			5273			5314			5355			5396			5437			5478	
	5233			5274			5315			5356			5397			5438			5479	
	5234			5275			5316			5357			5398			5439			5480	
	5235			5276			5317			5358			5399			5440			5481	
	5236			5277			5318			5359			5400			5441			5482	
	5237			5278			5319			5360			5401			5442			5483	
	5238			5279			5320			5361			5402			5443			5484	
	5239			5280			5321			5362			5403			5444			5485	
	5240			5281			5322			5363			5404			5445			5486	
	5241			5282			5323			5364			5405			5446			5487	
	5242			5283			5324			5365			5406			5447			5488	
	5243			5284			5325			5366			5407			5448			5489	
	5244			5285			5326			5367			5408			5449			5490	
	5245			5286			5327			5368			5409			5450			5491	
	5246			5287			5328			5369			5410			5451			5492	
	5247			5288			5329			5370			5411			5452			5493	
	5248			5289			5330			5371			5412			5453			5494	
	5249			5290			5331			5372			5413			5454			5495	
	5250			5291			5332			5373			5414			5455			5496	
	5251			5292			5333			5374			5415			5456			5497	
	5252			5293			5334			5375			5416			5457			5498	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	5499	5539
PPD	5540	5580
PPD	5581	5621
PPD	5622	5662
PPD	5663	5703
PPD	5704	5744
PPD	5745	5785

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	5786	5826
PPD	5827	5867
PPD	5868	5908
PPD	5909	5949
PPD	5950	5990
PPD	5991	6031
PPD	6032	6072

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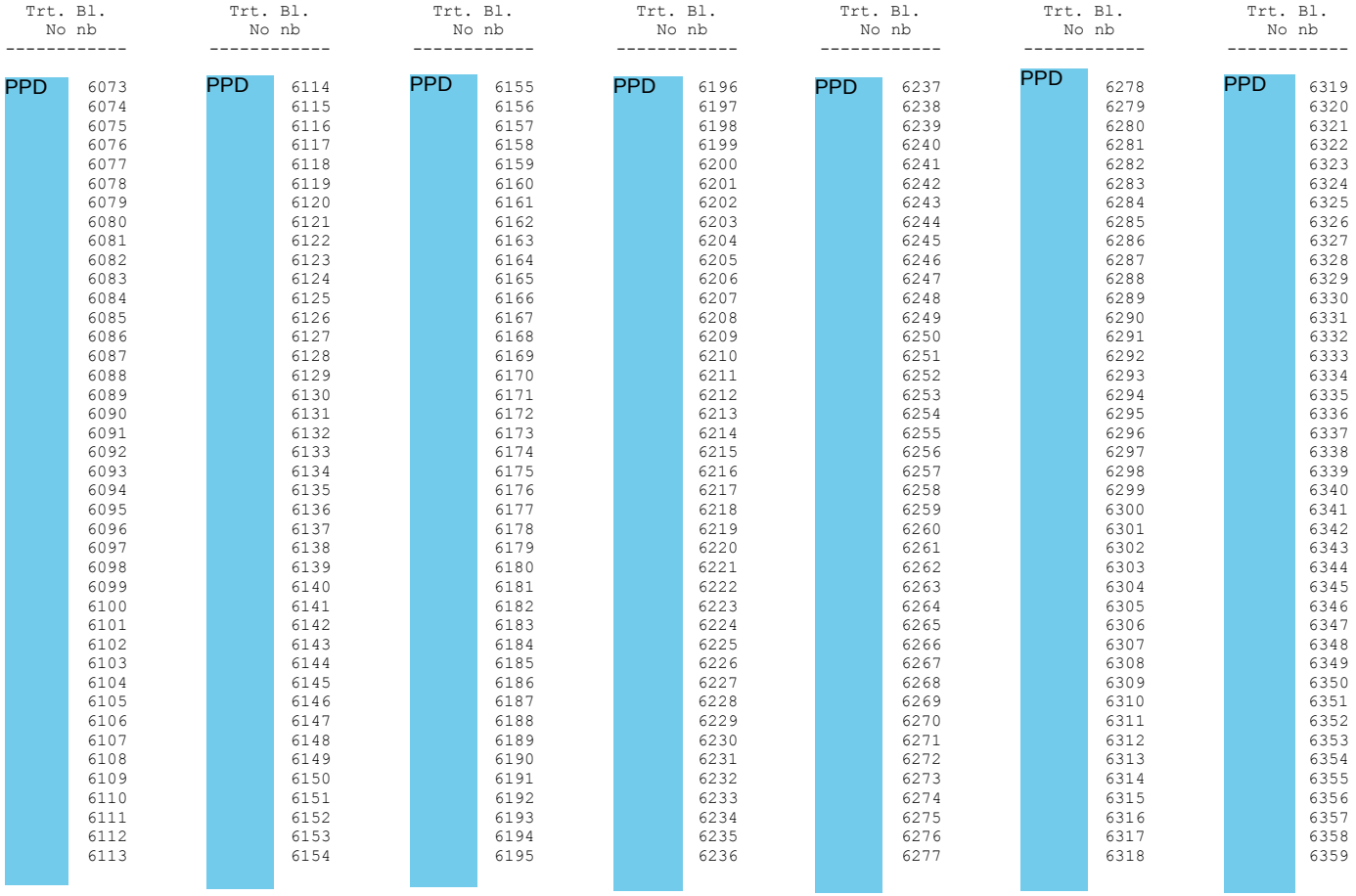
Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix



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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	6360	6400
	6361	6401
	6362	6402
	6363	6403
	6364	6404
	6365	6405
	6366	6406
	6367	6407
	6368	6408
	6369	6409
	6370	6410
	6371	6411
	6372	6412
	6373	6413
	6374	6414
	6375	6415
	6376	6416
	6377	6417
	6378	6418
	6379	6419
	6380	6420
	6381	6421
	6382	6422
	6383	6423
	6384	6424
	6385	6425
	6386	6426
	6387	6427
	6388	6428
	6389	6429
	6390	6430
	6391	6431
	6392	6432
	6393	6433
	6394	6434
	6395	6435
	6396	6436
	6397	6437
	6398	6438
	6399	6439
	6400	6440
		6441

Trt.	Bl. No	nb
PPD	6401	6441
	6402	6442
	6403	6443
	6404	6444
	6405	6445
	6406	6446
	6407	6447
	6408	6448
	6409	6449
	6410	6450
	6411	6451
	6412	6452
	6413	6453
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	6416	6456
	6417	6457
	6418	6458
	6419	6459
	6420	6460
	6421	6461
	6422	6462
	6423	6463
	6424	6464
	6425	6465
	6426	6466
	6427	6467
	6428	6468
	6429	6469
	6430	6470
	6431	6471
	6432	6472
	6433	6473
	6434	6474
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	6436	6476
	6437	6477
	6438	6478
	6439	6479
	6440	6480
	6441	6481
		6482

Trt.	Bl. No	nb
PPD	6442	6482
	6443	6483
	6444	6484
	6445	6485
	6446	6486
	6447	6487
	6448	6488
	6449	6489
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	6477	6517
	6478	6518
	6479	6519
	6480	6520
	6481	6521
	6482	6522
		6523

Trt.	Bl. No	nb
PPD	6483	6523
	6484	6524
	6485	6525
	6486	6526
	6487	6527
	6488	6528
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	6518	6558
	6519	6559
	6520	6560
	6521	6561
	6522	6562
	6523	6563
		6564

Trt.	Bl. No	nb
PPD	6524	6564
	6525	6565
	6526	6566
	6527	6567
	6528	6568
	6529	6569
	6530	6570
	6531	6571
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	6552	6592
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	6555	6595
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	6557	6597
	6558	6598
	6559	6599
	6560	6600
	6561	6601
	6562	6602
	6563	6603
	6564	6604
		6605

Trt.	Bl. No	nb
PPD	6565	6605
	6566	6606
	6567	6607
	6568	6608
	6569	6609
	6570	6610
	6571	6611
	6572	6612
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	6598	6638
	6599	6639
	6600	6640
	6601	6641
	6602	6642
	6603	6643
	6604	6644
	6605	6645
		6646

Trt.	Bl. No	nb
PPD	6606	6646
	6607	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	6647	6687
	6648	6688
	6649	6689
	6650	6690
	6651	6691
	6652	6692
	6653	6693
	6654	6694
	6655	6695
	6656	6696
	6657	6697
	6658	6698
	6659	6699
	6660	6700
	6661	6701
	6662	6702
	6663	6703
	6664	6704
	6665	6705
	6666	6706
	6667	6707
	6668	6708
	6669	6709
	6670	6710
	6671	6711
	6672	6712
	6673	6713
	6674	6714
	6675	6715
	6676	6716
	6677	6717
	6678	6718
	6679	6719
	6680	6720
	6681	6721
	6682	6722
	6683	6723
	6684	6724
	6685	6725
	6686	6726
	6687	6727
	6688	6728
PPD	6689	6729
	6690	6730
	6691	6731
	6692	6732
	6693	6733
	6694	6734
	6695	6735
	6696	6736
	6697	6737
	6698	6738
	6699	6739
	6700	6740
	6701	6741
	6702	6742
	6703	6743
	6704	6744
	6705	6745
	6706	6746
	6707	6747
	6708	6748
	6709	6749
	6710	6750
	6711	6751
	6712	6752
	6713	6753
	6714	6754
	6715	6755
	6716	6756
	6717	6757
	6718	6758
	6719	6759
	6720	6760
	6721	6761
	6722	6762
	6723	6763
	6724	6764
	6725	6765
	6726	6766
	6727	6767
	6728	6768
	6729	6769
PPD	6730	6770
	6731	6771
	6732	6772
	6733	6773
	6734	6774
	6735	6775
	6736	6776
	6737	6777
	6738	6778
	6739	6779
	6740	6780
	6741	6781
	6742	6782
	6743	6783
	6744	6784
	6745	6785
	6746	6786
	6747	6787
	6748	6788
	6749	6789
	6750	6790
	6751	6791
	6752	6792
	6753	6793
	6754	6794
	6755	6795
	6756	6796
	6757	6797
	6758	6798
	6759	6799
	6760	6800
	6761	6801
	6762	6802
	6763	6803
	6764	6804
	6765	6805
	6766	6806
	6767	6807
	6768	6808
	6769	6809
	6770	6810
PPD	6771	6811
	6772	6812
	6773	6813
	6774	6814
	6775	6815
	6776	6816
	6777	6817
	6778	6818
	6779	6819
	6780	6820
	6781	6821
	6782	6822
	6783	6823
	6784	6824
	6785	6825
	6786	6826
	6787	6827
	6788	6828
	6789	6829
	6790	6830
	6791	6831
	6792	6832
	6793	6833
	6794	6834
	6795	6835
	6796	6836
	6797	6837
	6798	6838
	6799	6839
	6800	6840
	6801	6841
	6802	6842
	6803	6843
	6804	6844
	6805	6845
	6806	6846
	6807	6847
	6808	6848
	6809	6849
	6810	6850
	6811	6851
PPD	6812	6852
	6813	6853
	6814	6854
	6815	6855
	6816	6856
	6817	6857
	6818	6858
	6819	6859
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	6823	6863
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	6826	6866
	6827	6867
	6828	6868
	6829	6869
	6830	6870
	6831	6871
	6832	6872
	6833	6873
	6834	6874
	6835	6875
	6836	6876
	6837	6877
	6838	6878
	6839	6879
	6840	6880
	6841	6881
	6842	6882
	6843	6883
	6844	6884
	6845	6885
	6846	6886
	6847	6887
	6848	6888
	6849	6889
	6850	6890
	6851	6891
	6852	6892
PPD	6853	6893
	6854	6894
	6855	6895
	6856	6896
	6857	6897
	6858	6898
	6859	6899
	6860	6900
	6861	6901
	6862	6902
	6863	6903
	6864	6904
	6865	6905
	6866	6906
	6867	6907
	6868	6908
	6869	6909
	6870	6910
	6871	6911
	6872	6912
	6873	6913
	6874	6914
	6875	6915
	6876	6916
	6877	6917
	6878	6918
	6879	6919
	6880	6920
	6881	6921
	6882	6922
	6883	6923
	6884	6924
	6885	6925
	6886	6926
	6887	6927
	6888	6928
	6889	6929
	6890	6930
	6891	6931
	6892	6932
	6893	6933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	6934	6974
PPD	6975	7015
PPD	7016	7056
PPD	7057	7097
PPD	7098	7138
PPD	7139	7179
PPD	7180	7220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1	7221
	2	7222
	3	7223
	4	7224
	5	7225
	6	7226
	7	7227
	8	7228
	9	7229
	10	7230
	11	7231
	12	7232
	13	7233
	14	7234
	15	7235
	16	7236
	17	7237
	18	7238
	19	7239
	20	7240
	21	7241
	22	7242
	23	7243
	24	7244
	25	7245
	26	7246
	27	7247
	28	7248
	29	7249
	30	7250
	31	7251
	32	7252
	33	7253
	34	7254
	35	7255
	36	7256
	37	7257
	38	7258
	39	7259
	40	7260
	41	7261
PPD	1	7262
	2	7263
	3	7264
	4	7265
	5	7266
	6	7267
	7	7268
	8	7269
	9	7270
	10	7271
	11	7272
	12	7273
	13	7274
	14	7275
	15	7276
	16	7277
	17	7278
	18	7279
	19	7280
	20	7281
	21	7282
	22	7283
	23	7284
	24	7285
	25	7286
	26	7287
	27	7288
	28	7289
	29	7290
	30	7291
	31	7292
	32	7293
	33	7294
	34	7295
	35	7296
	36	7297
	37	7298
	38	7299
	39	7300
	40	7301
	41	7302
PPD	1	7303
	2	7304
	3	7305
	4	7306
	5	7307
	6	7308
	7	7309
	8	7310
	9	7311
	10	7312
	11	7313
	12	7314
	13	7315
	14	7316
	15	7317
	16	7318
	17	7319
	18	7320
	19	7321
	20	7322
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	22	7324
	23	7325
	24	7326
	25	7327
	26	7328
	27	7329
	28	7330
	29	7331
	30	7332
	31	7333
	32	7334
	33	7335
	34	7336
	35	7337
	36	7338
	37	7339
	38	7340
	39	7341
	40	7342
	41	7343
PPD	1	7344
	2	7345
	3	7346
	4	7347
	5	7348
	6	7349
	7	7350
	8	7351
	9	7352
	10	7353
	11	7354
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	13	7356
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	15	7358
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	17	7360
	18	7361
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	21	7364
	22	7365
	23	7366
	24	7367
	25	7368
	26	7369
	27	7370
	28	7371
	29	7372
	30	7373
	31	7374
	32	7375
	33	7376
	34	7377
	35	7378
	36	7379
	37	7380
	38	7381
	39	7382
	40	7383
	41	7384
PPD	1	7385
	2	7386
	3	7387
	4	7388
	5	7389
	6	7390
	7	7391
	8	7392
	9	7393
	10	7394
	11	7395
	12	7396
	13	7397
	14	7398
	15	7399
	16	7400
	17	7401
	18	7402
	19	7403
	20	7404
	21	7405
	22	7406
	23	7407
	24	7408
	25	7409
	26	7410
	27	7411
	28	7412
	29	7413
	30	7414
	31	7415
	32	7416
	33	7417
	34	7418
	35	7419
	36	7420
	37	7421
	38	7422
	39	7423
	40	7424
	41	7425
PPD	1	7426
	2	7427
	3	7428
	4	7429
	5	7430
	6	7431
	7	7432
	8	7433
	9	7434
	10	7435
	11	7436
	12	7437
	13	7438
	14	7439
	15	7440
	16	7441
	17	7442
	18	7443
	19	7444
	20	7445
	21	7446
	22	7447
	23	7448
	24	7449
	25	7450
	26	7451
	27	7452
	28	7453
	29	7454
	30	7455
	31	7456
	32	7457
	33	7458
	34	7459
	35	7460
	36	7461
	37	7462
	38	7463
	39	7464
	40	7465
	41	7466
PPD	1	7467
	2	7468
	3	7469
	4	7470
	5	7471
	6	7472
	7	7473
	8	7474
	9	7475
	10	7476
	11	7477
	12	7478
	13	7479
	14	7480
	15	7481
	16	7482
	17	7483
	18	7484
	19	7485
	20	7486
	21	7487
	22	7488
	23	7489
	24	7490
	25	7491
	26	7492
	27	7493
	28	7494
	29	7495
	30	7496
	31	7497
	32	7498
	33	7499
	34	7500
	35	7501
	36	7502
	37	7503
	38	7504
	39	7505
	40	7506
	41	7507

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1	7508
	2	7509
	3	7510
	4	7511
	5	7512
	6	7513
	7	7514
	8	7515
	9	7516
	10	7517
	11	7518
	12	7519
	13	7520
	14	7521
	15	7522
	16	7523
	17	7524
	18	7525
	19	7526
	20	7527
	21	7528
	22	7529
	23	7530
	24	7531
	25	7532
	26	7533
	27	7534
	28	7535
	29	7536
	30	7537
	31	7538
	32	7539
	33	7540
	34	7541
	35	7542
	36	7543
	37	7544
	38	7545
	39	7546
	40	7547
	41	7548

Trt.	Bl. No	nb
PPD	1	7549
	2	7550
	3	7551
	4	7552
	5	7553
	6	7554
	7	7555
	8	7556
	9	7557
	10	7558
	11	7559
	12	7560
	13	7561
	14	7562
	15	7563
	16	7564
	17	7565
	18	7566
	19	7567
	20	7568
	21	7569
	22	7570
	23	7571
	24	7572
	25	7573
	26	7574
	27	7575
	28	7576
	29	7577
	30	7578
	31	7579
	32	7580
	33	7581
	34	7582
	35	7583
	36	7584
	37	7585
	38	7586
	39	7587
	40	7588
	41	7589

Trt.	Bl. No	nb
PPD	1	7590
	2	7591
	3	7592
	4	7593
	5	7594
	6	7595
	7	7596
	8	7597
	9	7598
	10	7599
	11	7600
	12	7601
	13	7602
	14	7603
	15	7604
	16	7605
	17	7606
	18	7607
	19	7608
	20	7609
	21	7610
	22	7611
	23	7612
	24	7613
	25	7614
	26	7615
	27	7616
	28	7617
	29	7618
	30	7619
	31	7620
	32	7621
	33	7622
	34	7623
	35	7624
	36	7625
	37	7626
	38	7627
	39	7628
	40	7629
	41	7630

Trt.	Bl. No	nb
PPD	1	7631
	2	7632
	3	7633
	4	7634
	5	7635
	6	7636
	7	7637
	8	7638
	9	7639
	10	7640
	11	7641
	12	7642
	13	7643
	14	7644
	15	7645
	16	7646
	17	7647
	18	7648
	19	7649
	20	7650
	21	7651
	22	7652
	23	7653
	24	7654
	25	7655
	26	7656
	27	7657
	28	7658
	29	7659
	30	7660
	31	7661
	32	7662
	33	7663
	34	7664
	35	7665
	36	7666
	37	7667
	38	7668
	39	7669
	40	7670
	41	7671

Trt.	Bl. No	nb
PPD	1	7672
	2	7673
	3	7674
	4	7675
	5	7676
	6	7677
	7	7678
	8	7679
	9	7680
	10	7681
	11	7682
	12	7683
	13	7684
	14	7685
	15	7686
	16	7687
	17	7688
	18	7689
	19	7690
	20	7691
	21	7692
	22	7693
	23	7694
	24	7695
	25	7696
	26	7697
	27	7698
	28	7699
	29	7700
	30	7701
	31	7702
	32	7703
	33	7704
	34	7705
	35	7706
	36	7707
	37	7708
	38	7709
	39	7710
	40	7711
	41	7712

Trt.	Bl. No	nb
PPD	1	7713
	2	7714
	3	7715
	4	7716
	5	7717
	6	7718
	7	7719
	8	7720
	9	7721
	10	7722
	11	7723
	12	7724
	13	7725
	14	7726
	15	7727
	16	7728
	17	7729
	18	7730
	19	7731
	20	7732
	21	7733
	22	7734
	23	7735
	24	7736
	25	7737
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	28	7740
	29	7741
	30	7742
	31	7743
	32	7744
	33	7745
	34	7746
	35	7747
	36	7748
	37	7749
	38	7750
	39	7751
	40	7752
	41	7753

Trt.	Bl. No	nb
PPD	1	7754
	2	7755
	3	7756
	4	7757
	5	7758
	6	7759
	7	7760
	8	7761
	9	7762
	10	7763
	11	7764
	12	7765
	13	7766
	14	7767
	15	7768
	16	7769
	17	7770
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	21	7774
	22	7775
	23	7776
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	25	7778
	26	7779
	27	7780
	28	7781
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	30	7783
	31	7784
	32	7785
	33	7786
	34	7787
	35	7788
	36	7789
	37	7790
	38	7791
	39	7792
	40	7793
	41	7794

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	1	7795
	2	7796
	3	7797
	4	7798
	5	7799
	6	7800
	7	7801
	8	7802
	9	7803
	10	7804
	11	7805
	12	7806
	13	7807
	14	7808
	15	7809
	16	7810
	17	7811
	18	7812
	19	7813
	20	7814
	21	7815
	22	7816
	23	7817
	24	7818
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	28	7822
	29	7823
	30	7824
	31	7825
	32	7826
	33	7827
	34	7828
	35	7829
	36	7830
	37	7831
	38	7832
	39	7833
	40	7834
	41	7835

Trt.	Bl. No	nb
PPD	1	7836
	2	7837
	3	7838
	4	7839
	5	7840
	6	7841
	7	7842
	8	7843
	9	7844
	10	7845
	11	7846
	12	7847
	13	7848
	14	7849
	15	7850
	16	7851
	17	7852
	18	7853
	19	7854
	20	7855
	21	7856
	22	7857
	23	7858
	24	7859
	25	7860
	26	7861
	27	7862
	28	7863
	29	7864
	30	7865
	31	7866
	32	7867
	33	7868
	34	7869
	35	7870
	36	7871
	37	7872
	38	7873
	39	7874
	40	7875
	41	7876

Trt.	Bl. No	nb
PPD	1	7877
	2	7878
	3	7879
	4	7880
	5	7881
	6	7882
	7	7883
	8	7884
	9	7885
	10	7886
	11	7887
	12	7888
	13	7889
	14	7890
	15	7891
	16	7892
	17	7893
	18	7894
	19	7895
	20	7896
	21	7897
	22	7898
	23	7899
	24	7900
	25	7901
	26	7902
	27	7903
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	31	7907
	32	7908
	33	7909
	34	7910
	35	7911
	36	7912
	37	7913
	38	7914
	39	7915
	40	7916
	41	7917

Trt.	Bl. No	nb
PPD	1	7918
	2	7919
	3	7920
	4	7921
	5	7922
	6	7923
	7	7924
	8	7925
	9	7926
	10	7927
	11	7928
	12	7929
	13	7930
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	32	7949
	33	7950
	34	7951
	35	7952
	36	7953
	37	7954
	38	7955
	39	7956
	40	7957
	41	7958

Trt.	Bl. No	nb
PPD	1	7959
	2	7960
	3	7961
	4	7962
	5	7963
	6	7964
	7	7965
	8	7966
	9	7967
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	31	7989
	32	7990
	33	7991
	34	7992
	35	7993
	36	7994
	37	7995
	38	7996
	39	7997
	40	7998
	41	7999

Trt.	Bl. No	nb
PPD	1	8000
	2	8001
	3	8002
	4	8003
	5	8004
	6	8005
	7	8006
	8	8007
	9	8008
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	32	8031
	33	8032
	34	8033
	35	8034
	36	8035
	37	8036
	38	8037
	39	8038
	40	8039
	41	8040

Trt.	Bl. No	nb
PPD	1	8041
	2	8042
	3	8043
	4	8044
	5	8045
	6	8046
	7	8047
	8	8048
	9	8049
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	32	8072
	33	8073
	34	8074
	35	8075
	36	8076
	37	8077
	38	8078
	39	8079
	40	8080
	41	8081

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	8082	8122
PPD	8123	8163
PPD	8164	8204
PPD	8205	8245
PPD	8246	8286
PPD	8287	8327
PPD	8328	8368

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	8369	8409
PPD	8410	8450
PPD	8451	8491
PPD	8492	8532
PPD	8533	8573
PPD	8574	8614
PPD	8615	8655

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	8656	8696
PPD	8697	8737
PPD	8738	8778
PPD	8779	8819
PPD	8820	8860
PPD	8861	8901
PPD	8902	8942

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	8943	8983
PPD	8984	9024
PPD	9025	9065
PPD	9066	9106
PPD	9107	9147
PPD	9148	9188
PPD	9189	9229

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

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	9230		PPD	9271		PPD	9312		PPD	9353		PPD	9394		PPD	9435		PPD	9476	
	9231			9272			9313			9354			9395			9436			9477	
	9232			9273			9314			9355			9396			9437			9478	
	9233			9274			9315			9356			9397			9438			9479	
	9234			9275			9316			9357			9398			9439			9480	
	9235			9276			9317			9358			9399			9440			9481	
	9236			9277			9318			9359			9400			9441			9482	
	9237			9278			9319			9360			9401			9442			9483	
	9238			9279			9320			9361			9402			9443			9484	
	9239			9280			9321			9362			9403			9444			9485	
	9240			9281			9322			9363			9404			9445			9486	
	9241			9282			9323			9364			9405			9446			9487	
	9242			9283			9324			9365			9406			9447			9488	
	9243			9284			9325			9366			9407			9448			9489	
	9244			9285			9326			9367			9408			9449			9490	
	9245			9286			9327			9368			9409			9450			9491	
	9246			9287			9328			9369			9410			9451			9492	
	9247			9288			9329			9370			9411			9452			9493	
	9248			9289			9330			9371			9412			9453			9494	
	9249			9290			9331			9372			9413			9454			9495	
	9250			9291			9332			9373			9414			9455			9496	
	9251			9292			9333			9374			9415			9456			9497	
	9252			9293			9334			9375			9416			9457			9498	
	9253			9294			9335			9376			9417			9458			9499	
	9254			9295			9336			9377			9418			9459			9500	
	9255			9296			9337			9378			9419			9460			9501	
	9256			9297			9338			9379			9420			9461			9502	
	9257			9298			9339			9380			9421			9462			9503	
	9258			9299			9340			9381			9422			9463			9504	
	9259			9300			9341			9382			9423			9464			9505	
	9260			9301			9342			9383			9424			9465			9506	
	9261			9302			9343			9384			9425			9466			9507	
	9262			9303			9344			9385			9426			9467			9508	
	9263			9304			9345			9386			9427			9468			9509	
	9264			9305			9346			9387			9428			9469			9510	
	9265			9306			9347			9388			9429			9470			9511	
	9266			9307			9348			9389			9430			9471			9512	
	9267			9308			9349			9390			9431			9472			9513	
	9268			9309			9350			9391			9432			9473			9514	
	9269			9310			9351			9392			9433			9474			9515	
	9270			9311			9352			9393			9434			9475			9516	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	9517	9557
PPD	9558	9598
PPD	9599	9639
PPD	9640	9680
PPD	9681	9721
PPD	9722	9762
PPD	9763	9803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	9804	9844
PPD	9845	9885
PPD	9886	9926
PPD	9927	9967
PPD	9968	10008
PPD	10009	10049
PPD	10050	10090

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	10091	10091
	10092	10092
	10093	10093
	10094	10094
	10095	10095
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	10099	10099
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	10131	10131
PPD	10132	10132
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PPD	10173	10173
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PPD	10214	10214
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	10254	10254
PPD	10255	10255
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	10260	10260
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PPD	10296	10296
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	10301	10301
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PPD	10337	10337
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	10378	10418
PPD	10419	10459
PPD	10460	10500
PPD	10501	10541
PPD	10542	10582
PPD	10583	10623
PPD	10624	10664

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Rotarix

Trt.	Bl. No	nb
PPD	10665	
	10666	
	10667	
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	10680	
	10681	
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	10685	
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	10688	
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	10699	
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Trt.	Bl. No	nb
PPD	10706	
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Trt.	Bl. No	nb
PPD	10747	
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Trt.	Bl. No	nb
PPD	10788	
	10789	
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Trt.	Bl. No	nb
PPD	10829	
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Trt.	Bl. No	nb
PPD	10870	
	10871	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	20907	
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PPD	20948	
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PPD	20989	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	21194	
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Trt.	Bl. No	nb
PPD	21235	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	21317	
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Trt.	Bl. No	nb
PPD	21358	
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Trt.	Bl. No	nb
PPD	21399	
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Trt.	Bl. No	nb
PPD	21440	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	21522	
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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	21645	
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Trt.	Bl. No	nb
PPD	21686	
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Trt.	Bl. No	nb
PPD	21727	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	21768	21808
PPD	21809	21849
PPD	21850	21890
PPD	21891	21931
PPD	21932	21972
PPD	21973	22013
PPD	22014	22054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	22055
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	35	22089
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	37	22091
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	39	22093
	40	22094
	41	22095

Trt.	Bl. No	nb
PPD	1	22096
	2	22097
	3	22098
	4	22099
	5	22100
	6	22101
	7	22102
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	39	22134
	40	22135
	41	22136

Trt.	Bl. No	nb
PPD	1	22137
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	3	22139
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	37	22173
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	39	22175
	40	22176
	41	22177

Trt.	Bl. No	nb
PPD	1	22178
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	3	22180
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	33	22210
	34	22211
	35	22212
	36	22213
	37	22214
	38	22215
	39	22216
	40	22217
	41	22218

Trt.	Bl. No	nb
PPD	1	22219
	2	22220
	3	22221
	4	22222
	5	22223
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	13	22231
	14	22232
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	36	22254
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	39	22257
	40	22258
	41	22259

Trt.	Bl. No	nb
PPD	1	22260
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	39	22298
	40	22299
	41	22300

Trt.	Bl. No	nb
PPD	1	22301
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
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	31	22372
	32	22373
	33	22374
	34	22375
	35	22376
	36	22377
	37	22378
	38	22379
	39	22380
	40	22381
	41	22382

Trt.	Bl. No	nb
PPD	1	22383
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	5	22387
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Trt.	Bl. No	nb
PPD	1	22424
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Trt.	Bl. No	nb
PPD	1	22465
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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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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	22629	
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Trt.	Bl. No	nb
PPD	22670	
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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	22793	
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Trt.	Bl. No	nb
PPD	22834	
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Trt.	Bl. No	nb
PPD	22875	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	22916	22956
PPD	22957	22997
PPD	22998	23038
PPD	23039	23079
PPD	23080	23120
PPD	23121	23161
PPD	23162	23202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	23244	
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Trt.	Bl. No	nb
PPD	23285	
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Trt.	Bl. No	nb
PPD	23326	
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Trt.	Bl. No	nb
PPD	23367	
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Trt.	Bl. No	nb
PPD	23408	
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Trt.	Bl. No	nb
PPD	23449	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	23531	
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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	23654	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	23859	
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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	24023	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	24146	24187
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Trt.	Bl. No	nb
PPD	24228	24269
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	24256	24297
	24257	24298
	24258	24299
	24259	24300
	24260	24301
	24261	24302
	24262	24303
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	24264	24305
	24265	24306
	24266	24307
	24267	24308
	24268	24309

Trt.	Bl. No	nb
PPD	24310	24350
	24311	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	24351	
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Trt.	Bl. No	nb
PPD	24392	
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	24399	
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Trt.	Bl. No	nb
PPD	24433	
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Trt.	Bl. No	nb
PPD	24474	
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Trt.	Bl. No	nb
PPD	24515	
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Trt.	Bl. No	nb
PPD	24556	
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Trt.	Bl. No	nb
PPD	24597	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	24638	24678
PPD	24679	24719
PPD	24720	24760
PPD	24761	24801
PPD	24802	24842
PPD	24843	24883
PPD	24884	24924

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	24925	24965
PPD	24966	25006
PPD	25007	25047
PPD	25048	25088
PPD	25089	25129
PPD	25130	25170
PPD	25171	25211

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	25212
	2	25213
	3	25214
	4	25215
	5	25216
	6	25217
	7	25218
	8	25219
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	13	25224
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	15	25226
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	19	25230
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	30	25241
	31	25242
	32	25243
	33	25244
	34	25245
	35	25246
	36	25247
	37	25248
	38	25249
	39	25250
	40	25251
	41	25252

Trt.	Bl. No	nb
PPD	1	25253
	2	25254
	3	25255
	4	25256
	5	25257
	6	25258
	7	25259
	8	25260
	9	25261
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	37	25289
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	39	25291
	40	25292
	41	25293

Trt.	Bl. No	nb
PPD	1	25294
	2	25295
	3	25296
	4	25297
	5	25298
	6	25299
	7	25300
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	37	25330
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	39	25332
	40	25333
	41	25334

Trt.	Bl. No	nb
PPD	1	25335
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	5	25339
	6	25340
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	39	25373
	40	25374
	41	25375

Trt.	Bl. No	nb
PPD	1	25376
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	4	25379
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	40	25415
	41	25416

Trt.	Bl. No	nb
PPD	1	25417
	2	25418
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	36	25452
	37	25453
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	39	25455
	40	25456
	41	25457

Trt.	Bl. No	nb
PPD	1	25458
	2	25459
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	5	25462
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	25499	
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Trt.	Bl. No	nb
PPD	25540	
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Trt.	Bl. No	nb
PPD	25581	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	25663	
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Trt.	Bl. No	nb
PPD	25704	
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Trt.	Bl. No	nb
PPD	25745	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	25786
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	41	25826

Trt.	Bl. No	nb
PPD	1	25827
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	39	25865
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	41	25867

Trt.	Bl. No	nb
PPD	1	25868
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Trt.	Bl. No	nb
PPD	1	25909
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Trt.	Bl. No	nb
PPD	1	25950
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Trt.	Bl. No	nb
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	12	26002
	13	26003
	14	26004
	15	26005
	16	26006
	17	26007
	18	26008
	19	26009
	20	26010
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	40	26030
	41	26031

Trt.	Bl. No	nb
PPD	1	26032
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	3	26034
	4	26035
	5	26036
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	39	26070
	40	26071
	41	26072

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	26073	26114
	26074	26115
	26075	26116
	26076	26117
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	26108	26149
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	26111	26152
	26112	26153
	26113	26154

Trt.	Bl. No	nb
PPD	26155	26196
	26156	26197
	26157	26198
	26158	26199
	26159	26200
	26160	26201
	26161	26202
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	26172	26213
	26173	26214
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	26181	26222
	26182	26223
	26183	26224
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	26186	26227
	26187	26228
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	26189	26230
	26190	26231
	26191	26232
	26192	26233
	26193	26234
	26194	26235
	26195	26236

Trt.	Bl. No	nb
PPD	26237	26278
	26238	26279
	26239	26280
	26240	26281
	26241	26282
	26242	26283
	26243	26284
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	26268	26309
	26269	26310
	26270	26311
	26271	26312
	26272	26313
	26273	26314
	26274	26315
	26275	26316
	26276	26317
	26277	26318

Trt.	Bl. No	nb
PPD	26319	
	26320	
	26321	
	26322	
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	26360
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	34	26393
	35	26394
	36	26395
	37	26396
	38	26397
	39	26398
	40	26399
	41	26400

Trt.	Bl. No	nb
PPD	1	26401
	2	26402
	3	26403
	4	26404
	5	26405
	6	26406
	7	26407
	8	26408
	9	26409
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	40	26440
	41	26441

Trt.	Bl. No	nb
PPD	1	26442
	2	26443
	3	26444
	4	26445
	5	26446
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	32	26473
	33	26474
	34	26475
	35	26476
	36	26477
	37	26478
	38	26479
	39	26480
	40	26481
	41	26482

Trt.	Bl. No	nb
PPD	1	26483
	2	26484
	3	26485
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	7	26489
	8	26490
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	16	26498
	17	26499
	18	26500
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	20	26502
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	37	26519
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	39	26521
	40	26522
	41	26523

Trt.	Bl. No	nb
PPD	1	26524
	2	26525
	3	26526
	4	26527
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	36	26559
	37	26560
	38	26561
	39	26562
	40	26563
	41	26564

Trt.	Bl. No	nb
PPD	1	26565
	2	26566
	3	26567
	4	26568
	5	26569
	6	26570
	7	26571
	8	26572
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	33	26597
	34	26598
	35	26599
	36	26600
	37	26601
	38	26602
	39	26603
	40	26604
	41	26605

Trt.	Bl. No	nb
PPD	1	26606
	2	26607
	3	26608
	4	26609
	5	26610
	6	26611
	7	26612
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	41	26646

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	26647
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	29	26675
	30	26676
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	32	26678
	33	26679
	34	26680
	35	26681
	36	26682
	37	26683
	38	26684
	39	26685
	40	26686
	41	26687
PPD	42	26688
	43	26689
	44	26690
	45	26691
	46	26692
	47	26693
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	82	26728
PPD	83	26729
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	117	26763
	118	26764
	119	26765
	120	26766
	121	26767
	122	26768
	123	26769
PPD	124	26770
	125	26771
	126	26772
	127	26773
	128	26774
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	161	26807
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	163	26809
	164	26810
PPD	165	26811
	166	26812
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	169	26815
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	199	26845
	200	26846
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	204	26850
	205	26851
PPD	206	26852
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	208	26854
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	243	26889
	244	26890
	245	26891
	246	26892
PPD	247	26893
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	249	26895
	250	26896
	251	26897
	252	26898
	253	26899
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	287	26933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	26934	26974
PPD	26975	27015
PPD	27016	27056
PPD	27057	27097
PPD	27098	27138
PPD	27139	27179
PPD	27180	27220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	27221	27261
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	27223	27263
	27224	27264
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	27227	27267
	27228	27268
	27229	27269
	27230	27270
	27231	27271
	27232	27272
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	27234	27274
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	27238	27278
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	27240	27280
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	27256	27296
	27257	27297
	27258	27298
	27259	27299
	27260	27300
	27261	27301
PPD	27262	27302
	27263	27303
	27264	27304
	27265	27305
	27266	27306
	27267	27307
	27268	27308
	27269	27309
	27270	27310
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	27272	27312
	27273	27313
	27274	27314
	27275	27315
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	27277	27317
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	27296	27336
	27297	27337
	27298	27338
	27299	27339
	27300	27340
	27301	27341
	27302	27342
PPD	27303	27343
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	27305	27345
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PPD	27344	27384
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	27409	27449
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	27418	27458
	27419	27459
	27420	27460
	27421	27461
	27422	27462
	27423	27463
	27424	27464
	27425	27465
PPD	27426	27466
	27427	27467
	27428	27468
	27429	27469
	27430	27470
	27431	27471
	27432	27472
	27433	27473
	27434	27474
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	27458	27498
	27459	27499
	27460	27500
	27461	27501
	27462	27502
	27463	27503
	27464	27504
	27465	27505
	27466	27506
PPD	27467	27507
	27468	
	27469	
	27470	
	27471	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	27508	27547
	27509	27548
	27510	27549
	27511	27550
	27512	27551
	27513	27552
	27514	27553
	27515	27554
	27516	27555
	27517	27556
	27518	27557
	27519	27558
	27520	27559
	27521	27560
	27522	27561
	27523	27562
	27524	27563
	27525	27564
	27526	27565
	27527	27566
	27528	27567
	27529	27568
	27530	27569
	27531	27570
	27532	27571
	27533	27572
	27534	27573
	27535	27574
	27536	27575
	27537	27576
	27538	27577
	27539	27578
	27540	27579
	27541	27580
	27542	27581
	27543	27582
	27544	27583
	27545	27584
	27546	27585
	27547	27586
	27548	27587
		27588
		27589

Trt.	Bl. No	nb
PPD	27549	27588
	27550	27589
	27551	27590
	27552	27591
	27553	27592
	27554	27593
	27555	27594
	27556	27595
	27557	27596
	27558	27597
	27559	27598
	27560	27599
	27561	27600
	27562	27601
	27563	27602
	27564	27603
	27565	27604
	27566	27605
	27567	27606
	27568	27607
	27569	27608
	27570	27609
	27571	27610
	27572	27611
	27573	27612
	27574	27613
	27575	27614
	27576	27615
	27577	27616
	27578	27617
	27579	27618
	27580	27619
	27581	27620
	27582	27621
	27583	27622
	27584	27623
	27585	27624
	27586	27625
	27587	27626
		27627
		27628
		27629
		27630

Trt.	Bl. No	nb
PPD	27590	27629
	27591	27630
	27592	27631
	27593	27632
	27594	27633
	27595	27634
	27596	27635
	27597	27636
	27598	27637
	27599	27638
	27600	27639
	27601	27640
	27602	27641
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	27606	27645
	27607	27646
	27608	27647
	27609	27648
	27610	27649
	27611	27650
	27612	27651
	27613	27652
	27614	27653
	27615	27654
	27616	27655
	27617	27656
	27618	27657
	27619	27658
	27620	27659
	27621	27660
	27622	27661
	27623	27662
	27624	27663
	27625	27664
	27626	27665
	27627	27666
	27628	27667
		27668
		27669
		27670
		27671

Trt.	Bl. No	nb
PPD	27631	27670
	27632	27671
	27633	27672
	27634	27673
	27635	27674
	27636	27675
	27637	27676
	27638	27677
	27639	27678
	27640	27679
	27641	27680
	27642	27681
	27643	27682
	27644	27683
	27645	27684
	27646	27685
	27647	27686
	27648	27687
	27649	27688
	27650	27689
	27651	27690
	27652	27691
	27653	27692
	27654	27693
	27655	27694
	27656	27695
	27657	27696
	27658	27697
	27659	27698
	27660	27699
	27661	27700
	27662	27701
	27663	27702
	27664	27703
	27665	27704
	27666	27705
	27667	27706
	27668	27707
	27669	27708
		27709
		27710
		27711
		27712

Trt.	Bl. No	nb
PPD	27672	27711
	27673	27712
	27674	27713
	27675	27714
	27676	27715
	27677	27716
	27678	27717
	27679	27718
	27680	27719
	27681	27720
	27682	27721
	27683	27722
	27684	27723
	27685	27724
	27686	27725
	27687	27726
	27688	27727
	27689	27728
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	27691	27730
	27692	27731
	27693	27732
	27694	27733
	27695	27734
	27696	27735
	27697	27736
	27698	27737
	27699	27738
	27700	27739
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	27702	27741
	27703	27742
	27704	27743
	27705	27744
	27706	27745
	27707	27746
	27708	27747
	27709	27748
	27710	27749
		27750
		27751
		27752
		27753

Trt.	Bl. No	nb
PPD	27713	27752
	27714	27753
	27715	27754
	27716	27755
	27717	27756
	27718	27757
	27719	27758
	27720	27759
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	27740	27779
	27741	27780
	27742	27781
	27743	27782
	27744	27783
	27745	27784
	27746	27785
	27747	27786
	27748	27787
	27749	27788
	27750	27789
	27751	27790
		27791
		27792
		27793
		27794

Trt.	Bl. No	nb
PPD	27754	27793
	27755	27794
	27756	
	27757	
	27758	
	27759	
	27760	
	27761	
	27762	
	27763	
	27764	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	27795	27835
PPD	27836	27876
PPD	27877	27917
PPD	27918	27958
PPD	27959	27999
PPD	28000	28040
PPD	28041	28081

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	28082
	2	28083
	3	28084
	4	28085
	5	28086
	6	28087
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	31	28112
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	33	28114
	34	28115
	35	28116
	36	28117
	37	28118
	38	28119
	39	28120
	40	28121
	41	28122
PPD	42	28123
	43	28124
	44	28125
	45	28126
	46	28127
	47	28128
	48	28129
	49	28130
	50	28131
	51	28132
	52	28133
	53	28134
	54	28135
	55	28136
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	69	28150
	70	28151
	71	28152
	72	28153
	73	28154
	74	28155
	75	28156
	76	28157
	77	28158
	78	28159
	79	28160
	80	28161
	81	28162
	82	28163
PPD	83	28164
	84	28165
	85	28166
	86	28167
	87	28168
	88	28169
	89	28170
	90	28171
	91	28172
	92	28173
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	115	28196
	116	28197
	117	28198
	118	28199
	119	28200
	120	28201
	121	28202
	122	28203
	123	28204
PPD	124	28205
	125	28206
	126	28207
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	158	28239
	159	28240
	160	28241
	161	28242
	162	28243
	163	28244
	164	28245
PPD	165	28246
	166	28247
	167	28248
	168	28249
	169	28250
	170	28251
	171	28252
	172	28253
	173	28254
	174	28255
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	183	28264
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	199	28280
	200	28281
	201	28282
	202	28283
	203	28284
	204	28285
	205	28286
PPD	206	28287
	207	28288
	208	28289
	209	28290
	210	28291
	211	28292
	212	28293
	213	28294
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	232	28313
	233	28314
	234	28315
	235	28316
	236	28317
	237	28318
	238	28319
	239	28320
	240	28321
	241	28322
	242	28323
	243	28324
	244	28325
	245	28326
	246	28327
PPD	247	28328
	248	28329
	249	28330
	250	28331
	251	28332
	252	28333
	253	28334
	254	28335
	255	28336
	256	28337
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	259	28340
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	262	28343
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	264	28345
	265	28346
	266	28347
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	268	28349
	269	28350
	270	28351
	271	28352
	272	28353
	273	28354
	274	28355
	275	28356
	276	28357
	277	28358
	278	28359
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	282	28363
	283	28364
	284	28365
	285	28366
	286	28367
	287	28368

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	28369	
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	28399	
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	28401	
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Trt.	Bl. No	nb
PPD	28410	
	28411	
	28412	
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	28418	
	28419	
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Trt.	Bl. No	nb
PPD	28451	
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Trt.	Bl. No	nb
PPD	28492	
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Trt.	Bl. No	nb
PPD	28533	
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Trt.	Bl. No	nb
PPD	28574	
	28575	
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	28610	
	28611	
	28612	
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Trt.	Bl. No	nb
PPD	28615	
	28616	
	28617	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	28656	28696
PPD	28697	28737
PPD	28738	28778
PPD	28779	28819
PPD	28820	28860
PPD	28861	28901
PPD	28902	28942

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	28943	28983
PPD	28984	29024
PPD	29025	29065
PPD	29066	29106
PPD	29107	29147
PPD	29148	29188
PPD	29189	29229

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	29230	29270
PPD	29271	29311
PPD	29312	29352
PPD	29353	29393
PPD	29394	29434
PPD	29435	29475
PPD	29476	29516

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	29517	29557
PPD	29558	29598
PPD	29599	29639
PPD	29640	29680
PPD	29681	29721
PPD	29722	29762
PPD	29763	29803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	29804	29844
PPD	29845	29885
PPD	29886	29926
PPD	29927	29967
PPD	29968	30008
PPD	30009	30049
PPD	30050	30090

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	1	30091
	2	30092
	3	30093
	4	30094
	5	30095
	6	30096
	7	30097
	8	30098
	9	30099
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	12	30102
	13	30103
	14	30104
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	34	30124
	35	30125
	36	30126
	37	30127
	38	30128
	39	30129
	40	30130
	41	30131
PPD	1	30132
	2	30133
	3	30134
	4	30135
	5	30136
	6	30137
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	31	30162
	32	30163
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	38	30169
	39	30170
	40	30171
	41	30172
PPD	1	30173
	2	30174
	3	30175
	4	30176
	5	30177
	6	30178
	7	30179
	8	30180
	9	30181
	10	30182
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	26	30198
	27	30199
	28	30200
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	35	30207
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	37	30209
	38	30210
	39	30211
	40	30212
	41	30213
PPD	1	30214
	2	30215
	3	30216
	4	30217
	5	30218
	6	30219
	7	30220
	8	30221
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	18	30231
	19	30232
	20	30233
	21	30234
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	35	30248
	36	30249
	37	30250
	38	30251
	39	30252
	40	30253
	41	30254
PPD	1	30255
	2	30256
	3	30257
	4	30258
	5	30259
	6	30260
	7	30261
	8	30262
	9	30263
	10	30264
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	18	30272
	19	30273
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	22	30276
	23	30277
	24	30278
	25	30279
	26	30280
	27	30281
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	29	30283
	30	30284
	31	30285
	32	30286
	33	30287
	34	30288
	35	30289
	36	30290
	37	30291
	38	30292
	39	30293
	40	30294
	41	30295
PPD	1	30296
	2	30297
	3	30298
	4	30299
	5	30300
	6	30301
	7	30302
	8	30303
	9	30304
	10	30305
	11	30306
	12	30307
	13	30308
	14	30309
	15	30310
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	17	30312
	18	30313
	19	30314
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	22	30317
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	26	30321
	27	30322
	28	30323
	29	30324
	30	30325
	31	30326
	32	30327
	33	30328
	34	30329
	35	30330
	36	30331
	37	30332
	38	30333
	39	30334
	40	30335
	41	30336
PPD	1	30337
	2	30338
	3	30339
	4	30340
	5	30341
	6	30342
	7	30343
	8	30344
	9	30345
	10	30346
	11	30347
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	16	30352
	17	30353
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	21	30357
	22	30358
	23	30359
	24	30360
	25	30361
	26	30362
	27	30363
	28	30364
	29	30365
	30	30366
	31	30367
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	36	30372
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	38	30374
	39	30375
	40	30376
	41	30377

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

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	30378	PPD	30419	PPD	30460	PPD	30501	PPD	30542	PPD	30583	PPD	30624
	30379		30420		30461		30502		30543		30584		30625
	30380		30421		30462		30503		30544		30585		30626
	30381		30422		30463		30504		30545		30586		30627
	30382		30423		30464		30505		30546		30587		30628
	30383		30424		30465		30506		30547		30588		30629
	30384		30425		30466		30507		30548		30589		30630
	30385		30426		30467		30508		30549		30590		30631
	30386		30427		30468		30509		30550		30591		30632
	30387		30428		30469		30510		30551		30592		30633
	30388		30429		30470		30511		30552		30593		30634
	30389		30430		30471		30512		30553		30594		30635
	30390		30431		30472		30513		30554		30595		30636
	30391		30432		30473		30514		30555		30596		30637
	30392		30433		30474		30515		30556		30597		30638
	30393		30434		30475		30516		30557		30598		30639
	30394		30435		30476		30517		30558		30599		30640
	30395		30436		30477		30518		30559		30600		30641
	30396		30437		30478		30519		30560		30601		30642
	30397		30438		30479		30520		30561		30602		30643
	30398		30439		30480		30521		30562		30603		30644
	30399		30440		30481		30522		30563		30604		30645
	30400		30441		30482		30523		30564		30605		30646
	30401		30442		30483		30524		30565		30606		30647
	30402		30443		30484		30525		30566		30607		30648
	30403		30444		30485		30526		30567		30608		30649
	30404		30445		30486		30527		30568		30609		30650
	30405		30446		30487		30528		30569		30610		30651
	30406		30447		30488		30529		30570		30611		30652
	30407		30448		30489		30530		30571		30612		30653
	30408		30449		30490		30531		30572		30613		30654
	30409		30450		30491		30532		30573		30614		30655
	30410		30451		30492		30533		30574		30615		30656
	30411		30452		30493		30534		30575		30616		30657
	30412		30453		30494		30535		30576		30617		30658
	30413		30454		30495		30536		30577		30618		30659
	30414		30455		30496		30537		30578		30619		30660
	30415		30456		30497		30538		30579		30620		30661
	30416		30457		30498		30539		30580		30621		30662
	30417		30458		30499		30540		30581		30622		30663
	30418		30459		30500		30541		30582		30623		30664

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Engerix

Trt.	Bl. No	nb
PPD	30665	30705
PPD	30706	30746
PPD	30747	30787
PPD	30788	30828
PPD	30829	30869
PPD	30870	30906

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	30907	
	30908	
	30909	
	30910	
	30911	
	30912	
	30913	
	30914	
	30915	
	30916	
	30917	
	30918	
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	30921	
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	30941	
	30942	
	30943	
	30944	
	30945	
	30946	
	30947	

Trt.	Bl. No	nb
PPD	30948	
	30949	
	30950	
	30951	
	30952	
	30953	
	30954	
	30955	
	30956	
	30957	
	30958	
	30959	
	30960	
	30961	
	30962	
	30963	
	30964	
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	30966	
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	30980	
	30981	
	30982	
	30983	
	30984	
	30985	
	30986	
	30987	
	30988	

Trt.	Bl. No	nb
PPD	30989	
	30990	
	30991	
	30992	
	30993	
	30994	
	30995	
	30996	
	30997	
	30998	
	30999	
	31000	
	31001	
	31002	
	31003	
	31004	
	31005	
	31006	
	31007	
	31008	
	31009	
	31010	
	31011	
	31012	
	31013	
	31014	
	31015	
	31016	
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	31018	
	31019	
	31020	
	31021	
	31022	
	31023	
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	31027	
	31028	
	31029	

Trt.	Bl. No	nb
PPD	31030	
	31031	
	31032	
	31033	
	31034	
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	31036	
	31037	
	31038	
	31039	
	31040	
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Trt.	Bl. No	nb
PPD	31071	
	31072	
	31073	
	31074	
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	31079	
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	31102	
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	31107	
	31108	
	31109	
	31110	
	31111	

Trt.	Bl. No	nb
PPD	31112	
	31113	
	31114	
	31115	
	31116	
	31117	
	31118	
	31119	
	31120	
	31121	
	31122	
	31123	
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	31150	
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Trt.	Bl. No	nb
PPD	31153	
	31154	
	31155	
	31156	
	31157	
	31158	
	31159	
	31160	
	31161	
	31162	
	31163	
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	31190	
	31191	
	31192	
	31193	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	31194	31234
PPD	31235	31275
PPD	31276	31316
PPD	31317	31357
PPD	31358	31398
PPD	31399	31439
PPD	31440	31480

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	31481	31521
PPD	31522	31562
PPD	31563	31603
PPD	31604	31644
PPD	31645	31685
PPD	31686	31726
PPD	31727	31767

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	31768	31808
PPD	31809	31849
PPD	31850	31890
PPD	31891	31931
PPD	31932	31972
PPD	31973	32013
PPD	32014	32054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	32055
	2	32056
	3	32057
	4	32058
	5	32059
	6	32060
	7	32061
	8	32062
	9	32063
	10	32064
	11	32065
	12	32066
	13	32067
	14	32068
	15	32069
	16	32070
	17	32071
	18	32072
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	21	32075
	22	32076
	23	32077
	24	32078
	25	32079
	26	32080
	27	32081
	28	32082
	29	32083
	30	32084
	31	32085
	32	32086
	33	32087
	34	32088
	35	32089
	36	32090
	37	32091
	38	32092
	39	32093
	40	32094
	41	32095
PPD	42	32096
	43	32097
	44	32098
	45	32099
	46	32100
	47	32101
	48	32102
	49	32103
	50	32104
	51	32105
	52	32106
	53	32107
	54	32108
	55	32109
	56	32110
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	58	32112
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	60	32114
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	62	32116
	63	32117
	64	32118
	65	32119
	66	32120
	67	32121
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	69	32123
	70	32124
	71	32125
	72	32126
	73	32127
	74	32128
	75	32129
	76	32130
	77	32131
	78	32132
	79	32133
	80	32134
	81	32135
	82	32136
PPD	83	32137
	84	32138
	85	32139
	86	32140
	87	32141
	88	32142
	89	32143
	90	32144
	91	32145
	92	32146
	93	32147
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	95	32149
	96	32150
	97	32151
	98	32152
	99	32153
	100	32154
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	105	32159
	106	32160
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	108	32162
	109	32163
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	113	32167
	114	32168
	115	32169
	116	32170
	117	32171
	118	32172
	119	32173
	120	32174
	121	32175
	122	32176
	123	32177
PPD	124	32178
	125	32179
	126	32180
	127	32181
	128	32182
	129	32183
	130	32184
	131	32185
	132	32186
	133	32187
	134	32188
	135	32189
	136	32190
	137	32191
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	151	32205
	152	32206
	153	32207
	154	32208
	155	32209
	156	32210
	157	32211
	158	32212
	159	32213
	160	32214
	161	32215
	162	32216
	163	32217
	164	32218
PPD	165	32219
	166	32220
	167	32221
	168	32222
	169	32223
	170	32224
	171	32225
	172	32226
	173	32227
	174	32228
	175	32229
	176	32230
	177	32231
	178	32232
	179	32233
	180	32234
	181	32235
	182	32236
	183	32237
	184	32238
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	186	32240
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	197	32251
	198	32252
	199	32253
	200	32254
	201	32255
	202	32256
	203	32257
	204	32258
	205	32259
PPD	206	32260
	207	32261
	208	32262
	209	32263
	210	32264
	211	32265
	212	32266
	213	32267
	214	32268
	215	32269
	216	32270
	217	32271
	218	32272
	219	32273
	220	32274
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	223	32277
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	229	32283
	230	32284
	231	32285
	232	32286
	233	32287
	234	32288
	235	32289
	236	32290
	237	32291
	238	32292
	239	32293
	240	32294
	241	32295
	242	32296
	243	32297
	244	32298
	245	32299
	246	32300
PPD	247	32301
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	249	32303
	250	32304
	251	32305
	252	32306
	253	32307
	254	32308
	255	32309
	256	32310
	257	32311
	258	32312
	259	32313
	260	32314
	261	32315
	262	32316
	263	32317
	264	32318
	265	32319
	266	32320
	267	32321
	268	32322
	269	32323
	270	32324
	271	32325
	272	32326
	273	32327
	274	32328
	275	32329
	276	32330
	277	32331
	278	32332
	279	32333
	280	32334
	281	32335
	282	32336
	283	32337
	284	32338
	285	32339
	286	32340
	287	32341

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	32342
	2	32343
	3	32344
	4	32345
	5	32346
	6	32347
	7	32348
	8	32349
	9	32350
	10	32351
	11	32352
	12	32353
	13	32354
	14	32355
	15	32356
	16	32357
	17	32358
	18	32359
	19	32360
	20	32361
	21	32362
	22	32363
	23	32364
	24	32365
	25	32366
	26	32367
	27	32368
	28	32369
	29	32370
	30	32371
	31	32372
	32	32373
	33	32374
	34	32375
	35	32376
	36	32377
	37	32378
	38	32379
	39	32380
	40	32381
	41	32382

Trt.	Bl. No	nb
PPD	1	32383
	2	32384
	3	32385
	4	32386
	5	32387
	6	32388
	7	32389
	8	32390
	9	32391
	10	32392
	11	32393
	12	32394
	13	32395
	14	32396
	15	32397
	16	32398
	17	32399
	18	32400
	19	32401
	20	32402
	21	32403
	22	32404
	23	32405
	24	32406
	25	32407
	26	32408
	27	32409
	28	32410
	29	32411
	30	32412
	31	32413
	32	32414
	33	32415
	34	32416
	35	32417
	36	32418
	37	32419
	38	32420
	39	32421
	40	32422
	41	32423

Trt.	Bl. No	nb
PPD	1	32424
	2	32425
	3	32426
	4	32427
	5	32428
	6	32429
	7	32430
	8	32431
	9	32432
	10	32433
	11	32434
	12	32435
	13	32436
	14	32437
	15	32438
	16	32439
	17	32440
	18	32441
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	21	32444
	22	32445
	23	32446
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	30	32453
	31	32454
	32	32455
	33	32456
	34	32457
	35	32458
	36	32459
	37	32460
	38	32461
	39	32462
	40	32463
	41	32464

Trt.	Bl. No	nb
PPD	1	32465
	2	32466
	3	32467
	4	32468
	5	32469
	6	32470
	7	32471
	8	32472
	9	32473
	10	32474
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	13	32477
	14	32478
	15	32479
	16	32480
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	19	32483
	20	32484
	21	32485
	22	32486
	23	32487
	24	32488
	25	32489
	26	32490
	27	32491
	28	32492
	29	32493
	30	32494
	31	32495
	32	32496
	33	32497
	34	32498
	35	32499
	36	32500
	37	32501
	38	32502
	39	32503
	40	32504
	41	32505

Trt.	Bl. No	nb
PPD	1	32506
	2	32507
	3	32508
	4	32509
	5	32510
	6	32511
	7	32512
	8	32513
	9	32514
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	14	32519
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	16	32521
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	35	32540
	36	32541
	37	32542
	38	32543
	39	32544
	40	32545
	41	32546

Trt.	Bl. No	nb
PPD	1	32547
	2	32548
	3	32549
	4	32550
	5	32551
	6	32552
	7	32553
	8	32554
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	18	32564
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	32	32578
	33	32579
	34	32580
	35	32581
	36	32582
	37	32583
	38	32584
	39	32585
	40	32586
	41	32587

Trt.	Bl. No	nb
PPD	1	32588
	2	32589
	3	32590
	4	32591
	5	32592
	6	32593
	7	32594
	8	32595
	9	32596
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	12	32599
	13	32600
	14	32601
	15	32602
	16	32603
	17	32604
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	22	32609
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	39	32626
	40	32627
	41	32628

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	32629	32669
PPD	32670	32710
PPD	32711	32751
PPD	32752	32792
PPD	32793	32833
PPD	32834	32874
PPD	32875	32915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	32916	PPD	32957	PPD	32998	PPD	33039	PPD	33080	PPD	33121	PPD	33162
	32917		32958		32999		33040		33081		33122		33163
	32918		32959		33000		33041		33082		33123		33164
	32919		32960		33001		33042		33083		33124		33165
	32920		32961		33002		33043		33084		33125		33166
	32921		32962		33003		33044		33085		33126		33167
	32922		32963		33004		33045		33086		33127		33168
	32923		32964		33005		33046		33087		33128		33169
	32924		32965		33006		33047		33088		33129		33170
	32925		32966		33007		33048		33089		33130		33171
	32926		32967		33008		33049		33090		33131		33172
	32927		32968		33009		33050		33091		33132		33173
	32928		32969		33010		33051		33092		33133		33174
	32929		32970		33011		33052		33093		33134		33175
	32930		32971		33012		33053		33094		33135		33176
	32931		32972		33013		33054		33095		33136		33177
	32932		32973		33014		33055		33096		33137		33178
	32933		32974		33015		33056		33097		33138		33179
	32934		32975		33016		33057		33098		33139		33180
	32935		32976		33017		33058		33099		33140		33181
	32936		32977		33018		33059		33100		33141		33182
	32937		32978		33019		33060		33101		33142		33183
	32938		32979		33020		33061		33102		33143		33184
	32939		32980		33021		33062		33103		33144		33185
	32940		32981		33022		33063		33104		33145		33186
	32941		32982		33023		33064		33105		33146		33187
	32942		32983		33024		33065		33106		33147		33188
	32943		32984		33025		33066		33107		33148		33189
	32944		32985		33026		33067		33108		33149		33190
	32945		32986		33027		33068		33109		33150		33191
	32946		32987		33028		33069		33110		33151		33192
	32947		32988		33029		33070		33111		33152		33193
	32948		32989		33030		33071		33112		33153		33194
	32949		32990		33031		33072		33113		33154		33195
	32950		32991		33032		33073		33114		33155		33196
	32951		32992		33033		33074		33115		33156		33197
	32952		32993		33034		33075		33116		33157		33198
	32953		32994		33035		33076		33117		33158		33199
	32954		32995		33036		33077		33118		33159		33200
	32955		32996		33037		33078		33119		33160		33201
	32956		32997		33038		33079		33120		33161		33202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	33203
	2	33204
	3	33205
	4	33206
	5	33207
	6	33208
	7	33209
	8	33210
	9	33211
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	11	33213
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	35	33237
	36	33238
	37	33239
	38	33240
	39	33241
	40	33242
	41	33243

Trt.	Bl. No	nb
PPD	1	33244
	2	33245
	3	33246
	4	33247
	5	33248
	6	33249
	7	33250
	8	33251
	9	33252
	10	33253
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	34	33277
	35	33278
	36	33279
	37	33280
	38	33281
	39	33282
	40	33283
	41	33284

Trt.	Bl. No	nb
PPD	1	33285
	2	33286
	3	33287
	4	33288
	5	33289
	6	33290
	7	33291
	8	33292
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	32	33316
	33	33317
	34	33318
	35	33319
	36	33320
	37	33321
	38	33322
	39	33323
	40	33324
	41	33325

Trt.	Bl. No	nb
PPD	1	33326
	2	33327
	3	33328
	4	33329
	5	33330
	6	33331
	7	33332
	8	33333
	9	33334
	10	33335
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	36	33361
	37	33362
	38	33363
	39	33364
	40	33365
	41	33366

Trt.	Bl. No	nb
PPD	1	33367
	2	33368
	3	33369
	4	33370
	5	33371
	6	33372
	7	33373
	8	33374
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	32	33398
	33	33399
	34	33400
	35	33401
	36	33402
	37	33403
	38	33404
	39	33405
	40	33406
	41	33407

Trt.	Bl. No	nb
PPD	1	33408
	2	33409
	3	33410
	4	33411
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	7	33414
	8	33415
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	33	33440
	34	33441
	35	33442
	36	33443
	37	33444
	38	33445
	39	33446
	40	33447
	41	33448

Trt.	Bl. No	nb
PPD	1	33449
	2	33450
	3	33451
	4	33452
	5	33453
	6	33454
	7	33455
	8	33456
	9	33457
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	31	33479
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	36	33484
	37	33485
	38	33486
	39	33487
	40	33488
	41	33489

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	33490	PPD	33531	PPD	33572	PPD	33613	PPD	33654	PPD	33695	PPD	33736
	33491		33532		33573		33614		33655		33696		33737
	33492		33533		33574		33615		33656		33697		33738
	33493		33534		33575		33616		33657		33698		33739
	33494		33535		33576		33617		33658		33699		33740
	33495		33536		33577		33618		33659		33700		33741
	33496		33537		33578		33619		33660		33701		33742
	33497		33538		33579		33620		33661		33702		33743
	33498		33539		33580		33621		33662		33703		33744
	33499		33540		33581		33622		33663		33704		33745
	33500		33541		33582		33623		33664		33705		33746
	33501		33542		33583		33624		33665		33706		33747
	33502		33543		33584		33625		33666		33707		33748
	33503		33544		33585		33626		33667		33708		33749
	33504		33545		33586		33627		33668		33709		33750
	33505		33546		33587		33628		33669		33710		33751
	33506		33547		33588		33629		33670		33711		33752
	33507		33548		33589		33630		33671		33712		33753
	33508		33549		33590		33631		33672		33713		33754
	33509		33550		33591		33632		33673		33714		33755
	33510		33551		33592		33633		33674		33715		33756
	33511		33552		33593		33634		33675		33716		33757
	33512		33553		33594		33635		33676		33717		33758
	33513		33554		33595		33636		33677		33718		33759
	33514		33555		33596		33637		33678		33719		33760
	33515		33556		33597		33638		33679		33720		33761
	33516		33557		33598		33639		33680		33721		33762
	33517		33558		33599		33640		33681		33722		33763
	33518		33559		33600		33641		33682		33723		33764
	33519		33560		33601		33642		33683		33724		33765
	33520		33561		33602		33643		33684		33725		33766
	33521		33562		33603		33644		33685		33726		33767
	33522		33563		33604		33645		33686		33727		33768
	33523		33564		33605		33646		33687		33728		33769
	33524		33565		33606		33647		33688		33729		33770
	33525		33566		33607		33648		33689		33730		33771
	33526		33567		33608		33649		33690		33731		33772
	33527		33568		33609		33650		33691		33732		33773
	33528		33569		33610		33651		33692		33733		33774
	33529		33570		33611		33652		33693		33734		33775
	33530		33571		33612		33653		33694		33735		33776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	33777	
	33778	
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	33780	
	33781	
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Trt.	Bl. No	nb
PPD	33818	
	33819	
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Trt.	Bl. No	nb
PPD	33859	
	33860	
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Trt.	Bl. No	nb
PPD	33900	
	33901	
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Trt.	Bl. No	nb
PPD	33941	
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Trt.	Bl. No	nb
PPD	33982	
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Trt.	Bl. No	nb
PPD	34023	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	34064	34065
	34066	34067
	34068	34069
	34070	34071
	34072	34073
	34074	34075
	34076	34077
	34078	34079
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	34090	34091
	34092	34093
	34094	34095
	34096	34097
	34098	34099
	34100	34101
	34102	34103
	34104	

Trt.	Bl. No	nb
PPD	34105	34106
	34107	34108
	34109	34110
	34111	34112
	34113	34114
	34115	34116
	34117	34118
	34119	34120
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	34129	34130
	34131	34132
	34133	34134
	34135	34136
	34137	34138
	34139	34140
	34141	34142
	34143	34144
	34145	

Trt.	Bl. No	nb
PPD	34146	34147
	34148	34149
	34150	34151
	34152	34153
	34154	34155
	34156	34157
	34158	34159
	34160	34161
	34162	34163
	34164	34165
	34166	34167
	34168	34169
	34170	34171
	34172	34173
	34174	34175
	34176	34177
	34178	34179
	34180	34181
	34182	34183
	34184	34185
	34186	

Trt.	Bl. No	nb
PPD	34187	34188
	34189	34190
	34191	34192
	34193	34194
	34195	34196
	34197	34198
	34199	34200
	34201	34202
	34203	34204
	34205	34206
	34207	34208
	34209	34210
	34211	34212
	34213	34214
	34215	34216
	34217	34218
	34219	34220
	34221	34222
	34223	34224
	34225	34226
	34227	

Trt.	Bl. No	nb
PPD	34228	34229
	34230	34231
	34232	34233
	34234	34235
	34236	34237
	34238	34239
	34240	34241
	34242	34243
	34244	34245
	34246	34247
	34248	34249
	34250	34251
	34252	34253
	34254	34255
	34256	34257
	34258	34259
	34260	34261
	34262	34263
	34264	34265
	34266	34267
	34268	

Trt.	Bl. No	nb
PPD	34269	34270
	34271	34272
	34273	34274
	34275	34276
	34277	34278
	34279	34280
	34281	34282
	34283	34284
	34285	34286
	34287	34288
	34289	34290
	34291	34292
	34293	34294
	34295	34296
	34297	34298
	34299	34300
	34301	34302
	34303	34304
	34305	34306
	34307	34308
	34309	

Trt.	Bl. No	nb
PPD	34310	34311
	34312	34313
	34314	34315
	34316	34317
	34318	34319
	34320	34321
	34322	34323
	34324	34325
	34326	34327
	34328	34329
	34330	34331
	34332	34333
	34334	34335
	34336	34337
	34338	34339
	34340	34341
	34342	34343
	34344	34345
	34346	34347
	34348	34349
	34350	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	34351	34391
PPD	34392	34432
PPD	34433	34473
PPD	34474	34514
PPD	34515	34555
PPD	34556	34596
PPD	34597	34637

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	34638	PPD	34679	PPD	34720	PPD	34761	PPD	34802	PPD	34843	PPD	34884
	34639		34680		34721		34762		34803		34844		34885
	34640		34681		34722		34763		34804		34845		34886
	34641		34682		34723		34764		34805		34846		34887
	34642		34683		34724		34765		34806		34847		34888
	34643		34684		34725		34766		34807		34848		34889
	34644		34685		34726		34767		34808		34849		34890
	34645		34686		34727		34768		34809		34850		34891
	34646		34687		34728		34769		34810		34851		34892
	34647		34688		34729		34770		34811		34852		34893
	34648		34689		34730		34771		34812		34853		34894
	34649		34690		34731		34772		34813		34854		34895
	34650		34691		34732		34773		34814		34855		34896
	34651		34692		34733		34774		34815		34856		34897
	34652		34693		34734		34775		34816		34857		34898
	34653		34694		34735		34776		34817		34858		34899
	34654		34695		34736		34777		34818		34859		34900
	34655		34696		34737		34778		34819		34860		34901
	34656		34697		34738		34779		34820		34861		34902
	34657		34698		34739		34780		34821		34862		34903
	34658		34699		34740		34781		34822		34863		34904
	34659		34700		34741		34782		34823		34864		34905
	34660		34701		34742		34783		34824		34865		34906
	34661		34702		34743		34784		34825		34866		34907
	34662		34703		34744		34785		34826		34867		34908
	34663		34704		34745		34786		34827		34868		34909
	34664		34705		34746		34787		34828		34869		34910
	34665		34706		34747		34788		34829		34870		34911
	34666		34707		34748		34789		34830		34871		34912
	34667		34708		34749		34790		34831		34872		34913
	34668		34709		34750		34791		34832		34873		34914
	34669		34710		34751		34792		34833		34874		34915
	34670		34711		34752		34793		34834		34875		34916
	34671		34712		34753		34794		34835		34876		34917
	34672		34713		34754		34795		34836		34877		34918
	34673		34714		34755		34796		34837		34878		34919
	34674		34715		34756		34797		34838		34879		34920
	34675		34716		34757		34798		34839		34880		34921
	34676		34717		34758		34799		34840		34881		34922
	34677		34718		34759		34800		34841		34882		34923
	34678		34719		34760		34801		34842		34883		34924

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	34925	PPD	34966	PPD	35007	PPD	35048	PPD	35089	PPD	35130	PPD	35171
	34926		34967		35008		35049		35090		35131		35172
	34927		34968		35009		35050		35091		35132		35173
	34928		34969		35010		35051		35092		35133		35174
	34929		34970		35011		35052		35093		35134		35175
	34930		34971		35012		35053		35094		35135		35176
	34931		34972		35013		35054		35095		35136		35177
	34932		34973		35014		35055		35096		35137		35178
	34933		34974		35015		35056		35097		35138		35179
	34934		34975		35016		35057		35098		35139		35180
	34935		34976		35017		35058		35099		35140		35181
	34936		34977		35018		35059		35100		35141		35182
	34937		34978		35019		35060		35101		35142		35183
	34938		34979		35020		35061		35102		35143		35184
	34939		34980		35021		35062		35103		35144		35185
	34940		34981		35022		35063		35104		35145		35186
	34941		34982		35023		35064		35105		35146		35187
	34942		34983		35024		35065		35106		35147		35188
	34943		34984		35025		35066		35107		35148		35189
	34944		34985		35026		35067		35108		35149		35190
	34945		34986		35027		35068		35109		35150		35191
	34946		34987		35028		35069		35110		35151		35192
	34947		34988		35029		35070		35111		35152		35193
	34948		34989		35030		35071		35112		35153		35194
	34949		34990		35031		35072		35113		35154		35195
	34950		34991		35032		35073		35114		35155		35196
	34951		34992		35033		35074		35115		35156		35197
	34952		34993		35034		35075		35116		35157		35198
	34953		34994		35035		35076		35117		35158		35199
	34954		34995		35036		35077		35118		35159		35200
	34955		34996		35037		35078		35119		35160		35201
	34956		34997		35038		35079		35120		35161		35202
	34957		34998		35039		35080		35121		35162		35203
	34958		34999		35040		35081		35122		35163		35204
	34959		35000		35041		35082		35123		35164		35205
	34960		35001		35042		35083		35124		35165		35206
	34961		35002		35043		35084		35125		35166		35207
	34962		35003		35044		35085		35126		35167		35208
	34963		35004		35045		35086		35127		35168		35209
	34964		35005		35046		35087		35128		35169		35210
	34965		35006		35047		35088		35129		35170		35211

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	35212	PPD	35253	PPD	35294	PPD	35335	PPD	35376	PPD	35417	PPD	35458
	35213		35254		35295		35336		35377		35418		35459
	35214		35255		35296		35337		35378		35419		35460
	35215		35256		35297		35338		35379		35420		35461
	35216		35257		35298		35339		35380		35421		35462
	35217		35258		35299		35340		35381		35422		35463
	35218		35259		35300		35341		35382		35423		35464
	35219		35260		35301		35342		35383		35424		35465
	35220		35261		35302		35343		35384		35425		35466
	35221		35262		35303		35344		35385		35426		35467
	35222		35263		35304		35345		35386		35427		35468
	35223		35264		35305		35346		35387		35428		35469
	35224		35265		35306		35347		35388		35429		35470
	35225		35266		35307		35348		35389		35430		35471
	35226		35267		35308		35349		35390		35431		35472
	35227		35268		35309		35350		35391		35432		35473
	35228		35269		35310		35351		35392		35433		35474
	35229		35270		35311		35352		35393		35434		35475
	35230		35271		35312		35353		35394		35435		35476
	35231		35272		35313		35354		35395		35436		35477
	35232		35273		35314		35355		35396		35437		35478
	35233		35274		35315		35356		35397		35438		35479
	35234		35275		35316		35357		35398		35439		35480
	35235		35276		35317		35358		35399		35440		35481
	35236		35277		35318		35359		35400		35441		35482
	35237		35278		35319		35360		35401		35442		35483
	35238		35279		35320		35361		35402		35443		35484
	35239		35280		35321		35362		35403		35444		35485
	35240		35281		35322		35363		35404		35445		35486
	35241		35282		35323		35364		35405		35446		35487
	35242		35283		35324		35365		35406		35447		35488
	35243		35284		35325		35366		35407		35448		35489
	35244		35285		35326		35367		35408		35449		35490
	35245		35286		35327		35368		35409		35450		35491
	35246		35287		35328		35369		35410		35451		35492
	35247		35288		35329		35370		35411		35452		35493
	35248		35289		35330		35371		35412		35453		35494
	35249		35290		35331		35372		35413		35454		35495
	35250		35291		35332		35373		35414		35455		35496
	35251		35292		35333		35374		35415		35456		35497
	35252		35293		35334		35375		35416		35457		35498

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	35499	PPD	35540	PPD	35581	PPD	35622	PPD	35663	PPD	35704	PPD	35745
	35500		35541		35582		35623		35664		35705		35746
	35501		35542		35583		35624		35665		35706		35747
	35502		35543		35584		35625		35666		35707		35748
	35503		35544		35585		35626		35667		35708		35749
	35504		35545		35586		35627		35668		35709		35750
	35505		35546		35587		35628		35669		35710		35751
	35506		35547		35588		35629		35670		35711		35752
	35507		35548		35589		35630		35671		35712		35753
	35508		35549		35590		35631		35672		35713		35754
	35509		35550		35591		35632		35673		35714		35755
	35510		35551		35592		35633		35674		35715		35756
	35511		35552		35593		35634		35675		35716		35757
	35512		35553		35594		35635		35676		35717		35758
	35513		35554		35595		35636		35677		35718		35759
	35514		35555		35596		35637		35678		35719		35760
	35515		35556		35597		35638		35679		35720		35761
	35516		35557		35598		35639		35680		35721		35762
	35517		35558		35599		35640		35681		35722		35763
	35518		35559		35600		35641		35682		35723		35764
	35519		35560		35601		35642		35683		35724		35765
	35520		35561		35602		35643		35684		35725		35766
	35521		35562		35603		35644		35685		35726		35767
	35522		35563		35604		35645		35686		35727		35768
	35523		35564		35605		35646		35687		35728		35769
	35524		35565		35606		35647		35688		35729		35770
	35525		35566		35607		35648		35689		35730		35771
	35526		35567		35608		35649		35690		35731		35772
	35527		35568		35609		35650		35691		35732		35773
	35528		35569		35610		35651		35692		35733		35774
	35529		35570		35611		35652		35693		35734		35775
	35530		35571		35612		35653		35694		35735		35776
	35531		35572		35613		35654		35695		35736		35777
	35532		35573		35614		35655		35696		35737		35778
	35533		35574		35615		35656		35697		35738		35779
	35534		35575		35616		35657		35698		35739		35780
	35535		35576		35617		35658		35699		35740		35781
	35536		35577		35618		35659		35700		35741		35782
	35537		35578		35619		35660		35701		35742		35783
	35538		35579		35620		35661		35702		35743		35784
	35539		35580		35621		35662		35703		35744		35785

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	35786	35826
PPD	35827	35867
PPD	35868	35908
PPD	35909	35949
PPD	35950	35990
PPD	35991	36031
PPD	36032	36072

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	36073	36113
PPD	36114	36154
PPD	36155	36195
PPD	36196	36236
PPD	36237	36277
PPD	36278	36318
PPD	36319	36359

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	36360
	2	36361
	3	36362
	4	36363
	5	36364
	6	36365
	7	36366
	8	36367
	9	36368
	10	36369
	11	36370
	12	36371
	13	36372
	14	36373
	15	36374
	16	36375
	17	36376
	18	36377
	19	36378
	20	36379
	21	36380
	22	36381
	23	36382
	24	36383
	25	36384
	26	36385
	27	36386
	28	36387
	29	36388
	30	36389
	31	36390
	32	36391
	33	36392
	34	36393
	35	36394
	36	36395
	37	36396
	38	36397
	39	36398
	40	36399
	41	36400

Trt.	Bl. No	nb
PPD	1	36401
	2	36402
	3	36403
	4	36404
	5	36405
	6	36406
	7	36407
	8	36408
	9	36409
	10	36410
	11	36411
	12	36412
	13	36413
	14	36414
	15	36415
	16	36416
	17	36417
	18	36418
	19	36419
	20	36420
	21	36421
	22	36422
	23	36423
	24	36424
	25	36425
	26	36426
	27	36427
	28	36428
	29	36429
	30	36430
	31	36431
	32	36432
	33	36433
	34	36434
	35	36435
	36	36436
	37	36437
	38	36438
	39	36439
	40	36440
	41	36441

Trt.	Bl. No	nb
PPD	1	36442
	2	36443
	3	36444
	4	36445
	5	36446
	6	36447
	7	36448
	8	36449
	9	36450
	10	36451
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	32	36473
	33	36474
	34	36475
	35	36476
	36	36477
	37	36478
	38	36479
	39	36480
	40	36481
	41	36482

Trt.	Bl. No	nb
PPD	1	36483
	2	36484
	3	36485
	4	36486
	5	36487
	6	36488
	7	36489
	8	36490
	9	36491
	10	36492
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	17	36499
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	20	36502
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	23	36505
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	31	36513
	32	36514
	33	36515
	34	36516
	35	36517
	36	36518
	37	36519
	38	36520
	39	36521
	40	36522
	41	36523

Trt.	Bl. No	nb
PPD	1	36524
	2	36525
	3	36526
	4	36527
	5	36528
	6	36529
	7	36530
	8	36531
	9	36532
	10	36533
	11	36534
	12	36535
	13	36536
	14	36537
	15	36538
	16	36539
	17	36540
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	25	36548
	26	36549
	27	36550
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	29	36552
	30	36553
	31	36554
	32	36555
	33	36556
	34	36557
	35	36558
	36	36559
	37	36560
	38	36561
	39	36562
	40	36563
	41	36564

Trt.	Bl. No	nb
PPD	1	36565
	2	36566
	3	36567
	4	36568
	5	36569
	6	36570
	7	36571
	8	36572
	9	36573
	10	36574
	11	36575
	12	36576
	13	36577
	14	36578
	15	36579
	16	36580
	17	36581
	18	36582
	19	36583
	20	36584
	21	36585
	22	36586
	23	36587
	24	36588
	25	36589
	26	36590
	27	36591
	28	36592
	29	36593
	30	36594
	31	36595
	32	36596
	33	36597
	34	36598
	35	36599
	36	36600
	37	36601
	38	36602
	39	36603
	40	36604
	41	36605

Trt.	Bl. No	nb
PPD	1	36606
	2	36607
	3	36608
	4	36609
	5	36610
	6	36611
	7	36612
	8	36613
	9	36614
	10	36615
	11	36616
	12	36617
	13	36618
	14	36619
	15	36620
	16	36621
	17	36622
	18	36623
	19	36624
	20	36625
	21	36626
	22	36627
	23	36628
	24	36629
	25	36630
	26	36631
	27	36632
	28	36633
	29	36634
	30	36635
	31	36636
	32	36637
	33	36638
	34	36639
	35	36640
	36	36641
	37	36642
	38	36643
	39	36644
	40	36645
	41	36646

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	36647	36687
PPD	36688	36728
PPD	36729	36769
PPD	36770	36810
PPD	36811	36851
PPD	36852	36892
PPD	36893	36933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	36934	36974
PPD	36975	37015
PPD	37016	37056
PPD	37057	37097
PPD	37098	37138
PPD	37139	37179
PPD	37180	37220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	37221
	2	37222
	3	37223
	4	37224
	5	37225
	6	37226
	7	37227
	8	37228
	9	37229
	10	37230
	11	37231
	12	37232
	13	37233
	14	37234
	15	37235
	16	37236
	17	37237
	18	37238
	19	37239
	20	37240
	21	37241
	22	37242
	23	37243
	24	37244
	25	37245
	26	37246
	27	37247
	28	37248
	29	37249
	30	37250
	31	37251
	32	37252
	33	37253
	34	37254
	35	37255
	36	37256
	37	37257
	38	37258
	39	37259
	40	37260
	41	37261

Trt.	Bl. No	nb
PPD	1	37262
	2	37263
	3	37264
	4	37265
	5	37266
	6	37267
	7	37268
	8	37269
	9	37270
	10	37271
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	12	37273
	13	37274
	14	37275
	15	37276
	16	37277
	17	37278
	18	37279
	19	37280
	20	37281
	21	37282
	22	37283
	23	37284
	24	37285
	25	37286
	26	37287
	27	37288
	28	37289
	29	37290
	30	37291
	31	37292
	32	37293
	33	37294
	34	37295
	35	37296
	36	37297
	37	37298
	38	37299
	39	37300
	40	37301
	41	37302

Trt.	Bl. No	nb
PPD	1	37303
	2	37304
	3	37305
	4	37306
	5	37307
	6	37308
	7	37309
	8	37310
	9	37311
	10	37312
	11	37313
	12	37314
	13	37315
	14	37316
	15	37317
	16	37318
	17	37319
	18	37320
	19	37321
	20	37322
	21	37323
	22	37324
	23	37325
	24	37326
	25	37327
	26	37328
	27	37329
	28	37330
	29	37331
	30	37332
	31	37333
	32	37334
	33	37335
	34	37336
	35	37337
	36	37338
	37	37339
	38	37340
	39	37341
	40	37342
	41	37343

Trt.	Bl. No	nb
PPD	1	37344
	2	37345
	3	37346
	4	37347
	5	37348
	6	37349
	7	37350
	8	37351
	9	37352
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	17	37360
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	20	37363
	21	37364
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	31	37374
	32	37375
	33	37376
	34	37377
	35	37378
	36	37379
	37	37380
	38	37381
	39	37382
	40	37383
	41	37384

Trt.	Bl. No	nb
PPD	1	37385
	2	37386
	3	37387
	4	37388
	5	37389
	6	37390
	7	37391
	8	37392
	9	37393
	10	37394
	11	37395
	12	37396
	13	37397
	14	37398
	15	37399
	16	37400
	17	37401
	18	37402
	19	37403
	20	37404
	21	37405
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	24	37408
	25	37409
	26	37410
	27	37411
	28	37412
	29	37413
	30	37414
	31	37415
	32	37416
	33	37417
	34	37418
	35	37419
	36	37420
	37	37421
	38	37422
	39	37423
	40	37424
	41	37425

Trt.	Bl. No	nb
PPD	1	37426
	2	37427
	3	37428
	4	37429
	5	37430
	6	37431
	7	37432
	8	37433
	9	37434
	10	37435
	11	37436
	12	37437
	13	37438
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	15	37440
	16	37441
	17	37442
	18	37443
	19	37444
	20	37445
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	25	37450
	26	37451
	27	37452
	28	37453
	29	37454
	30	37455
	31	37456
	32	37457
	33	37458
	34	37459
	35	37460
	36	37461
	37	37462
	38	37463
	39	37464
	40	37465
	41	37466

Trt.	Bl. No	nb
PPD	1	37467
	2	37468
	3	37469
	4	37470
	5	37471
	6	37472
	7	37473
	8	37474
	9	37475
	10	37476
	11	37477
	12	37478
	13	37479
	14	37480
	15	37481
	16	37482
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	18	37484
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	22	37488
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	24	37490
	25	37491
	26	37492
	27	37493
	28	37494
	29	37495
	30	37496
	31	37497
	32	37498
	33	37499
	34	37500
	35	37501
	36	37502
	37	37503
	38	37504
	39	37505
	40	37506
	41	37507

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	37508	37549
	37509	37550
	37510	37551
	37511	37552
	37512	37553
	37513	37554
	37514	37555
	37515	37556
	37516	37557
	37517	37558
	37518	37559
	37519	37560
	37520	37561
	37521	37562
	37522	37563
	37523	37564
	37524	37565
	37525	37566
	37526	37567
	37527	37568
	37528	37569
	37529	37570
	37530	37571
	37531	37572
	37532	37573
	37533	37574
	37534	37575
	37535	37576
	37536	37577
	37537	37578
	37538	37579
	37539	37580
	37540	37581
	37541	37582
	37542	37583
	37543	37584
	37544	37585
	37545	37586
	37546	37587
	37547	37588
	37548	37589

Trt.	Bl. No	nb
PPD	37590	37631
	37591	37632
	37592	37633
	37593	37634
	37594	37635
	37595	37636
	37596	37637
	37597	37638
	37598	37639
	37599	37640
	37600	37641
	37601	37642
	37602	37643
	37603	37644
	37604	37645
	37605	37646
	37606	37647
	37607	37648
	37608	37649
	37609	37650
	37610	37651
	37611	37652
	37612	37653
	37613	37654
	37614	37655
	37615	37656
	37616	37657
	37617	37658
	37618	37659
	37619	37660
	37620	37661
	37621	37662
	37622	37663
	37623	37664
	37624	37665
	37625	37666
	37626	37667
	37627	37668
	37628	37669
	37629	37670
	37630	37671

Trt.	Bl. No	nb
PPD	37672	37713
	37673	37714
	37674	37715
	37675	37716
	37676	37717
	37677	37718
	37678	37719
	37679	37720
	37680	37721
	37681	37722
	37682	37723
	37683	37724
	37684	37725
	37685	37726
	37686	37727
	37687	37728
	37688	37729
	37689	37730
	37690	37731
	37691	37732
	37692	37733
	37693	37734
	37694	37735
	37695	37736
	37696	37737
	37697	37738
	37698	37739
	37699	37740
	37700	37741
	37701	37742
	37702	37743
	37703	37744
	37704	37745
	37705	37746
	37706	37747
	37707	37748
	37708	37749
	37709	37750
	37710	37751
	37711	37752
	37712	37753

Trt.	Bl. No	nb
PPD	37754	
	37755	
	37756	
	37757	
	37758	
	37759	
	37760	
	37761	
	37762	
	37763	
	37764	
	37765	
	37766	
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	37783	
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	37790	
	37791	
	37792	
	37793	
	37794	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	37795	37835
PPD	37836	37876
PPD	37877	37917
PPD	37918	37958
PPD	37959	37999
PPD	38000	38040
PPD	38041	38081

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	38082
	2	38083
	3	38084
	4	38085
	5	38086
	6	38087
	7	38088
	8	38089
	9	38090
	10	38091
	11	38092
	12	38093
	13	38094
	14	38095
	15	38096
	16	38097
	17	38098
	18	38099
	19	38100
	20	38101
	21	38102
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	23	38104
	24	38105
	25	38106
	26	38107
	27	38108
	28	38109
	29	38110
	30	38111
	31	38112
	32	38113
	33	38114
	34	38115
	35	38116
	36	38117
	37	38118
	38	38119
	39	38120
	40	38121
	41	38122
PPD	1	38123
	2	38124
	3	38125
	4	38126
	5	38127
	6	38128
	7	38129
	8	38130
	9	38131
	10	38132
	11	38133
	12	38134
	13	38135
	14	38136
	15	38137
	16	38138
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	18	38140
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	23	38145
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	26	38148
	27	38149
	28	38150
	29	38151
	30	38152
	31	38153
	32	38154
	33	38155
	34	38156
	35	38157
	36	38158
	37	38159
	38	38160
	39	38161
	40	38162
	41	38163
PPD	1	38164
	2	38165
	3	38166
	4	38167
	5	38168
	6	38169
	7	38170
	8	38171
	9	38172
	10	38173
	11	38174
	12	38175
	13	38176
	14	38177
	15	38178
	16	38179
	17	38180
	18	38181
	19	38182
	20	38183
	21	38184
	22	38185
	23	38186
	24	38187
	25	38188
	26	38189
	27	38190
	28	38191
	29	38192
	30	38193
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	32	38195
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	34	38197
	35	38198
	36	38199
	37	38200
	38	38201
	39	38202
	40	38203
	41	38204
PPD	1	38205
	2	38206
	3	38207
	4	38208
	5	38209
	6	38210
	7	38211
	8	38212
	9	38213
	10	38214
	11	38215
	12	38216
	13	38217
	14	38218
	15	38219
	16	38220
	17	38221
	18	38222
	19	38223
	20	38224
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	22	38226
	23	38227
	24	38228
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	26	38230
	27	38231
	28	38232
	29	38233
	30	38234
	31	38235
	32	38236
	33	38237
	34	38238
	35	38239
	36	38240
	37	38241
	38	38242
	39	38243
	40	38244
	41	38245
PPD	1	38246
	2	38247
	3	38248
	4	38249
	5	38250
	6	38251
	7	38252
	8	38253
	9	38254
	10	38255
	11	38256
	12	38257
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	15	38260
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	18	38263
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	28	38273
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	32	38277
	33	38278
	34	38279
	35	38280
	36	38281
	37	38282
	38	38283
	39	38284
	40	38285
	41	38286
PPD	1	38287
	2	38288
	3	38289
	4	38290
	5	38291
	6	38292
	7	38293
	8	38294
	9	38295
	10	38296
	11	38297
	12	38298
	13	38299
	14	38300
	15	38301
	16	38302
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	27	38313
	28	38314
	29	38315
	30	38316
	31	38317
	32	38318
	33	38319
	34	38320
	35	38321
	36	38322
	37	38323
	38	38324
	39	38325
	40	38326
	41	38327
PPD	1	38328
	2	38329
	3	38330
	4	38331
	5	38332
	6	38333
	7	38334
	8	38335
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	38	38365
	39	38366
	40	38367
	41	38368

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	38369
	2	38370
	3	38371
	4	38372
	5	38373
	6	38374
	7	38375
	8	38376
	9	38377
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	12	38380
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	14	38382
	15	38383
	16	38384
	17	38385
	18	38386
	19	38387
	20	38388
	21	38389
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	25	38393
	26	38394
	27	38395
	28	38396
	29	38397
	30	38398
	31	38399
	32	38400
	33	38401
	34	38402
	35	38403
	36	38404
	37	38405
	38	38406
	39	38407
	40	38408
	41	38409
PPD	42	38410
	43	38411
	44	38412
	45	38413
	46	38414
	47	38415
	48	38416
	49	38417
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	51	38419
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	73	38441
	74	38442
	75	38443
	76	38444
	77	38445
	78	38446
	79	38447
	80	38448
	81	38449
	82	38450
PPD	83	38451
	84	38452
	85	38453
	86	38454
	87	38455
	88	38456
	89	38457
	90	38458
	91	38459
	92	38460
	93	38461
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	115	38483
	116	38484
	117	38485
	118	38486
	119	38487
	120	38488
	121	38489
	122	38490
	123	38491
PPD	124	38492
	125	38493
	126	38494
	127	38495
	128	38496
	129	38497
	130	38498
	131	38499
	132	38500
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	137	38505
	138	38506
	139	38507
	140	38508
	141	38509
	142	38510
	143	38511
	144	38512
	145	38513
	146	38514
	147	38515
	148	38516
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	150	38518
	151	38519
	152	38520
	153	38521
	154	38522
	155	38523
	156	38524
	157	38525
	158	38526
	159	38527
	160	38528
	161	38529
	162	38530
	163	38531
	164	38532
PPD	165	38533
	166	38534
	167	38535
	168	38536
	169	38537
	170	38538
	171	38539
	172	38540
	173	38541
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	177	38545
	178	38546
	179	38547
	180	38548
	181	38549
	182	38550
	183	38551
	184	38552
	185	38553
	186	38554
	187	38555
	188	38556
	189	38557
	190	38558
	191	38559
	192	38560
	193	38561
	194	38562
	195	38563
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	197	38565
	198	38566
	199	38567
	200	38568
	201	38569
	202	38570
	203	38571
	204	38572
	205	38573
PPD	206	38574
	207	38575
	208	38576
	209	38577
	210	38578
	211	38579
	212	38580
	213	38581
	214	38582
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	227	38595
	228	38596
	229	38597
	230	38598
	231	38599
	232	38600
	233	38601
	234	38602
	235	38603
	236	38604
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	238	38606
	239	38607
	240	38608
	241	38609
	242	38610
	243	38611
	244	38612
	245	38613
	246	38614
PPD	247	38615
	248	38616
	249	38617
	250	38618
	251	38619
	252	38620
	253	38621
	254	38622
	255	38623
	256	38624
	257	38625
	258	38626
	259	38627
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	261	38629
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	263	38631
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	270	38638
	271	38639
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	273	38641
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	277	38645
	278	38646
	279	38647
	280	38648
	281	38649
	282	38650
	283	38651
	284	38652
	285	38653
	286	38654
	287	38655

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	38656
	2	38657
	3	38658
	4	38659
	5	38660
	6	38661
	7	38662
	8	38663
	9	38664
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	11	38666
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	15	38670
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	17	38672
	18	38673
	19	38674
	20	38675
	21	38676
	22	38677
	23	38678
	24	38679
	25	38680
	26	38681
	27	38682
	28	38683
	29	38684
	30	38685
	31	38686
	32	38687
	33	38688
	34	38689
	35	38690
	36	38691
	37	38692
	38	38693
	39	38694
	40	38695
	41	38696

Trt.	Bl. No	nb
PPD	1	38697
	2	38698
	3	38699
	4	38700
	5	38701
	6	38702
	7	38703
	8	38704
	9	38705
	10	38706
	11	38707
	12	38708
	13	38709
	14	38710
	15	38711
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	18	38714
	19	38715
	20	38716
	21	38717
	22	38718
	23	38719
	24	38720
	25	38721
	26	38722
	27	38723
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	32	38728
	33	38729
	34	38730
	35	38731
	36	38732
	37	38733
	38	38734
	39	38735
	40	38736
	41	38737

Trt.	Bl. No	nb
PPD	1	38738
	2	38739
	3	38740
	4	38741
	5	38742
	6	38743
	7	38744
	8	38745
	9	38746
	10	38747
	11	38748
	12	38749
	13	38750
	14	38751
	15	38752
	16	38753
	17	38754
	18	38755
	19	38756
	20	38757
	21	38758
	22	38759
	23	38760
	24	38761
	25	38762
	26	38763
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	32	38769
	33	38770
	34	38771
	35	38772
	36	38773
	37	38774
	38	38775
	39	38776
	40	38777
	41	38778

Trt.	Bl. No	nb
PPD	1	38779
	2	38780
	3	38781
	4	38782
	5	38783
	6	38784
	7	38785
	8	38786
	9	38787
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	17	38795
	18	38796
	19	38797
	20	38798
	21	38799
	22	38800
	23	38801
	24	38802
	25	38803
	26	38804
	27	38805
	28	38806
	29	38807
	30	38808
	31	38809
	32	38810
	33	38811
	34	38812
	35	38813
	36	38814
	37	38815
	38	38816
	39	38817
	40	38818
	41	38819

Trt.	Bl. No	nb
PPD	1	38820
	2	38821
	3	38822
	4	38823
	5	38824
	6	38825
	7	38826
	8	38827
	9	38828
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	14	38833
	15	38834
	16	38835
	17	38836
	18	38837
	19	38838
	20	38839
	21	38840
	22	38841
	23	38842
	24	38843
	25	38844
	26	38845
	27	38846
	28	38847
	29	38848
	30	38849
	31	38850
	32	38851
	33	38852
	34	38853
	35	38854
	36	38855
	37	38856
	38	38857
	39	38858
	40	38859
	41	38860

Trt.	Bl. No	nb
PPD	1	38861
	2	38862
	3	38863
	4	38864
	5	38865
	6	38866
	7	38867
	8	38868
	9	38869
	10	38870
	11	38871
	12	38872
	13	38873
	14	38874
	15	38875
	16	38876
	17	38877
	18	38878
	19	38879
	20	38880
	21	38881
	22	38882
	23	38883
	24	38884
	25	38885
	26	38886
	27	38887
	28	38888
	29	38889
	30	38890
	31	38891
	32	38892
	33	38893
	34	38894
	35	38895
	36	38896
	37	38897
	38	38898
	39	38899
	40	38900
	41	38901

Trt.	Bl. No	nb
PPD	1	38902
	2	38903
	3	38904
	4	38905
	5	38906
	6	38907
	7	38908
	8	38909
	9	38910
	10	38911
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	32	38933
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	35	38936
	36	38937
	37	38938
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	39	38940
	40	38941
	41	38942

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	38943	PPD	38984	PPD	39025	PPD	39066	PPD	39107	PPD	39148	PPD	39189
	38944		38985		39026		39067		39108		39149		39190
	38945		38986		39027		39068		39109		39150		39191
	38946		38987		39028		39069		39110		39151		39192
	38947		38988		39029		39070		39111		39152		39193
	38948		38989		39030		39071		39112		39153		39194
	38949		38990		39031		39072		39113		39154		39195
	38950		38991		39032		39073		39114		39155		39196
	38951		38992		39033		39074		39115		39156		39197
	38952		38993		39034		39075		39116		39157		39198
	38953		38994		39035		39076		39117		39158		39199
	38954		38995		39036		39077		39118		39159		39200
	38955		38996		39037		39078		39119		39160		39201
	38956		38997		39038		39079		39120		39161		39202
	38957		38998		39039		39080		39121		39162		39203
	38958		38999		39040		39081		39122		39163		39204
	38959		39000		39041		39082		39123		39164		39205
	38960		39001		39042		39083		39124		39165		39206
	38961		39002		39043		39084		39125		39166		39207
	38962		39003		39044		39085		39126		39167		39208
	38963		39004		39045		39086		39127		39168		39209
	38964		39005		39046		39087		39128		39169		39210
	38965		39006		39047		39088		39129		39170		39211
	38966		39007		39048		39089		39130		39171		39212
	38967		39008		39049		39090		39131		39172		39213
	38968		39009		39050		39091		39132		39173		39214
	38969		39010		39051		39092		39133		39174		39215
	38970		39011		39052		39093		39134		39175		39216
	38971		39012		39053		39094		39135		39176		39217
	38972		39013		39054		39095		39136		39177		39218
	38973		39014		39055		39096		39137		39178		39219
	38974		39015		39056		39097		39138		39179		39220
	38975		39016		39057		39098		39139		39180		39221
	38976		39017		39058		39099		39140		39181		39222
	38977		39018		39059		39100		39141		39182		39223
	38978		39019		39060		39101		39142		39183		39224
	38979		39020		39061		39102		39143		39184		39225
	38980		39021		39062		39103		39144		39185		39226
	38981		39022		39063		39104		39145		39186		39227
	38982		39023		39064		39105		39146		39187		39228
	38983		39024		39065		39106		39147		39188		39229

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	39230	39270
PPD	39271	39311
PPD	39312	39352
PPD	39353	39393
PPD	39394	39434
PPD	39435	39475
PPD	39476	39516

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	39517
	2	39518
	3	39519
	4	39520
	5	39521
	6	39522
	7	39523
	8	39524
	9	39525
	10	39526
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	14	39530
	15	39531
	16	39532
	17	39533
	18	39534
	19	39535
	20	39536
	21	39537
	22	39538
	23	39539
	24	39540
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	31	39547
	32	39548
	33	39549
	34	39550
	35	39551
	36	39552
	37	39553
	38	39554
	39	39555
	40	39556
	41	39557

Trt.	Bl. No	nb
PPD	1	39558
	2	39559
	3	39560
	4	39561
	5	39562
	6	39563
	7	39564
	8	39565
	9	39566
	10	39567
	11	39568
	12	39569
	13	39570
	14	39571
	15	39572
	16	39573
	17	39574
	18	39575
	19	39576
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	25	39582
	26	39583
	27	39584
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	31	39588
	32	39589
	33	39590
	34	39591
	35	39592
	36	39593
	37	39594
	38	39595
	39	39596
	40	39597
	41	39598

Trt.	Bl. No	nb
PPD	1	39599
	2	39600
	3	39601
	4	39602
	5	39603
	6	39604
	7	39605
	8	39606
	9	39607
	10	39608
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	12	39610
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	22	39620
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	25	39623
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	29	39627
	30	39628
	31	39629
	32	39630
	33	39631
	34	39632
	35	39633
	36	39634
	37	39635
	38	39636
	39	39637
	40	39638
	41	39639

Trt.	Bl. No	nb
PPD	1	39640
	2	39641
	3	39642
	4	39643
	5	39644
	6	39645
	7	39646
	8	39647
	9	39648
	10	39649
	11	39650
	12	39651
	13	39652
	14	39653
	15	39654
	16	39655
	17	39656
	18	39657
	19	39658
	20	39659
	21	39660
	22	39661
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	24	39663
	25	39664
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	27	39666
	28	39667
	29	39668
	30	39669
	31	39670
	32	39671
	33	39672
	34	39673
	35	39674
	36	39675
	37	39676
	38	39677
	39	39678
	40	39679
	41	39680

Trt.	Bl. No	nb
PPD	1	39681
	2	39682
	3	39683
	4	39684
	5	39685
	6	39686
	7	39687
	8	39688
	9	39689
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	31	39711
	32	39712
	33	39713
	34	39714
	35	39715
	36	39716
	37	39717
	38	39718
	39	39719
	40	39720
	41	39721

Trt.	Bl. No	nb
PPD	1	39722
	2	39723
	3	39724
	4	39725
	5	39726
	6	39727
	7	39728
	8	39729
	9	39730
	10	39731
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	17	39738
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	19	39740
	20	39741
	21	39742
	22	39743
	23	39744
	24	39745
	25	39746
	26	39747
	27	39748
	28	39749
	29	39750
	30	39751
	31	39752
	32	39753
	33	39754
	34	39755
	35	39756
	36	39757
	37	39758
	38	39759
	39	39760
	40	39761
	41	39762

Trt.	Bl. No	nb
PPD	1	39763
	2	39764
	3	39765
	4	39766
	5	39767
	6	39768
	7	39769
	8	39770
	9	39771
	10	39772
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	12	39774
	13	39775
	14	39776
	15	39777
	16	39778
	17	39779
	18	39780
	19	39781
	20	39782
	21	39783
	22	39784
	23	39785
	24	39786
	25	39787
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	27	39789
	28	39790
	29	39791
	30	39792
	31	39793
	32	39794
	33	39795
	34	39796
	35	39797
	36	39798
	37	39799
	38	39800
	39	39801
	40	39802
	41	39803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	39804
PPD	1	39805
PPD	1	39806
PPD	1	39807
PPD	1	39808
PPD	1	39809
PPD	1	39810
PPD	1	39811
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PPD	1	39813
PPD	1	39814
PPD	1	39815
PPD	1	39816
PPD	1	39817
PPD	1	39818
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PPD	1	39832
PPD	1	39833
PPD	1	39834
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PPD	1	39836
PPD	1	39837
PPD	1	39838
PPD	1	39839
PPD	1	39840
PPD	1	39841
PPD	1	39842
PPD	1	39843
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PPD	1	39845
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PPD	1	39859
PPD	1	39860
PPD	1	39861
PPD	1	39862
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PPD	1	39864
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PPD	1	39866
PPD	1	39867
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PPD	1	39869
PPD	1	39870
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PPD	1	39876
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PPD	1	39878
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PPD	1	39882
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PPD	1	40033
PPD	1	40034
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PPD	1	40042
PPD	1	40043
PPD	1	40044
PPD	1	40045
PPD	1	40046
PPD	1	40047
PPD	1	40048
PPD	1	40049
PPD	1	40050
PPD	1	40051
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PPD	1	40056
PPD	1	40057
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PPD	1	40064
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PPD	1	40067
PPD	1	40068
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PPD	1	40078
PPD	1	40079
PPD	1	40080
PPD	1	40081
PPD	1	40082
PPD	1	40083
PPD	1	40084
PPD	1	40085
PPD	1	40086
PPD	1	40087
PPD	1	40088
PPD	1	40089
PPD	1	40090

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	40091	40131
PPD	40132	40172
PPD	40173	40213
PPD	40214	40254
PPD	40255	40295
PPD	40296	40336
PPD	40337	40377

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	40378	40418
PPD	40419	40459
PPD	40460	40500
PPD	40501	40541
PPD	40542	40582
PPD	40583	40623
PPD	40624	40664

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	40665	
	40666	
	40667	
	40668	
	40669	
	40670	
	40671	
	40672	
	40673	
	40674	
	40675	
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	40677	
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	40680	
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	40682	
	40683	
	40684	
	40685	
	40686	
	40687	
	40688	
	40689	
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	40691	
	40692	
	40693	
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	40697	
	40698	
	40699	
	40700	
	40701	
	40702	
	40703	
	40704	
	40705	

Trt.	Bl. No	nb
PPD	40706	
	40707	
	40708	
	40709	
	40710	
	40711	
	40712	
	40713	
	40714	
	40715	
	40716	
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	40743	
	40744	
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	40746	

Trt.	Bl. No	nb
PPD	40747	
	40748	
	40749	
	40750	
	40751	
	40752	
	40753	
	40754	
	40755	
	40756	
	40757	
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	40759	
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	40761	
	40762	
	40763	
	40764	
	40765	
	40766	
	40767	
	40768	
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	40770	
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	40772	
	40773	
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	40779	
	40780	
	40781	
	40782	
	40783	
	40784	
	40785	
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Trt.	Bl. No	nb
PPD	40788	
	40789	
	40790	
	40791	
	40792	
	40793	
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Trt.	Bl. No	nb
PPD	40829	
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	40862	
	40863	
	40864	
	40865	
	40866	
	40867	
	40868	
	40869	

Trt.	Bl. No	nb
PPD	40870	
	40871	
	40872	
	40873	
	40874	
	40875	
	40876	
	40877	
	40878	
	40879	
	40880	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	60907	
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PPD	60948	
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PPD	60989	
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PPD	61030	
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PPD	61112	
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PPD	61153	
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	61193	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	61194	PPD	61235	PPD	61276	PPD	61317	PPD	61358	PPD	61399	PPD	61440
	61195		61236		61277		61318		61359		61400		61441
	61196		61237		61278		61319		61360		61401		61442
	61197		61238		61279		61320		61361		61402		61443
	61198		61239		61280		61321		61362		61403		61444
	61199		61240		61281		61322		61363		61404		61445
	61200		61241		61282		61323		61364		61405		61446
	61201		61242		61283		61324		61365		61406		61447
	61202		61243		61284		61325		61366		61407		61448
	61203		61244		61285		61326		61367		61408		61449
	61204		61245		61286		61327		61368		61409		61450
	61205		61246		61287		61328		61369		61410		61451
	61206		61247		61288		61329		61370		61411		61452
	61207		61248		61289		61330		61371		61412		61453
	61208		61249		61290		61331		61372		61413		61454
	61209		61250		61291		61332		61373		61414		61455
	61210		61251		61292		61333		61374		61415		61456
	61211		61252		61293		61334		61375		61416		61457
	61212		61253		61294		61335		61376		61417		61458
	61213		61254		61295		61336		61377		61418		61459
	61214		61255		61296		61337		61378		61419		61460
	61215		61256		61297		61338		61379		61420		61461
	61216		61257		61298		61339		61380		61421		61462
	61217		61258		61299		61340		61381		61422		61463
	61218		61259		61300		61341		61382		61423		61464
	61219		61260		61301		61342		61383		61424		61465
	61220		61261		61302		61343		61384		61425		61466
	61221		61262		61303		61344		61385		61426		61467
	61222		61263		61304		61345		61386		61427		61468
	61223		61264		61305		61346		61387		61428		61469
	61224		61265		61306		61347		61388		61429		61470
	61225		61266		61307		61348		61389		61430		61471
	61226		61267		61308		61349		61390		61431		61472
	61227		61268		61309		61350		61391		61432		61473
	61228		61269		61310		61351		61392		61433		61474
	61229		61270		61311		61352		61393		61434		61475
	61230		61271		61312		61353		61394		61435		61476
	61231		61272		61313		61354		61395		61436		61477
	61232		61273		61314		61355		61396		61437		61478
	61233		61274		61315		61356		61397		61438		61479
	61234		61275		61316		61357		61398		61439		61480

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	61481	61521
PPD	61522	61562
PPD	61563	61603
PPD	61604	61644
PPD	61645	61685
PPD	61686	61726
PPD	61727	61767

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	61768	61808
PPD	61809	61849
PPD	61850	61890
PPD	61891	61931
PPD	61932	61972
PPD	61973	62013
PPD	62014	62054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	62055
	2	62056
	3	62057
	4	62058
	5	62059
	6	62060
	7	62061
	8	62062
	9	62063
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	11	62065
	12	62066
	13	62067
	14	62068
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	17	62071
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	25	62079
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	27	62081
	28	62082
	29	62083
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	33	62087
	34	62088
	35	62089
	36	62090
	37	62091
	38	62092
	39	62093
	40	62094
	41	62095
PPD	1	62096
	2	62097
	3	62098
	4	62099
	5	62100
	6	62101
	7	62102
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	12	62107
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	14	62109
	15	62110
	16	62111
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	22	62117
	23	62118
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	25	62120
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	30	62125
	31	62126
	32	62127
	33	62128
	34	62129
	35	62130
	36	62131
	37	62132
	38	62133
	39	62134
	40	62135
	41	62136
PPD	1	62137
	2	62138
	3	62139
	4	62140
	5	62141
	6	62142
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	37	62173
	38	62174
	39	62175
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	41	62177
PPD	1	62178
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	5	62182
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	41	62218
PPD	1	62219
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PPD	1	62260
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PPD	1	62301
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	41	62341

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	62342
	2	62343
	3	62344
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	33	62374
	34	62375
	35	62376
	36	62377
	37	62378
	38	62379
	39	62380
	40	62381
	41	62382

Trt.	Bl. No	nb
PPD	1	62383
	2	62384
	3	62385
	4	62386
	5	62387
	6	62388
	7	62389
	8	62390
	9	62391
	10	62392
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	35	62417
	36	62418
	37	62419
	38	62420
	39	62421
	40	62422
	41	62423

Trt.	Bl. No	nb
PPD	1	62424
	2	62425
	3	62426
	4	62427
	5	62428
	6	62429
	7	62430
	8	62431
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	10	62433
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	35	62458
	36	62459
	37	62460
	38	62461
	39	62462
	40	62463
	41	62464

Trt.	Bl. No	nb
PPD	1	62465
	2	62466
	3	62467
	4	62468
	5	62469
	6	62470
	7	62471
	8	62472
	9	62473
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	11	62475
	12	62476
	13	62477
	14	62478
	15	62479
	16	62480
	17	62481
	18	62482
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	32	62496
	33	62497
	34	62498
	35	62499
	36	62500
	37	62501
	38	62502
	39	62503
	40	62504
	41	62505

Trt.	Bl. No	nb
PPD	1	62506
	2	62507
	3	62508
	4	62509
	5	62510
	6	62511
	7	62512
	8	62513
	9	62514
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	15	62520
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	30	62535
	31	62536
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	33	62538
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	35	62540
	36	62541
	37	62542
	38	62543
	39	62544
	40	62545
	41	62546

Trt.	Bl. No	nb
PPD	1	62547
	2	62548
	3	62549
	4	62550
	5	62551
	6	62552
	7	62553
	8	62554
	9	62555
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	32	62578
	33	62579
	34	62580
	35	62581
	36	62582
	37	62583
	38	62584
	39	62585
	40	62586
	41	62587

Trt.	Bl. No	nb
PPD	1	62588
	2	62589
	3	62590
	4	62591
	5	62592
	6	62593
	7	62594
	8	62595
	9	62596
	10	62597
	11	62598
	12	62599
	13	62600
	14	62601
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	22	62609
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	32	62619
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	36	62623
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	40	62627
	41	62628

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	62629
	2	62630
	3	62631
	4	62632
	5	62633
	6	62634
	7	62635
	8	62636
	9	62637
	10	62638
	11	62639
	12	62640
	13	62641
	14	62642
	15	62643
	16	62644
	17	62645
	18	62646
	19	62647
	20	62648
	21	62649
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	25	62653
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	33	62661
	34	62662
	35	62663
	36	62664
	37	62665
	38	62666
	39	62667
	40	62668
	41	62669
PPD	42	62670
	43	62671
	44	62672
	45	62673
	46	62674
	47	62675
	48	62676
	49	62677
	50	62678
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	76	62704
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	78	62706
	79	62707
	80	62708
	81	62709
	82	62710
PPD	83	62711
	84	62712
	85	62713
	86	62714
	87	62715
	88	62716
	89	62717
	90	62718
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	119	62747
	120	62748
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	122	62750
	123	62751
PPD	124	62752
	125	62753
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	163	62791
	164	62792
PPD	165	62793
	166	62794
	167	62795
	168	62796
	169	62797
	170	62798
	171	62799
	172	62800
	173	62801
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	205	62833
PPD	206	62834
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	240	62868
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	245	62873
	246	62874
PPD	247	62875
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	285	62913
	286	62914
	287	62915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	62916	62956
PPD	62957	62997
PPD	62998	63038
PPD	63039	63079
PPD	63080	63120
PPD	63121	63161
PPD	63162	63202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	63203	63243
PPD	63244	63284
PPD	63285	63325
PPD	63326	63366
PPD	63367	63407
PPD	63408	63448
PPD	63449	63489

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	63490	63530
PPD	63531	63571
PPD	63572	63612
PPD	63613	63653
PPD	63654	63694
PPD	63695	63735
PPD	63736	63776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	63777	
	63778	
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Trt.	Bl. No	nb
PPD	63818	
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Trt.	Bl. No	nb
PPD	63859	
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Trt.	Bl. No	nb
PPD	63900	
	63901	
	63902	
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Trt.	Bl. No	nb
PPD	63941	
	63942	
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Trt.	Bl. No	nb
PPD	63982	
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Trt.	Bl. No	nb
PPD	64023	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	64064	PPD	64105	PPD	64146	PPD	64187	PPD	64228	PPD	64269	PPD	64310
	64065		64106		64147		64188		64229		64270		64311
	64066		64107		64148		64189		64230		64271		64312
	64067		64108		64149		64190		64231		64272		64313
	64068		64109		64150		64191		64232		64273		64314
	64069		64110		64151		64192		64233		64274		64315
	64070		64111		64152		64193		64234		64275		64316
	64071		64112		64153		64194		64235		64276		64317
	64072		64113		64154		64195		64236		64277		64318
	64073		64114		64155		64196		64237		64278		64319
	64074		64115		64156		64197		64238		64279		64320
	64075		64116		64157		64198		64239		64280		64321
	64076		64117		64158		64199		64240		64281		64322
	64077		64118		64159		64200		64241		64282		64323
	64078		64119		64160		64201		64242		64283		64324
	64079		64120		64161		64202		64243		64284		64325
	64080		64121		64162		64203		64244		64285		64326
	64081		64122		64163		64204		64245		64286		64327
	64082		64123		64164		64205		64246		64287		64328
	64083		64124		64165		64206		64247		64288		64329
	64084		64125		64166		64207		64248		64289		64330
	64085		64126		64167		64208		64249		64290		64331
	64086		64127		64168		64209		64250		64291		64332
	64087		64128		64169		64210		64251		64292		64333
	64088		64129		64170		64211		64252		64293		64334
	64089		64130		64171		64212		64253		64294		64335
	64090		64131		64172		64213		64254		64295		64336
	64091		64132		64173		64214		64255		64296		64337
	64092		64133		64174		64215		64256		64297		64338
	64093		64134		64175		64216		64257		64298		64339
	64094		64135		64176		64217		64258		64299		64340
	64095		64136		64177		64218		64259		64300		64341
	64096		64137		64178		64219		64260		64301		64342
	64097		64138		64179		64220		64261		64302		64343
	64098		64139		64180		64221		64262		64303		64344
	64099		64140		64181		64222		64263		64304		64345
	64100		64141		64182		64223		64264		64305		64346
	64101		64142		64183		64224		64265		64306		64347
	64102		64143		64184		64225		64266		64307		64348
	64103		64144		64185		64226		64267		64308		64349
	64104		64145		64186		64227		64268		64309		64350

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	64351	
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Trt.	Bl. No	nb
PPD	64392	
	64393	
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	64399	
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Trt.	Bl. No	nb
PPD	64433	
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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	64597	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	64638
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	37	64674
	38	64675
	39	64676
	40	64677
	41	64678

Trt.	Bl. No	nb
PPD	1	64679
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	41	64719

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	1	64761
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	1	64843
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	39	64881
	40	64882
	41	64883

Trt.	Bl. No	nb
PPD	1	64884
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	64925	65
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Trt.	Bl. No	nb
PPD	64966	65
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Trt.	Bl. No	nb
PPD	65007	65
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Trt.	Bl. No	nb
PPD	65048	65
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Trt.	Bl. No	nb
PPD	65089	65
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Trt.	Bl. No	nb
PPD	65130	65
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Trt.	Bl. No	nb
PPD	65171	65
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	65499	PPD	65540	PPD	65581	PPD	65622	PPD	65663	PPD	65704	PPD	65745
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	65501		65542		65583		65624		65665		65706		65747
	65502		65543		65584		65625		65666		65707		65748
	65503		65544		65585		65626		65667		65708		65749
	65504		65545		65586		65627		65668		65709		65750
	65505		65546		65587		65628		65669		65710		65751
	65506		65547		65588		65629		65670		65711		65752
	65507		65548		65589		65630		65671		65712		65753
	65508		65549		65590		65631		65672		65713		65754
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	65513		65554		65595		65636		65677		65718		65759
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	65517		65558		65599		65640		65681		65722		65763
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	65533		65574		65615		65656		65697		65738		65779
	65534		65575		65616		65657		65698		65739		65780
	65535		65576		65617		65658		65699		65740		65781
	65536		65577		65618		65659		65700		65741		65782
	65537		65578		65619		65660		65701		65742		65783
	65538		65579		65620		65661		65702		65743		65784
	65539		65580		65621		65662		65703		65744		65785

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	65786	65826
PPD	65827	65867
PPD	65868	65908
PPD	65909	65949
PPD	65950	65990
PPD	65991	66031
PPD	66032	66072

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	66073	66113
PPD	66114	66154
PPD	66155	66195
PPD	66196	66236
PPD	66237	66277
PPD	66278	66318
PPD	66319	66359

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	66360	66360
		66361
		66362
		66363
		66364
		66365
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		66370
		66371
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		66395
		66396
		66397
		66398
		66399
		66400

Trt.	Bl. No	nb
PPD	66401	66401
		66402
		66403
		66404
		66405
		66406
		66407
		66408
		66409
		66410
		66411
		66412
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		66439
		66440
		66441

Trt.	Bl. No	nb
PPD	66442	66442
		66443
		66444
		66445
		66446
		66447
		66448
		66449
		66450
		66451
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		66476
		66477
		66478
		66479
		66480
		66481
		66482

Trt.	Bl. No	nb
PPD	66483	66483
		66484
		66485
		66486
		66487
		66488
		66489
		66490
		66491
		66492
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		66500
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		66519
		66520
		66521
		66522
		66523

Trt.	Bl. No	nb
PPD	66524	66524
		66525
		66526
		66527
		66528
		66529
		66530
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		66561
		66562
		66563
		66564

Trt.	Bl. No	nb
PPD	66565	66565
		66566
		66567
		66568
		66569
		66570
		66571
		66572
		66573
		66574
		66575
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		66599
		66600
		66601
		66602
		66603
		66604
		66605

Trt.	Bl. No	nb
PPD	66606	66606
		66607
		66608
		66609
		66610
		66611
		66612
		66613
		66614
		66615
		66616
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		66645
		66646

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	66647
	2	66648
	3	66649
	4	66650
	5	66651
	6	66652
	7	66653
	8	66654
	9	66655
	10	66656
	11	66657
	12	66658
	13	66659
	14	66660
	15	66661
	16	66662
	17	66663
	18	66664
	19	66665
	20	66666
	21	66667
	22	66668
	23	66669
	24	66670
	25	66671
	26	66672
	27	66673
	28	66674
	29	66675
	30	66676
	31	66677
	32	66678
	33	66679
	34	66680
	35	66681
	36	66682
	37	66683
	38	66684
	39	66685
	40	66686
	41	66687
PPD	1	66688
	2	66689
	3	66690
	4	66691
	5	66692
	6	66693
	7	66694
	8	66695
	9	66696
	10	66697
	11	66698
	12	66699
	13	66700
	14	66701
	15	66702
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	40	66727
	41	66728
PPD	1	66729
	2	66730
	3	66731
	4	66732
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	31	66759
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	35	66763
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	37	66765
	38	66766
	39	66767
	40	66768
	41	66769
PPD	1	66770
	2	66771
	3	66772
	4	66773
	5	66774
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	35	66804
	36	66805
	37	66806
	38	66807
	39	66808
	40	66809
	41	66810
PPD	1	66811
	2	66812
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PPD	1	66852
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PPD	1	66893
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	40	66932
	41	66933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	66934	66974
PPD	66975	67015
PPD	67016	67056
PPD	67057	67097
PPD	67098	67138
PPD	67139	67179
PPD	67180	67220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	67221	PPD	67262	PPD	67303	PPD	67344	PPD	67385	PPD	67426	PPD	67467
	67222		67263		67304		67345		67386		67427		67468
	67223		67264		67305		67346		67387		67428		67469
	67224		67265		67306		67347		67388		67429		67470
	67225		67266		67307		67348		67389		67430		67471
	67226		67267		67308		67349		67390		67431		67472
	67227		67268		67309		67350		67391		67432		67473
	67228		67269		67310		67351		67392		67433		67474
	67229		67270		67311		67352		67393		67434		67475
	67230		67271		67312		67353		67394		67435		67476
	67231		67272		67313		67354		67395		67436		67477
	67232		67273		67314		67355		67396		67437		67478
	67233		67274		67315		67356		67397		67438		67479
	67234		67275		67316		67357		67398		67439		67480
	67235		67276		67317		67358		67399		67440		67481
	67236		67277		67318		67359		67400		67441		67482
	67237		67278		67319		67360		67401		67442		67483
	67238		67279		67320		67361		67402		67443		67484
	67239		67280		67321		67362		67403		67444		67485
	67240		67281		67322		67363		67404		67445		67486
	67241		67282		67323		67364		67405		67446		67487
	67242		67283		67324		67365		67406		67447		67488
	67243		67284		67325		67366		67407		67448		67489
	67244		67285		67326		67367		67408		67449		67490
	67245		67286		67327		67368		67409		67450		67491
	67246		67287		67328		67369		67410		67451		67492
	67247		67288		67329		67370		67411		67452		67493
	67248		67289		67330		67371		67412		67453		67494
	67249		67290		67331		67372		67413		67454		67495
	67250		67291		67332		67373		67414		67455		67496
	67251		67292		67333		67374		67415		67456		67497
	67252		67293		67334		67375		67416		67457		67498
	67253		67294		67335		67376		67417		67458		67499
	67254		67295		67336		67377		67418		67459		67500
	67255		67296		67337		67378		67419		67460		67501
	67256		67297		67338		67379		67420		67461		67502
	67257		67298		67339		67380		67421		67462		67503
	67258		67299		67340		67381		67422		67463		67504
	67259		67300		67341		67382		67423		67464		67505
	67260		67301		67342		67383		67424		67465		67506
	67261		67302		67343		67384		67425		67466		67507

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	67508	67549
	67509	67550
	67510	67551
	67511	67552
	67512	67553
	67513	67554
	67514	67555
	67515	67556
	67516	67557
	67517	67558
	67518	67559
	67519	67560
	67520	67561
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	67535	67576
	67536	67577
	67537	67578
	67538	67579
	67539	67580
	67540	67581
	67541	67582
	67542	67583
	67543	67584
	67544	67585
	67545	67586
	67546	67587
	67547	67588
	67548	67589

Trt.	Bl. No	nb
PPD	67590	67631
	67591	67632
	67592	67633
	67593	67634
	67594	67635
	67595	67636
	67596	67637
	67597	67638
	67598	67639
	67599	67640
	67600	67641
	67601	67642
	67602	67643
	67603	67644
	67604	67645
	67605	67646
	67606	67647
	67607	67648
	67608	67649
	67609	67650
	67610	67651
	67611	67652
	67612	67653
	67613	67654
	67614	67655
	67615	67656
	67616	67657
	67617	67658
	67618	67659
	67619	67660
	67620	67661
	67621	67662
	67622	67663
	67623	67664
	67624	67665
	67625	67666
	67626	67667
	67627	67668
	67628	67669
	67629	67670
	67630	67671

Trt.	Bl. No	nb
PPD	67672	67713
	67673	67714
	67674	67715
	67675	67716
	67676	67717
	67677	67718
	67678	67719
	67679	67720
	67680	67721
	67681	67722
	67682	67723
	67683	67724
	67684	67725
	67685	67726
	67686	67727
	67687	67728
	67688	67729
	67689	67730
	67690	67731
	67691	67732
	67692	67733
	67693	67734
	67694	67735
	67695	67736
	67696	67737
	67697	67738
	67698	67739
	67699	67740
	67700	67741
	67701	67742
	67702	67743
	67703	67744
	67704	67745
	67705	67746
	67706	67747
	67707	67748
	67708	67749
	67709	67750
	67710	67751
	67711	67752
	67712	67753

Trt.	Bl. No	nb
PPD	67713	67754
	67714	67755
	67715	67756
	67716	67757
	67717	67758
	67718	67759
	67719	67760
	67720	67761
	67721	67762
	67722	67763
	67723	67764
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	67738	67779
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	67740	67781
	67741	67782
	67742	67783
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	67744	67785
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	67748	67789
	67749	67790
	67750	67791
	67751	67792
	67752	67793
	67753	67794

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	67795	67835
PPD	67836	67876
PPD	67877	67917
PPD	67918	67958
PPD	67959	67999
PPD	68000	68040
PPD	68041	68081

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	68082	68123
	68083	68124
	68084	68125
	68085	68126
	68086	68127
	68087	68128
	68088	68129
	68089	68130
	68090	68131
	68091	68132
	68092	68133
	68093	68134
	68094	68135
	68095	68136
	68096	68137
	68097	68138
	68098	68139
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	68113	68154
	68114	68155
	68115	68156
	68116	68157
	68117	68158
	68118	68159
	68119	68160
	68120	68161
	68121	68162
	68122	68163

Trt.	Bl. No	nb
PPD	68164	68205
	68165	68206
	68166	68207
	68167	68208
	68168	68209
	68169	68210
	68170	68211
	68171	68212
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	68183	68224
	68184	68225
	68185	68226
	68186	68227
	68187	68228
	68188	68229
	68189	68230
	68190	68231
	68191	68232
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	68194	68235
	68195	68236
	68196	68237
	68197	68238
	68198	68239
	68199	68240
	68200	68241
	68201	68242
	68202	68243
	68203	68244
	68204	68245

Trt.	Bl. No	nb
PPD	68246	68287
	68247	68288
	68248	68289
	68249	68290
	68250	68291
	68251	68292
	68252	68293
	68253	68294
	68254	68295
	68255	68296
	68256	68297
	68257	68298
	68258	68299
	68259	68300
	68260	68301
	68261	68302
	68262	68303
	68263	68304
	68264	68305
	68265	68306
	68266	68307
	68267	68308
	68268	68309
	68269	68310
	68270	68311
	68271	68312
	68272	68313
	68273	68314
	68274	68315
	68275	68316
	68276	68317
	68277	68318
	68278	68319
	68279	68320
	68280	68321
	68281	68322
	68282	68323
	68283	68324
	68284	68325
	68285	68326
	68286	68327

Trt.	Bl. No	nb
PPD	68287	68328
	68288	68329
	68289	68330
	68290	68331
	68291	68332
	68292	68333
	68293	68334
	68294	68335
	68295	68336
	68296	68337
	68297	68338
	68298	68339
	68299	68340
	68300	68341
	68301	68342
	68302	68343
	68303	68344
	68304	68345
	68305	68346
	68306	68347
	68307	68348
	68308	68349
	68309	68350
	68310	68351
	68311	68352
	68312	68353
	68313	68354
	68314	68355
	68315	68356
	68316	68357
	68317	68358
	68318	68359
	68319	68360
	68320	68361
	68321	68362
	68322	68363
	68323	68364
	68324	68365
	68325	68366
	68326	68367
	68327	68368

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	68369	68410
	68370	68411
	68371	68412
	68372	68413
	68373	68414
	68374	68415
	68375	68416
	68376	68417
	68377	68418
	68378	68419
	68379	68420
	68380	68421
	68381	68422
	68382	68423
	68383	68424
	68384	68425
	68385	68426
	68386	68427
	68387	68428
	68388	68429
	68389	68430
	68390	68431
	68391	68432
	68392	68433
	68393	68434
	68394	68435
	68395	68436
	68396	68437
	68397	68438
	68398	68439
	68399	68440
	68400	68441
	68401	68442
	68402	68443
	68403	68444
	68404	68445
	68405	68446
	68406	68447
	68407	68448
	68408	68449
	68409	68450

Trt.	Bl. No	nb
PPD	68451	68492
	68452	68493
	68453	68494
	68454	68495
	68455	68496
	68456	68497
	68457	68498
	68458	68499
	68459	68500
	68460	68501
	68461	68502
	68462	68503
	68463	68504
	68464	68505
	68465	68506
	68466	68507
	68467	68508
	68468	68509
	68469	68510
	68470	68511
	68471	68512
	68472	68513
	68473	68514
	68474	68515
	68475	68516
	68476	68517
	68477	68518
	68478	68519
	68479	68520
	68480	68521
	68481	68522
	68482	68523
	68483	68524
	68484	68525
	68485	68526
	68486	68527
	68487	68528
	68488	68529
	68489	68530
	68490	68531
	68491	68532

Trt.	Bl. No	nb
PPD	68533	68574
	68534	68575
	68535	68576
	68536	68577
	68537	68578
	68538	68579
	68539	68580
	68540	68581
	68541	68582
	68542	68583
	68543	68584
	68544	68585
	68545	68586
	68546	68587
	68547	68588
	68548	68589
	68549	68590
	68550	68591
	68551	68592
	68552	68593
	68553	68594
	68554	68595
	68555	68596
	68556	68597
	68557	68598
	68558	68599
	68559	68600
	68560	68601
	68561	68602
	68562	68603
	68563	68604
	68564	68605
	68565	68606
	68566	68607
	68567	68608
	68568	68609
	68569	68610
	68570	68611
	68571	68612
	68572	68613
	68573	68614

Trt.	Bl. No	nb
PPD	68615	68655
	68616	
	68617	
	68618	
	68619	
	68620	
	68621	
	68622	
	68623	
	68624	
	68625	
	68626	
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	68641	
	68642	
	68643	
	68644	
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	68647	
	68648	
	68649	
	68650	
	68651	
	68652	
	68653	
	68654	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	68656	68696
PPD	68697	68737
PPD	68738	68778
PPD	68779	68819
PPD	68820	68860
PPD	68861	68901
PPD	68902	68942

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	68943
	2	68944
	3	68945
	4	68946
	5	68947
	6	68948
	7	68949
	8	68950
	9	68951
	10	68952
	11	68953
	12	68954
	13	68955
	14	68956
	15	68957
	16	68958
	17	68959
	18	68960
	19	68961
	20	68962
	21	68963
	22	68964
	23	68965
	24	68966
	25	68967
	26	68968
	27	68969
	28	68970
	29	68971
	30	68972
	31	68973
	32	68974
	33	68975
	34	68976
	35	68977
	36	68978
	37	68979
	38	68980
	39	68981
	40	68982
	41	68983
PPD	1	68984
	2	68985
	3	68986
	4	68987
	5	68988
	6	68989
	7	68990
	8	68991
	9	68992
	10	68993
	11	68994
	12	68995
	13	68996
	14	68997
	15	68998
	16	68999
	17	69000
	18	69001
	19	69002
	20	69003
	21	69004
	22	69005
	23	69006
	24	69007
	25	69008
	26	69009
	27	69010
	28	69011
	29	69012
	30	69013
	31	69014
	32	69015
	33	69016
	34	69017
	35	69018
	36	69019
	37	69020
	38	69021
	39	69022
	40	69023
	41	69024
PPD	1	69025
	2	69026
	3	69027
	4	69028
	5	69029
	6	69030
	7	69031
	8	69032
	9	69033
	10	69034
	11	69035
	12	69036
	13	69037
	14	69038
	15	69039
	16	69040
	17	69041
	18	69042
	19	69043
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	21	69045
	22	69046
	23	69047
	24	69048
	25	69049
	26	69050
	27	69051
	28	69052
	29	69053
	30	69054
	31	69055
	32	69056
	33	69057
	34	69058
	35	69059
	36	69060
	37	69061
	38	69062
	39	69063
	40	69064
	41	69065
PPD	1	69066
	2	69067
	3	69068
	4	69069
	5	69070
	6	69071
	7	69072
	8	69073
	9	69074
	10	69075
	11	69076
	12	69077
	13	69078
	14	69079
	15	69080
	16	69081
	17	69082
	18	69083
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	33	69098
	34	69099
	35	69100
	36	69101
	37	69102
	38	69103
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	40	69105
	41	69106
PPD	1	69107
	2	69108
	3	69109
	4	69110
	5	69111
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	7	69113
	8	69114
	9	69115
	10	69116
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	34	69140
	35	69141
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	37	69143
	38	69144
	39	69145
	40	69146
	41	69147
PPD	1	69148
	2	69149
	3	69150
	4	69151
	5	69152
	6	69153
	7	69154
	8	69155
	9	69156
	10	69157
	11	69158
	12	69159
	13	69160
	14	69161
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	26	69173
	27	69174
	28	69175
	29	69176
	30	69177
	31	69178
	32	69179
	33	69180
	34	69181
	35	69182
	36	69183
	37	69184
	38	69185
	39	69186
	40	69187
	41	69188
PPD	1	69189
	2	69190
	3	69191
	4	69192
	5	69193
	6	69194
	7	69195
	8	69196
	9	69197
	10	69198
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	13	69201
	14	69202
	15	69203
	16	69204
	17	69205
	18	69206
	19	69207
	20	69208
	21	69209
	22	69210
	23	69211
	24	69212
	25	69213
	26	69214
	27	69215
	28	69216
	29	69217
	30	69218
	31	69219
	32	69220
	33	69221
	34	69222
	35	69223
	36	69224
	37	69225
	38	69226
	39	69227
	40	69228
	41	69229

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	69230	69270
PPD	69271	69311
PPD	69312	69352
PPD	69353	69393
PPD	69394	69434
PPD	69435	69475
PPD	69476	69516

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	69517	69558
	69518	69559
	69519	69560
	69520	69561
	69521	69562
	69522	69563
	69523	69564
	69524	69565
	69525	69566
	69526	69567
	69527	69568
	69528	69569
	69529	69570
	69530	69571
	69531	69572
	69532	69573
	69533	69574
	69534	69575
	69535	69576
	69536	69577
	69537	69578
	69538	69579
	69539	69580
	69540	69581
	69541	69582
	69542	69583
	69543	69584
	69544	69585
	69545	69586
	69546	69587
	69547	69588
	69548	69589
	69549	69590
	69550	69591
	69551	69592
	69552	69593
	69553	69594
	69554	69595
	69555	69596
	69556	69597
	69557	69598

Trt.	Bl. No	nb
PPD	69599	69640
	69600	69641
	69601	69642
	69602	69643
	69603	69644
	69604	69645
	69605	69646
	69606	69647
	69607	69648
	69608	69649
	69609	69650
	69610	69651
	69611	69652
	69612	69653
	69613	69654
	69614	69655
	69615	69656
	69616	69657
	69617	69658
	69618	69659
	69619	69660
	69620	69661
	69621	69662
	69622	69663
	69623	69664
	69624	69665
	69625	69666
	69626	69667
	69627	69668
	69628	69669
	69629	69670
	69630	69671
	69631	69672
	69632	69673
	69633	69674
	69634	69675
	69635	69676
	69636	69677
	69637	69678
	69638	69679
	69639	69680

Trt.	Bl. No	nb
PPD	69681	69722
	69682	69723
	69683	69724
	69684	69725
	69685	69726
	69686	69727
	69687	69728
	69688	69729
	69689	69730
	69690	69731
	69691	69732
	69692	69733
	69693	69734
	69694	69735
	69695	69736
	69696	69737
	69697	69738
	69698	69739
	69699	69740
	69700	69741
	69701	69742
	69702	69743
	69703	69744
	69704	69745
	69705	69746
	69706	69747
	69707	69748
	69708	69749
	69709	69750
	69710	69751
	69711	69752
	69712	69753
	69713	69754
	69714	69755
	69715	69756
	69716	69757
	69717	69758
	69718	69759
	69719	69760
	69720	69761
	69721	69762

Trt.	Bl. No	nb
PPD	69722	69763
	69723	69764
	69724	69765
	69725	69766
	69726	69767
	69727	69768
	69728	69769
	69729	69770
	69730	69771
	69731	69772
	69732	69773
	69733	69774
	69734	69775
	69735	69776
	69736	69777
	69737	69778
	69738	69779
	69739	69780
	69740	69781
	69741	69782
	69742	69783
	69743	69784
	69744	69785
	69745	69786
	69746	69787
	69747	69788
	69748	69789
	69749	69790
	69750	69791
	69751	69792
	69752	69793
	69753	69794
	69754	69795
	69755	69796
	69756	69797
	69757	69798
	69758	69799
	69759	69800
	69760	69801
	69761	69802
	69762	69803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	1	69804
	2	69805
	3	69806
	4	69807
	5	69808
	6	69809
	7	69810
	8	69811
	9	69812
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	25	69828
	26	69829
	27	69830
	28	69831
	29	69832
	30	69833
	31	69834
	32	69835
	33	69836
	34	69837
	35	69838
	36	69839
	37	69840
	38	69841
	39	69842
	40	69843
	41	69844
PPD	1	69845
	2	69846
	3	69847
	4	69848
	5	69849
	6	69850
	7	69851
	8	69852
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	10	69854
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	13	69857
	14	69858
	15	69859
	16	69860
	17	69861
	18	69862
	19	69863
	20	69864
	21	69865
	22	69866
	23	69867
	24	69868
	25	69869
	26	69870
	27	69871
	28	69872
	29	69873
	30	69874
	31	69875
	32	69876
	33	69877
	34	69878
	35	69879
	36	69880
	37	69881
	38	69882
	39	69883
	40	69884
	41	69885
PPD	1	69886
	2	69887
	3	69888
	4	69889
	5	69890
	6	69891
	7	69892
	8	69893
	9	69894
	10	69895
	11	69896
	12	69897
	13	69898
	14	69899
	15	69900
	16	69901
	17	69902
	18	69903
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	35	69920
	36	69921
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	38	69923
	39	69924
	40	69925
	41	69926
PPD	1	69927
	2	69928
	3	69929
	4	69930
	5	69931
	6	69932
	7	69933
	8	69934
	9	69935
	10	69936
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	33	69959
	34	69960
	35	69961
	36	69962
	37	69963
	38	69964
	39	69965
	40	69966
	41	69967
PPD	1	69968
	2	69969
	3	69970
	4	69971
	5	69972
	6	69973
	7	69974
	8	69975
	9	69976
	10	69977
	11	69978
	12	69979
	13	69980
	14	69981
	15	69982
	16	69983
	17	69984
	18	69985
	19	69986
	20	69987
	21	69988
	22	69989
	23	69990
	24	69991
	25	69992
	26	69993
	27	69994
	28	69995
	29	69996
	30	69997
	31	69998
	32	69999
	33	70000
	34	70001
	35	70002
	36	70003
	37	70004
	38	70005
	39	70006
	40	70007
	41	70008
PPD	1	70009
	2	70010
	3	70011
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	27	70035
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	29	70037
	30	70038
	31	70039
	32	70040
	33	70041
	34	70042
	35	70043
	36	70044
	37	70045
	38	70046
	39	70047
	40	70048
	41	70049
PPD	1	70050
	2	70051
	3	70052
	4	70053
	5	70054
	6	70055
	7	70056
	8	70057
	9	70058
	10	70059
	11	70060
	12	70061
	13	70062
	14	70063
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	32	70081
	33	70082
	34	70083
	35	70084
	36	70085
	37	70086
	38	70087
	39	70088
	40	70089
	41	70090

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	70091	70092
	70093	70094
	70095	70096
	70097	70098
	70099	70100
	70101	70102
	70103	70104
	70105	70106
	70107	70108
	70109	70110
	70111	70112
	70113	70114
	70115	70116
	70117	70118
	70119	70120
	70121	70122
	70123	70124
	70125	70126
	70127	70128
	70129	70130
	70131	

Trt.	Bl. No	nb
PPD	70132	70133
	70134	70135
	70136	70137
	70138	70139
	70140	70141
	70142	70143
	70144	70145
	70146	70147
	70148	70149
	70150	70151
	70152	70153
	70154	70155
	70156	70157
	70158	70159
	70160	70161
	70162	70163
	70164	70165
	70166	70167
	70168	70169
	70170	70171
	70172	

Trt.	Bl. No	nb
PPD	70173	70174
	70175	70176
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	70199	70200
	70201	70202
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	70211	70212
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Trt.	Bl. No	nb
PPD	70214	70215
	70216	70217
	70218	70219
	70220	70221
	70222	70223
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	70232	70233
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	70238	70239
	70240	70241
	70242	70243
	70244	70245
	70246	70247
	70248	70249
	70250	70251
	70252	70253
	70254	

Trt.	Bl. No	nb
PPD	70255	70256
	70257	70258
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	70273	70274
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	70293	70294
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Trt.	Bl. No	nb
PPD	70296	70297
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	70300	70301
	70302	70303
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	70316	70317
	70318	70319
	70320	70321
	70322	70323
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	70332	70333
	70334	70335
	70336	

Trt.	Bl. No	nb
PPD	70337	70338
	70339	70340
	70341	70342
	70343	70344
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	70353	70354
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	70371	70372
	70373	70374
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

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	70378	PPD	70419	PPD	70460	PPD	70501	PPD	70542	PPD	70583	PPD	70624
	70379		70420		70461		70502		70543		70584		70625
	70380		70421		70462		70503		70544		70585		70626
	70381		70422		70463		70504		70545		70586		70627
	70382		70423		70464		70505		70546		70587		70628
	70383		70424		70465		70506		70547		70588		70629
	70384		70425		70466		70507		70548		70589		70630
	70385		70426		70467		70508		70549		70590		70631
	70386		70427		70468		70509		70550		70591		70632
	70387		70428		70469		70510		70551		70592		70633
	70388		70429		70470		70511		70552		70593		70634
	70389		70430		70471		70512		70553		70594		70635
	70390		70431		70472		70513		70554		70595		70636
	70391		70432		70473		70514		70555		70596		70637
	70392		70433		70474		70515		70556		70597		70638
	70393		70434		70475		70516		70557		70598		70639
	70394		70435		70476		70517		70558		70599		70640
	70395		70436		70477		70518		70559		70600		70641
	70396		70437		70478		70519		70560		70601		70642
	70397		70438		70479		70520		70561		70602		70643
	70398		70439		70480		70521		70562		70603		70644
	70399		70440		70481		70522		70563		70604		70645
	70400		70441		70482		70523		70564		70605		70646
	70401		70442		70483		70524		70565		70606		70647
	70402		70443		70484		70525		70566		70607		70648
	70403		70444		70485		70526		70567		70608		70649
	70404		70445		70486		70527		70568		70609		70650
	70405		70446		70487		70528		70569		70610		70651
	70406		70447		70488		70529		70570		70611		70652
	70407		70448		70489		70530		70571		70612		70653
	70408		70449		70490		70531		70572		70613		70654
	70409		70450		70491		70532		70573		70614		70655
	70410		70451		70492		70533		70574		70615		70656
	70411		70452		70493		70534		70575		70616		70657
	70412		70453		70494		70535		70576		70617		70658
	70413		70454		70495		70536		70577		70618		70659
	70414		70455		70496		70537		70578		70619		70660
	70415		70456		70497		70538		70579		70620		70661
	70416		70457		70498		70539		70580		70621		70662
	70417		70458		70499		70540		70581		70622		70663
	70418		70459		70500		70541		70582		70623		70664

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : ActHib

Trt.	Bl. No	nb
PPD	70665	70705
PPD	70706	70746
PPD	70747	70787
PPD	70788	70828
PPD	70829	70869
PPD	70870	70906

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	40907	
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Trt.	Bl. No	nb
PPD	40948	
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Trt.	Bl. No	nb
PPD	40989	
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	40999	
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	41002	
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	41007	
	41008	
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Trt.	Bl. No	nb
PPD	41030	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	41112	
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Trt.	Bl. No	nb
PPD	41153	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	41194	41234
PPD	41235	41275
PPD	41276	41316
PPD	41317	41357
PPD	41358	41398
PPD	41399	41439
PPD	41440	41480

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	41481	41521
PPD	41522	41562
PPD	41563	41603
PPD	41604	41644
PPD	41645	41685
PPD	41686	41726
PPD	41727	41767

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	41768	41808
PPD	41809	41849
PPD	41850	41890
PPD	41891	41931
PPD	41932	41972
PPD	41973	42013
PPD	42014	42054

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	42055	42095
PPD	42096	42136
PPD	42137	42177
PPD	42178	42218
PPD	42219	42259
PPD	42260	42300
PPD	42301	42341

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	42342	
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Trt.	Bl. No	nb
PPD	42383	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	42465	
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Trt.	Bl. No	nb
PPD	42506	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	42588	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	42629	42669
PPD	42670	42710
PPD	42711	42751
PPD	42752	42792
PPD	42793	42833
PPD	42834	42874
PPD	42875	42915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	42916	42956
PPD	42957	42997
PPD	42998	43038
PPD	43039	43079
PPD	43080	43120
PPD	43121	43161
PPD	43162	43202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	43203	
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Trt.	Bl. No	nb
PPD	43244	
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Trt.	Bl. No	nb
PPD	43285	
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Trt.	Bl. No	nb
PPD	43326	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	43408	
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Trt.	Bl. No	nb
PPD	43449	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	43490	43530
PPD	43531	43571
PPD	43572	43612
PPD	43613	43653
PPD	43654	43694
PPD	43695	43735
PPD	43736	43776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	43777	
	43778	
	43779	
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Trt.	Bl. No	nb
PPD	43818	
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Trt.	Bl. No	nb
PPD	43859	
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Trt.	Bl. No	nb
PPD	43900	
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Trt.	Bl. No	nb
PPD	43941	
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Trt.	Bl. No	nb
PPD	43982	
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Trt.	Bl. No	nb
PPD	44023	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	44064	44105
	44065	44106
	44066	44107
	44067	44108
	44068	44109
	44069	44110
	44070	44111
	44071	44112
	44072	44113
	44073	44114
	44074	44115
	44075	44116
	44076	44117
	44077	44118
	44078	44119
	44079	44120
	44080	44121
	44081	44122
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	44083	44124
	44084	44125
	44085	44126
	44086	44127
	44087	44128
	44088	44129
	44089	44130
	44090	44131
	44091	44132
	44092	44133
	44093	44134
	44094	44135
	44095	44136
	44096	44137
	44097	44138
	44098	44139
	44099	44140
	44100	44141
	44101	44142
	44102	44143
	44103	44144
	44104	44145

Trt.	Bl. No	nb
PPD	44146	44187
	44147	44188
	44148	44189
	44149	44190
	44150	44191
	44151	44192
	44152	44193
	44153	44194
	44154	44195
	44155	44196
	44156	44197
	44157	44198
	44158	44199
	44159	44200
	44160	44201
	44161	44202
	44162	44203
	44163	44204
	44164	44205
	44165	44206
	44166	44207
	44167	44208
	44168	44209
	44169	44210
	44170	44211
	44171	44212
	44172	44213
	44173	44214
	44174	44215
	44175	44216
	44176	44217
	44177	44218
	44178	44219
	44179	44220
	44180	44221
	44181	44222
	44182	44223
	44183	44224
	44184	44225
	44185	44226
	44186	44227

Trt.	Bl. No	nb
PPD	44228	44269
	44229	44270
	44230	44271
	44231	44272
	44232	44273
	44233	44274
	44234	44275
	44235	44276
	44236	44277
	44237	44278
	44238	44279
	44239	44280
	44240	44281
	44241	44282
	44242	44283
	44243	44284
	44244	44285
	44245	44286
	44246	44287
	44247	44288
	44248	44289
	44249	44290
	44250	44291
	44251	44292
	44252	44293
	44253	44294
	44254	44295
	44255	44296
	44256	44297
	44257	44298
	44258	44299
	44259	44300
	44260	44301
	44261	44302
	44262	44303
	44263	44304
	44264	44305
	44265	44306
	44266	44307
	44267	44308
	44268	44309

Trt.	Bl. No	nb
PPD	44310	44350
	44311	
	44312	
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	44317	
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	44319	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	44351	44390
	44352	44391
	44353	44392
	44354	44393
	44355	44394
	44356	44395
	44357	44396
	44358	44397
	44359	44398
	44360	44399
	44361	44400
	44362	44401
	44363	44402
	44364	44403
	44365	44404
	44366	44405
	44367	44406
	44368	44407
	44369	44408
	44370	44409
	44371	44410
	44372	44411
	44373	44412
	44374	44413
	44375	44414
	44376	44415
	44377	44416
	44378	44417
	44379	44418
	44380	44419
	44381	44420
	44382	44421
	44383	44422
	44384	44423
	44385	44424
	44386	44425
	44387	44426
	44388	44427
	44389	44428

Trt.	Bl. No	nb
PPD	44392	44431
	44393	44432
	44394	44433
	44395	44434
	44396	44435
	44397	44436
	44398	44437
	44399	44438
	44400	44439
	44401	44440
	44402	44441
	44403	44442
	44404	44443
	44405	44444
	44406	44445
	44407	44446
	44408	44447
	44409	44448
	44410	44449
	44411	44450
	44412	44451
	44413	44452
	44414	44453
	44415	44454
	44416	44455
	44417	44456
	44418	44457
	44419	44458
	44420	44459
	44421	44460
	44422	44461
	44423	44462
	44424	44463
	44425	44464
	44426	44465
	44427	44466
	44428	44467
	44429	44468
	44430	44469

Trt.	Bl. No	nb
PPD	44433	44472
	44434	44473
	44435	44474
	44436	44475
	44437	44476
	44438	44477
	44439	44478
	44440	44479
	44441	44480
	44442	44481
	44443	44482
	44444	44483
	44445	44484
	44446	44485
	44447	44486
	44448	44487
	44449	44488
	44450	44489
	44451	44490
	44452	44491
	44453	44492
	44454	44493
	44455	44494
	44456	44495
	44457	44496
	44458	44497
	44459	44498
	44460	44499
	44461	44500
	44462	44501
	44463	44502
	44464	44503
	44465	44504
	44466	44505
	44467	44506
	44468	44507
	44469	44508
	44470	44509
	44471	44510

Trt.	Bl. No	nb
PPD	44474	44513
	44475	44514
	44476	44515
	44477	44516
	44478	44517
	44479	44518
	44480	44519
	44481	44520
	44482	44521
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	44498	44537
	44499	44538
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	44503	44542
	44504	44543
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	44509	44548
	44510	44549
	44511	44550
	44512	44551

Trt.	Bl. No	nb
PPD	44515	44554
	44516	44555
	44517	44556
	44518	44557
	44519	44558
	44520	44559
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	44550	44589
	44551	44590
	44552	44591
	44553	44592

Trt.	Bl. No	nb
PPD	44556	44595
	44557	44596
	44558	44597
	44559	44598
	44560	44599
	44561	44600
	44562	44601
	44563	44602
	44564	44603
	44565	44604
	44566	44605
	44567	44606
	44568	44607
	44569	44608
	44570	44609
	44571	44610
	44572	44611
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	44589	44628
	44590	44629
	44591	44630
	44592	44631
	44593	44632
	44594	44633

Trt.	Bl. No	nb
PPD	44597	44636
	44598	44637
	44599	
	44600	
	44601	
	44602	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	44638	44678
PPD	44679	44719
PPD	44720	44760
PPD	44761	44801
PPD	44802	44842
PPD	44843	44883
PPD	44884	44924

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	44925	44965
PPD	44966	45006
PPD	45007	45047
PPD	45048	45088
PPD	45089	45129
PPD	45130	45170
PPD	45171	45211

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	45212	
	45213	
	45214	
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Trt.	Bl. No	nb
PPD	45253	
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Trt.	Bl. No	nb
PPD	45294	
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Trt.	Bl. No	nb
PPD	45335	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	45417	
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Trt.	Bl. No	nb
PPD	45458	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	45499	
	45500	
	45501	
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Trt.	Bl. No	nb
PPD	45540	
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Trt.	Bl. No	nb
PPD	45581	
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Trt.	Bl. No	nb
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Trt.	Bl. No	nb
PPD	45663	
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Trt.	Bl. No	nb
PPD	45704	
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Trt.	Bl. No	nb
PPD	45745	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	45786	45826
PPD	45827	45867
PPD	45868	45908
PPD	45909	45949
PPD	45950	45990
PPD	45991	46031
PPD	46032	46072

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	46073	
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Trt.	Bl. No	nb
PPD	46114	
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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

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	46360	46400
PPD	46401	46441
PPD	46442	46482
PPD	46483	46523
PPD	46524	46564
PPD	46565	46605
PPD	46606	46646

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	46647	46687
PPD	46688	46728
PPD	46729	46769
PPD	46770	46810
PPD	46811	46851
PPD	46852	46892
PPD	46893	46933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	46934	46974
PPD	46975	47015
PPD	47016	47056
PPD	47057	47097
PPD	47098	47138
PPD	47139	47179
PPD	47180	47220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	1	47221
	2	47222
	3	47223
	4	47224
	5	47225
	6	47226
	7	47227
	8	47228
	9	47229
	10	47230
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	32	47252
	33	47253
	34	47254
	35	47255
	36	47256
	37	47257
	38	47258
	39	47259
	40	47260
	41	47261
PPD	1	47262
	2	47263
	3	47264
	4	47265
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	6	47267
	7	47268
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	9	47270
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	35	47296
	36	47297
	37	47298
	38	47299
	39	47300
	40	47301
	41	47302
PPD	1	47303
	2	47304
	3	47305
	4	47306
	5	47307
	6	47308
	7	47309
	8	47310
	9	47311
	10	47312
	11	47313
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	15	47317
	16	47318
	17	47319
	18	47320
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	29	47331
	30	47332
	31	47333
	32	47334
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	41	47343
PPD	1	47344
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PPD	1	47385
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	41	47425
PPD	1	47426
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	35	47460
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	39	47464
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	41	47466
PPD	1	47467
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	35	47501
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	47508	47548
PPD	47549	47589
PPD	47590	47630
PPD	47631	47671
PPD	47672	47712
PPD	47713	47753
PPD	47754	47794

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	47795	
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Trt.	Bl. No	nb
PPD	47836	
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Trt.	Bl. No	nb
PPD	47877	
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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

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	48082	48083
	48084	48085
	48086	48087
	48088	48089
	48090	48091
	48092	48093
	48094	48095
	48096	48097
	48098	48099
	48100	48101
	48102	48103
	48104	48105
	48106	48107
	48108	48109
	48110	48111
	48112	48113
	48114	48115
	48116	48117
	48118	48119
	48120	48121
	48122	
PPD	48123	48124
	48125	48126
	48127	48128
	48129	48130
	48131	48132
	48133	48134
	48135	48136
	48137	48138
	48139	48140
	48141	48142
	48143	48144
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	48147	48148
	48149	48150
	48151	48152
	48153	48154
	48155	48156
	48157	48158
	48159	48160
	48161	48162
	48163	
PPD	48164	48165
	48166	48167
	48168	48169
	48170	48171
	48172	48173
	48174	48175
	48176	48177
	48178	48179
	48180	48181
	48182	48183
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	48188	48189
	48190	48191
	48192	48193
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	48196	48197
	48198	48199
	48200	48201
	48202	48203
	48204	
PPD	48205	48206
	48207	48208
	48209	48210
	48211	48212
	48213	48214
	48215	48216
	48217	48218
	48219	48220
	48221	48222
	48223	48224
	48225	48226
	48227	48228
	48229	48230
	48231	48232
	48233	48234
	48235	48236
	48237	48238
	48239	48240
	48241	48242
	48243	48244
	48245	
PPD	48246	48247
	48248	48249
	48250	48251
	48252	48253
	48254	48255
	48256	48257
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	48264	48265
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	48272	48273
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PPD	48287	48288
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	48317	48318
	48319	48320
	48321	48322
	48323	48324
	48325	48326
	48327	
PPD	48328	48329
	48330	48331
	48332	48333
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	48360	48361
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	48369	48409
PPD	48410	48450
PPD	48451	48491
PPD	48492	48532
PPD	48533	48573
PPD	48574	48614
PPD	48615	48655

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	48656	48696
PPD	48697	48737
PPD	48738	48778
PPD	48779	48819
PPD	48820	48860
PPD	48861	48901
PPD	48902	48942

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	48943	48983
PPD	48984	49024
PPD	49025	49065
PPD	49066	49106
PPD	49107	49147
PPD	49148	49188
PPD	49189	49229

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	49230	
	49231	
	49232	
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Trt.	Bl. No	nb
PPD	49271	
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Trt.	Bl. No	nb
PPD	49312	
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Trt.	Bl. No	nb
PPD	49353	
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Trt.	Bl. No	nb
PPD	49394	
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	49431	
	49432	
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Trt.	Bl. No	nb
PPD	49435	
	49436	
	49437	
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	49439	
	49440	
	49441	
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	49443	
	49444	
	49445	
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	49470	
	49471	
	49472	
	49473	
	49474	
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Trt.	Bl. No	nb
PPD	49476	
	49477	
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	49485	
	49486	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	49517	49557
PPD	49558	49598
PPD	49599	49639
PPD	49640	49680
PPD	49681	49721
PPD	49722	49762
PPD	49763	49803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	49804	49845
	49805	49846
	49806	49847
	49807	49848
	49808	49849
	49809	49850
	49810	49851
	49811	49852
	49812	49853
	49813	49854
	49814	49855
	49815	49856
	49816	49857
	49817	49858
	49818	49859
	49819	49860
	49820	49861
	49821	49862
	49822	49863
	49823	49864
	49824	49865
	49825	49866
	49826	49867
	49827	49868
	49828	49869
	49829	49870
	49830	49871
	49831	49872
	49832	49873
	49833	49874
	49834	49875
	49835	49876
	49836	49877
	49837	49878
	49838	49879
	49839	49880
	49840	49881
	49841	49882
	49842	49883
	49843	49884
	49844	49885

Trt.	Bl. No	nb
PPD	49886	49927
	49887	49928
	49888	49929
	49889	49930
	49890	49931
	49891	49932
	49892	49933
	49893	49934
	49894	49935
	49895	49936
	49896	49937
	49897	49938
	49898	49939
	49899	49940
	49900	49941
	49901	49942
	49902	49943
	49903	49944
	49904	49945
	49905	49946
	49906	49947
	49907	49948
	49908	49949
	49909	49950
	49910	49951
	49911	49952
	49912	49953
	49913	49954
	49914	49955
	49915	49956
	49916	49957
	49917	49958
	49918	49959
	49919	49960
	49920	49961
	49921	49962
	49922	49963
	49923	49964
	49924	49965
	49925	49966
	49926	49967

Trt.	Bl. No	nb
PPD	49968	50009
	49969	50010
	49970	50011
	49971	50012
	49972	50013
	49973	50014
	49974	50015
	49975	50016
	49976	50017
	49977	50018
	49978	50019
	49979	50020
	49980	50021
	49981	50022
	49982	50023
	49983	50024
	49984	50025
	49985	50026
	49986	50027
	49987	50028
	49988	50029
	49989	50030
	49990	50031
	49991	50032
	49992	50033
	49993	50034
	49994	50035
	49995	50036
	49996	50037
	49997	50038
	49998	50039
	49999	50040
	50000	50041
	50001	50042
	50002	50043
	50003	50044
	50004	50045
	50005	50046
	50006	50047
	50007	50048
	50008	50049

Trt.	Bl. No	nb
PPD	50050	50090
	50051	
	50052	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	50091	50132
	50092	50133
	50093	50134
	50094	50135
	50095	50136
	50096	50137
	50097	50138
	50098	50139
	50099	50140
	50100	50141
	50101	50142
	50102	50143
	50103	50144
	50104	50145
	50105	50146
	50106	50147
	50107	50148
	50108	50149
	50109	50150
	50110	50151
	50111	50152
	50112	50153
	50113	50154
	50114	50155
	50115	50156
	50116	50157
	50117	50158
	50118	50159
	50119	50160
	50120	50161
	50121	50162
	50122	50163
	50123	50164
	50124	50165
	50125	50166
	50126	50167
	50127	50168
	50128	50169
	50129	50170
	50130	50171
	50131	50172

Trt.	Bl. No	nb
PPD	50173	50214
	50174	50215
	50175	50216
	50176	50217
	50177	50218
	50178	50219
	50179	50220
	50180	50221
	50181	50222
	50182	50223
	50183	50224
	50184	50225
	50185	50226
	50186	50227
	50187	50228
	50188	50229
	50189	50230
	50190	50231
	50191	50232
	50192	50233
	50193	50234
	50194	50235
	50195	50236
	50196	50237
	50197	50238
	50198	50239
	50199	50240
	50200	50241
	50201	50242
	50202	50243
	50203	50244
	50204	50245
	50205	50246
	50206	50247
	50207	50248
	50208	50249
	50209	50250
	50210	50251
	50211	50252
	50212	50253
	50213	50254

Trt.	Bl. No	nb
PPD	50255	50296
	50256	50297
	50257	50298
	50258	50299
	50259	50300
	50260	50301
	50261	50302
	50262	50303
	50263	50304
	50264	50305
	50265	50306
	50266	50307
	50267	50308
	50268	50309
	50269	50310
	50270	50311
	50271	50312
	50272	50313
	50273	50314
	50274	50315
	50275	50316
	50276	50317
	50277	50318
	50278	50319
	50279	50320
	50280	50321
	50281	50322
	50282	50323
	50283	50324
	50284	50325
	50285	50326
	50286	50327
	50287	50328
	50288	50329
	50289	50330
	50290	50331
	50291	50332
	50292	50333
	50293	50334
	50294	50335
	50295	50336

Trt.	Bl. No	nb
PPD	50337	
	50338	
	50339	
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	1	50378
	2	50379
	3	50380
	4	50381
	5	50382
	6	50383
	7	50384
	8	50385
	9	50386
	10	50387
	11	50388
	12	50389
	13	50390
	14	50391
	15	50392
	16	50393
	17	50394
	18	50395
	19	50396
	20	50397
	21	50398
	22	50399
	23	50400
	24	50401
	25	50402
	26	50403
	27	50404
	28	50405
	29	50406
	30	50407
	31	50408
	32	50409
	33	50410
	34	50411
	35	50412
	36	50413
	37	50414
	38	50415
	39	50416
	40	50417
	41	50418

Trt.	Bl. No	nb
PPD	1	50419
	2	50420
	3	50421
	4	50422
	5	50423
	6	50424
	7	50425
	8	50426
	9	50427
	10	50428
	11	50429
	12	50430
	13	50431
	14	50432
	15	50433
	16	50434
	17	50435
	18	50436
	19	50437
	20	50438
	21	50439
	22	50440
	23	50441
	24	50442
	25	50443
	26	50444
	27	50445
	28	50446
	29	50447
	30	50448
	31	50449
	32	50450
	33	50451
	34	50452
	35	50453
	36	50454
	37	50455
	38	50456
	39	50457
	40	50458
	41	50459

Trt.	Bl. No	nb
PPD	1	50460
	2	50461
	3	50462
	4	50463
	5	50464
	6	50465
	7	50466
	8	50467
	9	50468
	10	50469
	11	50470
	12	50471
	13	50472
	14	50473
	15	50474
	16	50475
	17	50476
	18	50477
	19	50478
	20	50479
	21	50480
	22	50481
	23	50482
	24	50483
	25	50484
	26	50485
	27	50486
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	31	50490
	32	50491
	33	50492
	34	50493
	35	50494
	36	50495
	37	50496
	38	50497
	39	50498
	40	50499
	41	50500

Trt.	Bl. No	nb
PPD	1	50501
	2	50502
	3	50503
	4	50504
	5	50505
	6	50506
	7	50507
	8	50508
	9	50509
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	12	50512
	13	50513
	14	50514
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	33	50533
	34	50534
	35	50535
	36	50536
	37	50537
	38	50538
	39	50539
	40	50540
	41	50541

Trt.	Bl. No	nb
PPD	1	50542
	2	50543
	3	50544
	4	50545
	5	50546
	6	50547
	7	50548
	8	50549
	9	50550
	10	50551
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	13	50554
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	15	50556
	16	50557
	17	50558
	18	50559
	19	50560
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	21	50562
	22	50563
	23	50564
	24	50565
	25	50566
	26	50567
	27	50568
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	32	50573
	33	50574
	34	50575
	35	50576
	36	50577
	37	50578
	38	50579
	39	50580
	40	50581
	41	50582

Trt.	Bl. No	nb
PPD	1	50583
	2	50584
	3	50585
	4	50586
	5	50587
	6	50588
	7	50589
	8	50590
	9	50591
	10	50592
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	13	50595
	14	50596
	15	50597
	16	50598
	17	50599
	18	50600
	19	50601
	20	50602
	21	50603
	22	50604
	23	50605
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	25	50607
	26	50608
	27	50609
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	33	50615
	34	50616
	35	50617
	36	50618
	37	50619
	38	50620
	39	50621
	40	50622
	41	50623

Trt.	Bl. No	nb
PPD	1	50624
	2	50625
	3	50626
	4	50627
	5	50628
	6	50629
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	31	50654
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	39	50662
	40	50663
	41	50664

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Infanrix

Trt.	Bl. No	nb
PPD	1	50665
	2	50666
	3	50667
	4	50668
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	6	50670
	7	50671
	8	50672
	9	50673
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	11	50675
	12	50676
	13	50677
	14	50678
	15	50679
	16	50680
	17	50681
	18	50682
	19	50683
	20	50684
	21	50685
	22	50686
	23	50687
	24	50688
	25	50689
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	27	50691
	28	50692
	29	50693
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	31	50695
	32	50696
	33	50697
	34	50698
	35	50699
	36	50700
	37	50701
	38	50702
	39	50703
	40	50704
	41	50705

Trt.	Bl. No	nb
PPD	1	50706
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	3	50708
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	5	50710
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	35	50740
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	39	50744
	40	50745
	41	50746

Trt.	Bl. No	nb
PPD	1	50747
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	3	50749
	4	50750
	5	50751
	6	50752
	7	50753
	8	50754
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	13	50759
	14	50760
	15	50761
	16	50762
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	32	50778
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	36	50782
	37	50783
	38	50784
	39	50785
	40	50786
	41	50787

Trt.	Bl. No	nb
PPD	1	50788
	2	50789
	3	50790
	4	50791
	5	50792
	6	50793
	7	50794
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	40	50827
	41	50828

Trt.	Bl. No	nb
PPD	1	50829
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	32	50860
	33	50861
	34	50862
	35	50863
	36	50864
	37	50865
	38	50866
	39	50867
	40	50868
	41	50869

Trt.	Bl. No	nb
PPD	1	50870
	2	50871
	3	50872
	4	50873
	5	50874
	6	50875
	7	50876
	8	50877
	9	50878
	10	50879
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	14	50883
	15	50884
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	17	50886
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	19	50888
	20	50889
	21	50890
	22	50891
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	26	50895
	27	50896
	28	50897
	29	50898
	30	50899
	31	50900
	32	50901
	33	50902
	34	50903
	35	50904
	36	50905
	37	50906

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	50907	
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Trt.	Bl. No	nb
PPD	50948	
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Trt.	Bl. No	nb
PPD	50989	
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	51024	
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Trt.	Bl. No	nb
PPD	51030	
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Trt.	Bl. No	nb
PPD	51071	
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	51107	
	51108	
	51109	
	51110	
	51111	

Trt.	Bl. No	nb
PPD	51112	
	51113	
	51114	
	51115	
	51116	
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	51118	
	51119	
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Trt.	Bl. No	nb
PPD	51153	
	51154	
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	51193	

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	51194
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	31	51224
	32	51225
	33	51226
	34	51227
	35	51228
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	39	51232
	40	51233
	41	51234

Trt.	Bl. No	nb
PPD	1	51235
	2	51236
	3	51237
	4	51238
	5	51239
	6	51240
	7	51241
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	13	51247
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	24	51258
	25	51259
	26	51260
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	29	51263
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	31	51265
	32	51266
	33	51267
	34	51268
	35	51269
	36	51270
	37	51271
	38	51272
	39	51273
	40	51274
	41	51275

Trt.	Bl. No	nb
PPD	1	51276
	2	51277
	3	51278
	4	51279
	5	51280
	6	51281
	7	51282
	8	51283
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	30	51305
	31	51306
	32	51307
	33	51308
	34	51309
	35	51310
	36	51311
	37	51312
	38	51313
	39	51314
	40	51315
	41	51316

Trt.	Bl. No	nb
PPD	1	51317
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	3	51319
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	37	51353
	38	51354
	39	51355
	40	51356
	41	51357

Trt.	Bl. No	nb
PPD	1	51358
	2	51359
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	13	51370
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	39	51396
	40	51397
	41	51398

Trt.	Bl. No	nb
PPD	1	51399
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	39	51437
	40	51438
	41	51439

Trt.	Bl. No	nb
PPD	1	51440
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	41	51480

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	51481
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PPD	1	51563
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
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	40	52381
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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

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

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PPD	206	52834
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PPD	247	52875
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	285	52913
	286	52914
	287	52915

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	52916
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	35	52950
	36	52951
	37	52952
	38	52953
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	41	52956
PPD	1	52957
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	39	52995
	40	52996
	41	52997
PPD	1	52998
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	41	53038
PPD	1	53039
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PPD	1	53080
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	38	53117
	39	53118
	40	53119
	41	53120
PPD	1	53121
	2	53122
	3	53123
	4	53124
	5	53125
	6	53126
	7	53127
	8	53128
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	38	53158
	39	53159
	40	53160
	41	53161
PPD	1	53162
	2	53163
	3	53164
	4	53165
	5	53166
	6	53167
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	40	53201
	41	53202

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
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	33	53235
	34	53236
	35	53237
	36	53238
	37	53239
	38	53240
	39	53241
	40	53242
	41	53243
PPD	1	53244
	2	53245
	3	53246
	4	53247
	5	53248
	6	53249
	7	53250
	8	53251
	9	53252
	10	53253
	11	53254
	12	53255
	13	53256
	14	53257
	15	53258
	16	53259
	17	53260
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	33	53276
	34	53277
	35	53278
	36	53279
	37	53280
	38	53281
	39	53282
	40	53283
	41	53284
PPD	1	53285
	2	53286
	3	53287
	4	53288
	5	53289
	6	53290
	7	53291
	8	53292
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	35	53319
	36	53320
	37	53321
	38	53322
	39	53323
	40	53324
	41	53325
PPD	1	53326
	2	53327
	3	53328
	4	53329
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	8	53333
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PPD	1	53367
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	41	53448
PPD	1	53449
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	41	53489

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	53490	53530
PPD	53531	53571
PPD	53572	53612
PPD	53613	53653
PPD	53654	53694
PPD	53695	53735
PPD	53736	53776

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	53777
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	3	53779
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	5	53781
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	27	53803
	28	53804
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	30	53806
	31	53807
	32	53808
	33	53809
	34	53810
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	36	53812
	37	53813
	38	53814
	39	53815
	40	53816
	41	53817
PPD	1	53818
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	3	53820
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	36	53853
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	38	53855
	39	53856
	40	53857
	41	53858
PPD	1	53859
	2	53860
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	41	54063

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	54064
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	28	54091
	29	54092
	30	54093
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	33	54096
	34	54097
	35	54098
	36	54099
	37	54100
	38	54101
	39	54102
	40	54103
	41	54104
PPD	1	54105
	2	54106
	3	54107
	4	54108
	5	54109
	6	54110
	7	54111
	8	54112
	9	54113
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	37	54141
	38	54142
	39	54143
	40	54144
	41	54145
PPD	1	54146
	2	54147
	3	54148
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	41	54186
PPD	1	54187
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	33	54219
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	39	54225
	40	54226
	41	54227
PPD	1	54228
	2	54229
	3	54230
	4	54231
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	36	54263
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	38	54265
	39	54266
	40	54267
	41	54268
PPD	1	54269
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	3	54271
	4	54272
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	30	54298
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	32	54300
	33	54301
	34	54302
	35	54303
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	37	54305
	38	54306
	39	54307
	40	54308
	41	54309
PPD	1	54310
	2	54311
	3	54312
	4	54313
	5	54314
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	40	54349
	41	54350

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	54351
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	3	54353
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	9	54359
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	11	54361
	12	54362
	13	54363
	14	54364
	15	54365
	16	54366
	17	54367
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	30	54380
	31	54381
	32	54382
	33	54383
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	35	54385
	36	54386
	37	54387
	38	54388
	39	54389
	40	54390
	41	54391
PPD	1	54392
	2	54393
	3	54394
	4	54395
	5	54396
	6	54397
	7	54398
	8	54399
	9	54400
	10	54401
	11	54402
	12	54403
	13	54404
	14	54405
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	38	54429
	39	54430
	40	54431
	41	54432
PPD	1	54433
	2	54434
	3	54435
	4	54436
	5	54437
	6	54438
	7	54439
	8	54440
	9	54441
	10	54442
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	31	54463
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PPD	1	54474
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	38	54511
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	41	54514
PPD	1	54515
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	41	54555
PPD	1	54556
	2	54557
	3	54558
	4	54559
	5	54560
	6	54561
	7	54562
	8	54563
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	35	54590
	36	54591
	37	54592
	38	54593
	39	54594
	40	54595
	41	54596
PPD	1	54597
	2	54598
	3	54599
	4	54600
	5	54601
	6	54602
	7	54603
	8	54604
	9	54605
	10	54606
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	40	54636
	41	54637

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	54638	54678
PPD	54679	54719
PPD	54720	54760
PPD	54761	54801
PPD	54802	54842
PPD	54843	54883
PPD	54884	54924

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	54925
	2	54926
	3	54927
	4	54928
	5	54929
	6	54930
	7	54931
	8	54932
	9	54933
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	31	54955
	32	54956
	33	54957
	34	54958
	35	54959
	36	54960
	37	54961
	38	54962
	39	54963
	40	54964
	41	54965

Trt.	Bl. No	nb
PPD	1	54966
	2	54967
	3	54968
	4	54969
	5	54970
	6	54971
	7	54972
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	10	54975
	11	54976
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	13	54978
	14	54979
	15	54980
	16	54981
	17	54982
	18	54983
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	27	54992
	28	54993
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	32	54997
	33	54998
	34	54999
	35	55000
	36	55001
	37	55002
	38	55003
	39	55004
	40	55005
	41	55006

Trt.	Bl. No	nb
PPD	1	55007
	2	55008
	3	55009
	4	55010
	5	55011
	6	55012
	7	55013
	8	55014
	9	55015
	10	55016
	11	55017
	12	55018
	13	55019
	14	55020
	15	55021
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	17	55023
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	22	55028
	23	55029
	24	55030
	25	55031
	26	55032
	27	55033
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	32	55038
	33	55039
	34	55040
	35	55041
	36	55042
	37	55043
	38	55044
	39	55045
	40	55046
	41	55047

Trt.	Bl. No	nb
PPD	1	55048
	2	55049
	3	55050
	4	55051
	5	55052
	6	55053
	7	55054
	8	55055
	9	55056
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	32	55079
	33	55080
	34	55081
	35	55082
	36	55083
	37	55084
	38	55085
	39	55086
	40	55087
	41	55088

Trt.	Bl. No	nb
PPD	1	55089
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	34	55122
	35	55123
	36	55124
	37	55125
	38	55126
	39	55127
	40	55128
	41	55129

Trt.	Bl. No	nb
PPD	1	55130
	2	55131
	3	55132
	4	55133
	5	55134
	6	55135
	7	55136
	8	55137
	9	55138
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	33	55162
	34	55163
	35	55164
	36	55165
	37	55166
	38	55167
	39	55168
	40	55169
	41	55170

Trt.	Bl. No	nb
PPD	1	55171
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	3	55173
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	41	55211

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	55212
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	12	55223
	13	55224
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	15	55226
	16	55227
	17	55228
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	19	55230
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	32	55243
	33	55244
	34	55245
	35	55246
	36	55247
	37	55248
	38	55249
	39	55250
	40	55251
	41	55252

Trt.	Bl. No	nb
PPD	1	55253
	2	55254
	3	55255
	4	55256
	5	55257
	6	55258
	7	55259
	8	55260
	9	55261
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	37	55289
	38	55290
	39	55291
	40	55292
	41	55293

Trt.	Bl. No	nb
PPD	1	55294
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	37	55330
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	39	55332
	40	55333
	41	55334

Trt.	Bl. No	nb
PPD	1	55335
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Trt.	Bl. No	nb
PPD	1	55376
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Trt.	Bl. No	nb
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	39	55455
	40	55456
	41	55457

Trt.	Bl. No	nb
PPD	1	55458
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	40	55497
	41	55498

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	55499
	2	55500
	3	55501
	4	55502
	5	55503
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	36	55534
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	39	55537
	40	55538
	41	55539

Trt.	Bl. No	nb
PPD	1	55540
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	31	55570
	32	55571
	33	55572
	34	55573
	35	55574
	36	55575
	37	55576
	38	55577
	39	55578
	40	55579
	41	55580

Trt.	Bl. No	nb
PPD	1	55581
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	41	55621

Trt.	Bl. No	nb
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	39	55660
	40	55661
	41	55662

Trt.	Bl. No	nb
PPD	1	55663
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	37	55699
	38	55700
	39	55701
	40	55702
	41	55703

Trt.	Bl. No	nb
PPD	1	55704
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	6	55709
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	40	55743
	41	55744

Trt.	Bl. No	nb
PPD	1	55745
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	5	55749
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	41	55785

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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
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	40	55825
	41	55826

Trt.	Bl. No	nb
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	41	55867

Trt.	Bl. No	nb
PPD	1	55868
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	40	55907
	41	55908

Trt.	Bl. No	nb
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Trt.	Bl. No	nb
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	39	55988
	40	55989
	41	55990

Trt.	Bl. No	nb
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	41	56031

Trt.	Bl. No	nb
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DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
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	38	56110
	39	56111
	40	56112
	41	56113
PPD	42	56114
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	56360
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	40	56399
	41	56400

Trt.	Bl. No	nb
PPD	1	56401
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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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	41	56646

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Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	56647
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	20	56666
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	23	56669
	24	56670
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	27	56673
	28	56674
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	37	56683
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	41	56687
PPD	1	56688
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PPD	1	56770
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PPD	1	56811
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PPD	1	56852
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PPD	1	56893
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	41	56933

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	56934	56974
PPD	56975	57015
PPD	57016	57056
PPD	57057	57097
PPD	57098	57138
PPD	57139	57179
PPD	57180	57220

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	57221
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	3	57223
	4	57224
	5	57225
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	10	57230
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	32	57252
	33	57253
	34	57254
	35	57255
	36	57256
	37	57257
	38	57258
	39	57259
	40	57260
	41	57261
PPD	42	57262
	43	57263
	44	57264
	45	57265
	46	57266
	47	57267
	48	57268
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	50	57270
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	79	57299
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PPD	83	57303
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	117	57337
	118	57338
	119	57339
	120	57340
	121	57341
	122	57342
	123	57343
PPD	124	57344
	125	57345
	126	57346
	127	57347
	128	57348
	129	57349
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	158	57378
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	160	57380
	161	57381
	162	57382
	163	57383
	164	57384
PPD	165	57385
	166	57386
	167	57387
	168	57388
	169	57389
	170	57390
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	172	57392
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	205	57425
PPD	206	57426
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	240	57460
	241	57461
	242	57462
	243	57463
	244	57464
	245	57465
	246	57466
PPD	247	57467
	248	57468
	249	57469
	250	57470
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	252	57472
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	254	57474
	255	57475
	256	57476
	257	57477
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	277	57497
	278	57498
	279	57499
	280	57500
	281	57501
	282	57502
	283	57503
	284	57504
	285	57505
	286	57506
	287	57507

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	57508	57548
PPD	57549	57589
PPD	57590	57630
PPD	57631	57671
PPD	57672	57712
PPD	57713	57753
PPD	57754	57794

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	57795
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	3	57797
	4	57798
	5	57799
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	7	57801
	8	57802
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	10	57804
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	13	57807
	14	57808
	15	57809
	16	57810
	17	57811
	18	57812
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	22	57816
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	25	57819
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	32	57826
	33	57827
	34	57828
	35	57829
	36	57830
	37	57831
	38	57832
	39	57833
	40	57834
	41	57835
PPD	1	57836
	2	57837
	3	57838
	4	57839
	5	57840
	6	57841
	7	57842
	8	57843
	9	57844
	10	57845
	11	57846
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	15	57850
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	24	57859
	25	57860
	26	57861
	27	57862
	28	57863
	29	57864
	30	57865
	31	57866
	32	57867
	33	57868
	34	57869
	35	57870
	36	57871
	37	57872
	38	57873
	39	57874
	40	57875
	41	57876
PPD	1	57877
	2	57878
	3	57879
	4	57880
	5	57881
	6	57882
	7	57883
	8	57884
	9	57885
	10	57886
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	14	57890
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	19	57895
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	23	57899
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	25	57901
	26	57902
	27	57903
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	29	57905
	30	57906
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	33	57909
	34	57910
	35	57911
	36	57912
	37	57913
	38	57914
	39	57915
	40	57916
	41	57917
PPD	1	57918
	2	57919
	3	57920
	4	57921
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	41	57958
PPD	1	57959
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	40	57998
	41	57999
PPD	1	58000
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PPD	1	58041
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	41	58081

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	58082
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	32	58113
	33	58114
	34	58115
	35	58116
	36	58117
	37	58118
	38	58119
	39	58120
	40	58121
	41	58122
PPD	1	58123
	2	58124
	3	58125
	4	58126
	5	58127
	6	58128
	7	58129
	8	58130
	9	58131
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	36	58158
	37	58159
	38	58160
	39	58161
	40	58162
	41	58163
PPD	1	58164
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	13	58340
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	33	58360
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	40	58367
	41	58368

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	58369
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	24	58392
	25	58393
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	28	58396
	29	58397
	30	58398
	31	58399
	32	58400
	33	58401
	34	58402
	35	58403
	36	58404
	37	58405
	38	58406
	39	58407
	40	58408
	41	58409
PPD	1	58410
	2	58411
	3	58412
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	6	58415
	7	58416
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	34	58443
	35	58444
	36	58445
	37	58446
	38	58447
	39	58448
	40	58449
	41	58450
PPD	1	58451
	2	58452
	3	58453
	4	58454
	5	58455
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	8	58458
	9	58459
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	22	58472
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	37	58487
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	39	58489
	40	58490
	41	58491
PPD	1	58492
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	40	58531
	41	58532
PPD	1	58533
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	3	58535
	4	58536
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	10	58542
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	37	58569
	38	58570
	39	58571
	40	58572
	41	58573
PPD	1	58574
	2	58575
	3	58576
	4	58577
	5	58578
	6	58579
	7	58580
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	9	58582
	10	58583
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	34	58607
	35	58608
	36	58609
	37	58610
	38	58611
	39	58612
	40	58613
	41	58614
PPD	1	58615
	2	58616
	3	58617
	4	58618
	5	58619
	6	58620
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	36	58650
	37	58651
	38	58652
	39	58653
	40	58654
	41	58655

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	58656
	2	58657
	3	58658
	4	58659
	5	58660
	6	58661
	7	58662
	8	58663
	9	58664
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	16	58671
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	25	58680
	26	58681
	27	58682
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	29	58684
	30	58685
	31	58686
	32	58687
	33	58688
	34	58689
	35	58690
	36	58691
	37	58692
	38	58693
	39	58694
	40	58695
	41	58696

Trt.	Bl. No	nb
PPD	1	58697
	2	58698
	3	58699
	4	58700
	5	58701
	6	58702
	7	58703
	8	58704
	9	58705
	10	58706
	11	58707
	12	58708
	13	58709
	14	58710
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	18	58714
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	32	58728
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	34	58730
	35	58731
	36	58732
	37	58733
	38	58734
	39	58735
	40	58736
	41	58737

Trt.	Bl. No	nb
PPD	1	58738
	2	58739
	3	58740
	4	58741
	5	58742
	6	58743
	7	58744
	8	58745
	9	58746
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	32	58769
	33	58770
	34	58771
	35	58772
	36	58773
	37	58774
	38	58775
	39	58776
	40	58777
	41	58778

Trt.	Bl. No	nb
PPD	1	58779
	2	58780
	3	58781
	4	58782
	5	58783
	6	58784
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	8	58786
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	35	58813
	36	58814
	37	58815
	38	58816
	39	58817
	40	58818
	41	58819

Trt.	Bl. No	nb
PPD	1	58820
	2	58821
	3	58822
	4	58823
	5	58824
	6	58825
	7	58826
	8	58827
	9	58828
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	32	58851
	33	58852
	34	58853
	35	58854
	36	58855
	37	58856
	38	58857
	39	58858
	40	58859
	41	58860

Trt.	Bl. No	nb
PPD	1	58861
	2	58862
	3	58863
	4	58864
	5	58865
	6	58866
	7	58867
	8	58868
	9	58869
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	32	58892
	33	58893
	34	58894
	35	58895
	36	58896
	37	58897
	38	58898
	39	58899
	40	58900
	41	58901

Trt.	Bl. No	nb
PPD	1	58902
	2	58903
	3	58904
	4	58905
	5	58906
	6	58907
	7	58908
	8	58909
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	40	58941
	41	58942

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	58943	58983
PPD	58984	59024
PPD	59025	59065
PPD	59066	59106
PPD	59107	59147
PPD	59148	59188
PPD	59189	59229

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	59230
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	3	59232
	4	59233
	5	59234
	6	59235
	7	59236
	8	59237
	9	59238
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	11	59240
	12	59241
	13	59242
	14	59243
	15	59244
	16	59245
	17	59246
	18	59247
	19	59248
	20	59249
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	23	59252
	24	59253
	25	59254
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	27	59256
	28	59257
	29	59258
	30	59259
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PPD	1	59271
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	3	59273
	4	59274
	5	59275
	6	59276
	7	59277
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	9	59279
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PPD	1	59353
	2	59354
	3	59355
	4	59356
	5	59357
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	41	59393
PPD	1	59394
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	38	59431
	39	59432
	40	59433
	41	59434
PPD	1	59435
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	4	59438
	5	59439
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	41	59475
PPD	1	59476
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	37	59512
	38	59513
	39	59514
	40	59515
	41	59516

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	59517	59557
PPD	59558	59598
PPD	59599	59639
PPD	59640	59680
PPD	59681	59721
PPD	59722	59762
PPD	59763	59803

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	59804
	2	59805
	3	59806
	4	59807
	5	59808
	6	59809
	7	59810
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	15	59818
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	18	59821
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	24	59827
	25	59828
	26	59829
	27	59830
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	29	59832
	30	59833
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	32	59835
	33	59836
	34	59837
	35	59838
	36	59839
	37	59840
	38	59841
	39	59842
	40	59843
	41	59844

Trt.	Bl. No	nb
PPD	1	59845
	2	59846
	3	59847
	4	59848
	5	59849
	6	59850
	7	59851
	8	59852
	9	59853
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	31	59875
	32	59876
	33	59877
	34	59878
	35	59879
	36	59880
	37	59881
	38	59882
	39	59883
	40	59884
	41	59885

Trt.	Bl. No	nb
PPD	1	59886
	2	59887
	3	59888
	4	59889
	5	59890
	6	59891
	7	59892
	8	59893
	9	59894
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	35	59920
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	37	59922
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	39	59924
	40	59925
	41	59926

Trt.	Bl. No	nb
PPD	1	59927
	2	59928
	3	59929
	4	59930
	5	59931
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	36	59962
	37	59963
	38	59964
	39	59965
	40	59966
	41	59967

Trt.	Bl. No	nb
PPD	1	59968
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	5	59972
	6	59973
	7	59974
	8	59975
	9	59976
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	30	59997
	31	59998
	32	59999
	33	60000
	34	60001
	35	60002
	36	60003
	37	60004
	38	60005
	39	60006
	40	60007
	41	60008

Trt.	Bl. No	nb
PPD	1	60009
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	3	60011
	4	60012
	5	60013
	6	60014
	7	60015
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	40	60048
	41	60049

Trt.	Bl. No	nb
PPD	1	60050
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	40	60089
	41	60090

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	60091
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	3	60093
	4	60094
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	7	60097
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	41	60131

Trt.	Bl. No	nb
PPD	1	60132
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	41	60172

Trt.	Bl. No	nb
PPD	1	60173
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	40	60212
	41	60213

Trt.	Bl. No	nb
PPD	1	60214
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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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	41	60377

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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	60378
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Trt.	Bl. No	nb
PPD	1	60419
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Trt.	Bl. No	nb
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	41	60500

Trt.	Bl. No	nb
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	40	60540
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Trt.	Bl. No	nb
PPD	1	60542
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Trt.	Bl. No	nb
PPD	1	60583
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Trt.	Bl. No	nb
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Randomisation list

DTPA-HBV-IPV-135 (A.15MAR2018)

Treatment number associated to material : Hiberix

Trt.	Bl. No	nb
PPD	1	60665
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	39	60703
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	41	60705
PPD	42	60706
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PPD	124	60788
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	241	60905
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Audit Certificates

AUDIT CERTIFICATE

Study Number: 117119

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/these study(s), the following independent audits were performed by or on behalf of GlaxoSmithKline.

Study Number	Type	Conducted by	Centre number	Country	Audit Date
117119	Investigator Site	GSK-CQA	PPD	USA	4-6 Nov 2014
117119	Investigator Site	GSK-CQA		USA	21-23 Oct 2014
117119	Investigator Site	GSK-CQA		USA	4-6 Nov 2014
117119	Investigator Site	GSK-CQA		USA	4-5 Nov 2014
117119	Investigator Site	GSK-CQA		USA	13-14 Oct 2014
117119	Investigator Site	GSK-CQA		USA	24-26 Aug 2015

Clinical 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: 06 Mar 2018**

Role: Senior Manager CQA

Clinical Quality Assurance
GlaxoSmithKline Research and Development

Documentation of statistical methods

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Statistical Analysis Plan

Detailed Title:	A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa™ vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar® and Rotarix™ with a booster dose of GSK Biologicals' Infanrix® and Hiberix™ vaccines at 15-18 months of age
eTrack study number and Abbreviated Title	117119 (DTPA-HBV-IPV-135)
Scope:	All data pertaining to the above study.
Date of Statistical Analysis Plan	29-Nov-2017 (Amendment 2)
Co-ordinating author:	PPD (Lead statistician)
Other author:	PPD (statistician)
Adhoc reviewers for first version:	PPD (Regulatory representative) , PPD PPD (Safety representative)
Approved by:	PPD (Clinical and Epidemiology R&D Project Leader), PPD Clinical Research and Development Lead (CRDL), PPD (Lead Statistician), PPD (Scientific Writer), PPD (Lead statistical analyst)

APP 9000058193 Statistical Analysis Plan Template (Effective date: 14April 2017)

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117119 (DTPA-HBV-IPV-135)
Statistical Analysis Plan Amendment 2 Final

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LIST OF ABBREVIATIONS

AE	Adverse event
ANCOVA	Analysis of Co-variance
ANOVA	Analysis of Variance
ATP	According-To-Protocol
CI	Confidence Interval
CSR	Clinical Study Report
D	Diphtheria
EL.U/ml	ELISA unit per milliliter
ELISA	Enzyme-linked immunosorbent assay
Eli Type	Internal GSK database code for type of elimination code
ESFU	Extended Safety Follow-up
FHA	Filamentous hemagglutinin
GMC	Geometric mean antibody concentration
GMT	Geometric mean antibody titer
GSK	GlaxoSmithKline
HBs	Hepatitis B surface antigen
HHE	Hypotonic Hyporesponsive Episode
Hib	Haemophilus influenzae (H. influenzae) type b
IU/ml	International units per milliliter
LL	Lower Limit of the confidence interval
MedDRA	Medical Dictionary for Regulatory Activities
NOCD	New Onset of Chronic Disease
PRN	Pertactin
PRP	Polyribosyl-Ribitol-Phosphate: polysaccharide component of the Hib bacterium capsule
PT	Pertussis toxoid: a secreted exotoxin of the *Bordetella pertussis* bacterium
RCC	Reverse Cumulative Curve
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SBIR	GSK Biological's Internet Randomization System
SD	Standard Deviation

SR	Study Report
T	Tetanus
TFL	Tables Figures and Listing template annexed to SAP
TVC	Total Vaccinated cohort
UL	Upper Limit of the confidence interval

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1. DOCUMENT HISTORY

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, annex (-es) (called TFL) describing the flow and format of tables, figures and listings to be annexed to the SR. For this study, there is only one annex TFL.

The following table presents the history of the statistical analysis plan development:

Date	Description	Protocol Version
10-Mar-2015	Version 1	Protocol Amendment 1 - 18-SEP-2014
06-May-2015	Version 2 (Amendment 1). The SAP has been updated to incorporate the changes in the sequence of analysis as per the protocol amendment 2	Protocol Amendment 2 - 17-Apr-2015
29-Nov-2017	Amendment 2*	Protocol Amendment 2 - 17-Apr-2015

* statistical analysis amendment 2 included the following changes:

1. During the course of the study, the assays used to measure the anti-D, -T, -PT, -FHA and -PRN IgG concentrations were re-developed and re-validated and both assay units and assay cut-offs were adapted. The new ELISAs for PT, FHA and PRN were calibrated against the WHO International Standard (NIBSC 06/140). This allowed the expression of concentrations measured with the new ELISAs in International Units per milliliter (IU/mL) instead of the formerly used ELISA units per milliliter (EL.U/mL). The newly validated DTPa ELISA's have a lower assay cut-off as compared to the one described in the protocol. The current assay cut-off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T, 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA and 2.187 IU/mL for anti-PRN. Since for anti-D, anti-T a threshold of 0.1 IU/mL provided a conservative estimate of the percentage of subjects deemed to be protected, the anti-D, anti-T seroposivity endpoints initially defined by the previous assay cut-off of 0.1 IU/mL were replaced by seroprotection rate endpoints defined as the percentage of subjects with concentration above 0.1 IU/mL. In the absence of a correlate of protection for the *B. pertussis* antigens, the pertussis vaccine response endpoints were redefined based on the assay cut-off.
2. A descriptive summary per lot was added for anti-PRP post priming.
3. The ANCOVA model was revised to include the 3 study groups rather than the 2 groups compared. This allowed identical adjusted GMC estimate regardless of the groups involved in the comparison.
4. The DTPA-HBV-IPV-135 (117119) Abridged Interim Report Main (19-Oct-2015) included immunogenicity data against Polyribosyl-Ribitol-Phosphate (PRP) antigen at Visit 4 using an assay which was not fully validated. For the final analysis, the visit 4 samples were retested together with the samples pre- and post booster using a newly validated assay. In the final analysis, the results of both assays will be descriptively presented at visit 4.

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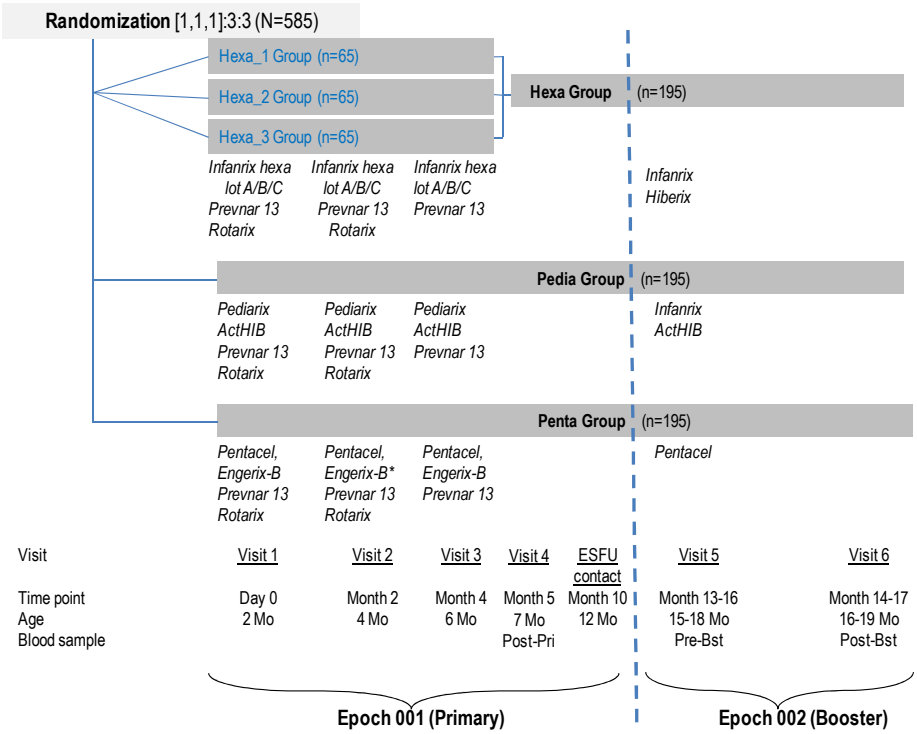
2. STUDY DESIGN



N = number of subjects in the study; n = number of subjects in each group; Mo = months
Visit 3 should be conducted at least 8 weeks after Visit 2, with subjects at least 24 weeks of age, in order to comply with US recommendations on hepatitis B dosing
Post-Pri = blood sample collected from subjects, one month after the administration of the third dose in the Epoch 001
Pre-Bst = blood sample collected from subjects, before the administration of the booster dose in the Epoch 002
Post-Bst = blood sample collected from subjects, one month after the administration of booster dose in the Epoch 002
* *Engerix-B* should not be given at Month 2 (4 months of age) if a dose of hepatitis B vaccine was given at birth up to 30 days prior to study dose 1 to the subject in the Penta Group
ESFU = Extended safety follow-up

- Experimental design: Phase III, open-label, randomized, controlled, multi-centric, single-country study with five parallel groups
- Duration of the study: The intended duration of the study per subject is approximately 14-17 months.
  - **Epoch 001:** Primary, starting at Visit 1 (Day 0) and ending at safety follow up contact (i.e. six months following the third dose, Month 10),
  - **Epoch 002:** Booster, starting at Visit 5 (Month 13-16) and ending at Visit 6 (Month 14-17).

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- Control: active controls.
  - Epoch 001: *Pediarix* + *ActHIB* and *Pentacel* + *Engerix-B*
  - Epoch 002: *Infanrix* + *ActHIB* and *Pentacel*.
- Vaccination schedules:

  Epoch 001

  - **Hexa Group:** Subjects in this group will receive three doses of *Infanrix hexa* (lot A, lot B or lot C as per the group allocation) co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
    - Hexa_1 Group: Subjects will receive lot A of *Infanrix hexa,*
    - Hexa_2 Group: Subjects will receive lot B of *Infanrix hexa*
    - Hexa_3 Group: Subjects will receive lot C of *Infanrix hexa*.
  - **Pedia Group:** Subjects in this group will receive three doses of *Pediarix* and *ActHIB* co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.
  - **Penta Group**: Subjects in this group will receive three doses of *Pentacel* and *Engerix-B** co-administered with *Prevnar13* at 2, 4 and 6 months of age and *Rotarix* at 2 and 4 months of age.

    *Subjects in the Penta Group who have received a dose of hepatitis B vaccine from birth up to 30 days prior to study vaccination should not receive Engerix-B at 4 months of age (Visit 2).

  Epoch 002

  - **Hexa Group**: Subjects will receive a booster dose of *Infanrix* and *Hiberix* vaccines at 15-18 months of age.
  - **Pedia Group**: Subjects will receive a booster dose of *Infanrix* and *ActHIB* vaccines at 15-18 months of age.
  - **Penta Group**: Subjects will receive a booster dose of *Pentacel* vaccine at 15-18 months of age.

  The fourth dose of pneumococcal conjugate vaccine is recommended to be administered at approximately 12-15 months of age. Since the booster dose of the candidate vaccine/active controls will be given in this study at 15-18 months of age, the fourth dose of *Prevnar13* will not be administered as part of the study protocol. Subject's parent(s)/Legally Acceptable Representative(s) (LARs) will be reminded at Visit 3 and Visit 4 to consult their primary health care provider regarding the fourth dose of *Prevnar13* at 12-15 months for their child.
- As the analyses will be performed regardless of the lot of *Infanrix hexa* received, unless otherwise specified, the Hexa_1, Hexa_2 and Hexa_3 groups will be pooled together for the analysis and will be called the Hexa group.

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- Treatment allocation: The subjects will be randomized at a [1:1:1]:3:3 ratio to Hexa_1, Hexa_2, Hexa_3, Pedia and Penta groups. This will be done at study entry using GSK Biologicals' central randomization system on internet (SBIR).
- Blinding: The study is open-label for both epochs due to the differences in the number of injections and the appearance of the vaccines administered. However, the laboratory in charge of the serology testing will be blinded to the treatment, and codes will be used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.
- Sampling schedule: Blood samples will be drawn from all subjects at the following time points:
  - Post-Pri (Visit 4): One month after the third dose of primary vaccination, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Pre-Bst (Visit 5): Before the administration of the booster dose, a volume of approximately 5.0 mL of whole blood (to provide approximately 1.7 mL of serum) will be collected.
  - Post-Bst (Visit 6): One month after the booster vaccination, a volume of at least 3.5 mL of whole blood (to provide at least 1.2 mL of serum) will be collected.
- Type of study: Self-contained.

The following group names will be used for the final statistical analyses:

Group order in tables	Group label in tables	Group definition for footnote	Pooled Groups label in tables	Pooled definition for footnote
1	Hexa_1 group	Subjects who received primary doses of Infanrix hexa from lot A and a booster dose of Infanrix and Hiberix vaccines	Hexa group	Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
2	Hexa_2 group	Subjects who received primary doses of Infanrix hexa from lot B and a booster dose of Infanrix and Hiberix vaccines	Hexa group	Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
3	Hexa_3 group	Subjects who received primary doses of Infanrix hexa from lot C and a booster dose of Infanrix and Hiberix vaccines	Hexa group	Subjects who received primary doses of Infanrix hexa and a booster dose of Infanrix and Hiberix vaccines
4	Pedia group	Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines	Pedia group	Subjects who received primary doses of Pediarix and ActHIB and a booster dose of Infanrix and ActHIB vaccines
5	Penta group	Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine	Penta group	Subjects who received primary doses of Pentacel and Engerix-B and a booster dose of Pentacel vaccine

3. OBJECTIVES

3.1. Primary objective

3.1.1. Epoch 001 (Primary vaccination)

- To demonstrate the non-inferiority of *Infanrix hexa* to *Pediarix* co-administered with *ActHIB*, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

  Criteria for non-inferiority:

  Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pedia divided by Hexa] is ≤ 1.5.

3.2. Secondary objectives

3.2.1. Epoch 001 (Primary vaccination)

- To assess the immune response to *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*, in terms of seroprotection status, seropositivity status and concentrations or titers of antibodies to D, T, HBs, pertussis, poliovirus types 1, 2 and 3 and PRP antigens, one month after the third dose of the primary vaccination.
- To assess the safety and reactogenicity of a 3-dose primary vaccination course of *Infanrix hexa,* of *Pentacel* co-administered with *Engerix-B,* and that of *Pediarix* co-administered with *ActHIB*, in terms of solicited local symptoms.
- To assess the safety and reactogenicity of all study vaccines in terms of solicited general events, unsolicited adverse events, new-onset chronic diseases (NOCDs) and serious adverse events.

3.2.2. Epoch 002 (Booster vaccination)

- To assess the immunogenicity of *Infanrix hexa, Pentacel, Engerix-B, Pediarix* and *ActHIB,* in terms of persistence of the antibodies to D, T, pertussis, HBs, poliovirus types 1, 2 and 3 and PRP antigens, before the booster dose.
- To assess the immune response to *Infanrix, Hiberix, ActHIB* and *Pentacel,* in terms of seroprotection status, seropositivity status and antibody concentrations or titers for D, T, pertussis and PRP antigens, and in terms of booster response for pertussis antigens following *Infanrix and Pentacel*, one month after the booster dose.
- To assess the safety and reactogenicity of booster doses of *Infanrix*, *Hiberix*, *ActHIB* and *Pentacel*.

4. ENDPOINTS

4.1. Primary endpoint

4.1.1. Epoch 001 (Primary vaccination)

- Immunogenicity with respect to pertussis components of the study vaccines *Infanrix hexa* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination.

4.2. Secondary endpoints

4.2.1. Epoch 001 (Primary vaccination)

- Immunogenicity (other parameters) with respect to the pertussis component of the study vaccines *Infanrix hexa, Pentacel* and *Pediarix.*
  - Anti-PT, anti-FHA, anti-PRN seropositivity status, one month after the third dose of the primary vaccination.
  - Anti-PT, anti-FHA, anti-PRN antibody concentrations, one month after the third dose of the primary vaccination (for *Pentacel* only).
- Immunogenicity with respect to the other components of the study vaccines *Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*.
  - Anti-D, anti-T, anti-HBs, anti-poliovirus types 1, 2 and 3 and anti-PRP seroprotection status, anti-PRP antibody concentrations ≥1.0 µg/mL and antibody concentrations/titers, one month after the third dose of the primary vaccination.
- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after each vaccination (*Infanrix hexa, Pediarix, ActHIB, Pentacel* and *Engerix-B*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after each vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after each vaccination, according to the **Med**ical **D**ictionary for **R**egulatory **A**ctivities (MedDRA) classification.

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- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to six months post primary vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from Day 0 up to six months post primary vaccination.

4.2.2. Epoch 002 (Booster vaccination)

- Immunogenicity with respect to all study vaccines.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-HBs, anti-PRP and anti-poliovirus 1, 2, 3 seroprotection/ seropositivity status, anti-PRP antibody concentrations ≥1 µg/mL and antibody concentrations/ titers before the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Pentacel*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN, anti-PRP seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccine *Infanrix*.
  - Anti-D, anti-T, anti- PT, anti-FHA and anti-PRN seroprotection/ seropositivity status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PT, anti-FHA and anti-PRN booster response one month after the booster dose (Dose 4).
  - Anti-D and anti-T antibody concentrations ≥1 IU/mL one month after the booster dose (Dose 4).
- Immunogenicity with respect to the study vaccines *ActHIB* and *Hiberix*.
  - Anti-PRP seroprotection status and antibody concentrations, one month after the booster dose (Dose 4).
  - Anti-PRP antibody concentrations ≥1 µg/mL one month after the booster dose (Dose 4)

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- Solicited local and general symptoms.
  - Occurrence of each solicited local symptom (any, ≥Grade 2, Grade 3 and symptoms requiring medical attention) within 4 days (Day 0 – Day 3) after booster vaccination (*Infanrix, Hiberix, ActHIB* and *Pentacel*).
  - Occurrence of each solicited general symptom (any, ≥Grade 2, Grade 3, symptoms requiring medical attention, related and Grade 3 related) within 4 days (Day 0 – Day 3) after booster vaccination.
- Unsolicited adverse events.
  - Occurrence of unsolicited AEs within 31 days (Day 0 – Day 30) after booster vaccination, according to the MedDRA classification.
- Specific adverse events.
  - Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies) from the booster dose up to one month after the booster vaccination.
- Serious adverse events.
  - Occurrence of serious adverse events from the booster dose up to one month after the booster vaccination.

5. STUDY POPULATION

Six cohorts are defined for the purpose of the analysis:

- Primary Total Vaccinated cohort
- Primary ATP cohort for analysis of safety
- Primary ATP cohort for analysis of immunogenicity
- Booster Total Vaccinated cohort
- Booster ATP cohort for analysis of safety
- Booster ATP cohort for analysis of immunogenicity

5.1.1. Primary Total vaccinated cohort

The Primary Total Vaccinated cohort (TVC) will include all vaccinated subjects for whom data are available.

- A safety analysis based on the Primary TVC will include all subjects with at least one vaccine administration documented.
- An immunogenicity analysis based on the Primary TVC will include all vaccinated subjects for whom data concerning at least one immunogenicity endpoint measure is available.

5.1.2. Primary ATP cohort for analysis of safety

The Primary ATP cohort for safety will consist of all subjects from the Primary TVC who complied with the protocol up to the end of Epoch 001, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received all planned study vaccines for each completed vaccination visit in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;
- who did not receive a product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2 of the protocol.

Note that for the purpose of ATP cohort definition, the Epoch 001 ends at Visit 4.

Adherence to the interval related to ESFU phone contact will not be taken into account for inclusion in ATP cohort for safety.

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5.1.3. Primary ATP cohort for analysis of immunogenicity

The Primary ATP cohort for immunogenicity will consist of all subjects from the Primary ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 of the protocol for the definition of the intervals) up to the post-dose 3 blood sample and had immunogenicity results for the post-dose 3 blood sample. The analysis will be performed per treatment (first dose) actually administered.

More specifically, the analysis post-dose 3 based on the ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 3 as per the vaccination schedule;
- for whom administration site and route of study vaccines up to dose 3 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.7.2 of the protocol
- who did not present with a medical condition before the blood sampling at Visit 4 (Month 5) leading to elimination from an ATP analysis as listed in Section 6.8 of the protocol.
- who comply with the post-dose 3 blood sample schedule, i.e. 21-48 days post-dose 3.
- who were not administered a vaccine not foreseen by the study protocol before the corresponding post-vaccination blood sample.
- who have immunogenicity results post-dose 3.

5.1.4. Booster Total vaccinated cohort

The Booster TVC will include all subjects from primary TVC that received the booster vaccine dose.

- For the Booster-TVC analysis of safety, this will include all subjects with booster vaccine administration documented.
- For the Booster-TVC analysis of immunogenicity, this will include vaccinated subjects for whom data concerning immunogenicity endpoint measures are available.

5.1.5. Booster ATP cohort for analysis of safety

The Booster ATP cohort for safety will consist of all subjects from the Booster TVC who complied with the protocol up to the end of Epoch 002, namely all subjects:

- who meet all inclusion criteria and no exclusion criteria for the study
- who have received the planned booster dose at 15-18 months of age;

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- who received 3 doses in Epoch 001;
- for whom administration site of study vaccines is known and is according to protocol;
- who did not receive a product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis as listed in Section 6.7.2 of the protocol.

5.1.6. Booster ATP cohort for analysis of immunogenicity

The Booster ATP cohort for immunogenicity will consist of all subjects from the Booster ATP cohort for safety who complied with eligibility criteria and study procedures (see Table 5 of the protocol for the definition of the intervals) up to the post-dose 4 blood sample and had immunogenicity results for the post-dose 4 blood sample.

More specifically, the analysis pre- and post-dose 4 based on the Booster ATP cohort for immunogenicity will include all eligible subjects:

- who receive all the study vaccines up to dose 4 as per the vaccination schedule;
- for whom administration site and route of the study vaccines up to dose 4 is as per protocol;
- who did not receive a medication/product before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.7.2 of the protocol);
- who did not present with a medical condition before the blood sampling at Visit 6 (Months 14-17) leading to elimination from an ATP analysis (see Section 6.8 of the protocol);
- who comply with the booster vaccination schedule at 15-18 months of age and with the post-dose 4 blood sample schedule i.e. 21-48 days for post-dose 4;
- who have immunogenicity results post-dose 4.

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
Primary ATP cohort for analysis for safety	1030-2100	PR
Primary ATP cohort for analysis for immunogenicity	1030-2100	PR
Booster ATP cohort for analysis for safety	1030-2100	BO
Booster ATP cohort for analysis for immunogenicity	1030-2100	BO

6. STATISTICAL METHODS

6.1. Final analysis of the Epoch 001

6.1.1. Analysis of demographics

Demographic characteristics (age [weeks], gender, geographical ancestry, height in length [cm], weight [kg] at first dose, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status will be summarised by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as center;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects enrolled among the study sites will be tabulated as a whole and per group.

6.1.2. Analysis of immunogenicity

The primary analysis will be based on the Primary ATP cohort for immunogenicity. An analysis on the Primary Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point, more than 5% of the vaccinated subjects with immunological data post-dose 3 are excluded from the Primary ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

6.1.2.1. Within group assessment

For each group, one month post-dose 3 and for each assay for which a serological result is available:

- Seropositivity and seroprotection rates with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.
- For each antigen, antibody concentration or titer distribution one month post-vaccination will be tabulated and displayed using reverse cumulative curves (RCCs).
- For anti-PRP post primary vaccinate at visit 4, seropositivity and seroprotection rates and GMCs will be calculated per *Infanrix hexa* lot.

All the above within group analysis for Epoch 001, except the reverse cumulative curves and the presentation per *Infanrix hexa* lot, will also be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and by Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

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6.1.2.2. Between group assessment

At one month post-dose 3,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection rates will be computed for each antigen.

• Antigen	• Threshold considered for protection
• Anti-D	• 0.1 IU/mL (short term protection) • 1 IU/mL (long term protection)
• Anti-T	• 0.1 IU/mL (short term protection) • 1 IU/mL (long term protection)
• Anti-polio	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (short term protection) • 1 µg/mL (long term protection)
• Anti-Hbs	• 10 mIU/mL

- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) will be computed using an Analysis of Variance (ANOVA) model on the logarithm-transformed concentrations/titers except for GMC ratio (Penta group divided by Hexa group) for pertussis antigens. The ANOVA model will include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as continuous regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor leading to an Analysis of Co-variance (ANCOVA) model. The model will include the data from the 3 groups compared. For analysis purpose, we will consider DTP vaccination of the mother during pregnancy and Hepatitis B at birth as continuous variables. More specifically 2 continuous indicator variables will be used for Tdap vaccination of mother during pregnancy (an indicator for no Tdap vaccination at birth and an indicator for unknown vaccination at birth) while one indicator of hepatitis B at birth will be used.

6.1.2.3. Interpretation of analyses

Except for analyses addressing criteria specified in the primary objective, comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

6.1.3. Analysis of safety

The primary analysis will be based on the primary Total Vaccinated cohort. If, in any vaccine group and at any time point of the Epoch 001, the percentage of vaccinated subjects excluded from the primary ATP cohort for safety is more than 5%, a second

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analysis based on the primary ATP cohort for safety will be performed to complement the primary Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) or 31-day (Days 0-30) follow-up period will be tabulated after each vaccine dose and overall (for the Epoch 001) with exact 95% CI.
- The percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 4-day or 31-day follow-up period will be tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses with local AEs (solicited and unsolicited) will be calculated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines, as well as overall (all sites considered) during the 4-day follow-up period will be tabulated over the primary vaccination period, with exact 95% CI.
- The percentage of subjects/doses reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated for each group as follows:
  - Over the primary doses, the percentage of subjects with the symptom and its exact 95% CI.
  - Over the primary doses, the percentage of doses with the symptom and its exact 95% CI.
  - At each study dose, the percentage of subjects with the symptom and its exact 95% CI.

  The exact 95% CIs will be calculated assuming independence between doses.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects/doses reporting each individual solicited local (any grade, grade 2, grade 3, medical advice) during the 4-day follow-up period will also be tabulated at each injection site for *Infanrix hexa, Pediarix, ActHIB, Pentacel and Engerix-B* vaccines with exact 95% CI after each vaccine dose and overall where the same row on the table is used for all vaccines given at the same site across the three study groups (e.g. *Infanrix hexa*, *Pentacel* and *Pediarix* together are in one row and *ActHIB* and *Engerix-B* together are in one row). The percentage of subjects/doses reporting each individual general solicited symptom (any grade, Grade ≥2, Grade 3, causally related, Grade 3 causally related, medical advice) during the 4-day follow-up period will also be tabulated with exact 95% CI. For fever, analyses will also be performed by 0.5°C increments.
- The percentage of subjects/doses with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated after each dose and over the Epoch 001.

- The verbatim reports of unsolicited AEs will be reviewed by a Clinical Research and Development Lead and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects/doses with unsolicited AEs occurring within 31 days with exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.
- Subjects who experienced AEs of specific interest (i.e. convulsions, Hypotonic Hyporesponsive Episode) during 31 days with exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for AEs considered related to vaccination. Subjects who experienced AEs of specific interest will also be described in detail.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from Day 0 up to 6 months after the last primary vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE reported before the database lock for the Epoch 001 analysis with an onset date in the Epoch 001 will be tabulated with MedDRA primary preferred term.
- All the above safety and reactogenicity analysis for Epoch 001 will also be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry) except the percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period.

6.2. Final analysis of the Epoch 002

6.2.1. Analysis of demographics/baseline characteristics

Demographic characteristics (age [months] at Visit 5, gender, geographical ancestry, Hep B vaccination history, vaccination history of mother with respect to administration of Tdap vaccine during pregnancy) and withdrawal status will be summarized by group using descriptive statistics:

- Frequency tables will be generated for categorical variables such as race/ethnicity;
- Mean, median and standard error will be provided for continuous data such as age.

The distribution of subjects vaccinated at Visit 5 among the study sites will be tabulated as a whole and per group.

For enrolled subjects that do not participate in the Epoch 002, the reason for not participating will be summarized.

6.2.2. Analysis of immunogenicity

The primary analysis will be based on the booster ATP cohort for immunogenicity. An analysis on the booster Total Vaccinated cohort will be performed only if, in any vaccine group and at any time point of the Epoch 002, more than 5% of the vaccinated subjects with immunological data are excluded from the booster ATP cohort for immunogenicity.

The following section describes the analyses that will be performed.

6.2.2.1. Within group assessment

For each group, prior to the booster dose and one month post-booster dose and for each assay, for which a serological result is available:

- Seropositivity and seroprotection rates and booster response rates for pertussis with exact 95% CIs will be calculated.
- GMCs/GMTs with 95% CIs will be tabulated.
- For each antigen, antibody concentration or titer distribution before and one month Post-booster (when available) will be tabulated and displayed using RCCs.

All the above within group analysis for Epoch 002 except the reverse cumulative curves will also be performed by gender, by geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestries, namely White Caucasian versus any other geographical ancestry), by Tdap vaccination history of mothers during pregnancy and Hepatitis B vaccination of the subjects at birth (for anti-HBs antigen).

6.2.2.2. Between group assessment

At pre-booster and at one month post-booster,

- The asymptotic standardized 95% CI for the group difference (Pedia group minus Hexa group and Penta group minus Hexa group) in the seroprotection/ seropositivity rates will be computed for each antigen except for group difference (Penta group minus Hexa group) in the seroprotection/ seropositivity rates for pertussis antigens.

• Antigen	• Threshold considered for protection
• Anti-D	• 0.1 IU/mL (short term protection) • 1 IU/mL (long term protection)
• Anti-T	• 0.1 IU/mL (short term protection) • 1 IU/mL (long term protection)
• Anti-polio	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (short term protection) • 1 µg/mL (long term protection)
• Anti-Hbs	• 10 mIU/mL

- The 95% CI for each group GMC/GMT ratio (Pedia group divided by Hexa group and Penta group divided by Hexa group) will be computed using an ANOVA model on the logarithm-transformed concentrations/titers except for GMC ratio (Penta group divided by Hexa group) for pertussis antigens. The ANOVA model will include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA). For hepatitis B antigen, the hepatitis B at birth vaccine dose status will also be used as regressor leading to an ANCOVA model. The model will include the data from the 3 groups compared. For analysis purpose, we will consider DTP vaccination of the mother during pregnancy and Hepatitis B at birth as continuous variables. More specifically 2 continuous indicator variables will be used for Tdap vaccination of mother during pregnancy (an indicator for no Tdap vaccination at birth and an indicator for unknown vaccination at birth) while one indicator of hepatitis B at birth will be used.

6.2.2.3. Interpretation of analyses

In Epoch 002, all comparative analyses will be descriptive/ exploratory with the aim to characterise the difference between groups in immunogenicity. These descriptive/exploratory analyses should not be interpreted for formal conclusions since there is no adjustment for multiplicity of endpoints.

6.2.3. Analysis of safety

The primary analysis for the Epoch 002 will be based on the booster Total Vaccinated cohort and will only look at the booster dose. If, in any vaccine group, the percentage of vaccinated subjects excluded from the booster ATP cohort for safety is more than 5%, a second analysis based on the booster ATP cohort for safety will be performed to complement the booster Total Vaccinated cohort analysis.

- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose, will be tabulated with exact 95% CI for each group.
- The incidence of local AEs (solicited and unsolicited) will be calculated at each injection site as well as overall (all sites considered) for each group during the 4-day (Days 0-3) follow-up period after the booster dose.
- The percentage of subjects reporting each individual solicited local and general AE during the 4-day follow-up period will be tabulated with its exact 95% CI for each group.
- All computations mentioned above will be done for Grade ≥2 (solicited symptoms only) and Grade 3 symptoms, for symptoms considered related to vaccination (general symptoms only), for Grade 3 symptoms considered related to vaccination (general symptoms only) and for symptoms that resulted in a medically-attended visit. The percentage of subjects reporting each individual solicited local symptoms (any grade, Grade ≥2, Grade 3, medical advice) during the 4-day follow-up period will

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also be tabulated at each injection site for *Infanrix, Hiberix, ActHIB* and *Pentacel* vaccines with exact 95% CI after each vaccine dose and overall where vaccination with same vaccine site is considered together (e.g. *Infanrix* and *Pentacel* together are on one row and *ActHIB* and *Hiberix* together are on one row). The percentage of subjects reporting each individual general solicited symptom (any grade, Grade ≥2, Grade 3, causally related, Grade 3 causally related, medical advice) during the 4-day follow-up period will also be tabulated with exact 95% CI. For fever, analyses will also be performed by 0.5°C increments.

- The percentage of subjects with concomitant medication, antipyretic medication and prophylactic antipyretic medication during the 4-day and 31-day follow-up period post-vaccination will be tabulated for each group.
- The verbatim reports of unsolicited AEs will be reviewed by a Clinical Research and Development Lead and the signs and symptoms will be coded according to MedDRA. Every verbatim term will be matched with the appropriate Preferred Term. The percentage of subjects with unsolicited AEs occurring within 31 days following the booster dose with its exact 95% CI will be tabulated by Preferred Term. Similar tabulations will be done for Grade 3 unsolicited AEs, for unsolicited AEs considered related to vaccination and for Grade 3 unsolicited AEs considered related to vaccination.

Additionally,

- Any large injection site reaction (defined as a swelling with a diameter > 50 mm, noticeable diffuse swelling or increase in limb circumference of greater than 50 mm) reported within 4 days (Days 0-3) following the booster dose will be tabulated.
- Subjects who experienced AEs of specific interest (i.e. new onset of chronic disease such as autoimmune disorders, asthma, type I diabetes and allergies) from booster dose up to one month after booster vaccination will be tabulated by Preferred Term.
- Subjects who experienced at least one SAE from the booster dose to study end will tabulated with MedDRA primary preferred term.

All the above safety and reactogenicity analysis for Epoch 002 will also be performed by gender and geographical ancestry (the most frequent geographical ancestry versus all other geographical ancestry, namely White Caucasian versus any other geographical ancestry) except percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general AE (solicited and unsolicited) and with any AE during the 4-day (Days 0-3) and 31-day (Days 0-30) follow-up period after the booster dose.

7. STATISTICAL CALCULATIONS

7.1. Derived and transformed data

7.1.1. Demography

For a given subject and a given demographic variable, missing measurement will not be replaced excepting for age.

Age will be calculated as the number of years between the date of birth and the date of vaccination.

To ensure that the collection of date of birth will not jeopardise the privacy of personally identifiable information, only a partial date of birth (MMYYYY) will be collected.

Therefore, the 15th of the month will be used to replace the missing date. In case the day and the months are missing, the date will be replaced by the June 30th of the year.

7.1.2. ImmunogenicityA seronegative subject is a subject whose antibody concentration/titer is below the assay cut-off.

- A seropositive subject is a subject whose antibody concentration/titer is greater than or equal to the assay cut-off.
- Note: Due to re-validation of all assays, the cut-offs presented in Table 7 of the protocol have changed as follows

• Antigen	• Threshold for positivity
• Anti-PT	• 2.693 IU/mL
• Anti-FHA	• 2.046 IU/mL
• Anti-PRN	• 2.187 IU/mL
• Anti-D	• 0.057 IU/mL
• Anti-T	• 0.043 IU/mL
• Anti-polio	• 8 dilution
• Anti-PRP	• 0.15 µg/mL (assay not fully qualified) • 0.066 µg/mL (new validated assay)
• Anti-Hbs	• 6.2 mIU/mL

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- A seroprotected subject is a subject whose antibody concentration/titer is greater than or equal to the level defining clinical protection. The following seroprotection thresholds are applicable:
  - Anti-diphtheria antibody concentrations ≥ 0.1 IU/mL.
  - Anti-tetanus antibody concentrations ≥ 0.1 IU/mL.
  - Anti-HBs antibody concentrations ≥ 10 mIU/mL.
  - Anti-poliovirus types 1, 2 and 3 antibody titers ≥ 8.
  - Anti-PRP antibody concentrations ≥ 0.15 µg/mL.
- Other cut-offs to be considered:
  - Anti-PRP antibody concentrations ≥ 1.0 µg/mL.
  - Anti-diphtheria and anti-tetanus antibody concentrations ≥ 1.0 IU/mL
- Booster responses for anti-PT, anti-FHA and anti-PRN antibodies are defined as:
  - initially seronegative subjects (pre-booster antibody concentration below the assay cut-off) presenting an increase of at least four times the assay cut-off one month after vaccination,
  - initially seropositive subjects with antibody concentration < four times the assay cut-off presenting an increase of at least four times the pre-booster antibody concentration one month after vaccination
  - initially seropositive subjects with anti-body concentration ≥ four times the assay cut-off presenting an increase of at least two times the pre-booster antibody concentration one month after vaccination
- The GMC/GMT calculations will be performed by taking the anti-log of the mean of the $\log_{10}$ titer/ concentration transformations. Antibody titers/concentrations below the cut-off of the assay will be given an arbitrary value of half the cut-off for the purpose of GMC/GMT calculation.
- Handling of missing data - For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements will not be replaced.

7.1.3. Safety/reactogenicity:

- For a given subject and the analysis of solicited symptom within 4 days post-vaccination, 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 vaccinated subjects and doses with documented safety data (i.e. symptom screen completed).
- For analysis of unsolicited adverse events, such as serious adverse events or adverse events by primary MedDRA term, and for the analysis of concomitant medications, all vaccinated subjects will be considered. Subjects who did not report the event or the concomitant medication will be considered as subjects without the event or the concomitant medication respectively.

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- For analysis of convulsion, the adverse event will be identified by using narrow standard MedDRA query.
- For analysis of Hypotonic Hyporesponsive Episode (HHE), the adverse event will be identified by using broad standard MedDRA query.
- For analysis of New Onset of Chronic Illness (NOCI), the adverse event will be identified by using narrow standard MedDRA query.
- For summaries reporting both solicited and unsolicited adverse events, all vaccinated subjects will be considered. Subjects for whom the event will not be reported will be considered as subjects without the event.
- Large injection site reactions are defined as either swelling with a diameter of >50 mm or a >50 mm increase in the circumference of any limb when compared to the baseline (pre-vaccination) measurement, or any diffuse swelling that interferes with or prevents everyday activities (for example, active playing, eating, sleeping).
- For the analysis, temperatures by any route will be coded as follows:

Grade	Temperature
0	< 38.0°C
1	≥ 38.0°C - ≤ 39.0°C
2	> 39.0°C - ≤ 40.0°C
3	> 40.0°C

- The way the percentage of subjects will be derived will depend on the event analysed (see table below for details). As a result, the N value will differ from one table to another.

Event	N used for deriving % per subject for Vaccination phase
Concomitant vaccination	All subjects with study vaccine administered
Solicited general symptom	All subjects with at least one solicited general symptom documented as either present or absent (i.e. symptom screen completed)
Solicited local symptom	All subjects with at least one solicited local symptom documented as either present or absent (i.e. symptom screen completed)
Unsolicited symptom	All subjects with study vaccine administered
Concomitant medication	All subjects with study vaccine administered

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7.2. Data presentation description

The following decimal description from the decision rules will be used for the demography, immunogenicity and safety/ reactogenicity.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	SD (age)	1
anti-T	GMC	3
anti-D	GMC	3
anti-PT	GMC	1
anti-PHA	GMC	1
anti-PRN	GMC	1
anti-HBs	GMC	1
anti-PRP	GMC	3
anti-Polio 1	GMT	1
anti-Polio 2	GMT	1
anti-Polio 3	GMT	1
Immunogenicity	Ratio of GMT/C	2
Reactogenicity	Mean, Min, Q1, Median, Q3, Max for duration	1
All summaries	% of count, including LL & UL of CI	1
All summaries	% of difference, including LL & UL of CI	2

7.3. Methodology for computing confidence intervals

- All CI computed will be two-sided 95% CI.
- The exact 95% CIs for a proportion within a group will be based on the method by Clopper [Clopper, 1934*].
- The standardised asymptotic 95% CI for the group difference in proportions will be based on the method 6 described in paper by Newcombe [R Newcombe, 1998, method six**].
- The 95% CI for geometric mean titers/concentrations (GMTs/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 GMTs/GMCs will be then obtained by exponential-transformation of the 95% CI for the mean of log-transformed titer/concentration.

  The GMC/GMT group ratio will be computed using an ANOVA model on the logarithm10 transformation of the concentrations/titers. The ANOVA model will include the vaccine group as fixed effect and the Tdap vaccination of the mother during pregnancy as regressor leading to an Analysis of Co-variance (ANCOVA) model. For hepatitis B antigen, the hepatitis B vaccination at birth vaccine dose status will also be used as regressor leading to an Analysis of Co-variance (ANCOVA) model.

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8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

The analyses will be performed stepwise:

1. A partial analysis of Epoch 001 up to one month after the third primary vaccine dose will be conducted. This analysis will include the final analysis of anti-PRP, solicited and unsolicited symptoms on data as clean as possible. This analysis will be displayed on GSK clinical trial registry as soon as possible.
2. The final data analysis of the study covering both the epochs will be conducted at the end of the study. All these analyses will be presented in a final clinical study report.

Following analysis folder will be created in SDD and CARS with given analysis ID to perform analysis and archival of statistical reports

Description	Analysis ID (SDD & CARS sub-folder)	Disclosure	TFL reference
Primary Epoch - Anti-PRP and safety	E1_01	CTRS	From TFL Version 1 dated 10-Mar-2015, following tables will be generated for time point - one month post vaccination dose 3. • Post-Text table section – Table-29, 34, 35, 38, 39. • CTRS table sections – Table 1-5, 10, 12-15) • Annex table section – Table 3 Please note that the tables from post text section will be generated with output destination 'ANNEX'.
Final	E1_02	CTRS, Clinical Study report, Publication	TFL Version 2 dated 17-Nov-2017

8.2. Statistical considerations for interim analyses

All analyses will be conducted on final data and therefore no statistical adjustment for interim analyses is required.

9. MAJOR CHANGES FROM PLANNED ANALYSES

The following are the changes in the SAP from the protocol:-

- The analysis of percentage of doses followed by at least one local AE (solicited and unsolicited), by at least one general AE (solicited and unsolicited) and by any AE during the 31-day (Days 0-30) follow-up period will not be tabulated over the primary vaccination period and also over booster vaccination period, with exact 95% CI. Also the same analysis by gender and geographical ancestry will not be performed.
- During the course of the study, the assays used to measure the anti-D, -T, -PT, -FHA and -PRN IgG concentrations were re-developed and re-validated and both assay units and assay cut-off were adapted. The new ELISAs for PT, FHA and PRN were calibrated against the WHO International Standard (NIBSC 06/140). This allowed the expression of concentrations measured with the new ELISAs in International Units per milliliter (IU/mL) instead of the formerly used ELISA units per milliliter (EL.U/mL). The newly validated DTPa ELISA's have a lower assay cut-offs as compared to the one described in the protocol. The current assay cut-off is 0.057 IU/mL for anti-D, 0.043 IU/mL for anti-T, 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA and 2.187 IU/mL for anti-PRN. Since for anti-D, anti-T a threshold of 0.1 IU/mL provided a conservative estimate of the percentage of subjects deemed to be protected, the anti-D, anti-T seroposivity endpoints initially defined by the previous assay cut-off of 0.1 IU/mL were replaced by seroprotection rate endpoints defined as the percentage of subjects with concentration above 0.1 IU/mL. In the absence of a correlate of protection for the *B. pertussis* antigens, the pertussis vaccine response endpoints were redefined based on the assay cut-off.
- A descriptive summary per lot was added for anti-PRP post priming.
- The ANCOVA model was revised to include the 3 study groups rather than the 2 groups compared. This allowed identical adjusted GMC estimate regardless of the groups involved in the comparison.
- The DTPA-HBV-IPV-135 (117119) Abridged Interim Report Main (19-Oct-2015) included immunogenicity data against Polyribosyl-Ribitol-Phosphate (PRP) antigen at Visit 4 using an assay which was not fully validated. For the final analysis, the visit 4 samples were retested together with the samples pre- and post booster using a newly validated assay. In the final analysis, the results of both assays will be descriptively presented at visit 4.

10. REFERENCE

* Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of binomial. *Biometrika*. 1934;26:404-413

** *Robert G. Newcombe, interval estimation for the difference between independent proportions: comparison of eleven methods, Statist Med. 1998; 17, 873-890*

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

Not Applicable

CRF /eCRFs for deaths, other SAEs and withdrawals due to adverse events

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Study Administrative Table

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Monitoring	Central Study Monitor (Central Study co-ordinator)	• co-ordinates operational aspects of running the study from preparation of study supplies and data capture tools, to study tracking • has regular contacts with local monitors in order to review the study progress and any issue raised by the local monitor. In this way compliance with the protocol and GCP/ICH guidelines is ensured during preparation, active and cleaning phases of the study • is responsible for maintaining and archiving a comprehensive study file. If required, transitioning of a study from one monitor to another is documented in the study file • is responsible for reviewing and signing off of the clinical study report	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Monitoring	Local Monitor	*Prior to study start:* • is responsible for the evaluation of the study site and ensures that the staff and facilities are trained and appropriate for running of the study according to protocol and GCP guidelines • is involved in the preparation of study package for submission to Ethics Committee and/or Independent Review Board (EC/IRBs) and appropriate authorities	GSK United States: GlaxoSmithKline Biologicals Slaoui Center for Vaccine Research, 14200 Shady Grove Road, Rockville MD 20850. Novella: 1700 Perimeter Park Dr, Morrisville, NC 27560

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
		At study initiation: • conducts study specific training *While trial is ongoing*: • discusses all aspects of the trial with the study staff • verifies source documents and Case Report Forms (CRFs) • conducts a 100% review of all Informed Consent documentation • checks accountability of investigational product and its storage conditions • checks the collection and storage of biological samples and transport to central laboratory • reviews each SAE report All monitoring visits are documented via a monitoring visit report (MVR), which will be reviewed by the monitor's manager. These reports allow the identification of protocol violation, re-education of site staff and communication of significant issues (SAEs, quality, efficacy and GCP compliance) to the central organisation. In this way the Local Monitors oversee the progress of the clinical trial and ensure that it is conducted, recorded and reported in accordance with the protocol and current GCP/ICH guidelines. The Local Monitor works in close partnership with the Local Medical Advisor and the Central Study Monitor.	

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Data Management	Data Manager	Responsibilities involve: • the design of the Case Report Form (CRF) • the creation of data entry application • the collection and handling of study data • the cleaning of study data (in conjunction with the Clinical Development Manager, Central Study and Local Monitors) in order to provide cleaned database for the statistical analysis	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Statistics	Statistician	• is involved in the study design and is responsible for calculating the sample size, preparation of the randomisation list, identification of appropriate statistical tests to analyse the data, conducting the statistical analysis on the data collected, issuing the statistical report and interpretation of the statistical findings • reviews the final study report to ensure that all aspects of the statistical analysis and findings are accurately represented in the final report	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

Laboratory assessments	GlaxoSmithKline Biologicals,
	Global Vaccine Clinical Laboratory (GVCL) now known as Clinical Laboratories Sciences (CLS).
		• Testing for the analysis of the immune response:
		  • SERUM:
		  • Corynebacterium diphtheria Diphtheria Toxoid Ab.IgG (ELISA)
		  • Clostridium tetani.Tetanus Toxoid Ab.IgG (ELISA)
		  • Bordetella pertussis.Pertussis Toxin Ab.IgG (ELISA)
		  • Bordetella pertussis.Filamentous Hemaglutinin Ab.IgG (ELISA)
		  • Bordetella pertussis.Pertactin Ab.IgG (ELISA)
		  • Hepatitis B Virus.Surface Ab (CLIA)
		  • Poliovirus Sabin Types 1, 2 and 3 (NEUTRA)
		  • Haemophilus influenzae type b.Polyribosyl Ribitol Phosphate Ab (ELISA)
			GlaxoSmithKline Biologicals, Global Vaccine Clinical Laboratory (GVCL)) now known as Clinical Laboratories Sciences (CLS) GSK Rixensart Rue de l'Institut, 89 B-1330 Rixensart – Belgium

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Randomization	Clinical Operations, Department of Biometrics	• computer-generated a randomisation list which was used to number the vaccines • A randomisation blocking scheme was used to ensure that the balance between vaccine groups was maintained. The randomisation number uniquely identified the vaccine dose to be administered to any subject. • A randomisation blocking scheme was used to ensure that the balance between vaccine groups was maintained. The randomisation number uniquely identified the vaccine dose to be administered to any subject.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) (using SAS macro)
Medical writing	Scientific Writer	• In collaboration with the study team, prepares study protocols, Subject Information Sheet (SIS) Informed Consent Forms (IC), protocol amendments and the Clinical Study Reports (CSR). • Co-ordinates the review of the final study report with the study team (including the investigators) to ensure that the report is an accurate account of the study and findings.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Central Safety	Central Safety Department	During the conduct of pre-licensure clinical studies, the Central Safety Department is responsible for: • centralising collection, review and follow-up of all reported SAEs • the issue of Expedited Investigator Safety Reports to inform all investigators in the programme and IRBs of unexpected and related SAEs • the preparation and review of consolidated safety reports related to investigational vaccines • the analysis of safety issues and review of the safety content of the final study report.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Other information			
Location of trial master file	Local Study Monitor	The Sponsor's Trial Master file is composed of the following: • The *country monitoring study file*. This part of the master file is located at the particular GSK office involved in the study. The type of documents retained by the GSK office is given in Annex 1.	Slaoui Center for Vaccine Research, 14200 Shady Grove Road, Rockville MD 20850
	Central Study Monitor	• The *central study file*. This part of the master file is located at the GSK offices in Rixensart. The type of documents retained by the GSK central office in Rixensart is given in Annex 2.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Site(s) of manufacture	GSK Biologicals	LOT_NUMBER_LIST AC21VB448C (DTPa-HBV-IPV)	
		AHIBC950C (Hib)	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
		AC21B514A (DTPa-HBV-IPV)	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) GlaxoSmithKline Biologicals, SA, Avenue Fleming, 20, B-1300 Wavre (Belgium)
		AHIBC907D (Hib)	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
		AC21B510B (DTPa-HBV-IPV) AHIBC954A (Hib)	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) GlaxoSmithKline Biologicals, SA, Avenue Fleming, 20, B-1300 Wavre (Belgium)
		AC21VB448C (Pediarix)	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
		DLOCA102AY (DTaP-IPV Sanofi) DLOCA102AZ (ActHib for Pentacel) DLOCA108AY DLOCA108AZ	Sanofi Pasteur Limited, Toronto Ontario Canada and Sanofi Pasteur Inc. Swiftwater PA, USA
		AC14B195A (DTPa=Infanrix)	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) GlaxoSmithKline Biologicals, SA, Avenue Fleming, 20, B-1300 Wavre (Belgium)
		AHIBC875A (Hib)	GlaxoSmithKline Biologicals Rue de l'Institut 89,

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
			1330 Rixensart (Belgium)
		DEXTA517AZ (diluent NaCl)	Secondary packaging: GlaxoSmithKline Biologicals, SA, Avenue Fleming, 20, B-1300 Wavre (Belgium)
		DLOCA150AY DLOCA150AZ	Manufacturer : Hollister-Stier
		DLOCA144AY DLOCA144AZ	Sanofi Pasteur Limited, Toronto Ontario Canada and Sanofi Pasteur Inc. Swiftwater PA, USA
			Sanofi Pasteur Limited, Toronto Ontario Canada and Sanofi Pasteur Inc. Swiftwater PA, USA
Site of release in Europe	GSK Biologicals	-	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

Signature of principal or coordinating investigator

GlaxoSmithKline Biologicals
Vaccines R&D
Investigator Approval Page

STUDY TITLE: A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age.

Study: 117119 (DTPA-HBV-IPV-135) Development Phase: III

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:	Dr. Nicola Klein
Affiliation /investigational centre:	Kaiser Permanente Oakland, One Kaiser Plaza, Oakland, CA, USA
Signature of Investigator:	PPD
Date:	11 Jul 2018

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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

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Study: 117119 (DTPA-HBV-IPV-135) Development Phase: III

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:	Narcisa Elena Mesaros
Title of Sponsor Signatory:	MD, Clinical and Epidemiology R&D Project Leader, DTP, Polio and Hib containing vaccines – R&D Centre Belgium, GlaxoSmithKline Biologicals
Signature:	PPD
Date:	16 JUL 2018

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