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*

V59_77 CSR Table of Contents

CLINICAL STUDY REPORT

1. TITLE PAGE

Study Title:	A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.
Protocol Number:	V59_77
Investigational Product:	Meningococcal vaccine (Menveo) containing Meningococcal A, C, W and Y oligosaccharide diphtheria cross reactive material (CRM)-197 conjugate
Indication:	Prophylaxis of meningococcal disease caused by serogroups A, C, W and Y
Sponsor:	GlaxoSmithKline Biologicals S.A (GSK)
Development Phase:	3b
Study Initiation Date:	First subject enrolled: 08 DEC 16
Study Completion Date:	Last subject completed: 07 DEC 17
Coordinating/Principal Investigator:	Mary Tipton, M.D.
Date of the Report:	22 MAY 18

This study was conducted according to the principles of Good Clinical Practice as described in International Conference on Harmonisation guidelines, including the archiving of essential documents.

2. SYNOPSIS

Name of Sponsor GlaxoSmithKline Biologicals (GSK), SA, Rixensart, Belgium	Individual Study Table Referring to Part [ ] of the Dossier VOLUME: PAGE:	*For National Authority Use Only*
Name of Finished Product Meningococcal ACWY Conjugate Vaccine (Menveo)		
Name of Active Ingredient Cross reactive material (CRM_{197})-MenA conjugate CRM_{197}-MenC conjugate CRM_{197}-MenW conjugate CRM_{197}-MenY conjugate		

Title of Study: A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.

Protocol Number: V59_77

Coordinating/Principal Investigator: Mary Tipton, M.D.

Study Centers: 1 study center in Puerto Rico; 40 study centers in the United States (US). Three centers in the US were initiated but did not enroll any subjects. Please refer to section 16.1.4 for the detailed list of study centers.

Publication (reference): None

Study Period: Approximately 6 months for each subject

Date of first enrollment: 08 DEC 16
Date of last visit: 07 DEC 17

Phase of Development: 3b

Objectives:

Primary objectives:

- To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with human serum bactericidal assay (hSBA) seroresponse[1] against *N meningitidis* serogroups A, C, W and Y at day 29 after vaccination.
- To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse[1] against *N meningitidis* serogroups A, C, W and Y at day 29 after vaccination

Criteria to demonstrate immune response sufficiency: The immune response sufficiency was to be tested sequentially; first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra. The immune response was to be considered as sufficient if the lower limit (LL) of the one-sided 97.5% confidence interval (CI) for percentage of subjects with hSBA seroresponse[1] against serogroups A, C, W and Y was greater than 75%. The study was to be considered successful if the immune response sufficiency was demonstrated at least in the group of subjects who received primary vaccination with Menveo.

Secondary objectives:

- To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo, subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled vaccine group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA seroresponse[1], hSBA titers ≥ 8 and ≥ 16, and hSBA geometric mean titers (GMTs) against *N meningitidis* serogroups A, C, W and Y at day 1, day 4, day 6, and day 29 after vaccination.
- To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the primary vaccination with Menactra in comparison with naturally-acquired levels in

[1] Seroresponse was defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

vaccine-Naive individuals, as measured by the percentages of subjects with hSBA titers ≥ 8 and hSBA GMTs at day 1.

Safety objectives:

- To assess reactogenicity and safety of MenACWY-CRM vaccine when administered to subjects who previously received Menveo or Menactra and vaccine-Naive individuals.

Methodology:

Study Design: This was a phase 3b, controlled, open-label, multi-center study to evaluate safety and immunogenicity of Menveo after a single vaccination in healthy individuals who were vaccinated with Menveo or Menactra 4 to 6 years before and in vaccine- Naive individuals.

Study population: Approximately 700 healthy subjects 15 through 55 years of age were to be enrolled in the study.

Duration of the study: The duration of this study was approximately 6 months per subject.

Written informed consent and, as applicable according to local guidelines, written assent were to be obtained before conducting any study-specific procedures.

Vaccination schedule: All subjects were to receive a single dose of Menveo at day 1.

Study groups:

- Group Menveo-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menveo 4 to 6 years before, were to receive 1 dose of Menveo.
- Group Menactra-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menactra 4 to 6 years before, were to receive 1 dose of Menveo.
- Group Naive: approximately 100 subjects, of similar age to subjects enrolled in other primed groups, with enrollment distributed across all clinical sites, who had not received any meningococcal vaccination, were to receive 1 dose of Menveo.

Randomization / Stratification:

Within each study group, subjects were to be randomized into one of two different blood draw schedules according to a 1:1 ratio, described as follows:

- Subjects getting blood draws at day 1, day 4 and day 29.
- Subjects getting blood draws at day 1, day 6 and day 29.

Blinding: open-label study.

Data collection: Electronic case report form.

Study clinic visits: Three clinic visits at day 1, day 4 or day 6 and day 29 were planned for each subject. Schematic diagram of the study design is provided in Table 2-1.

Reminder phone calls: Two reminder phone calls were to be conducted at day 3 and day 5 after the study vaccination to remind the subject/ legal guardian to complete the diary card.

Safety phone calls: Three safety phone calls (at day 15, day 91 and day 181) were to be conducted to collect any medically-attended adverse events (AEs), AEs leading to withdrawal, serious adverse events (SAEs), related medications and any vaccinations. In addition, all unsolicited AEs and related medications occurring after the vaccination were to be collected during the safety call at day 15. The day 181 safety phone call was also to serve as the termination visit.

Solicited AEs: Injection site pain, erythema, induration, fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever occurring on the day of vaccination and the following six days (day 1 through day 7) were to be recorded daily using a diary card for all subjects.

Unsolicited AEs occurring within 28 days after study vaccination were to be collected. Qualified site staff were to interview the subject by phone approximately 14 days after vaccination and in person at the study site approximately 28 days after study vaccination to assess the occurrence of any unsolicited AEs.

Medically-attended AEs, AEs leading to study withdrawal and SAEs were to be collected during the entire study period. These data were to be captured by interviewing the subject and/or subjects' parents / guardian (as applicable) during the site visits and phone calls and by review of available medical records. Subjects and/or parents/guardian were to be encouraged to call the site in the event of any medically-attended AEs or any AEs which they perceived as being of concern during the entire study period.

Table 2-1 Schematic diagram of the V59_77 study design.

day 1	day 4	day 6	day 15	day 29	day 91	day 181
Blood draw (all subjects) Menveo	Blood draw (50% of subjects)	Blood draw (50% of subjects)	Safety phone call	Blood draw (all subjects)	Safety phone call	Safety phone call Study termination

Three blood samples of approximately 10 mL each were to be collected according to the blood draw schedule in Table 2-2.

Table 2-2 Blood Draw Schedule by Study Group

Vaccine History	Vaccination in current study	Blood draw schedule
Menveo N=300	Menveo	Blood draw day 1, 4, 29 (N=150)
		Blood draw day 1, 6, 29 (N=150)
Menactra N=300	Menveo	Blood draw day 1, 4, 29 (N=150)
		Blood draw day 1, 6, 29 (N=150)
Vaccine-Naive N=100	Menveo	Blood draw day 1, 4, 29 (N=50)
		Blood draw day 1, 6, 29 (N=50)

The number of planned and enrolled subjects is summarized under Number of Subjects (planned and analyzed) section, below.

Number of Subjects (planned and analyzed):

Approximately 700 subjects were planned for enrollment into this study. It was assumed a 10% drop-out rate that was to provide approximately 630 evaluable subjects. The number of planned and enrolled subjects is provided in Table 2-3.

Table 2-3 Number of Subjects Enrolled (Planned and Actual) per Study Group

Study Groups	Menveo-Menveo		Menactra-Menveo		Naive		Total	
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
Blood draw days 1, 4, 29	150	151	150	150	50	52	**350**	**353**
Blood draw days 1, 6, 29	150	150	150	151	50	50	**350**	**351**
Total	300	301	300	301	100	102	**700**	**704**

Source: Modified from Table 1 of V59_77 study protocol, version 1.0, issued on 24 Jun 16; Table 14.1.1.6.

Diagnosis and Main Criteria for Inclusion and Exclusion:

The list of inclusion and exclusion criteria is included in clinical study report (CSR) section 9.3, Selection of Study Population.

Test Vaccine, Dose, Mode of Administration, Lot Number:

The study vaccine specific to this study was the MenACWY-CRM vaccine (Menveo, GSK Biologicals).

One 0.5 mL single dose of Menveo was to be administered by intramuscular injection in the deltoid area of non-dominant arm (preferably) in Menveo-Menveo, Menactra-Menveo treatment groups and to treatment Naive group on day 1.

Lot number: A16013 – (DEXTG006AY - Men A lyo); X16013 – (DEXTG006AZ - MenCWY-135 liquid)

The full list of vaccine components may be found in section 9.4.2.

Duration of Study:

The duration of the study for an individual subject was approximately 6 months.

Reference Vaccine, Dose, Mode of Administration, Lot Number:

No reference (control) vaccine was used in this study.

Criteria for Evaluation:

Primary Endpoint(s):

- Percentage of subjects with hSBA seroresponse[1] against *N meningitides* serogroups A, C, W and Y at day 29 for Menveo-Menveo and Menactra-Menveo groups.

Secondary Endpoints:

Immunogenicity endpoints:

The following measures were summarized for Menveo-Menveo, Menactra-Menveo, Naive and the pooled (Menveo-Menveo and Menactra-Menveo) groups:

- Percentage of subjects with hSBA titer ≥ 8 and ≥ 16 against *N meningitidis* serogroups A, C, W and Y at day 1, day 4, day 6 and day 29 and between-group differences;

[1] Seroresponse was defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

- Percentages of subjects with hSBA seroresponse[1] against *N meningitidis* serogroups A, C, W and Y at day 4, day 6 and day 29 and between-group differences;
- hSBA GMTs against *N meningitidis* serogroup A, C, W and Y at day 1, day 4, day 6 and day 29;
- Ratios of hSBA GMTs at day 1, day 4, day 6 and day 29 (between study groups);
- hSBA Geometric Mean Ratios (GMRs) at day 4, day 6, and day 29 compared to day 1 (within study groups).

Safety endpoints:

Safety of the study vaccine was assessed in the Menveo-Menveo and Menactra-Menveo groups and the pooled vaccine groups (Menveo-Menveo and Menactra - Menveo) and the vaccine-naive group in terms of the frequencies (percentages) of reported AEs including:

1. Any unsolicited AEs reported within 30 minutes after vaccination;
2. Solicited local and systemic AEs reported from day 1 (6 hours) through day 7 after vaccination;
3. Other indicators of reactogenicity (eg, use of analgesics / antipyretics, body temperature) within 7 days after vaccination;
4. All unsolicited AEs reported from day 1 through day 29 after vaccination;
5. Medically-attended AEs, AEs leading to withdrawal and SAEs reported from day 1 through day 181 (during the entire study period).

Statistical Methods:

Primary Immunogenicity Objective

The primary population for the analysis of sufficient immune response was the per protocol set (PPS), and consisted of the Menveo-Menveo group (n=270 evaluable subjects) and Menactra-Menveo group (n=270 evaluable subjects).

For each individual vaccine group (Menveo-Menveo and Menactra-Menveo) and each A, C, W, and Y serogroup, the percentage of subjects with seroresponse[1] were computed, along with associated two-sided 95% Clopper-Pearson CIs.

[1] Seroresponse was defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

To demonstrate immune response sufficiency after Menveo booster vaccine administration, the lower limit of the one-sided 97.5% CI for the percentage of subjects with hSBA seroresponse[1] against each of serogroups A, C, W and Y had to be greater than 75%. This was to be tested sequentially first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra.

Secondary Immunogenicity Objectives:

The primary population for the analysis of the secondary immunogenicity objectives was the PPS.

Seroresponse (day 4, day 6 and day 29) and Percentage of subjects with hSBA titer≥ 8 and ≥ 16 (day 1, day 4, day 6, and day 29):

The percentage of subjects with seroresponse[1], the percentage of subjects with hSBA titer ≥ 8 and ≥ 16, and their associated two-sided 95% Clopper-Pearson CIs were computed by group (Menveo-Menveo, Menactra-Menveo, Naive, and pooled Menveo-Menveo and Menactra-Menveo) and by *N meningitidis* serogroup. Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - each of the previously vaccinated groups (individually and pooled) was compared to the Naive group. Also the two previously vaccinated study groups were compared to each other.

Between-group ratios of GMTs (adjusted and unadjusted):

The between-group ratio of hSBA GMTs and corresponding 95% CI, at each of visit day 1 (persistence), day 4, day 6 and day 29 against each *N meningitidis* serogroup were obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified.

Additionally, adjusted ratios of GMTs were obtained from Analysis of Covariance models including pre-vaccination titer as factor in the model.

The previously vaccinated groups (individually and pooled Menveo-Menveo and Menactra-Menveo) were compared to the Naive group at each timepoint – descriptively –

[1] Seroresponse was defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

using the ratios of GMTs. The two previously vaccinated groups were also compared to each other at each time point using GMT ratios.

Within-group GMRs (adjusted and unadjusted):

Within each study group and for each serogroup, GMRs were calculated, as applicable, at:

- Visit day 4 versus at Visit day 1;
- Visit day 6 versus at Visit day 1; and
- Visit day 29 versus at Visit day 1.

The unadjusted GMRs and 95% CIs were constructed by exponentiating the mean within-group differences in log-transformed titers and the corresponding 95% CIs.

Secondary Safety Objectives

Solicited AEs:

The analyses of post-vaccination solicited AEs reported from day 1 to day 7 were performed based on 3 intervals: 6 hours-day 3, day 4-day 7 and 6 hours-day 7. The analyses of solicited AEs were done separately for 30 minutes.

Unsolicited AEs:

All the unsolicited AEs occurring during the study, judged either as probably related, possibly related, or not related to vaccination by the investigator, were recorded. The original verbatim terms used by investigators to identify AEs in the case report forms were mapped to preferred terms (PTs) using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary. The unsolicited AEs were then grouped by MedDRA preferred terms into frequency tables according to system organ class (SOC). AEs judged by the investigator as at least possibly related to study vaccine were summarized by vaccine group, according to SOC and preferred term within SOC.

Summary and Conclusions:

Study Population

- In total, 704 subjects were enrolled in the study: 301 in the Menveo-Menveo group, 301 in the Menactra-Menveo group, and 102 in the Naive group. Across study groups, 91%-99% of subjects were included in the PPS data sets for analysis of primary and secondary objectives.
- Demographic and other baseline characteristics were generally balanced between both primed groups (Menveo-Menveo and Menactra-Menveo). The mean age of subjects

enrolled in the study was 17.1±3.66 years in the Menveo-Menveo group and 17.8±4.53 years in the Menactra-Menveo group. The Naive group enrolled mostly adults (mean age: 38.8±10.49), and more female (67%) than male (33%) subjects.

Immunogenicity Results

Primary Immunogenicity Objectives

- At day 29 after the Menveo booster dose the percentage of subjects with hSBA seroresponse for serogroups A, C, W, and Y ranged from 95.49% to 96.86% across serogroups in the Menveo-Menveo group and from 93.24% to 96.45% across serogroups in the Menactra-Menveo group (Table 2-4).
- For both primary immunogenicity objectives, the criterion to demonstrate a sufficient immune response following a booster dose of Menveo was met. The lower limit of the one-sided 97.5% CI for the percentage of subjects with hSBA seroresponse against serogroups A, C, W and Y at Day 29 after booster vaccination with Menveo was greater than 75%, both for subjects who previously were administered Menveo and for those who were previously administered Menactra (Table 2-4).

Secondary Immunogenicity Objectives

hSBA seroresponse at day 4, day 6, and day 29

- A booster dose of Menveo induced an anamnestic immune response in subjects who previously received either Menveo or Menactra, as shown by the higher percentages of subjects with hSBA seroresponse against *N meningitidis* serogroups A, C, W, and Y in the Menveo-Menveo, Menactra-Menveo, and pooled Menveo/Menactra-Menveo groups compared to subjects who received a first dose of Menveo (Naive group) observed from day 6 (Table 11.4.1-2). By day 29, across serogroups 93.24%-96.86% of subjects in the Menveo-Menveo and Menactra-Menveo groups had hSBA seroresponse, compared to 35.87%-65.59% of subjects in the Naive group.

hSBA titers ≥ 8 and ≥ 16 at day1, day 4, day 6, and day 29

- The anamnestic immune response to a booster dose of Menveo in subjects who previously received either Menveo or Menactra was also shown by the higher percentages of subjects with hSBA titers ≥ 8 and ≥ 16 against *N meningitidis* serogroups A, C, W, and Y in the Menveo-Menveo, Menactra-Menveo, and pooled Menveo/Menactra-Menveo groups compared to the Naive group observed from day 4, with non-overlapping 95% CIs between primed and Naive groups observed starting from day 6 (Table 11.4.1-3). By day 29, at least 98.62% of subjects in the primed groups had hSBA titers ≥ 8 against any serogroup (100% against serogroup W in both primed groups; Table 11.4.1-3), and at least 97.52% had hSBA titers ≥ 16 against any serogroup (Table 11.4.1-4).

hSBA GMTs at day1, day 4, day 6, and day 29

- In subjects who previously received either Menveo or Menactra, also hSBA GMTs against *N meningitidis* serogroups A, C, W, and Y were higher compared to subjects who received a first dose of Menveo (Naive group) from day 6 (Table 11.4.1-5). By day 29, hSBA GMTs against all serogroups had further increased in all study groups, with GMRs compared to day 1 ranging between 63.63-123.41 across serogroups in the Menveo-Menveo and Menactra-Menveo groups, and between 4.57-14.14 across serogroups in the Naive group.

hSBA Titers ≥ 8 at day 1 (Persistence)

- Percentages of subjects with hSBA titers ≥ 8 at day 1 were 12.46% and 15.46% against serogroup A in Menveo-Menveo and Menactra-Menveo groups, and were higher than in the Naive group, with a vaccine group difference between the Menveo-Menveo and Menactra-Menveo groups vs. the Naive group of 8.29% (95% CI: 1.55%-13.44%) and 11.30% (95% CI: 4.40%-16.78%), respectively (Table 14.2.1.3). For the other serogroups percentages ranged from 53.63% to 61.82% for serogroup C, from 76.09% to 76.63% for serogroup W, and from 47.24% to 53.90% for serogroup Y, across subjects primed 4 to 6 years before, percentages that were higher in the Menveo-Menveo and Menactra-Menveo groups than those seen in the Naive group, with vaccine group differences between Menveo-Menveo and Menactra-Menveo group vs. the Naive group ranging between 14.64%-26.41% across serogroups (LLs of the 95% CIs all > 0; Table 14.2.1.3).

hSBA GMTs at day 1 (Persistence)

- At baseline (day 1), hSBA GMTs ranged between 2.80 (against serogroup A in the Menveo-Menveo group) and 23.33 (against serogroup W in the Menactra-Menveo group) in the primed groups, and were higher than those observed at day 1 in the Naive group (ranging from 2.26 against serogroup A to 12.33 against serogroup W; Table 11.4.1-8).

Safety results

Solicited AEs and Other Indicators of Reactogenicity

- Between 6 hours through day 7, at least 1 solicited AE was reported in 65% of primed subjects (pooled Menveo/Menactra-Menveo group) and 55% subjects in the Naive group (Table 2-5). Solicited local AEs were reported by 36% of primed subjects and 42% of vaccine-naive subjects, and solicited systemic AEs by 52% of primed subjects and 36% of vaccine-naive subjects.
- The most frequently reported solicited local AEs was injection site pain, both for primed subjects (36%) and vaccine-naive subjects (41%; Table 12.2.3-1) and the most

frequently reported systemic reactions was fatigue (38% of primed subjects and 20% of vaccine-naive subjects; Table 12.2.3-2).

- Most of the solicited AEs were mild to moderate in intensity, had their onset between 6 hours and day 3 after vaccination (Table 14.3.1.7) and resolved within 3 days from onset (Table 14.3.1.5).
- Fever (body temperature ≥ 38.0°C) was reported in 7 (1%) primed subjects and by none of the subjects in the Naive group (Table 12.2.3-2). All cases of fever resolved within 2 days after vaccination (Table 14.3.1.5). Fever with a body temperature ≥ 40.0°C was not reported by any subject in the study (Table 12.2.3-2).
- Both in the pooled Menveo/Menactra-Menveo and in the Naive group, 5% of subjects used antipyretics and/or analgesics for prevention of pain and/or fever; 7% and 10% of primed and vaccine-naive subjects, respectively, used antipyretics and/or analgesics for the treatment of pain and/or fever (Table 12.2.3-2).

Unsolicited AEs

- Overall, 9 subjects (8 primed subjects [pooled Menveo/Menactra-Menveo group] and 1 in the Naive group) reported at least 1 unsolicited AE within 30 minutes after vaccination (Table 14.3.1.13.2).
- Overall, 25% of primed subjects and 22% of subjects in the Naive group reported any unsolicited AE between day 1 and day 29 after vaccination (Table 2-6). The most frequently reported unsolicited AE between day 1 and day 29 after vaccination, by preferred term, was headache (reported in 3% of primed and vaccine-naive subjects; Table 14.3.1.12.1).
- Overall, 8% of primed subjects and 11% of subjects in the Naive group reported at least 1 possibly related unsolicited AE between day 1 and day 29 after vaccination (Table 2-6; Table 12.2.3-3). The only at least possibly related AEs reported in more than 1% of subjects in either the pooled Menveo/Menactra-Menveo or the Naïve group were fatigue (reported in 2% of primed subjects), injection site erythema (4% in the Naive group), and injection site pruritus (2% in the Naive group).
- Medically attended AEs were reported in 30% of primed subjects and 19% of vaccine-naive subjects, respectively (Table 2-7). Overall, across primed and vaccine-naive subjects, 5 subjects reported medically attended AEs that were considered at least possibly related to the study vaccine by the investigator (Table 2-7; more details are provided in Table 14.3.2.7.5).
- Few SAEs were reported during the study: 5 (1%) primed subjects and 3 (3%) vaccine-naive subjects reported at least 1 SAE; none of the SAEs reported in this study was considered at least possibly related to the study vaccine (Table 2-7).
- There were no AEs leading to premature withdrawal from the study or deaths reported in this study (Table 12.2.1-3).

Conclusions

This was a phase 3b study that enrolled 704 subjects to evaluate the response to a single booster dose of Menveo administered to healthy adolescents and adults 15 through 55 years of age approximately 4-6 years after primary vaccination with meningococcal ACWY vaccine (either Menveo or Menactra).

The study was successful in demonstrating that a single booster dose of Menveo induced a sufficient immune response (the lower limit of the one-sided 97.5% CI for the percentage of subject with hSBA seroresponse at day 29 against serogroups A, C, W, and Y was greater than 75%), irrespective of the meningococcal quadrivalent conjugated vaccine used for priming (Menveo or Menactra). The response to the booster dose was anamnestic, as evidenced by exponentially higher hSBA titers after a booster dose in primed subjects (GMRs at day 29 compared to day 1 ranging 63.63-123.41 across serogroups) compared with Naive individuals given a first dose of meningococcal vaccine (GMRs at day 29 compared to day 1 ranging 4.57-14.14). Percentages of primed subjects with hSBA titer $\geq$ 8 ranged from 47.14%-97.86% already at study day 6.

Persistence of immune responses at 4-6 years after primary vaccination was measured by percentages of subjects with hSBA $\geq$ 8 and GMTs at day 1 (pre-vaccination). Percentages of subjects with hSBA $\geq$ 8 were 12.46% (Menveo-Menveo) and 15.46% (Menactra-Menveo) for serogroup A, 61.82% and 53.63% for serogroup C, 76.09% and 76.63% for serogroup W, and 53.90% and 47.24% for serogroup Y. GMTs were higher in primed subjects compared to vaccine-naive controls, especially against serogroup C, W and Y.

Overall, the safety profile of the vaccine was similar in subjects who were primed compared to subject were given a first dose in this study.

The frequencies of unsolicited AEs reported within 1 month after vaccination were also balanced between all study groups, and few at least possibly related unsolicited AEs were reported across groups. All reported SAEs (13 in 8 subjects) were considered not related to study vaccination. No deaths or AEs leading to withdrawal from the study were reported.

In conclusion, Menveo induced an anamnestic response within 5 days after vaccination in individuals primed with a quadrivalent conjugate meningococcal vaccine 4-6 years earlier. The vaccine was generally well tolerated and was not associated with any safety concern.

Table 2-4 Numbers and Percentages of Subjects (95% CI) with hSBA Seroresponse against *N meningitidis* serogroups A, C, W and Y at day 29 After Vaccination, (Per Protocol Set, day 29[a])

Study Groups	Menveo-Menveo	Menactra-Menveo	Met success criteria for both groups
	N=290	N=282	Yes/No
Serogroup A	279 (96.54%) (**93.73%**-98.33%) N=289	272 (96.45%) (**93.58%**-98.29%)	Yes
Serogroup C	275 (95.49%) (**92.40%**-97.57%) N=288	269 (96.07%) (**93.08%**-98.02%) N=280	Yes
Serogroup W	277 (95.85%) (**92.86%**-97.84%) N=289	262 (93.24%) (**89.64%**-95.88%) N=281	Yes
Serogroup Y	278 (96.86%) (**94.13%**-98.56%) N=287	264 (94.29%) (**90.89%**-96.70%) N=280	Yes

Source: Table 14.2.1.1.
Abbreviations: CI, confidence interval; hSBA, human serum bactericidal assay; N; total number of subjects.
[a] Includes subjects with results at day 1 and day 29 for at least one serogroup.
Note: Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers < 4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.
The immune response was considered as sufficient if the lower limit of the one-sided 97.5% CI for percentage of subjects with hSBA seroresponse against serogroups A, C, W and Y was greater than 75%.

Table 2-5 Overview of Subjects With Solicited AEs With Onset From day 1 Through 7 After Vaccination – Solicited Safety Set (6 hours – day 7)

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=592	N=97
Any Solicited AE	382 (65%)	53 (55%)
Local	216 (36%)	41 (42%)
Systemic	310 (52%)	35 (36%)

Source: Table 14.3.1.1.
Abbreviation: AE, adverse event

Table 2-6 Overview of Subjects With Unsolicited AEs With Onset From day 1 Through day 29 – Unsolicited Safety Set

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=601	N=100
Any AE	152 (25%)	22 (22%)
At least possibly related AE	50 (8%)	11 (11%)

Source: Table 14.3.1.13.1; Table 14.3.1.16.1.
Abbreviation: AE, adverse event.

Table 2-7 Overview of Subjects With SAEs, Medically Attended AEs and AEs leading to withdrawal With Onset From day 1 Through 181 – Unsolicited Safety Set

Study Groups	Pooled Menveo/Menactra-Menveo	Naive
	N=601	N=100
Any SAE	5 (1%)	3 (3%)
At least possibly related SAE	0	0
Medically attended AEs	181 (30%)	19 (19%)
Possibly related medically attended AEs	4 (1%)	1 (1%)
AE leading to premature withdrawal	0	0
Death	0	0

Source: Table 14.3.2.1; Table 14.3.2.2; Table 14.3.2.3; Table 14.3.2.4; Table 14.3.2.6; Table 14.3.2.7.5.
Abbreviations: AEs, adverse events; SAEs, serious adverse events.

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4. LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AE	Adverse event
ANCOVA	Analysis of Covariance
CI	Confidence interval
CRDL	Clinical Research and Development Leader
CRF	Case Report Form
CRM	Cross Reactive material
CSR	Clinical Study Report
DMC	Data Monitoring Committee
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FAS	Full Analysis Set
FDA	Food and Drug Administration
GCP	Good clinical practice
GMR	Geometric Mean Ratio
GMT	Geometric Mean Titer
GSK	GlaxoSmithKline Biologicals
hSBA	Human Serum Bactericidal Assay
ICF	Informed Consent Form
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEC	Independent Ethics Committee
IM	Intramuscular
IV	Intravenous
IRB	Institutional Review Board
LAR	Legally Acceptable Representative
LDL	Local Delivery Lead
LL	Lower Limit
LSLV	Last Subject Last Visit
MCAR	Missing Completely At Random

MedDRA	Medical Dictionary for Regulatory Activities
MenACWY-CRM	Quadrivalent meningococcal oligosaccharide diphtheria CRM-197 conjugate vaccine
N meningitidis	*Neisseria meningitides*
PI	Principal Investigator
PP	Per Protocol
PPS	Per Protocol Set
PT	Preferred Term
QA	Quality Assurance
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SBIR	Source Data Base for Internet Randomization
SDAF	Source Documentation Agreement Form
SOC	System Organ Class
SUSAR	Suspected Unexpected Serious Adverse Reaction
US	United States
VSAE	Vaccines Serious Adverse Event
WHO	World Health Organization

5. ETHICS

5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The study protocol, any amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational centre IEC or IRB. Properly constituted IRB/IEC is defined in International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice (GCP) E6 (R1), Section 3 (ICH, 1997). A signed and dated statement that the protocol and informed consent have been approved by the IRB/IEC was given to GlaxoSmithKline Biologicals (GSK) before study initiation.

Prior to study start and at any time the protocol was amended during study conduct, the investigator was required to sign a protocol signature page confirming his/her agreement to conduct the study in accordance with these documents and all of the instructions and procedures found in this protocol and to give access to all relevant data and records to GSK monitors, auditors, GSK Clinical Quality Assurance (QA) representatives, designated agents of GSK, IRBs/IECs, and regulatory authorities as required. If an inspection of the clinical site was requested by a regulatory authority, the investigator had to inform GSK immediately that this request has been made.

5.2 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 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 GSK's attention by other oversight mechanisms, these issues were investigated and appropriate corrective and/or preventive actions where possible were taken.

5.3 Subject Information and Consent

Written informed consent was obtained from each adult subject. For subjects below 18 years of age, a written informed assent from each subject's parent(s)/legally acceptable representative (LAR) prior to the performance of any study-specific procedures was obtained.

Eligible subjects were included in the study after providing written informed consent or assent, as described in protocol section 5. The informed consent form (ICF) sign-off was allowed up to 5 days prior to any study procedure on day 1. Before the start of the trial, the investigator had the informed consent and any other materials that were to be provided to the subjects reviewed and approved by the IRB/IEC. This review and

approval was documented and stored with other study documents. The investigator or designee fully had to inform the subject's parent(s) or LAR(s) of all pertinent aspects of the trial. A copy of the written informed consent was given to the subject or the designee. The subject/designee was allowed ample time to ask about the details of the trial and to make a decision as to whether or not to participate in the study. The subject and/or parent or legal guardian had to sign the consent form indicating their agreement to participate in the study before any study-related procedures were conducted. If the subject and/or parent or legal guardian was unable to read and write, a witness was present during the informed consent discussion and at the time of informed consent signature.

Electronic case report forms (eCRFs) were provided for each subject's data to be recorded.

A sample consent and assent form is located in Appendix 16.1.3.

Further information may be found in section 5.1.1 of V59_77 study protocol (Appendix 16.1.1).

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

Prior to trial initiation, the investigator at the site provided GSK with a fully executed and a signed financial disclosure form. Financial disclosure forms were also completed for all sub-investigators listed on the Form 1572 who were directly involved in the treatment or evaluation of research subjects in this trial.

The trial was administered and monitored by employees or representatives of GSK. The Clinical Research and Development Leader (CRDL) (Appendix 16.1.4) was readily available to provide appropriate medical expertise on trial-related medical questions. GSK's Regulatory Affairs or Pharmacovigilance departments were responsible for the timely reporting of the serious adverse events (SAEs).

The Company functions/roles that materially affected the execution of the study included the Clinical and Epidemiology Project Lead, Lead Statistician, CRDL, Local medical Lead (LML), Study Delivery Lead, and Local Delivery Lead (LDL). The actual names of the associates covering these roles, as well as the list of the study centers, investigators with their affiliations, and the clinical research organization(s) used, are provided in Appendix 16.1.4. Appendix 16.1.4 also provides the following information:

- names/affiliation of the individuals responsible for study monitoring, data management, and laboratory assessment
- names/affiliation of the Statistician, Statistical Programmer, and Scientific Writer
- site(s) of manufacture and site(s) of release of the investigational product
- site of trial master file

Coordinating/Principal Investigator: Mary Tipton, M.D.

7. INTRODUCTION

Neisseria meningitidis (N meningitidis) is a leading cause of bacterial meningitis and sepsis worldwide, capable of causing outbreaks and epidemics of invasive disease. Meningococcal disease is associated with high morbidity and mortality even among patients who receive early antibiotic treatment. Most cases of invasive disease worldwide are caused by serogroups A, B, C, W and Y.

The quadrivalent meningococcal oligosaccharide diphtheria cross reactive material (CRM)-197 conjugate vaccine (MenACWY-CRM; Menveo, GSK) is approved for active immunization of individuals from 2 months through 55 years of age in the United States (US). As of March 2018, more than 30,000 of subjects have been exposed to MenACWY-CRM vaccine in completed clinical studies and more than 43 million doses of the vaccine have been distributed globally.

The US Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with a quadrivalent conjugated meningococcal vaccine for adolescents at 11-12 years of age with a booster dose administered 5 years later. While a substantial body of data exist showing a robust immune response and good antibody persistence after a single dose of Menveo in adolescents, the response to a booster dose of Menveo in this age group has only been evaluated in 2 clinical studies with limited number of subjects.

A robust anamnestic immune response to a booster dose of Menveo vaccine administered at approximately 5 years after previous vaccination with the same vaccine or a licensed meningococcal polysaccharide vaccine (Menomune) was demonstrated in the phase 2 clinical study V59P6E1. High titers of bactericidal antibodies against the vaccine serogroups were achieved at 7 and 30 days after booster dose in Menveo-primed subjects. However, the number of subjects included in this study was relatively small (N=101, including 50 subjects who received a booster dose after the primary Menveo vaccination).

In the phase 3b clinical study V59P13E1, a booster dose of Menveo was given 3 years after primary vaccination with either Menveo or Menactra (a meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) in adolescents. A booster dose was able to substantially increase antibody titers against all 4 serogroups irrespective of the priming vaccine. Overall 160 subjects received the Menveo booster, (83 who received primary Menveo and 77 who received MenACWY-D).

In the light of the current ACIP recommendation for a booster dose of Menveo, there exists a need to evaluate the response to a Menveo booster given at ~5 years after primary vaccination in meningococcal-vaccine primed adolescents. Generation of this data would also be of relevance in outbreak management and vaccination of travelers to endemic areas.

8. STUDY OBJECTIVES

Primary Objectives

Immunogenicity Objectives:

1. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with human serum bactericidal assay (hSBA) seroresponse[1] against *N meningitidis* serogroups A, C, W and Y at day 29 after vaccination.
2. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse[1] against *N meningitidis* serogroups A, C, W and Y at day 29 after vaccination.

Criteria to demonstrate immune response sufficiency: The immune response sufficiency was to be tested sequentially; first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra. The immune response was to be considered as sufficient if the lower limit (LL) of the one-sided 97.5% confidence interval (CI) for percentage of subjects with hSBA seroresponse[1] against serogroups A, C, W and Y was greater than 75%. The study was to be considered successful if the immune response sufficiency was demonstrated at least in the group of subjects who received primary vaccination with Menveo.

Secondary objectives

Secondary Immunogenicity Objectives

1. To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo, subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled vaccine group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA seroresponse[1], hSBA titers ≥ 8 and ≥ 16, and hSBA geometric mean titers (GMTs) against *N meningitidis* serogroups A, C, W and Y at day 1, day 4, day 6, and day 29 after vaccination.
2. To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the

[1] Seroresponse defined for this study was as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

primary vaccination with Menactra in comparison with naturally-acquired level in vaccine-naive individuals, as measured by the percentages of subjects with hSBA titers ≥ 8 and hSBA GMTs at day 1.

Secondary Safety Objectives

1. To assess the reactogenicity and safety of MenACWY-CRM vaccine when administered to subjects who previously received Menveo or Menactra and vaccine-naive individuals.

9. INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan

This was a phase 3b, controlled, open-label, multi-center study to evaluate safety and immunogenicity of Menveo after a single vaccination in healthy individuals who were vaccinated with Menveo or Menactra 4 to 6 years before and in vaccine-naive individuals.

Study population: Approximately 700 healthy subjects 15 through 55 years of age were to be enrolled in the study.

Duration of the study: The duration of this study was approximately 6 months per subject.

Written informed consent and, as applicable according to local guidelines, written assent were to be obtained before conducting any study-specific procedures.

Vaccination schedule: All subjects were to receive a single dose of Menveo at day 1.

Study groups:

Group Menveo-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menveo 4 to 6 years before, were to receive 1 dose of Menveo.

Group Menactra-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menactra 4 to 6 years before, were to receive 1 dose of Menveo.

Group Naive: approximately 100 subjects equally enrolled across all clinical sites, who had not received any meningococcal vaccination, were to receive 1dose of Menveo.

Randomization / Stratification:

Within each study group, subjects were to be randomized into one of two different blood draw schedules according to a 1:1 ratio, also described as in Table 9.1-3.

- Subjects getting blood draws at day 1, day 4 and day 29.
- Subjects getting blood draws at day 1, day 6 and day 29.

Study clinic visits: Three clinic visits at day 1, day 4 or day 6 and day 29 were planned for each subject. Each subject was expected to participate in the study for 6 months, from the time of enrolment through the last study visit.

The schematic diagram of the V59_77 study visits is presented in Table 9.1-1.

Table 9.1-1 Schematic Diagram of the V59_77 Study Design

day 1	day 4	day 6	day 15	day 29	day 91	day 181
Blood draw (all subjects) Menveo	Blood draw (50% of subjects)	Blood draw (50% of subjects)	Safety phone call	Blood draw (all subjects)	Safety phone call	Safety phone call Study termination

Source: Table 3.1-2 of V59_77 study protocol, version 1.0, issued on 24 Jun 16.

Number of subjects planned and actually enrolled is provided in Table 9.1-2.

Table 9.1-2 Number of Subjects Enrolled (Planned and Actual) per Study Group

Study Groups	Menveo-Menveo		Menactra-Menveo		Naive		Total	
	Planned	**Actual**	**Planned**	**Actual**	**Planned**	**Actual**	**Planned**	**Actual**
Blood draw days 1, 4, 29	150	151	150	150	50	52	**350**	**353**
Blood draw days 1, 6, 29	150	150	150	151	50	50	**350**	**351**
Total	300	301	300	301	100	102	**700**	**704**

Source: Modified from Table 1 of V59_77 study protocol, version 1.0, issued on 24 Jun 16; Table 14.1.1.6.

Data collection: eCRF.

The following data was to be collected from each subject over the duration of their study participation:

- Demographic information
- Adverse events (AEs)
- Medical history
- Concomitant medications/vaccinations
- Information on the blood samples

Blood samples: Three blood samples of approximately 10 mL each were to be collected according to the blood draw schedule in Table 9.1-3.

Table 9.1-3 Schematic Diagram of Blood Draw Schedule the V59_77 Study Groups

Vaccine History	Vaccination in current study	Blood draw schedule
Menveo N=300	Menveo N=300	Blood draw days 1, 4, 29 (N=150)
		Blood draw days 1, 6, 29 (N=150)
Menactra N=300	Menveo N=300	Blood draw days 1, 4, 29 (N=150)
		Blood draw days 1, 6, 29 (N=150)
Vaccine-Naive N=100	Menveo N=100	Blood draw days 1, 4, 29 (N=50)
		Blood draw days 1, 6, 29 (N=50)

Source: Table 3.1-1 of V59_77 study protocol, version 1.0, issued on 24 Jun 16.
N = number of planned subjects.

Post-vaccination evaluations

Reminder Phone calls: Two reminder phone calls were to be conducted at day 3 and day 5 after the study vaccination to remind the subject/legal guardian to complete the diary card.

Safety phone calls: Three safety phone calls (at day 15, day 91 and day 181) were to be conducted to collect any medically-attended AEs, AEs leading to withdrawal, SAEs, related medications and any vaccinations. In addition, all unsolicited AEs and related medications occurring after the vaccination were to be collected during the safety call at day 15. The day 181 Safety Phone call was to serve as the termination visit.

Solicited AEs: Injection site pain, erythema, induration, fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever occurring on the day of vaccination and the following six days (day 1 through day 7) were to be recorded daily using a diary card for all subjects.

Unsolicited AEs occurring within 28 days after study vaccination were to be collected. Qualified site staff were to interview the subject by phone approximately 14 days after vaccination and in person at the study site approximately 28 days after study vaccination to assess the occurrence of any unsolicited AEs.

Medically-attended AEs, AEs leading to study withdrawal and SAEs were to be collected during the entire study period. These data were to be captured by interviewing the subject and/or subjects' parents / guardian (as applicable) during the site visits and phone calls and by review of available medical records. Subjects and/or parents / guardian were to be encouraged to call the site in the event of any medically-attended AEs or any AEs which they perceive as being of concern during the entire study period.

No Data Monitoring Committee (DMC) was utilized for the study.

No interim analysis of data from this study was planned.

9.2 Discussion of Study Design, Including Choice of Control Group

The inclusion of vaccine-naive subjects in a separate study arm was to enable comparison of the rapidity and magnitude of an anamnestic response to a booster dose (in primed individuals) or the primary response to a first dose (in naive individuals) of Menveo.

9.3 Selection of Study Population

9.3.1 Inclusion Criteria

In order to participate in this study, all individuals had to meet all of the following criteria at study entry:

1. Individuals of 15 through 55 years of age on the day of informed consent or assent.
2. Individuals who received Menveo 4 to 6 years prior to enrollment at an age of 11 years or older (Menveo-Menveo group)

Or

Individuals who received Menactra 4 to 6 years prior to enrollment at an age of 11 years or older (Menactra-Menveo group)

Or

Individuals who had not received any previous meningococcal vaccine (Naive group).

3. Individuals who voluntarily gave written informed consent (and/or assent, if applicable) after the nature of the study had been explained according to local regulatory requirements, prior to study entry. If the subject was under age 18 at the time of enrolment, the parent(s)/LAR(s) of the subject was to voluntarily give written informed consent.
4. Individuals who were able to comply with study procedures including follow-up[1].
5. Males

Or

[1] A subject and/or parent(s)/LAR(s) was/were considered to be compliant if the investigator judged that the subject completed the subject diary and returned for all the follow-up visits scheduled in the study.

Females of non-childbearing potential[1]

Or

Females of childbearing potential who were using an effective birth control method[2] which they intend to use for at least 30 days after the study vaccination.

9.3.2 Exclusion Criteria

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

Each individual must not have:

1. History of any meningococcal vaccine administration other than the single vaccination given 4 to 6 years before (Menveo-Menveo and Menactra-Menveo groups)

   Or

   History of any meningococcal vaccine administration (Naive group).
2. Current or previous, confirmed or suspected disease caused by *N meningitidis*.
3. Household contact with and/or intimate exposure to an individual with any laboratory confirmed *N meningitidis* infection within 60 days prior to study vaccination.
4. Progressive, unstable or uncontrolled clinical conditions.
5. Hypersensitivity, including allergy, to any component of vaccines, medicinal products or medical equipment whose use was foreseen in this study.

---

[1] A female was considered to be of non-childbearing potential prior to menarche and after natural or induced menopause. Natural menopause is recognized to have occurred after 12 consecutive months of amenorrhea for which there is no other obvious pathological or physiological cause. Induced menopause is recognized to have occurred after hysterectomy, after bilateral oophorectomy, or iatrogenic ablation of ovarian function.

[2] The following birth control methods were considered effective:

- Abstinence
- Hormonal contraceptive (such as oral, injection, transdermal patch, implant) if used for at least 30 days prior to informed consent
- Diaphragm preferably with spermicide, tubal occlusion device
- Intrauterine device
- Tubal ligation
- Male partner using condom preferably with spermicide
- Male partner having been vasectomized at least six months prior to informed consent

6. Clinical conditions representing a contraindication to intramuscular (IM) vaccination and blood draws.
7. Abnormal function of the immune system resulting from:
    a. Clinical conditions.
    b. Systemic administration of corticosteroids [oral (PO)/intravenous (IV)/IM] for more than 14 consecutive days within 90 days prior to study vaccination.
    c. Administration of antineoplastic and immunomodulating agents or radiotherapy within 90 days prior to study vaccination.
8. Received immunoglobulins or any blood products within 180 days prior to informed consent.
9. Received systemic antibiotic treatment (PO/IV/IM) within 3 days prior to study vaccination or blood draw.
10. Received an investigational or non-registered medicinal product within 30 days prior to study vaccination.
11. Study personnel was an immediate family or household member.
12. Individuals who had received any other vaccines within 7 days (for inactivated vaccines) or 14 days (for live vaccines) prior to vaccination in this study or who were planning to receive any vaccine within 28 days from the study vaccination.
13. Individuals who had experienced a moderate or severe acute infection and/or fever defined as a temperature ≥38°C (100.4°F) within 3 days prior to study vaccination.
14. Any other clinical condition that, in the opinion of the investigator, might pose additional risk to the subject due to participation in the study.

9.3.3 Removal of Subjects from Therapy or Assessment

A subject could discontinue study participation at any time prior to the last planned study visit. This was referred to as premature withdrawal from the study. The reasons for premature withdrawal from the study included:

- Adverse event
- Death
- Withdrawal of consent
- Lost to follow-up
- Administrative reasons
- Protocol deviation

- Other

9.4 Vaccines

9.4.1 Vaccines Administered

The term ‘study vaccine’ refers to those vaccines provided by the Sponsor, which were evaluated as part of the study objectives. The study vaccine specific to this study was the MenACWY-CRM vaccine (Menveo, GSK Biologicals; lot number: X16013).

The meningococcal ACWY conjugate vaccine was to be reconstituted just before injection of the lyophilized MenA-CRM component with the MenCWY-CRM full liquid vaccine. The pharmaceutical form was a powder and solution for injection. Menveo was provided as vial/vial presentation. MenA lyophilised conjugate component (glass vial) and MenCWY liquid conjugate component (glass vial). After reconstitution, Menveo had the following composition per 0.5 mL of injectable solution (see Table 9.4.2-1).

One 0.5 mL dose of MenACWY was to be administered by IM injection in the deltoid area of non-dominant arm (preferably) in Menveo-Menveo and Menactra-Menveo and Naive treatment groups.

Detailed vaccine preparation and administration instructions were to be provided to the investigators in the clinical trials supply manual prior to study start.

9.4.2 Identity of Investigational Product

The composition of the MenACWY-CRM vaccine is given in Table 9.4.2-1.

Table 9.4.2-1 MenACWY-CRM Composition

Name of Ingredient	Unit and/or Percentage Formula (Dose 0.5 mL)
Drug Substances	
CRM_{197}-MenA conjugate	10 µg MenA, 16.7 – 33.3 µg CRM_{197}
CRM_{197}-MenC conjugate	5 µg MenC, 7.1 - 12.5 µg CRM_{197}
CRM_{197}-MenW conjugate	5 µg MenW, 3.3 – 8.3 µg CRM_{197}
CRM_{197}-MenY conjugate	5 µg MenY, 5.6 – 10 µg CRM_{197}
Sodium chloride	4.5 mg
Excipients	
Sucrose	12.5 mg
Sodium phosphate buffer Sodium dihydrogen phosphate Disodium hydrogen phosphate dehydrate	10 mM 2.5 mM 7.5mM
Potassium dihydrogen phosphate	5 mM
Water for Injection	q.s 0.5 mL
Volume of Formulation	0.6 mL
Appearance	Colorless to light yellow
Vaccine Presentation	A single dose of two vials

Source: Table 6.1-1 of V59_77 study protocol, version 1.0, issued on 24 Jun 16.

9.4.3 Method of Assigning Subjects to Vaccination Groups

Enrolled subjects were to be randomized using Source Data Base for Internet Randomization (SBIR) system to one of two different blood draw schedules according to a 1:1 ratio, described as follows:

- Subjects getting blood draws at day 1, day 4 and day 29.
- Subjects getting blood draws at day 1, day 6 and day 29.

Allocation of the subject to a blood draw schedule at the investigator site was to be performed using a central SBIR.

The randomization algorithm was to use a minimization procedure accounting for the previous vaccination status (Menveo, Menactra or Vaccine-Naive study group).

SBIR was also used to ensure adequate and appropriate distribution of enrollment of naive subjects across all sites.

If for any reason, after signing the ICF, the subject who was eligible and enrolled but failed to randomize, this was defined as a randomization failure and the early termination study procedures were to be applied. The reason for all randomization failures were to be recorded in the Screening and Enrolment Log and in the source document as specified in the Source Documentation Agreement Form (SDAF). The information on subjects who were randomization failures was to be kept distinct from subjects who were screen failures.

If for any reason after enrollment, the subject failed to undergo treatment/study procedures this was an early termination and the reason was to be recorded in source document as specified in the SDAF. The information on these early terminated subjects was to be kept distinct in the source documentation from subjects who were screen failures.

9.4.4 Selection of Doses Used in the Study

The dose of Menveo used in 3 groups was based on the previous study (V59P13E1) and was the dose used to assess the immunogenicity of a booster dose.

Menveo is recommended as a single dose for use in adolescents and adults. A single dose of Menveo was also used as a booster in previous studies (V59P13E1 and V59P6E1) that assessed effects of a booster, and is in line with current ACIP recommendations for meningococcal vaccinations.

9.4.5 Selection and Timing of Dose for Each Subject

No provisions were made regarding the time of day or time relationship to meals.

9.4.6 Blinding

This was an open-label study and hence no blinding procedures were applied.

The laboratory personnel performing serology assays were blinded to visit and vaccine group assignments.

9.4.7 Prior and Concomitant Therapy

All medications, vaccines and blood products taken or received by the subject within 30 days prior to the start of the study were to be recorded on the prior and concomitant medications case report form (CRF).

In addition, the following were considered prior medications for this protocol: all medication/vaccines described in the inclusion and exclusion criteria of this clinical study report (CSR) including:

- Systemic administration of corticosteroids (PO/IV/IM) for more than 14 consecutive days within 90 days prior to study vaccination;
- Administration of antineoplastic and immunomodulating agents or radiotherapy within 90 days prior to study vaccination
- Immunoglobulins or any blood products within 180 days prior to informed consent
- Systemic antibiotic treatment within 3 days prior to study vaccination or blood draw
- Any investigational or non-registered medicinal product within 30 days prior to study vaccination;
- Administration of vaccines within 7 days (for inactivated vaccines) or 14 days (for live vaccines) prior to vaccination in this study or who were planning to receive any vaccine within 28 days from the study vaccination.

Use of analgesics/antipyretics to prevent or treat solicited AEs was to be captured in the Subject Diary from day 1-7 following each vaccination. Medications taken for prophylaxis were those intended to prevent the onset of symptoms. Medications taken for treatment were intended to reduce or eliminate the presence of symptoms that were present.

Concomitant medications included all prescription and non-prescription medications (including vaccines) taken by/administered to the subject during the 30 days after study vaccination and were to be documented on the Concomitant Medications CRF. Mineral supplements and vitamins were not considered concomitant medications.

When recording concomitant medications/vaccines, they were to be checked against the study entry and continuation criteria in section 9.3 Selection of Study Population to ensure that the subject was enrolled/continued in the study.

Concomitant medication administered for treatment of AEs with medically-attended visits, AEs leading to study withdrawal and SAEs were to be documented during the entire study period.

Any vaccine not foreseen in the study protocol in the period starting at day 1 and ending at day 181 was to be recorded in the eCRF.

9.4.8 Vaccine Compliance

The investigator and study staff were responsible for appropriate documentation of administration of vaccine to study subjects which included the date, dosage, batch/serial numbers, expiration dates, unique identifying numbers assigned to subjects, and time of vaccination.

9.5 Immunogenicity and Safety Variables

9.5.1 Immunogenicity and Safety Measurements Assessed

All study related procedures are detailed in Table 9.5.1-1.

Table 9.5.1-1 Time and Events

Visit Type	Clinic Visit	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Phone Call
Study period	**Screening**	**Treatment**	**Treatment**	**Treatment**	**Treatment**	**Treatment**	**Follow-up**	**Follow-up**
Study Day		**1**	**3, 5**	**4/6[a]**	**15**	**29**	**91**	**181**
Visit Window (Days)	**-5 to 1**	**0**	**2 days (-1/+1), 4 days (0/+2) after vacc**	**3/5 days (-1/+1) after vacc**	**14 days (-2/+2) after vacc**	**28 days (-7/+14) after vacc**	**90 days (-14/+14) after vacc**	**180 days (-14/+14) after vacc**
Visit Number	**Pre-vaccination**	**1**	**N/A**	**2**	**3**	**4**	**5**	**6**
Study Event								
Study Treatment								
Vaccination (vacc)		X						
Screening and Safety								
Informed consent[b]	X							
Medical history	X							
Physical examination	X	X[c]		X		X		
Pregnancy test	X	X[c]						
Exclusion/inclusion criteria[d]	X	X						
• Randomization		X[c]						
• 30 minutes post injection assessment		X						
Subject diary dispensed with training		X						
• Subject diary reminder call			X[e]	X[e]				
• Subject diary reviewed and collected						X		

Visit Type	Clinic Visit	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Phone Call
Study period	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Follow-up	Follow-up
Study Day		1	3, 5	4/6[a]	15	29	91	181
Visit Window (Days)	-5 to 1	0	2 days (-1/+1), 4 days (0/+2) after vacc	3/5 days (-1/+1) after vacc	14 days (-2/+2) after vacc	28 days (-7/+14) after vacc	90 days (-14/+14) after vacc	180 days (-14/+14) after vacc
Visit Number	Pre-vaccination	1	N/A	2	3	4	5	6
Study Event								
Assess unsolicited AEs		X		X	X	X		
Assess SAEs		X		X	X	X	X	X
Assess for medically attended AEs and AEs leading to withdrawal		X		X	X	X	X	X
Assess relevant medications/vaccinations	X	X		X	X	X	X	X
Immunogenicity								
Serology blood draw		X[b]		X		X		
Study Completion Procedure								
Study termination[f]								X

Source: Table 4 of V59_77 study protocol, version 1.0, issued on 24 Jun 16

Abbreviations: AEs, adverse events; SAEs, serious adverse events.

[a] Subject were to be randomized into a blood draw schedule in a 1:1 ratio. The second clinic visit was to occur at day 4 OR day 6.

[b] Confirm consent form(s) signed prior to any procedures.

[c] Procedure to be performed prior to vaccination.

[d] Reminder: for previously vaccinated subjects, appropriate written documentation of the identity of the primary meningococcal vaccination (Menveo or Menactra) and vaccination date had to be provided prior to enrollment.

[e] If the clinic visit at day 4 was overlapping with the specified window of the day 3 reminder call, the day 3 reminder call could be omitted. If the clinic visit at day 6 was overlapping with the specified window of the day 5 reminder call, the day 5 reminder call could be omitted.

[f] Subjects who terminated the study early were to be recommended to complete certain study-related procedures. See section 5.5 of the protocol version 1.0 issued on 24 Jun 16 for further details.

9.5.1.1 Immunogenicity Variable(s)

The functional measure of immunogenicity used in this study, hSBA, is a measure of the ability of antibodies, together with human complement, to kill meningococci, and is widely used and generally recognized as the serological correlate of protection. The key measures of immunogenicity were the percentages of subjects with seroresponse, percentages of subjects who achieved hSBA titers ≥ 8, and the hSBA GMTs against serogroups A, C, W and Y reference strains.

Seroresponse to *N meningitidis* serogroups A, C, W and Y for this booster study was defined as: For subjects with pre-vaccination titers < 4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

These measurements were assessed in serology samples collected at visit days 1, 4 or 6 and day 29. The measures of immunogenicity used in this study are standard, ie, widely used and generally recognized as reliable, accurate, and relevant (able to describe the quality and extent of the immune response).

The serology assay was performed in a blinded fashion.

All subjects had to undergo a blood draw at day 1, before vaccination. Subsequent blood draws were to be at either day 4 or day 6, and at day 29.

Testing was to be conducted by qualified and certified laboratories. All assays were to be performed in GSK Clinical Laboratory Sciences, or delegate laboratory.

9.5.1.2 Safety Variables - Adverse Events

The measures of safety used in this study were routine clinical procedures. They included a close vigilance for, and stringent reporting of, selected local and systemic AEs routinely monitored in vaccine clinical studies as indicators of reactogenicity.

The period of observation for AEs extended from the time the subject signed informed consent until he or she completed the specified safety follow-up period of 180 days or terminated the study early (whichever comes first). AEs occurring after the ICF was signed but prior to receiving study vaccine/product were to be documented as an AE and recorded within source document. However, any AEs occurring prior to receipt of any study vaccine were to be analyzed separately from “treatment emergent” AEs (AEs occurring after administration of the first study vaccine).

Adverse events were collected as either solicited or unsolicited AEs. Solicited events were derived from organized data collection systems, such as subject diaries.

Solicited Adverse Events

The term "reactogenicity" refers to solicited signs and symptoms ("solicited AEs") occurring in the hours and days following a vaccination, to be collected by the subject and/or parent(s)/LAR for 7 consecutive days, using a pre-defined Subject Diary.

The following solicited AEs were included in the subject diary. Each AE was to be assessed using the scoring system reported in Table 9.5.1.2-1.

Solicited Local Adverse Events

Injection site pain, erythema, induration.

Solicited Systemic Adverse Events

Fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills, and fever.

Table 9.5.1.2-1 Severity Grading for Solicited Local and Systemic Adverse Events

	Mild	Moderate	Severe
Pain	No interference with daily activity	Interferes with daily activity	Prevents daily activity
Erythema	25-50mm	51-100 mm	> 100 mm
Induration	25-50 mm	51-100 mm	> 100 mm
Fatigue	No interference with daily activity	Interferes with daily activity	Prevents daily activity
Headache	No interference with activity	Interferes with daily activity	Prevents daily activity
Myalgia	No interference with activity	Interferes with daily activity	Prevents daily activity
Arthralgia	No interference with activity	Interferes with daily activity	Prevents daily activity
Loss of appetite	Eating less than usual with no effect on normal activity	Eating less than usual / interfered with normal activity	Not eating at all
Nausea	No interference with daily activity	Interferes with daily activity	Prevents daily activity
Chills	No interference with activity	Interferes with daily activity	prevents daily activity

Source: Table 7.1.1-1 of V59_77 study protocol, version 1.0, issued on 24 Jun 16.

Fever was defined and measured by a body temperature ≥ 38.0°C (100.4°F). Route of temperature measurement was preferably oral.

Other Indicators of Reactogenicity:

- Use of analgesics/antipyretics for prophylaxis (days 1-7)
- Use of analgesics/antipyretics for treatment (days 1-7)

- Body temperature, described in degrees Celsius and summarized by route of measurement and in 0.5°C increments from ≥36.0°C.

The study staff had to review the data entered into the subject diary as described in section 3.4.2, Tools Used for Data Collection and section 5.3.1 of protocol version 1.0 issued on 24 JUN 16.

Note: Any solicited AE that met any of the following criteria had to be entered into subjects' source document and also as an AE on the "Adverse Event CRF":

- Solicited local or systemic AE that continued beyond day 7 after vaccination.
- Solicited local or systemic AE that led to a visit to a healthcare provider (medically attended AE).
- Solicited local or systemic AE leading to the subject withdrawing from the study or the subject being withdrawn from the study by the investigator (AE leading to withdrawal).
- Solicited local or systemic AE that otherwise met the definition of an SAE (see below).

Unsolicited Adverse Events

An unsolicited AE is an AE that was not solicited using a subject diary and that was spontaneously communicated by a subject and/or parent(s)/LAR who had signed the informed consent.

Potential unsolicited AEs could be medically attended (defined as symptoms or illnesses requiring hospitalization, or emergency room visit, or visit to/by a health care provider), or were of concern to the subject and/or parent(s)/LAR. In case of such events, subjects and/or parent(s)/LAR were to be instructed to contact the site as soon as possible to report the event(s). The detailed information about the reported unsolicited AEs was to be collected by the qualified site personnel during the interview and was to be documented in the subject's records.

Unsolicited AEs that were not medically attended nor perceived as a concern by subjects and/or parent(s)/LAR were to be collected during interview with the subject [and/or parent(s)/LAR and by review of available medical records at the next visit.

Evaluation of Adverse Events

Adverse events, reported at a clinic visit or at a scheduled safety call, were to be recorded in the eCRF verbatim, as reported by the subject.

The severity of events reported on the Adverse Events CRF was to be determined by the investigator as:

Mild: transient with no limitation in normal daily activity.
Moderate: some limitation in normal daily activity.
Severe: unable to perform normal daily activity.

The relationship of the study treatment to an AE was to be determined by the investigator based on the following definitions:

1. Not Related

The AE was not related to an investigational vaccine if there was evidence that clearly indicated an alternative explanation. If the subject had not received the vaccine, the timing of the exposure to the vaccine and the onset of the AE were not reasonably related in time, or other facts, evidence or arguments existed that reasonably suggest an alternative explanation, then the AE was not related.

2. Possibly Related

The administration of the investigational vaccine and AE were considered reasonably related in time and the AE could be explained by exposure to the investigational vaccine or by other causes.

3. Probably Related

Exposure to the investigational vaccine and AE were reasonably related in time and no alternative explanation had been identified.

The relationship of the study treatment to an unsolicited AE was to be determined by the investigator.

Note: solicited AEs were not to be evaluated for relationship to study treatment. Grading for severity of solicited local and systemic AEs is described above in Table 9.5.1.2-1.

Adverse events were also to be evaluated by the investigator for the co-existence of any of the other following conditions:

- Medically attended AE: an AE that leads to a visit to a healthcare provider.
- Adverse events leading to withdrawal: AEs leading to study or vaccine withdrawal.

If solicited or unsolicited AEs were reported and the subject and/or parent(s)/LAR(s)indicated that the symptoms required medical attendance or were of concern, the subject and/or parent(s)/LAR was to be contacted for further information.

When the subject and/or parent(s)/LAR was contacted for any of these reasons, the contact was to be documented in the subject's source documentation.

All AEs, regardless of severity, were to be monitored until resolution or until the investigator assessed them as chronic or stable. All subjects experiencing AEs - whether

considered associated with the use of the study vaccine or not - were to be monitored until symptoms subsided and any abnormal laboratory values returned to baseline, or until there was a satisfactory explanation for the changes observed, or until death, in which case a full pathologist's report was to be supplied, if possible. The investigator's assessment of ongoing AEs at the time of each subject's last visit was to be documented in the subject's medical chart.

Serious Adverse Events

Each subject was instructed to contact the investigator immediately if they manifested any signs or symptoms they perceived as serious.

An SAE was defined as any untoward medical occurrence that at any dose results in one or more of the following:

- Death.
- Was life-threatening (ie, the subject was, in the opinion of the investigator, at immediate risk of death from the event as it occurred); it does not refer to an event which hypothetically might have caused death if it were more severe.
- Required or prolonged hospitalization.
- Persistent or significant disability/incapacity (ie, the event causes a substantial disruption of a person's ability to conduct normal life functions).
- Congenital anomaly/or birth defect.
- An important and significant medical event that could not be immediately life threatening or resulting in death or hospitalization but, based upon appropriate medical judgment, could jeopardize the subject or could require intervention to prevent one of the other outcomes listed above.

Adverse events which did not fall into these categories were defined as non-serious.

It was to be noted that a severe AE need not be serious in nature and that an SAE need not, by definition, be severe.

Serious adverse events were to be captured both on the Vaccines Serious Adverse Event (VSAE) form as well as on the AE CRF. All SAEs were to be evaluated by the investigator for relationship of the event to study vaccine. SAEs that were judged to be possibly or probably related to the study vaccine were to be reported to the Sponsor as related events.

The relationship of the study treatment to an SAE was to be determined by the investigator based on the following definitions:

1. Related

The SAE was judged by the investigator to be possibly or probably related to the study vaccine on the AE CRF page (see section 7.1.3 of protocol, Evaluation of Adverse Events).

2. Not Related

The SAE was not related if exposure to the study vaccine had not occurred, **or** the occurrence of the SAE was not reasonably related in time, **or** the SAE was considered unlikely to be related to use of the study vaccine, ie, there were no facts (evidence) or arguments to suggest a causal relationship.

The relationship of the study vaccine to an SAE was to be determined by the investigator.

In addition, SAEs were to be evaluated by the Sponsor or designee for "expectedness." An unexpected AE was one that was not listed in the current Summary of Product Characteristics or the Investigator's Brochure or an event that was by nature more specific or more severe than a listed event.

In addition, a pre-existing event or condition that resulted in hospitalization was to be recorded on the Medical History CRF. If the onset of an event occurred before the subject entered the study (eg, any pre-planned hospitalization for conditions like cosmetic treatments or for non-emergency routine visits for a pre-existing condition), the hospitalization would not lead to an AE being classified as serious unless, in the view of the investigator, hospitalization was prolonged as a result of participation in the clinical study or was necessary due to a worsening of the pre-existing condition.

Methods for Recording Adverse Events and Serious Adverse Events

Findings regarding AEs were to be reported on an AE CRF, as specified in section 9.5.1.2, and on the VSAE form, if applicable, which was part of the Investigator Site File. All findings in subjects experiencing AEs were to be reported also in the subject's source document.

All SAEs which occurred during the course of the study, whether considered to be associated with the study vaccination or not, had to be reported within 24 hours of the site becoming aware of the event to GSK or its designee. Specific instructions and contact details for collecting and reporting SAEs to GSK were provided to the investigator. Specifically, once an investigator became aware that an SAE had occurred in a study subject, the investigator (or designate) had to complete a paper expedited AEs report and forward it to GSK within 24 hours. The report was to always be completed as thoroughly as possible with all available details of the event and then dated and signed by the investigator (or designate). Even if the investigator did not have all information regarding a SAE, the report was to still be completed and forwarded to GSK within 24 hours. Once additional relevant information was received, the report was to be updated and forwarded to GSK within 24 hours. The investigator was to always provide an assessment of

causality at the time of the initial report. All SAEs were also to be documented on the AE CRF. Any medication or other therapeutic measures used to treat the AE was to be recorded on the appropriate CRF(s) in addition to the outcome of the AE.

After receipt of the initial report, representatives of GSK or its designee was to contact the investigator if it was necessary to obtain further information for assessment of the event. Of note, 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, and within 2 weeks for pregnancies).

All SAEs had to be reported by the investigator to his/her corresponding IEC/IRB applicable regulatory authorities in accordance with institutional policy/regulatory requirements and adequate documentation of this notification had to be provided to the Sponsor.

GSK or its designee had to also comply with the applicable regulatory requirement(s) related to the reporting of suspected unexpected serious adverse reactions (SUSARs) to the regulatory authority(ies) and the IRB/IEC. If a SUSAR or other safety signal relating to use of one of the study vaccines was reported to GSK or its designee, the Sponsor was to communicate the information to the investigator and the investigator was responsible for submitting this information to the IRB/IEC and other relevant authorities.

Post-Study Events

Any SAE that occurred outside of the protocol-specified follow-up period and considered to be caused by the study vaccine was to be reported to GSK or its designee. These SAEs were to be processed by GSK or its designee as during the course of the study, until 1 month after Last Subject Last Visit (LSLV). Instructions and contact details for collecting and reporting these suspected SAEs were to be provided to the investigator.

Pregnancies

To ensure subjects' safety, each pregnancy in a subject after study vaccination was to be reported to GSK or delegate in due time of the site learning of its occurrence. If the subject agreed to submit this information, the pregnancy was to be followed up to determine outcome, including spontaneous or voluntary termination, details of the birth, and the presence or absence of any birth defects, congenital abnormalities, or maternal and/or newborn complications. This follow-up was to occur even if intended duration of safety follow-up for the study was ended.

Pregnancy data was to be recorded on a Pregnancy Report CRF (initial report) and Pregnancy Follow-Up CRF (outcome report) and reported to GSK or delegate. Instructions and contact details for submitting the Pregnancy CRFs were provided to the investigator.

Any pregnancy outcome meeting the definition of an SAE was also to be reported on the VSAE Report Form. The following were always to be considered as SAE.

- Spontaneous pregnancy loss, including:
  - spontaneous abortion, (spontaneous pregnancy loss before/at 22 weeks of gestation)
  - ectopic and molar pregnancy
  - still birth (intrauterine death of fetus after 22 weeks of gestation)

Note: the 22 weeks cut-off in gestational age was based on World Health Organization (WHO) International Statistical Classification of Diseases and Related Health Problems 10th version noted in the European Medicines Agency Guideline on pregnancy exposure.

- Any early neonatal death (ie, death of a live born infant occurring within the first 7 days of life).
- Any congenital anomaly or birth defect (as per the Metropolitan Atlanta Congenital Defects Program guidelines) identified in the offspring of a study subject (either during pregnancy, at birth or later) regardless of whether the fetus was delivered dead or alive. This includes anomalies identified by prenatal ultrasound, amniocentesis or examination of the products of conception after elective or spontaneous abortion.

9.5.2 Appropriateness of Measurements

The measures of safety used in this study were routine clinical procedures. They included a close vigilance for, and stringent reporting of, selected local and systemic AEs routinely monitored in vaccine clinical studies as indicators of reactogenicity.

The measures of immunogenicity used in this study were standard, ie, widely used and generally recognized as reliable, accurate, and relevant (able to describe the quality and extent of the immune response).

9.5.3 Primary Immunogenicity Variable(s)

The primary immunogenicity objective was assessed, by hSBA assay, in terms of percentage of the subjects with hSBA seroresponse against *N meningitidis* serogroups A, C, W and Y at day 29.

9.5.4 Drug Concentration Measurements

This study was not designed to assess pharmacokinetics and drug concentration measurements were not performed.

9.6 Data Quality Assurance

Data Entry and Management

In this study, all clinical data (including, but not limited to, AE/SAEs, concomitant medications, medical history, and physical assessments), safety data, and immunogenicity data was to be entered onto CRFs in a timely fashion by the investigator and/or the investigator's dedicated site staff. Data entered onto CRFs were to be stored on a secure website. The data collected on this secure website were to be assimilated into an electronic data capture (EDC) system, which was compliant with Title 21 Part 11 policies of the Code of Federal Regulations (Food and Drug Administration [FDA] 1997). The data system included password protection and internal quality checks. The EDC system was designed and validated by the Sponsor prior to activation for data entry by sites. The investigator or designated delegate was to review data entered and electronically sign the CRFs to verify their accuracy.

Access to the EDC system for data entry or review required training and distinct individual access code assignments to those site staff members who were to enter study data and those involved in study oversight who could review study data. Data were collected within the EDC system, to which the Sponsor and site monitors had exclusively "read only" access.

Data Clarification

As part of the conduct of the trial, the Sponsor and/or its representatives could have questions about the data entered by the site, referred to as "queries". The monitors and the Sponsor and/or its represenatives were the only parties that could generate a query. All corrections and clarifications were to be entered into the EDC system and were to be identified by the person entering the information, the reason for the change, as well as the time of the changes made. If changes were made to a previously and electronically signed CRF, the investigator had to confirm and endorse the changes.

Data Protection

GSK respects the subjects' rights to privacy and ensure the confidentiality of their medical information in accordance with all applicable laws and regulations.

9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size

9.7.1 Statistical and Analytical Plans

All Enrolled Set:

All screened subjects who provided informed consent and provided demographic and/or baseline screening assessments, regardless of the subject's randomization and treatment status in the study, and received a subject identification number.

All Exposed Set:

All subjects in the enrolled set who received a study vaccination.

Safety Set:

Solicited safety set (solicited local and systemic adverse events and other solicited adverse events):

All subjects in the exposed set with any solicited AE data.

Unsolicited safety set (unsolicited adverse events):

All subjects in the exposed set with unsolicited AE data.

Overall safety set:

All subjects who were in the solicited safety set and/or unsolicited safety set.

Full Analysis Set Efficacy/Immunogenicity Set

Full analysis set (FAS) immunogenicity:

FAS (day 1)

All subjects in the all enrolled set who:

- were randomized;
- provided evaluable serum samples at day 1 whose result was available for at least one serogroup.

FAS (day 29)

All subjects in the all enrolled set who:

- were randomized;
- received the study vaccination;
- provided evaluable serum samples at day 1 whose results were available for at least one serogroup (except for hSBA titer ≥ 8 and ≥ 16, GMTs and geometric mean ratios (GMR)s calculated at specific timepoints);

- provided evaluable serum samples at day 29 whose result was available for at least one serogroup.

Per Protocol (PP) Immunogenicity Set

A per protocol set (PPS) was defined for each FAS described in the previous section with additional criteria specified below.

All subjects in the FAS Immunogenicity who:

- Had no protocol deviations leading to exclusion (see protocol deviation[1]) as defined prior to unblinding/analysis.
- Were not excluded due to other reasons defined prior to unblinding or analysis (see protocol deviation[1])
- Examples for subjects excluded due to other reasons than protocol deviations were:
  - Subjects who withdrew informed consent.

Other Analysis Sets

There was no other analysis sets used in this study.

Subgroups

Using the PPS (day 29), the analyses of the primary objectives were replicated by sex and race.

Analysis of Demographics and Other Baseline Characteristics

Descriptive statistics (mean, standard deviation, median, minimum and maximum) for age, height and weight at enrolment was calculated overall and by study group.

Distributions of subjects by sex, race and ethnic origin was summarized overall and by study group.

[1] A protocol deviation was any change, divergence, or departure from the study design or procedures of a study protocol. A protocol deviation could be a reason to remove data from an analysis set at the time of analysis. CSR-reportable reportable protocol deviations were defined as exclusionary from the analysis according to protocol objectives and endpoints, which were specified in the statistical analysis plan. (SAP).. In some cases exclusion of data could be due to a reason other than a protocol deviation, e.g. early termination.

The frequencies and percentages of subjects with medical history were presented by Medical Dictionary for Regulatory Activities (MedDRA) system organ class (SOC) and preferred term (PT), by study group and overall.

Medical history and demographic data were tabulated for the all enrolled, PPS (day 29) and overall safety set.

Analysis of Primary Immunogenicity Objective(s)

Statistical Hypotheses:

Null hypothesis: $P_{ij} \leq 0.75$

versus

Alternative hypothesis: $P_{ij} > 0.75$

Where: P_{ij} is the population booster seroresponse rate; j=1,2 refer to group Menveo-Menveo (first test) and Menactra-Menveo (second test) respectively; i=1,2,3,4 refer to serogroup A, C, W and Y, respectively. The level of significance was fixed at one-sided 0.025.

Analysis Sets:

The analysis of population to be used for the primary objectives was the PPS (day 29). Analyses of primary objectives were to be repeated on the FAS (day 29) to assess robustness of results.

Statistical Methods:

General:

Missing immunogenicity values were assumed missing completely at random (MCAR) and therefore could not contain information that impact the result of the analysis (ie not informative). Imputation methods were therefore not used.

Overall significance level for all hypothesis tests was one-sided $\alpha = 2.5\%$.

Seroresponse (day 29):

Seroresponse for this booster study was defined as: a) post-vaccination hSBA titer ≥ 16 for subjects with a pre-vaccination hSBA titer < 4; b) for subjects with a pre-vaccination hSBA titer ≥ 4, an increase of at least four times the pre-vaccination hSBA titer.

For each individual vaccine group (Menveo-Menveo and Menactra-Menveo) and each ACWY serogroup, the percentages of subjects with seroresponse were computed, along with associated two-sided 95% Clopper-Pearson CIs.

Further details of the statistical methods are provided in the SAP.

Analysis of Secondary Immunogenicity Objective(s)

Statistical Hypotheses:

Analyses related to the secondary immunogenicity objectives were descriptive; no formal statistical tests were to be performed.

Analysis Sets:

Analyses of secondary immunogenicity were to be based on the PPS and repeated on the FAS.

Statistical Methods:

General:

The hSBA titers at each visit were to belogarithmically transformed (base10) to obtain approximately normally distributed data.

For comparison of percentages and GMT ratios, unadjusted estimates were to be obtained along with adjusted estimates from regression models to account for potential baseline imbalance between study groups. For each *N meningitidis* serogroup A, C, W and Y, unadjusted GMTs were to be calculated, with their associated two-sided 95% CIs, by exponentiating the corresponding log-transformed means and their 95% CIs. Adjusted GMTs were to be obtained from Analysis of Covariance (ANCOVA) models.

Seroresponse (day 4, day 6 and day 29):

The percentage of subjects with seroresponse and associated two-sided 95% Clopper-Pearson CIs were computed by group (Menveo-Menveo, Menactra-Menveo, the Naive and the pooled [Menveo-Menveo and Menactra-Menveo] groups) and *N meningitidis* serogroups A, C, W and Y test strains. Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - each of the previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) was compared to the Naive group. Also the two previously vaccinated study groups were compared to each other.

As sensitivity analyses, the difference in percentages was also to be obtained from a log-linear model adjusting for pre-vaccination titer.

Percentage of subjects with hSBA titer≥ 8 and ≥ 16 (day 1, day 4, day 6, and day 29):

For each study group and in the pooled group (Menveo-Menveo and Menactra-Menveo), the percentage of subjects with hSBA titer ≥ 8 and ≥ 16 and associated two-sided 95% Clopper-Pearson CIs were computed by the *N meningitidis* serogroups A, C, W and Y test strains on day 1, day 4, day 6 and day 29 (as applicable, depending on blood draw schedule).

Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - the previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) were compared to the Naive group. Also the two previously vaccinated groups were compared to each other.

As sensitivity analyses, the difference in percentages were also obtained from a log-linear model adjusting for pre-vaccination titer.

Between-group ratios of GMTs (adjusted and unadjusted):

The between-group ratio of hSBA GMTs and corresponding 95% CI, at each of visit day 1 (persistence), day 4, day 6 and day 29 against each *N meningitidis* serogroups A, C, W and Y test strains were obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified.

Additionally, adjusted ratios of GMTs were obtained from ANCOVA models including pre-vaccination titer as factor in the model.

The previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) were compared to the Naive group at each timepoint – descriptively – using the ratios of GMTs. The two previously vaccinated groups were also compared to each other at each time point using GMT ratios.

Within-group GMRs (adjusted and unadjusted):

Within each study group and for each serogroup, GMRs were calculated, as applicable, at:

- Visit day 4 versus at Visit day 1;
- Visit day 6 versus at Visit day 1; and

- Visit day 29 versus at Visit day 1.

The unadjusted GMRs and 95% CIs were constructed by exponentiating the mean within-group differences in log-transformed titers and the corresponding 95% CIs.

Analysis of safety objectives:

Analysis of Extent of Exposure

Subjects were analyzed to the extent that they were exposed to study vaccines and according to the available safety data for the subject during any study period. Subjects who withdrew early or who lost to follow-up were removed from the summary table denominator for the time period in which they had no available safety data collected.

Analysis of Solicited Local, Systemic and Other Adverse Events

All solicited AEs were summarized according to defined severity grading scales.

Frequencies and percentages of subjects experiencing each AE were presented for each symptom severity. Summary tables showing the occurrence of any local or systemic AE overall and at each time point were also presented.

Post-vaccination solicited AEs reported from day 1 to day 7 were summarized for the intervals day 1 (6 hours) – day 3, days 4-7, day 1 (6 hours) – day 7 by maximal severity and by study group. Separate analyses were performed for solicited AEs reported 30 minutes after vaccination. The severity of solicited local AEs, including injection-site erythema and induration, was categorized based on linear measurement: None (0-24 mm), Mild (25-50 mm), Moderate (51-100 mm), Severe (> 100 mm).

Injection site pain and systemic reactions, including fatigue, headache, myalgia, arthralgia, chills, nausea, loss of appetite, occurring up to 7 days after each vaccination were summarized according to “mild”, “moderate” or “severe”.

Each solicited local and systemic AE was also further summarized as “none” versus “any”.

Use of antipyretics and analgesics were summarized by frequency, by type of use (prophylactic versus treatment) and percentage of subjects reporting use.

Body temperature was summarized separately according to the 3 schemes described below and was broken down according to route of measurement:

- by 0.5°C increments from 36.0°C up to ≥40°C;
- by 1°C increments: < 36.0, 36.0-36.9, 37.0-37.9, 38.0-38.9, 39.0-39.9, ≥40°C;
- According to different cut-offs (< versus ≥): 38.0, 38.5, 39.0, 39.5, 40.0°C.

Analysis of Unsolicited Adverse Events

This analysis applied to all AEs occurring during the study, judged either as probably related, possibly related, or not related to vaccination by the investigator, recorded in AE CRF, with a start date on or after the date of first vaccination. Only AEs starting after the first vaccination were listed. The original verbatim terms used by investigators to identify AEs in the eCRFs were mapped to preferred terms using the MedDRA dictionary. The AEs were then grouped by MedDRA preferred terms into frequency tables according to SOC.

All reported AEs, as well as AEs judged by the investigator as at least possibly related to study vaccine, were summarized according to SOC and preferred term within SOC. These summaries were presented by study group and by interval of study observation. When an AE occurred more than once for a subject, the maximal severity and strongest relationship to the vaccine were counted.

Separate summaries were produced for the following categories:

- Adverse events that were possibly or probably related to vaccine
- Unsolicited AEs reported within 30 minutes after vaccination
- Unsolicited AEs reported within 29 days after vaccination
- Adverse events leading to withdrawal
- Adverse events leading to a medically attended visit
- SAEs

Data listings of all AEs were provided by subject. In addition, AEs in the categories above were provided as listed data.

Statistical Hypotheses

There were no statistical hypotheses associated with the secondary safety objectives.

Analysis Sets

Analyses of solicited AEs - and other solicited reactions - and unsolicited AEs were performed on the relevant safety sets.

Statistical Methods

For unsolicited AEs, the entire study period was divided into the following intervals: onset within 30 minutes after vaccination, onset within 28 days after vaccination; and from day 1 through day 181. For solicited AEs, the solicited study period was divided

into intervals: from 6 hours through day 3; from day 4 through day 7; and from 6 hours through day 7.

No imputation methods were used to address missing safety data.

Summaries of safety were presented using frequencies and percentages within each study group. No statistical comparisons among the study groups with respect to any of the safety parameters were performed.

9.7.2 Determination of Sample Size

Statistical power was estimated based on observed data from study V59P13E1 assessing the immunogenicity of a booster dose of Menveo among subjects who had previously been vaccinated with either Menveo or Menactra 3 years prior in another study (V59P13) while subjects were 11-18 years old. Data from study V59P13E1 were used to compute booster seroresponse rates at one-month post booster dose of Menveo using the following definition of booster seroresponse: a) post-vaccination hSBA titer ≥ 16 for subjects with a pre-vaccination hSBA titer < 4; b) for subjects with a pre-vaccination hSBA titer ≥4, an increase of at least four times the pre-vaccination hSBA titer (Table 9.7.2-1).

Table 9.7.2-1 hSBA Seroresponse at One Month Following the Booster at 3 Years After Vaccination, by Serogroup - Booster- PP Population

	Vaccination	ACWY/ACWY	Menactra/ACWY
		Group IV	Group V
SerogroupA	Overall seroresponse	68 (97%) (90-100) N=70	70 (100%) (95-100) N=70
SerogroupC	Overall seroresponse	66 (93%) (84-98) N=71	65 (93%) (84-98) N=70
SerogroupW	Overall seroresponse	63 (91%) (82-97) N=69	64 (93%) (84-98) N=69
SerogroupY	Overall seroresponse	63 (90%) (80-96) N=70	64 (91%) (82-97) N=70

Source: Table 8.5-1 of protocol version 1 dated 24 JUN 16.
Abbreviations: hSBA, human serum bactericidal assay; N, number of subjects; PP, per protocol

Assumptions for sample size evaluation

Assuming the true booster seroresponse rates in the Menveo-Menveo group range from 90% to 97% (alternative hypothesis) for each serotype, a sample size of n=270 was to

have at least 96% power to show sufficiency of immune response to a booster dose of Menveo, compared with a pre-specified reference booster seroresponse of 75% (null hypothesis) using an exact test with 0.025 one-sided significance level (Table 9.7.2-2).

Assuming the true booster seroresponse rates in the Menactra-Menveo group range from 91% to 100% (alternative hypothesis) for each serotype, a sample size of n=270 was to have at least 96% power to show sufficiency of immune response to a booster dose of Menveo, compared with a pre-specified reference booster seroresponse of 75% (null hypothesis) using an exact test with 0.025 one-sided significance level (Table 9.7.2-3).

Table 9.7.2-2 Statistical Power to Test for Sufficiency of Immune Response Given a Range of True Booster Seroresponse Rates for Evaluable Sample Size of 270 subjects in the Menveo-Menveo group

Serotype	True Seroresponse Rate	Power
A	0.97	0.99
C	0.93	0.99
W	0.91	0.99
Y	0.90	0.99
Total Power		0.96

Source: Table 8.5-2a of protocol version 1.0 issued on 24 JUN 16.
Calculations have been done with nQuery Advisor (Version 7.0).

Table 9.7.2-3 Statistical Power to Test for Sufficiency of Immune Response Given a Range of True Booster Seroresponse Rates for Evaluable Sample Size of 270 subjects in the Menactra-Menveo group

Serotype	True Seroresponse Rate	Power
A	> 0.99	0.99
C	0.93	0.99
W	0.93	0.99
Y	0.91	0.99
Total Power		0.96

Source: Table 8.5-2b of protocol version 1.0 issued on 24 JUN 16.
Calculations have been done with nQuery Advisor (Version 7.0).

Overall statistical power to show sufficiency of immune response to a booster dose of Menveo for each serotype in both the Menveo-Menveo and the Menactra-Menveo group was to be at least 92%.

When taking a 10% dropout rate into account, N=300 previously vaccinated subjects with Menveo and N=300 previously vaccinated subjects with Menactra had to be enrolled in the study.

Calculations were done with nQuery Advisor (Version 7.0).

9.8 Changes in the Conduct of the Study or Planned Analyses

Changes to the protocol:

The first version of the protocol was issued on 24 June 2016; the protocol was not amended.

Changes to analysis plan:

The first version of the SAP was issued on 29 September 2016; the SAP was not amended.

Change in planned analysis:

A log-linear model with pre-vaccination titer and vaccine groups as independent variables was specified in the protocol and SAP for sensitivity analyses of seroresponse and percentage of subjects of titers ≥8 and ≥16. Given that the response is a "Yes or No" variable instead of a count variable, a binary model with a logit link was used, instead of a log-linear model. The obtained estimates were back-transformed from a logit scale to a probability scale.

GCP compliance:

- The Principal Investigator (PI) of center PPD reported a quality incident to the Radiant Research QA Site Management Organization for a non GSK study that he was responsible for. Radiant Research QA launched an investigation and performed an audit of the PI, which confirmed physicians were backdating reports. The practice at the site was for the investigator to sign and date in manner that was not contemporaneous with the visit, sometimes days following the visit. The backdating had occurred on a study not related to study V59_77.

  The study monitor reviewed the study documentation for study V59_77 at the site and did not detect any back dating. There were no patient safety or data integrity concerns and all patient assessments were done per protocol, so a sensitivity analysis was not deemed necessary. The monitoring close out visit was completed.

  The PI made a decision to close his research practice and this was completed on 26 May 2017. Subjects in study V59_77 were transferred to another center PPD within the Radiant Research umbrella. The study had 7 subjects who required final safety follow up phone call after site closure. Radiant Research performed an

investigator site audit at center PPD There were no concerns relating to backdating as was previously identified at center PPD

- On 4 December 2017, GSK was notified that the PI of center PPD passed away on PPD 2017. The GSK LDL notified the IRB on 11 December and the coordinator at the site prepared a Note to File to document the PI's death and the plan of action for PI sign off and site close out, including site responsible staff for questions and records after close out. The coordinator added a sub investigator (listed on Statement of Investigator [Form FDA 1572]) to the Delegation Log for casebook sign off and signed the delegation log on behalf of the PI on 13 December 2017. The GSK LDL contacted the IRB on 13 December 2017 and informed them about the plan to have the sub investigator signing the casebooks on behalf of the PI and that the PI would not be replaced. The IRB acknowledged and accepted the plan. The sub investigator completed eCRF casebook sign off on 15 December 2017.

  LSLV at the site had occurred on 28 July 2017 and none of the subjects had reported any SAEs. The coordinator/sub investigator at the site sent a letter to all subjects at the site on 19 December 2017 to inform them about what happened and that the research center would close on 31 January 2018, providing them with contact details of GSK in case of any study related questions. This letter was also sent to the IRB and approved on 9 January 2018.

- There were 3 subjects who were eligible for the study, were consented and underwent a study procedure (blood sampling) but could not be enrolled into SBIR as the randomization arm was full. Consequently, the system did not assign them to a treatment group, and they were excluded by investigators from study participation prior to vaccination. GSK investigated the issue and discovered that the investigators did not follow the correct chronology of events per study protocol, which is to first enroll subjects into SBIR after subject consent and prior to blood draw.

  The issue was detected prior to Database Freeze. The subjects were excluded from the primary and safety analysis as they were not vaccinated but were included in the all enrolled dataset and will contribute to demography and provide immunogenicity data for one of the secondary objectives, the analysis of persistence at day 1.

Protocol deviations, analyzed by subject, are summarized in section 10.2 and a detailed listing is provided in Appendix 16.2.2.1.

10. STUDY SUBJECTS

10.1 Disposition of Subjects

A summary of study terminations is presented in Table 10.1-1. An overview of subject disposition is presented in Figure 10.1-1.

A total of 704 subjects (301 in the Menveo-Menveo group, 301 in the Menactra-Menveo group and 102 in the Naive group) who provided informed consent were enrolled in the study. One subject in the Menactra-Menveo group and 2 subjects in the Naive group did not receive study vaccination because they could not be randomized (see also section 9.8). All other subjects received study vaccination. In total, 18 subjects withdrew from the study prematurely after they received study vaccination: 16 (2%) were lost to follow-up and 2 (< 1%) withdrew consent.

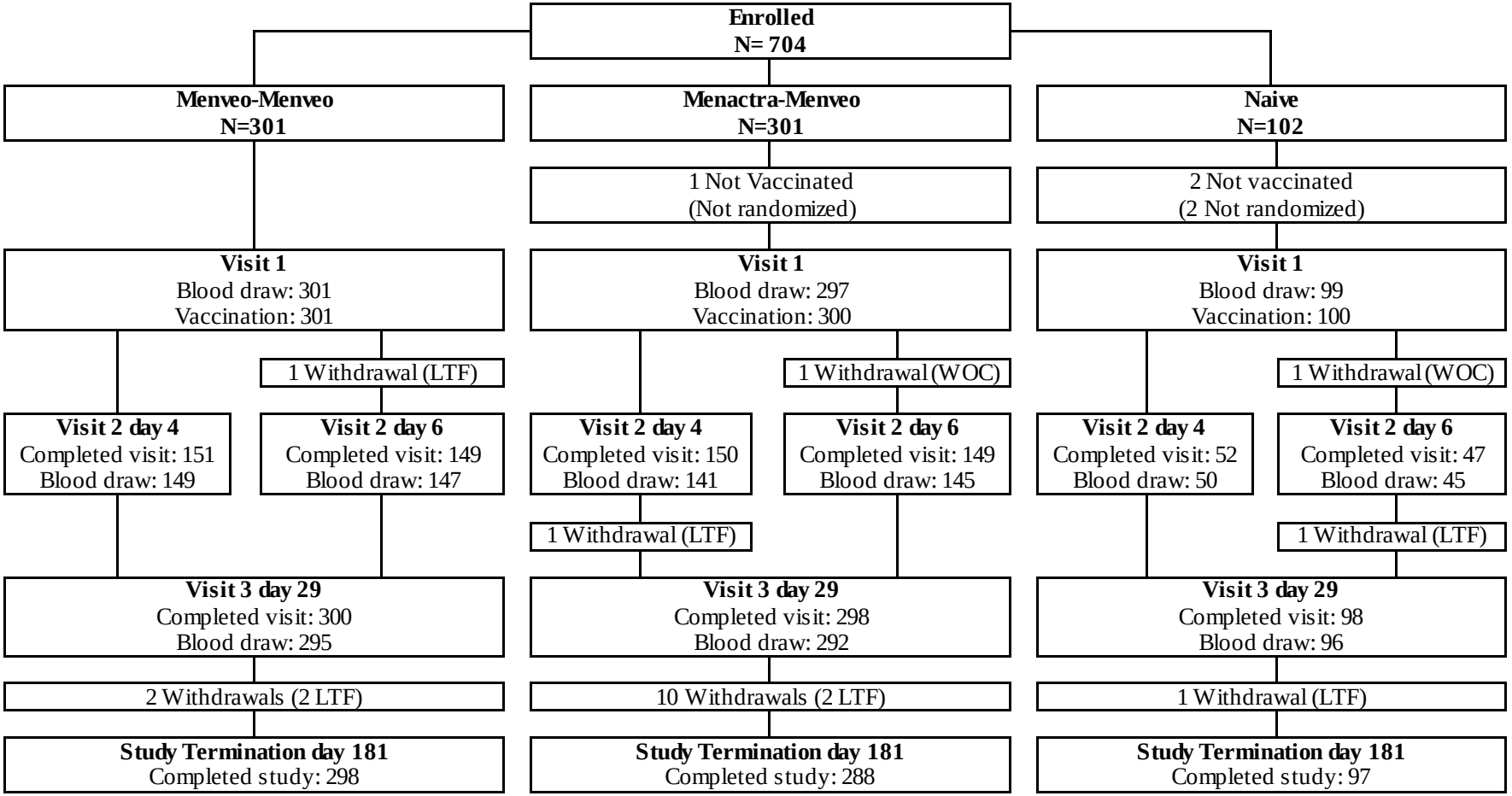
Table 10.1-1 Summary of Study Terminations – Enrolled Set

Study Groups	Menveo-Menveo	Menactra-Menveo	Naive	Total
	N=301	N=301	N=102	N=704
Enrolled	301 (100%)	301 (100%)	102 (100%)	704 (100%)
Exposed	301 (100%)	300 (> 99%)	100 (98%)	701 (> 99%)
Completed	298 (99%)	288 (96%)	97 (95%)	683 (97%)
Premature withdrawals				
Lost to follow-up	3 (1%)	11 (4%)	2 (2%)	16 (2%)
Withdrawal of consent	0	1 (< 1%)	1 (1%)	2 (< 1%)
Other	0	1 (< 1%)	2 (2%)	3 (< 1%)
Enrollment group closed prior to subject being randomized	0	0	1 (1%)	1 (< 1%)
Site unable to randomize subject in SBIR due to enrollment target for vaccine naive group being met	0	0	1 (1%)	1 (< 1%)
Subject was not randomized due to Menactra arm closed	0	1 (< 1%)	0	1 (< 1%)

Source: Table 14.1.1.2.

Abbreviations: N, total number of subjects; SBIR, Source Data Base for Internet Randomization.

Figure 10.1-1 Subject Disposition Flowchart



Source: Table 14.1.1.5; Table 14.1.1.2; Table 14.1.1.6; Appendix16.2.1.1.
Abbreviations: LTF, lost to follow-up; WOC, withdrawal of consent.
Note: the numbers of subjects provided for "Blood draw" refer to the numbers of subjects who had their blood draw within the pre-specified window.

10.2 Protocol Deviations

A total of 37 (5%) subjects had protocol deviations: 10 (3%) in the Menveo-Menveo group, 19 (6%) in the Menactra-Menveo group, and 8 (8%) in the Naive group. The most common reason for deviating from the protocol was "subject did not comply with blood draw schedule", reported by a total of 13 (2%) subjects. Of these 13 subjects, 11 (3 in the Menveo-Menveo group, 6 in the Menactra-Menveo group, and 2 in the Naive group) had the blood draw outside the window of the day 29 visit (Appendix 16.2.2.1). The other 2 subjects (both Menactra-Menveo) had the blood draw outside of the window of the day 1 visit.

A listing of all protocol deviations is given in Appendix 16.2.2.1.

Table 10.2-1 Summary of Protocol Deviations – Enrolled Set

Study Groups	Menveo-Menveo	Menactra-Menveo	Naive	Total
	N=301	N=301	N=102	N=704
Any deviation	10 (3%)	19 (6%)	8 (8%)	37 (5%)
Reasons:				
Key study procedures missed or performed out of window	6 (2%)	10 (3%)	6 (6%)	22 (3%)
Serological results not available post-vaccination	3 (1%)	2 (1%)	4 (4%)	9 (1%)
Subject did not comply with blood draw schedule	3 (1%)	8 (3%)	2 (2%)	13 (2%)
Subject randomized and did not satisfy the entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)
Subject did not meet entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)
Subject received the wrong treatment or incorrect dose	0	1 (< 1%)	2 (2%)	3 (< 1%)
Study vaccine not administered at all but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)
Subject took an excluded concomitant medication	1 (< 1%)	3 (1%	0	4 (1%)
Administration of any medication forbidden by the protocol	1 (< 1%)	3 (1%)	0	4 (1%)

Source: Table 14.1.1.8.
Abbreviation: N, total number of subjects.

11. IMMUNOGENICITY EVALUATION

11.1 Data Sets Analyzed

The immunogenicity analysis was performed on the PPS (primary analysis) for immunogenicity and on the FAS.

The summary of subjects excluded from different data sets for various reasons are detailed in Table 14.1.1.9, Table 14.1.1.9.1 and Table 14.1.1.9.2.

The results presented in Table 11.1-1 below are for immunogenicity data analyzed up to Day 29, for subjects in the immunogenicity subset.

In total, 704 subjects were enrolled in the study: 301 in the Menveo-Menveo group, 301 in the Menactra-Menveo group, and 102 in the Naive group. Across study groups, 91%-99% of subjects were included in the PPS for analysis of primary and secondary objectives; 94%-100% of subjects were included in the FAS data sets used to repeat analysis of primary and secondary immunogenicity objectives to assess robustness of results.

Table 11.1-1 Overview of Population Analyzed

Study Groups	Menveo-Menveo	Menactra-Menveo	Naive	Total
Population	**N=301**	**N=301**	**N=102**	**N=704**
Enrolled	301 (100%)	301 (100%)	102 (100%)	704 (100%)
Immunogenicity PPS				
day 1	298 (99%)	291 (97%)	96 (94%)	685 (97%)
day 29	290 (96%)	282 (94%)	93 (91%)	665 (94%)
Immunogenicity FAS				
day 1	301 (100%)	298 (99%)	97 (95%)	696 (99%)
day 29	297 (99%)	296 (98%)	96 (94%)	689 (98%)

Source: Table 14.1.1.1
Abbreviations: N, total number of subjects; FAS, full analysis set; PPS, per protocol set.

11.2 Demographic and Other Baseline Characteristics

Demographic and other baseline characteristics were generally balanced between both primed groups (Menveo-Menveo and Menactra-Menveo). The mean age of subjects enrolled in the study was 17.1±3.66 years in the Menveo-Menveo group and 17.8±4.53 years in the Menactra-Menveo group. The Naive group enrolled mostly adults (mean age: 38.8±10.49), and more female (67%) than male (33%) subjects. The age difference between the subjects in the primed groups and those in the Naive group is in line with expected enrolment, given the ACIP recommendation for a universal vaccination with a quadrivalent conjugated meningococcal vaccine at 11-12 years of age. Across study groups, most of the subjects (78%-83%) were 'White', and of 'Not Hispanic or Latino' ethnic origin. At least 98% of subjects in any group met study entry criteria (Table 11.2-1).

Table 11.2-1 Demographic and Other Baseline Characteristics – Enrolled Set

Study Groups	Menveo-Menveo	Menactra-Menveo	Naive	Total
	N=301	N=301	N=102	N=704
Age (years) ± SD	17.1 ± 3.66	17.8 ± 4.53	38.8 ± 10.49	20.6 ± 9.32
Gender:				
Female	144 (48%)	156 (52%)	68 (67%)	368 (52%)
Male	157 (52%)	145 (48%)	34 (33%)	336 (48%)
Race				
American Indian or Alaska Native	2 (1%)	6 (2%)	1 (1%)	9 (1%)
Asian	4 (1%)	14 (5%)	3 (3%)	21 (3%)
Black or African American	24 (8%)	23 (8%)	12 (12%)	59 (8%)
Native Hawaiian or other Pacific Islander	3 (1%)	1 (< 1%)	0	4 (1%)
Other	17 (6%)	23 (8%)	5 (5%)	45 (6%)
White	251 (83%)	234 (78%)	81 (79%)	566 (80%)
Ethnic origin:				
Hispanic or Latino	40 (13%)	75 (25%)	11 (11%)	126 (18%)
Not Hispanic or Latino	258 (86%)	223 (74%)	91 (89%)	572 (81%)
Not reported	3 (1%)	3 (1%)	0	6 (1%)
Weight (kg) ± SD	72.8 ± 21.61	72.6 ± 20.00	89.4 ± 25.41	75.2 ± 22.30
Height (cm) ± SD	171.2 ± 9.21	169.8 ± 10.35	169.2 ± 9.78	170.3 ± 9.81
Met entry criteria	298 (99%)	296 (98%)	101 (99%)	695 (99%)

Source: Table 14.1.1.3.
Abbreviation: SD, standard deviation.
Categorical parameters: Number (%) of subjects; non-categorical parameters: mean ± standard deviation.

11.3 Measurements of Vaccination Compliance

The summary of vaccine administration is detailed in Table 14.1.1.5. A detailed listing of subject vaccination data is given in Appendix 16.2.5.1.

11.4 Immunogenicity Results and Tabulations of Individual Subject Data

11.4.1 Analysis of Immunogenicity

Primary Objectives:

1. *To demonstrate a sufficient immune response following a booster dose of Menveo vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with hSBA seroresponse against N meningitidis serogroups A, C, W and Y at day 29 after vaccination*

At day 29 after the Menveo booster dose the percentage of subjects with hSBA seroresponse for serogroups A, C, W, and Y ranged from 95.49% to 96.86% across serogroups in the Menveo-Menveo group.

The lower limits of the 1-sided 97.5% CI for the percentages of subjects in the Menveo-Menveo group with hSBA seroresponse were greater than 75% for all serogroups (Table 11.4.1-1). This demonstrates a sufficient immune response following a booster dose of Menveo vaccine, given to subjects who previously received Menveo.

2. *To demonstrate a sufficient immune response following a booster dose of Menveo vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse against N meningitidis serogroups A, C, W and Y at day 29 after vaccination*

At day 29 after the Menveo booster dose the percentage of subjects with hSBA seroresponse for serogroups A, C, W, and Y ranged from 93.24% to 96.45% across serogroups in the Menactra-Menveo group.

The lower limits of the 1-sided 97.5% CI for the percentages of subjects in the Menactra-Menveo group with hSBA seroresponse were greater than 75% for all serogroups (Table 11.4.1-1). This demonstrates a sufficient immune response following a booster dose of Menveo vaccine, given to subjects who previously received Menactra.

Table 11.4.1-1 Numbers and Percentages of Subjects (95% CI) with hSBA Seroresponse against *N meningitidis* serogroups A, C, W and Y at day 29 After Vaccination, (Per Protocol Set, day 29[a])

Study Groups	Menveo-Menveo	Menactra-Menveo	Met success criteria for both groups
	N=290	N=282	Yes/No
Serogroup A	279 (96.54%) (**93.73%** -98.33%) N=289	272 (96.45%) (**93.58%** -98.29%)	Yes
Serogroup C	275 (95.49%) (**92.40%** -97.57%) N=288	269 (96.07%) (**93.08%** -98.02%) N=280	Yes
Serogroup W	277 (95.85%) (**92.86%** -97.84%) N=289	262 (93.24%) (**89.64%** -95.88%) N=281	Yes
Serogroup Y	278 (96.86%) (**94.13%** -98.56%) N=287	264 (94.29%) (**90.89%** -96.70%) N=280	Yes

Source: Table 14.2.1.1.

Abbreviations: CI, confidence interval; hSBA, human serum bactericidal assay; N, total number of subjects.

[a] Includes subjects with results at day 1 and day 29 for at least one serogroup.

Note: Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers < 4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

The immune response was considered as sufficient if the lower limit of the one-sided 97.5% CI for percentage of subjects with hSBA seroresponse against serogroups A, C, W and Y was greater than 75%.

Secondary Objectives:

1. *To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo, subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled vaccine group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA seroresponse, hSBA titers ≥ 8 and ≥ 16, and hSBA GMTs against N meningitidis serogroups A, C, W and Y at day 1, day 4, day 6, and day 29 after vaccination.*

Percentage of subjects with hSBA seroresponse at day 4, day 6, and day 29

The percentages of subjects with hSBA seroresponse against *N meningitidis* serogroups A, C, W, and Y at day 4, day 6, and day 29 after vaccination are provided in Table 11.4.1-2. The differences between the Menveo-Menveo, Menactra-Menveo, pooled Menveo/Menactra-Menveo and Naive groups are provided in Table 14.2.1.1.

Seroresponse at day 4 was low for all study groups and serogroups. By day 4, no more than 10.14% of subjects in any of the study groups had hSBA seroresponse against serogroups A, C, W, or Y. Group differences did not exceed 7.75% for any serogroup or group comparison. The only group difference that had a CI which did not include 0 was the difference between the Menveo-Menveo group vs the Naive group for serogroup Y (difference: 7.75%; CI: 0.15%-13.36%).

By day 6, the percentages of subjects with hSBA seroresponse against each serogroup had increased in all groups. The percentages of subjects with hSBA seroresponse against serogroup A was 39.31% in the Menveo-Menveo group and 31.43% in the Menactra-Menveo group (pooled Menveo/Menactra-Menveo: 35.44%), and against serogroups C, W, and Y percentages ranged between 48.20%-57.14% across primed groups (pooled: 49.82% [serogroup C and W]-53.00% [serogroup Y]). In the Naive group, the percentage of subjects with hSBA seroresponse against any of the serogroups ranged between 4.55% [serogroup A]-11.36% [serogroups C and W] at day 6. Vaccine group difference between the pooled Menveo/Menactra-Menveo group vs. the Naive group ranged between 30.89% (serogroup A)-43.91% (serogroup Y) across serogroups at day 6, with all LLs of the 95% CIs > 0.

By day 29, a further increase in the percentages of subjects with hSBA seroresponse against each serogroup was observed in all groups. Across serogroups, between 93.24%-96.86% of subjects in the Menveo-Menveo and Menactra-Menveo groups (pooled Menveo/Menactra-Menveo: 94.56%-96.50%) had hSBA seroresponse. In the Naive group, between 35.87% (serogroup W)-65.59% (serogroup A) of subjects had hSBA seroresponse against any of the serogroups. Vaccine group difference between the pooled Menveo/Menactra-Menveo group vs. the Naive group ranged between 30.91% (serogroup A)-58.69% (serogroup W) across serogroups at day 29, with all LLs of the 95% CIs > 0.

Table 11.4.1-2 Numbers and Percentages of Subjects (95% CI) with hSBA Seroresponse against *N meningitidis* serogroups A, C, W and Y at day 4, day 6 and day 29 after Vaccination (Per Protocol Set, day 29)

Study group		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
	Study day	**N=290**	**N=282**	**N=572**	**N=93**
Serogroup A	day 4	2 (1.39%) (0.17%-4.93%) N=144	3 (2.17%) (0.45%-6.22%) N=138	5 (1.77%) (0.58%-4.09%) N=282	0 (0%) (0%-7.40%) N=48
	day 6	57 (39.31%) (31.31%-47.76%) N=145	44 (31.43%) (23.85%-39.81%) N=140	101 (35.44%) (29.89%-41.30%) N=285	2 (4.55%) (0.56%-15.47%) N=44
	day 29	279 (96.54%) (93.73%-98.33%) N=289	272 (96.45%) (93.58%-98.29%)	551 (96.50%) (94.64%-97.85%) N=571	61 (65.59%) (55.02%-75.14%)
Serogroup C	day 4	4 (2.80%) (0.77%-7.01%) N=143	12 (8.76%) (4.61%-14.80%) N=137	16 (5.71%) (3.30%-9.11%) N=280	3 (6.25%) (1.31%-17.20%) N=48
	day 6	74 (51.39%) (42.92%-59.80%) N=144	67 (48.20%) (39.65%-56.83%) N=139	141 (49.82%) (43.85%-55.80%) N=283	5 (11.36%) (3.79%-24.56%) N=44
	day 29	275 (95.49%) (92.40%-97.57%) N=288	269 (96.07%) (93.08%-98.02%) N=280	544 (95.77%) (93.78%-97.27%) N=568	53 (56.99%) (46.31%-67.22%)
Serogroup W	day 4	4 (2.78%) (0.76%-6.96%) N=144	14 (10.14%) (5.66%-16.44%) N=138	18 (6.38%) (3.83%-9.90%) N=282	3 (6.25%) (1.31%-17.20%) N=48
	day 6	73 (50.34%) (41.93%-58.75%) N=145	69 (49.29%) (40.74%-57.86%) N=140	142 (49.82%) (43.87%-55.78%) N=285	5 (11.36%) (3.79%-24.56%) N=44
	day 29	277 (95.85%) (92.86%-97.84%) N=289	262 (93.24%) (89.64%-95.88%) N=281	539 (94.56%) (92.37%-96.28%) N=570	33 (35.87%) (26.13%-46.54%) N=92
Serogroup Y	day 4	11 (7.75%) (3.93%-13.44%) N=142	6 (4.38%) (1.62%-9.29%) N=137	17 (6.09%) (3.59%-9.58%) N=279	0 (0%) (0%-7.40%) N=48
	day 6	70 (48.95%) (40.51%-57.44%) N=143	80 (57.14%) (48.51%-65.47%) N=140	150 (53.00%) (47.01%-58.94%) N=283	4 (9.09%) (2.53%-21.67%) N=44
	day 29	278 (96.86%) (94.13%-98.56%) N=287	264 (94.29%) (90.89%-96.70%) N=280	542 (95.59%) (93.56%-97.13%) N=567	48 (51.61%) (41.01%-62.11%)

Source: Table 14.2.1.1.
Abbreviations: CI, confidence interval; hSBA, human serum bactericidal assay; N, total number of subjects.

Note: Seroresponse defined for this study was as follows: For subjects with pre-vaccination titers < 4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

Percentage of subjects with hSBA titers ≥ 8 (and ≥ 16) at Day1, day 4, day 6, and day 29

The percentages of subjects with hSBA titers ≥ 8 against *N meningitidis* serogroups A, C, W, and Y at day 1, day 4, day 6, and day 29 are provided in Table 11.4.1-3. The differences between the Menveo-Menveo, Menactra-Menveo, pooled Menveo/Menactra-Menveo and Naive groups are provided in Table 14.2.1.2.

By day 4, the percentages of subjects with hSBA titers ≥ 8 remained similar (serogroup A) or slightly increased (serogroups C, W, and Y) in all groups compared to day 1 (pre-vaccination).

By day 6, the percentages of subjects with hSBA titers ≥ 8 increased in all groups. Against serogroup A, they were 53.42% and 47.14% in the Menveo-Menveo and Menactra-Menveo groups, respectively (pooled Menveo/Menactra-Menveo: 50.35%), and they ranged between 85.52%-97.86% (pooled: 86.67% [serogroup Y]-95.80%[serogroup W]) against serogroups C, W, and Y. Vaccine group differences between the pooled Menveo/Menactra-Menveo group vs. the Naive group ranged between 32.17% (serogroup W)-46.61% (serogroup C) across serogroups, with all LLs of the 95% CIs > 0.

By day 29, the percentages of subjects with hSBA titers ≥ 8 against each serogroup further increased in all groups. At least 98.62% of subjects in the Menveo-Menveo and Menactra-Menveo groups (pooled Menveo/Menactra-Menveo: at least 98.78%) had hSBA titers ≥ 8 against all serogroups (in the Menveo-Menveo group 100% of subjects had hSBA titers ≥ 8 against serogroups C, W, and Y). In the Naive group, the percentages of subjects with hSBA titers ≥ 8 ranged across serogroups between 70.97% (serogroup A)-87.10% (serogroup C). Vaccine group differences between the pooled Menveo/Menactra-Menveo group vs. the Naive group ranged between 12.73% (serogroup C)-27.81% (serogroup A) across serogroups, with all LLs of the 95% Cis > 0.

Similar results were observed for the percentages of subjects with hSBA titers ≥ 16 against serogroups A, C, W, and Y (Table 11.4.1-4). In the Menveo-Menveo group, 100% of subjects had hSBA titers ≥ 16 against serogroups W and Y at day 29.

Reverse cumulative distribution curves of hSBA titers against *N Meningitidis* serogroups A, C, W and Y from the PPS (day 29) at day 1 (pre-vaccination; Figure 14.2.2.1.1), day 4 (Figure 14.2.2.1.2), day 6 (Figure 14.2.2.1.3), and day 29 (Figure 14.2.2.1.4), and from the FAS (day 29) at day 1 (pre-vaccination; Figure 14.2.2.2.1), day 4 (Figure 14.2.2.2.2), day 6 (Figure 14.2.2.2.3), and day 29 (Figure 14.2.2.2.4) after vaccination demonstrate the same pattern of antibody responses as described above.

Table 11.4.1-3 Numbers and Percentages of Subjects (95% CI) with hSBA titer ≥ 8 against *N meningitidis* serogroups A, C, W and Y at day 1, day 4, day 6 and day 29 after Vaccination (Per Protocol Set, day 29)

Study Groups		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra -Menveo	Naive
	Study day	**N=290**	**N=282**	**N=572**	**N=93**
Serogroup A	day 1	36 ((12.46%) (8.88%-16.83%) N=289	42 (14.89%) (10.95%-19.59%)	78 (13.66%) (10.95%-16.75%) N=571	4 (4.30%) (1.18%-10.65%)
	day 4	16 (11.11%) (6.49%-17.42%) N=144	18 (13.04%) (7.92%-19.83%) N=138	34 (12.06%) (8.50%-16.44%) N=282	2 (4.17%) (0.51%-14.25%) N=48
	day 6	78 (53.42%) (44.99%-61.71%) N=146	66 (47.14%) (38.66%-55.75%) N=140	144 (50.35%) (44.40%-56.29%) N=286	4 (9.09%) (2.53%-21.67%) N=44
	day 29	286 (98.62%) (96.51%-99.62%)	279 (98.94%) (96.92%-99.78%)	565 (98.78%) (97.49%-99.51%)	66 (70.97%) (60.64%-79.92%)
Serogroup C	day 1	176 (61.11%) (55.22%-66.77%) N=288	151 (53.74%) (47.72%-59.68%) N=281	327 (57.47%) (53.29%-61.57%) N=569	31 (33.33%) (23.89%-43.87%) N=93
	day 4	102 (70.83%) (62.68%-78.10%) N=144	83 (60.14%) (51.47%-68.38%) N=138	185 (65.60%) (59.74%-71.13%) N=282	21 (43.75%) (29.48%-58.82%) N=48
	day 6	127 (87.59%) (81.09%-92.47%) N=145	128 (92.09%) (86.28%-95.98%) N=139	255 (89.79%) (85.66%-93.05%) N=284	19 (43.18%) (28.35%-58.97%) N=44
	day 29	290 (100%) (98.74%-100%)	280 (99.64%) (98.03%-99.99%) N=281	570 (99.82%) (99.03%-100.00%) N=571	81 (87.10%) (78.55%-93.15%)

Study Groups		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra -Menveo	Naive
	Study day	**N=290**	**N=282**	**N=572**	**N=93**
Serogroup W	day 1	218 (75.43%) (70.05%-80.29%) N=289	217 (76.95%) (71.59%-81.74%)	435 (76.18%) (72.47%-79.62%) N=571	57 (61.29%) (50.62%-71.22%)
	day 4	118 (81.94%) (74.67%-87.85%) N=144	114 (82.61%) (75.24%-88.53%) N=138	232 (82.27%) (77.30%-86.54%) N=282	30 (62.50%) (47.35%-76.05%) N=48
	day 6	137 (93.84%) (88.62%-97.14%) N=146	137 (97.86%) (93.87%-99.56%) N=140	274 (95.80%) (92.79%-97.81%) N=286	28 (63.64%) (47.77%-77.59%) N=44
	day 29	290 (100%) (98.74%-100%)	281 (100%) (98.70%-100%) N=281	571 (100%) (99.36%-100%) N=571	78 (84.78%) (75.79%-91.42%) N=92
Serogroup Y	day 1	155 (54.01%) (48.05%-59.88%) N=287	132 (46.98%) (41.02%-52.99%) N=281	287 (50.53%) (46.33%-54.72%) N=568	30 (32.26%) (22.93%-42.75%)
	day 4	79 (55.24%) (46.71%-63.56%) N=143	77 (55.80%) (47.10%-64.24%) N=138	156 (55.52%) (49.50%-61.42%) N=281	16 (33.33%) (20.40%-48.41%) N=48
	day 6	124 (85.52%) (78.72%-90.81%) N=145	123 (87.86%) (81.27%-92.76%) N=140	247 (86.67%) (82.16%-90.39%) N=285	20 (45.45%) (30.39%-61.15%) N=44
	day 29	290 (100%) (98.74%-100%)	280 (99.64%) (98.03%-99.99%) N=281	570 (99.82%) (99.03%-100.00%) N=571	72 (77.42%) (67.58%-85.45%)

Source: Table 14.2.1.2.
Abbreviations: CI, confidence interval; hSBA, human serum bactericidal assay; N, total number of subjects.

Table 11.4.1-4 Numbers and Percentages of Subjects (95% CI) with hSBA titer ≥ 16 against *N meningitidis* serogroups A, C, W and Y at day 1, day 4, day 6 and day 29 after Vaccination (Per Protocol Set, day 29)

Study Groups		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra -Menveo	Naive
	Study day	**N=290**	**N=282**	**N=572**	**N=93**
Serogroup A	day 1	24 (8.30%) (5.39%-12.10%) N=289	27 (9.57%) (6.40%-13.62%)	51 (8.93%) (6.72%-11.58%) N=571	1 (1.08%) (0.03%-5.85%)
	day 4	12 (8.33%) (4.38%-14.10%) N=144	12 (8.70%) (4.57%-14.70%) N=138	24 (8.51%) (5.53%-12.40%) N=282	1 (2.08%) (0.05%-11.07%) N=48
	day 6	67 (45.89%) (37.62%-54.33%) N=146	58 (41.43%) (33.17%-50.05%) N=140	125 (43.71%) (37.87%-49.67%) N=286	2 (4.55%) (0.56%-15.47%) N=44
	day 29	285 (98.28%) (96.02%-99.44%)	275 (97.52%) (94.95%-99.00%)	560 (97.90%) (96.36%-98.91%)	62 (66.67%) (56.13%-76.11%)
Serogroup C	day 1	136 (47.22%) (41.34%-53.16%) N=288	107 (38.08%) (32.38%-44.04%) N=281	243 (42.71%) (38.60%-46.89%) N=569	16 (17.20%) (10.17%-26.43%)
	day 4	78 (54.17%) (45.67%-62.49%) N=144	62 (44.93%) (36.46%-53.62%) N=138	140 (49.65%) (43.66%-55.64%) N=282	14 (29.17%) (16.95%-44.06%) N=48
	day 6	119 (82.07%) (74.84%-87.94%) N=145	113 (81.29%) (73.81%-87.40%) N=139	232 (81.69%) (76.69%-86.01%) N=284	14 (31.82%) (18.61%-47.58%) N=44
	day 29	289 (99.66%) (98.09%-99.99%)	280 (99.64%) (98.03%-99.99%) N=281	569 (99.65%) (98.74%-99.96%) N=571	65 (69.89%) (59.50%-78.97%)
Serogroup W	day 1	190 (65.74%) 59.96%-71.20%) N=289	187 (66.31%) (60.47%-71.81%)	377 (66.02%) (61.98%-69.91%) N=571	45 (48.39%) (37.89%-58.99%)
	day 4	99 (68.75%) (60.50%-76.21%) N=144	106 (76.81%) (68.87%-83.57%) N=138	205 (72.70%) (67.10%-77.81%) N=282	26 (54.17%) (39.17%-68.63%) N=48
	day 6	130 (89.04%) (82.81%-93.60%) N=146	129 (92.14%) (86.38%-96.01%) N=140	259 (90.56%) (86.56%-93.69%) N=286	22 (50.00%) (34.56%-65.44%) N=44
	day 29	290 (100%) (98.74%-100%)	281 (100%) (98.70%-100%) N=281	571 (100%) (99.36%-100%) N=571	74 (80.43%) (70.85%-87.97%) N=92

Study Groups		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra -Menveo	Naive
	Study day	**N=290**	**N=282**	**N=572**	**N=93**
Serogroup Y	day 1	112 (39.02%) (33.35%-44.93%) N=287	98 (34.88%) (29.31%-40.76%) N=281	210 (36.97%) (32.99%-41.09%) N=568	16 (17.20%) (10.17%-26.43%)
	day 4	56 (39.16%) (31.11%-47.67%) N=143	54 (39.13%) (30.94%-47.80%) N=138	110 (39.15%) (33.40%-45.12%) N=281	10 (20.83%) (10.47%-34.99%) N=48
	day 6	117 (80.69%) (73.31%-86.77%) N=145	112 (80.00%) (72.41%-86.28%) N=140	229 (80.35%) (75.26%-84.80%) N=285	14 (31.82%) (18.61%-47.58%) N=44
	day 29	290 (100%) (98.74%-100%)	277 (98.58%) (96.40%-99.61%) N=281	567 (99.30%) (98.22%-99.81%) N=571	60 (64.52%) (53.91%-74.17%)

Source: Table 14.2.1.2.
Abbreviations: CI, confidence interval; hSBA, human serum bactericidal assay; N, total number of subjects.

hSBA GMTs at day 1, day 4, day 6, and day 29

hSBA GMTs against *N meningitidis* serogroups A, C, W, and Y at day 1, day 4, day 6, and day 29, and vaccine group ratios of hSBA GMTs at day 4, day 6, and day 29 are provided in Table 11.4.1-5. GMRs at day 4, day 6, and day 29 compared to day 1 are provided in Table 11.4.1-6.

By day 4, hSBA GMTs against all serogroups remained similar (serogroup A) or only slightly increased (serogroups C, W, and Y) compared to day 1, with GMRs between 0.99-1.40 across serogroups and study groups. The vaccine group GMT ratios between the pooled Menveo/Menactra-Menveo group and the Naive group ranged between 1.29 (serogroup A)-2.72 (serogroup C) across serogroups, with LLs of the 95% CI above 1 for serogroups C, W, and Y.

By day 6, hSBA GMTs against all serogroups had increased in the Menveo-Menveo and Menactra-Menveo groups, with GMRs compared to day 1 between 3.25-8.59 across serogroups and study groups. In the Naive group, GMTs at day 6 had remained similar or only increased slightly across serogroups, with GMRs compared to day 1 ranging 1.09-1.48 across serogroups. The vaccine group GMT ratios between the pooled Menveo/Menactra-Menveo group and the Naive group ranged between 4.62 (serogroup A)-13.59 (serogroup C) across serogroups, with all LLs of the 95% CIs > 1.

By day 29, hSBA GMTs against all serogroups had further increased in all study groups, with GMRs compared to day 1 ranging between 63.63-123.41 across serogroups in the Menveo-Menveo and Menactra-Menveo groups, and between 4.57-14.14 across serogroups in the Naive group. The vaccine group ratios between the pooled Menveo/Menactra-Menveo group and the Naive group ranged between 6.94 (serogroup A)-29.24 (serogroup W) across serogroups, with all LLs of the 95% Cis > 1.

Table 11.4.1-5 hSBA GMTs (95% CI) against *N meningitidis* serogroups A, C, W and Y and Vaccine Group Ratios of hSBA GMTs at day 1, day 4, day 6 and day 29 after Vaccination (Per Protocol Set, day 29)

		Vaccine Groups				Vaccine Group Ratio			
	Study Groups	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive	Menveo-Menveo : Menactra-Menveo	Menveo-Menveo : Naive	Menactra-Menveo : Naive	Pooled Menveo/ Menactra-Menveo : Naive
	Study day	**N=290**	**N=282**	**N=572**	**N=93**				
Serogroup A	day 1	2.81 (2.54-3.11) N=289	2.95 (2.67-3.27)	2.88 (2.68-3.09) N=571	2.27 (1.90-2.71)				
	day 4	2.83 (2.43-3.29) N=144	3.00 (2.57-3.51) N=138	2.91 (2.61-3.25) N=282	2.25 (1.73-2.93) N=48	0.94 (0.76-1.17)	1.26 (0.93-1.70)	1.34 (0.98-1.82)	1.29 (0.97-1.72
	day 6	12.87 (9.63-17.19) N=146	10.17 (7.57-13.66) N=140	11.47 (9.32-14.10) N=286	2.48 (1.46-4.20) N=44	1.27 (0.84-1.91)	5.19 (2.84-9.47)	4.10 (2.24-7.50)	4.62 (2.62-8.15)
	day 29	210.10 (181.07-243.78)	236.69 (203.56-275.20)	222.81 (200.43-247.70)	32.11 (24.70-41.76)	0.89 (0.72-1.10)	6.54 (4.84-8.85)	7.37 (5.44-9.98)	6.94 (5.23-9.21)
Serogroup C	day 1	16.11 (13.28-19.54) N=288	10.72 (8.82-13.03) N=281	13.17 (11.48-15.12) N=569	5.06 (3.60-7.10)				
	day 4	22.96 (17.31-30.45) N=144	14.29 (10.71-19.07) N=138	18.21 (14.86-22.31) N=282	6.69 (4.10-10.90) N=48	1.61 (1.07-2.40)	3.43 (1.95-6.04)	2.14 (1.21-3.77)	2.72 (1.60-4.64)
	day 6	92.27 (68.91-123.56) N=145	90.06 (66.84-121.35) N=139	91.18 (74.04-112.30) N=284	6.71 (3.95-11.40) N=44	1.02 (0.67-1.56)	13.75 (7.51-25.19)	13.42 (7.31-24.66)	13.59 (7.70-24.00)

		Vaccine Groups				Vaccine Group Ratio			
	Study Groups	**Menveo-Menveo**	**Menactra-Menveo**	**Pooled Menveo/ Menactra-Menveo**	**Naive**	**Menveo-Menveo : Menactra-Menveo**	**Menveo-Menveo : Naive**	**Menactra-Menveo : Naive**	**Pooled Menveo/ Menactra-Menveo : Naive**
	Study day	**N=290**	**N=282**	**N=572**	**N=93**				
	day 29	1159.93 (977.33-1376.63)	1057.66 (888.74-1258.68) N=281	1108.42 (981.09-1252.27) N=571	59.70 (44.12-80.78)	1.10 (0.86-1.40)	19.43 (13.73-27.51)	17.72 (12.50-25.12)	18.57 (13.40-25.73)
Serogroup W	day 1	22.07 (18.54-26.29) N=289	23.46 (19.66-28.00)	22.75 (20.09-25.76) N=571	12.21 (8.98-16.62)				
	day 4	25.90 (20.13-33.32) N=144	33.87 (26.18-43.82) N=138	29.53 (24.66-35.37) N=282	13.80 (8.92-21.35) N=48	0.76 (0.53-1.10)	1.88 (1.13-3.11)	2.46 (1.48-4.08)	2.14 (1.33-3.44)
	day 6	112.49 (86.26-146.71) N=146	143.75 (109.61-188.54) N=140	126.84 (104.90-153.37) N=286	15.98 (9.85-25.93) N=44	0.78 (0.54-1.14)	7.04 (4.05-12.22)	8.99 (5.16-15.66)	7.94 (4.72-13.35)
	day 29	1394.65 (1176.59-1653.11)	1883.96 (1585.12-2239.15) N=281	1617.11 (1431.93-1826.23) N=571	55.31 (40.90-74.80) N=92	0.74 (0.58-0.94)	25.21 (17.83-35.65)	34.06 (24.06-48.23)	29.24 (21.09-40.52)
Serogroup Y	day 1	9.24 (7.81-10.94) N=287	8.22 (6.93-9.75) N=281	8.72 (7.74-9.83) N=568	4.56 (3.39-6.13)				
	day 4	10.87 (8.26-14.32) N=143	12.12 (9.16-16.04) N=138	11.47 (9.43-13.95) N=281	4.63 (2.88-7.44) N=48	0.90 (0.61-1.33)	2.35 (1.36-4.07)	2.62 (1.51-4.54)	2.48 (1.48-4.14)

	Vaccine Groups				Vaccine Group Ratio			
Study Groups	**Menveo-Menveo**	**Menactra-Menveo**	**Pooled Menveo/ Menactra-Menveo**	**Naive**	**Menveo-Menveo : Menactra-Menveo**	**Menveo-Menveo : Naive**	**Menactra-Menveo : Naive**	**Pooled Menveo/ Menactra-Menveo : Naive**
Study day	**N=290**	**N=282**	**N=572**	**N=93**				
day 6	63.30 (47.73-83.95) N=145	61.56 (46.18-82.05) N=140	62.44 (51.06-76.34) N=285	6.44 (3.86-10.76) N=44	1.03 (0.69-1.54)	9.82 (5.47-17.64)	9.55 (5.31-17.19)	9.69 (5.59-16.79)
day 29	1066.66 (900.67-1263.25)	1007.62 (848.53-1196.54) N=281	1037.19 (919.46-1169.98) N=571	37.40 (27.75-50.42)	1.06 (0.83-1.35)	28.52 (20.23-40.20)	26.94 (19.09-38.02)	27.73 (20.10-38.26)

Source: Table 14.2.1.4.
Abbreviations: CI, confidence interval; GMTs, geometric mean titers; hSBA, human serum bactericidal assay; N, total number of subjects.

Table 11.4.1-6 hSBA Geometric Mean Ratios (GMRs) (95% CI) against *N meningitidis* serogroups A, C, W and Y at day 4, day 6 and day 29 compared to day 1 after Vaccination (Per Protocol Set, day 29)

	Vaccine Groups			
Study Groups	**Menveo-Menveo**	**Menactra-Menveo**	**Pooled Menveo/ Menactra-Menveo**	**Naive**
Geometric Mean Ratios	**N=290**	**N=282**	**N=572**	**N=93**
SerogroupA				
day 4/day1	1.02 (0.93-1.12) N=144	1.07 (0.97-1.17) N=138	1.04 (0.98-1.11) N=282	0.99 (0.84-1.16) N=48
day 6/day1	4.58 (3.49-6.00) N=145	3.25 (2.46-4.28) N=140	3.87 (3.19-4.70) N=285	1.09 (0.66-1.78) N=44
day 29/day1	75.02 (63.87-88.12) N=289	80.13 (68.09-94.30)	77.50 (69.12-86.90) N=571	14.14 (10.65-18.77)
SerogroupC				
day 4/day1	1.12 (0.99-1.28) N=143	1.35 (1.19-1.54) N=137	1.23 (1.12-1.35) N=280	1.21 (0.97-1.51) N=48
day 6/day1	7.25 (5.39-9.75) N=144	7.94 (5.87-10.73) N=139	7.58 (6.14-9.36) N=283	1.45 (0.85-2.48) N=44
day 29/day1	71.72 (58.88-87.37) N=288	97.13 (79.51-118.65) N=280	83.29 (72.34-95.89) N=568	11.81 (8.34-16.71)
SerogroupW				
day 4/day1	1.05 (0.91-1.23) N=144	1.40 (1.20-1.63) N=138	1.21 (1.09-1.35) N=282	1.14 (0.88-1.48) N=48
day 6/day1	5.71 (4.37-7.45) N=145	6.27 (4.78-8.23) N=140	5.98 (4.95-7.23) N=285	1.32 (0.81-2.15) N=44
day 29/day1	63.63 (51.37-78.81) N=289	80.61 (64.88-100.14) N=281	71.50 (61.38-83.27) N=570	4.57 (3.13-6.68) N=92

	Vaccine Groups			
Study Groups	**Menveo-Menveo**	**Menactra-Menveo**	**Pooled Menveo/ Menactra-Menveo**	**Naive**
Geometric Mean Ratios	**N=290**	**N=282**	**N=572**	**N=93**
Serogroup Y				
day 4/day1	1.35 (1.15-1.59) N=142	1.31 (1.11-1.54) N=137	1.33 (1.19-1.49) N=279	0.99 (0.75-1.31) N=48
day 6/day1	6.09 (4.53-8.19) N=143	8.59 (6.37-11.59) N=140	7.22 (5.85-8.92) N=283	1.48 (0.87-2.52) N=44
day 29/day1	116.58 (94.42-143.95) N=287	123.41 (99.69-152.78) N=280	119.91 (103.21-139.30) N=567	8.21 (5.67-11.89)

Source: Table 14.2.1.4.
Abbreviations: CI, confidence interval; GMRs, geometric mean ratios; hSBA, human serum bactericidal assay; N, total number of subjects.

2. *To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the primary vaccination with Menactra in comparison with naturally-acquired level in vaccine-naive individuals, as measured by the percentages of subjects with hSBA titers ≥ 8 and hSBA GMTs at day 1.*

Percentage of subjects with hSBA titers ≥ 8 at day 1 (persistence)

The numbers and percentages of subjects with hSBA titer ≥ 8 against *N meningitidis* serogroups A, C, W, and Y at day 1 are presented in Table 11.4.1-7. Group differences between the Menveo-Menveo, Menactra-Menveo, and Naive groups are provided in Table 14.2.1.3.

At day 1 (pre-vaccination), 12.46% of subjects in the Menveo-Menveo group and 15.46% of subjects in the Menactra-Menveo group had hSBA titers ≥ 8 against serogroup A. Percentages were, however, higher than in the Naive group (4.17%), with a vaccine group difference between the Menveo-Menveo and Menactra-Menveo groups vs. the Naive group of 8.29% (95% CI: 1.55%-13.44%) and 11.30% (95% CI: 4.40%-16.78%), respectively.

For the other serogroups percentages ranged from 53.63% to 61.82% for serogroup C, from 76.09% to 76.63% for serogroup W, and from 47.24% to 53.90% for serogroup Y, across subjects primed 4 to 6 years before, percentages that were higher in the Menveo-Menveo and Menactra-Menveo groups than those seen in the Naive group, with vaccine group differences between Menveo-Menveo and Menactra-Menveo group vs. the Naive group ranging between 14.64%-26.41% across serogroups (LLs of the 95% CIs all > 0; Table 14.2.1.3)..

Table 11.4.1-7 Numbers and Percentages of Subjects (95% CI) with hSBA titer ≥ 8 against *N meningitidis* serogroups A, C, W and Y at day 1 (Per Protocol Set, day 1)

Study Groups	Menveo-Menveo	Menactra-Menveo	Naive
	N=298	N=291	N=96
Serogroup A	37 (12.46%) (8.93%-16.76%) N=297	45 (15.46%) (11.51%-20.41%)	4 (4.17%) (1.15%-10.33%)
Serogroup C	183 (61.82%) (56.02%-67.38%) N=296	155 (53.63%) (47.70%-59.49%) N=289	34 (35.42%) (25.92%-45.84%)
Serogroup W	226 (76.09%) (70.83%-80.83%) N=297	223 (76.63%) (71.34%-81.37%)	59 (61.46%) (50.97%-71.22%)
Serogroup Y	159 (53.90%) (48.03%-59.69%) N=295	137 (47.24%) (41.38%-53.16%) N=290	30 (31.25%) (22.18%-41.52%)

Source: Table 14.2.1.3.
Abbreviations: CI, confidence interval; hSBA, human serum bactericidal assay; N, total number of subjects.

hSBA GMTs at Day1 (persistence)

Table 11.4.1-8 presents the hSBA GMTs against *N meningitidis* serogroups A, C, W, and Y at day 1. The vaccine group differences are provided in Table 14.2.1.5.

At day 1 (pre-vaccination), persistence of hSBA GMTs against serogroup A was low in both groups of subjects who previously received Menveo or Menactra, with GMTs of 2.80 and 3.01, respectively. They were, however, slightly higher than in the Naive group (GMT: 2.26) with a vaccine group difference of 1.24 (95% CI: 1.01-1.51) between the Menveo-Menveo and the Naive groups, and 1.33 (95% CI: 1.09-1.63) between the Menactra-Menveo and Naive groups.

Persistence of antibodies in terms of hSBA GMTs against serogroups C, W, and Y was higher, with GMTs at day 1 in ranging between 8.34-23.33 across serogroups in both groups of subjects who previously received Menveo or Menactra and between 4.44-12.33 in the Naive group. The group differences between the Menveo-Menveo and the Naive groups ranged between 1.83-3.05 across serogroups C, W, and Y; between the Menactra-Menveo and the Naive groups, the differences ranged between 1.88-2.03 across serogroups C, W, and Y. All LLs of the 95% CIs were > 1.

Table 11.4.1-8 hSBA GMTs (95% CI) against *N meningitidis* serogroups A, C, W and Y at day 1 (Per Protocol Set, day 1)

Study Groups	Menveo-Menveo	Menactra-Menveo	Naive
	N=298	N=291	N=96
SerogroupA	2.80 (2.53-3.09) N=297	3.01 (2.72-3.33)	2.26 (1.90-2.70)
SerogroupC	15.99 (13.23-19.31) N=296	10.63 (8.78-12.87) N=289	5.24 (3.76-7.30)
SerogroupW	22.54 (18.98-26.77) N=297	23.33 (19.61-27.75)	12.33 (9.11-16.68)
SerogroupY	9.12 (7.72-10.77) N=295	8.34 (7.05-9.87) N=290	4.44 (3.32-5.95)

Source: Table 14.2.1.5.
Abbreviations: CI, confidence interval; GMTs, geometric mean titers; hSBA, human serum bactericidal assay; N, total number of subjects.

11.4.2 Statistical/Analytical Issues

The general statistical approach planned for this trial has been described in section 9.7. This section is to address statistical issues specifically as they relate to data from this clinical study. These issues are discussed briefly here and the reader is referred to the statistical Appendix 16.1.9 for further details. Any departures from preplanned analyses are noted.

11.4.2.1 Adjustments for Covariates

As primary analyses, vaccine-group effects were not adjusted. As secondary analyses, vaccine-group effects were adjusted for the log-transformed pre-vaccination antibody titer. The group titers of Naive subjects were always summarized without any adjustment (ie unadjusted GMTs and percentages). Details are given in Appendix 16.1.9 of the CSR.

11.4.2.2 Handling of Dropouts or Missing Data

Missing immunogenicity values were assumed MCAR and therefore considered not informative. No imputation methods were used to address missing immunogenicity or safety data.

11.4.2.3 Interim Analyses and Data Monitoring

There were no planned interim analyses for this study.

No DMC was used for this study.

11.4.2.4 Multicenter Studies

Center was not included in the statistical model.

11.4.2.5 Multiple Comparisons/Multiplicity

The two hypotheses associated to the primary objective were tested in a hierarchical manner; therefore, no adjustment for multiplicity was needed.

11.4.2.6 Use of an "Immunogenicity Subset" of Subjects

To limit the amount of blood samples per subject and to be able to assess the immune response to Menveo both at day 4 and day 6 after vaccination, subjects in each study group (Menveo-Menveo, Menactra-Menveo, and Naive) were randomized into one of two different blood draw schedules according to a 1:1 ratio to have blood draws taken at either day 1, day 4 and day 29, or at day 1, day 6, and day 29.

11.4.2.7 Active-control Studies Intended to Show Equivalence

Not applicable.

11.4.2.8 Examination of Subgroups

Using the PPS (day 29), the analysis of the hSBA seroresponse against *N meningitidis* serogroups A, C, W, and Y was replicated by sex (Table 14.2.1.1.1) and race (Table 14.2.1.1.2). There was no meaningful effect of these factors seen on the percentages of subjects with hSBA seroresponse against any of the serogroups. However, there were very few subjects enrolled in some of the race categories, making the assessment difficult.

11.4.3 Tabulation of Individual Response Data

Response data are listed by subject in Appendix 16.2.6.

11.4.4 Drug Dose, Drug Concentration, and Relationships to Response

Not applicable.

11.4.5 Drug-drug and Drug-disease Interactions

Not applicable.

11.4.6 By-subject Displays

Not applicable.

11.4.7 Immunogenicity Conclusions

Primary Immunogenicity Objectives

- At day 29 after the Menveo booster dose the percentage of subjects with hSBA seroresponse for serogroups A, C, W, and Y ranged from 95.49% to 96.86% across serogroups in the Menveo-Menveo group and from 93.24% to 96.45% across serogroups in the Menactra-Menveo group (Table 11.4.1-1).
- For both primary immunogenicity objectives, the criterion to demonstrate a sufficient immune response following a booster dose of Menveo was met. The lower limit of the one-sided 97.5% CI for the percentage of subjects with hSBA seroresponse against serogroups A, C, W and Y at day 29 after booster vaccination with Menveo was greater than 75%, both for subjects who previously were administered Menveo and for those who were previously administered Menactra (Table 11.4.1-1).

Secondary Immunogenicity Objectives

hSBA seroresponse at day 4, day 6, and day 29

- A booster dose of Menveo induced an anamnestic immune response in subjects who previously received either Menveo or Menactra, as shown by the higher percentages of subjects with hSBA seroresponse against *N meningitidis* serogroups A, C, W, and Y in the Menveo-Menveo, Menactra-Menveo, and pooled Menveo/Menactra-Menveo groups compared to subjects who received a first dose of Menveo (Naive group) observed from day 6 (Table 11.4.1-2). By day 29, across serogroups 93.24%-96.86% of subjects in the Menveo-Menveo and Menactra-Menveo groups had hSBA seroresponse, compared to 35.87%-65.59% of subjects in the Naive group.

hSBA Titers ≥ 8 and ≥ 16 at day1, day 4, day 6, and day 29

- The anamnestic immune response to a booster dose of Menveo in subjects who previously received either Menveo or Menactra was also shown by the higher percentages of subjects with hSBA titers ≥ 8 and ≥ 16 against *N meningitidis* serogroups A, C, W, and Y in the Menveo-Menveo, Menactra-Menveo, and pooled Menveo/Menactra-Menveo groups compared to the Naive group observed from day 4, with non-overlapping 95% CIs between primed and Naive groups observed starting from day 6 (Table 11.4.1-3). By day 29, at least 98.62% of subjects in the primed groups had hSBA titers ≥ 8 against any serogroup (100% against serogroup W in both primed groups; Table 11.4.1-3), and at least 97.52% had hSBA titers ≥ 16 against any serogroup (Table 11.4.1-4).

hSBA GMTs at day1, day 4, day 6, and day 29

- In subjects who previously received either Menveo or Menactra, also hSBA GMTs against *N meningitidis* serogroups A, C, W, and Y were higher compared to subjects

who received a first dose of Menveo (Naive group) from day 6 (Table 11.4.1-5). By day 29, hSBA GMTs against all serogroups had further increased in all study groups, with GMRs compared to day 1 ranging between 63.63-123.41 across serogroups in the Menveo-Menveo and Menactra-Menveo groups, and between 4.57-14.14 across serogroups in the Naive group.

hSBA titers ≥ 8 at day 1 (Persistence)

- Percentages of subjects with hSBA titers ≥ 8 at day 1 were 12.46% and 15.46% against serogroup A in Menveo-Menveo and Menactra-Menveo groups, and were higher than in the Naive group, with a vaccine group difference between the Menveo-Menveo and Menactra-Menveo groups vs. the Naive group of 8.29% (95% CI: 1.55%-13.44%) and 11.30% (95% CI: 4.40%-16.78%), respectively (Table 14.2.1.3). For the other serogroups percentages ranged from 53.63% to 61.82% for serogroup C, from 76.09% to 76.63% for serogroup W, and from 47.24% to 53.90% for serogroup Y, across subjects primed 4 to 6 years before, percentages that were higher in the Menveo-Menveo and Menactra-Menveo groups than those seen in the Naive group, with vaccine group differences between Menveo-Menveo and Menactra-Menveo group vs. the Naive group ranging between 14.64%-26.41% across serogroups (LLs of the 95% CIs all > 0; Table 14.2.1.3).

hSBA GMTs at day 1 (Persistence)

- At baseline (day 1), hSBA GMTs ranged between 2.80 (against serogroup A in the Menveo-Menveo group) and 23.33 (against serogroup W in the Menactra-Menveo group) in the primed groups, and were higher than those observed at day 1 in the Naive group (ranging from 2.26 against serogroup A to 12.33 against serogroup W; Table 11.4.1-8).

12. SAFETY EVALUATION

12.1 Extent of Exposure

An overview of the safety populations analyzed in this study is provided in Table 12.1-1.

All enrolled subjects in the Menveo-Menveo group, 300/301 subject (>99%) in the Menactra-Menveo group, and 100/102 subjects (98%) in the Naive group were exposed to the study vaccine, provided unsolicited safety data and solicited safety data at 30 minutes after vaccination, and were included in the safety sets for unsolicited AEs and solicited AEs at 30 minutes (Table 12.1-1).

Table 12.1-1 Number (%) of Subjects Enrolled and Number (%) of Subjects Included in and Excluded From the Exposed, Solicited Safety, Unsolicited Safety, Overall Safety Sets, by Reason for Exclusion

Study Groups	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
	N=301	N=301	N=602	N=102
Population sets:				
Enrolled	301 (100%)	301 (100%)	602 (100%)	102 (100%)
Exposed	301 (100%)	300 (> 99%)	601 (> 99%)	100 (98%)
Study vaccine not administered at all	0	1 (< 1%)	1 (< 1%)	2 (2%)
Safety set - solicited AEs	301 (100%)	300 (> 99%)	601 (> 99%)	100 (98%)
Safety set – unsolicited AEs	301 (100%)	300 (> 99%)	601 (> 99%)	100 (98%)
Overall Safety Set	301 (100%)	300 (> 99%)	601 (> 99%)	100 (98%)

Source: Table 14.1.1.1; Table 14.1.1.10.
Abbreviations: AEs, adverse events.

12.2 Adverse Events

This section provides the results for the pooled Menveo/Menactra-Menveo group (also referred to as "primed subjects") and the Naive group. The results for the separate primed groups (Menveo-Menveo and Menactra-Menveo) are provided in Table 14.2.1.1 to Table 14.3.5.4.

12.2.1 Brief Summary of Adverse Events

Solicited AEs (6 Hours – day 7)

Between 6 hours through day 7, at least 1 solicited AE was reported in 65% of primed subjects (group) and 55% subjects in the Naive group (Table 12.2.1-1). At least one solicited local AE was reported in 36% of primed subjects and 42% of subjects in the Naive group, and solicited systemic AEs by 52% of primed subjects and 36% of subjects in the Naive group.

Table 12.2.1-1 Overview of Subjects With Solicited AEs With Onset From day 1 Through day 7 After Vaccination – Solicited Safety Set (6 hours – day 7)

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=592	N=97
Any Solicited AE	382 (65%)	53 (55%)
Local	216 (36%)	41 (42%)
Systemic	310 (52%)	35 (36%)

Source: Table 14.3.1.1.
Abbreviation: AE, adverse event.

Unsolicited AEs

All Unsolicited AEs Between day 1 – day 29

Between day 1 through day 29, at least 1 unsolicited AE was reported in 25% of primed subjects (group) and 22% subjects in the Naive group (Table 12.2.1-2). At least possibly related unsolicited AEs were reported in 8% of primed subjects and 11% of subjects in the Naive group.

SAEs, Medically Attended AEs, and AEs Leading to Withdrawal

Few SAEs were reported during the study. There were 5 (1%) primed subjects (Menveo/Menactra-Menveo group) and 3 (3%) vaccine-naive subjects (Naive group) that reported at least 1 SAE; none of the SAEs reported in this study was considered possibly or probably related to the study vaccine (Table 12.2.1-3).

Medically attended AEs were reported in 30% of primed subjects and 19% of vaccine-naive subjects, respectively (Table 12.2.1-3). At least one medically attended AE that was considered at least possibly related to the study vaccine by the investigator was reported in 4 (1%) primed subjects and 1 (1%) vaccine-naive subject (Table 12.2.1-3; more details are provided in Table 14.3.2.7.5). The following at least possibly related medically attended AEs (all non-serious) were reported: 2 cases of urticaria (onset on day 10 and day 130; Menactra-Menveo group); fatigue and headache with onset on day 1, followed by myalgia with onset at day 4 (Menactra-Menveo group); anxiety with onset on day 22 in a subject in Menactra-Menveo group; pyrexia with onset on day 1 in a Naive subject, Naive and lymphadenopathy with onset on day 3 in one subject in Menveo-Menveo group.

There were no AEs leading to premature withdrawal from the study or deaths reported in this study (Table 12.2.1-3).

Table 12.2.1-2 Overview of Subjects With Unsolicited AEs With Onset From day 1 Through day 29 After Vaccination – Unsolicited Safety Set

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=601	N=100
Any AE	152 (25%)	22 (22%)
At least possibly related AE	50 (8%)	11 (11%)

Source: Table 14.3.1.13.1; Table 14.3.1.16.1.
Abbreviation: AE, adverse event.

Table 12.2.1-3 Overview of Subjects With SAEs, Medically Attended AEs and AEs leading to withdrawal With Onset From day 1 Through 181 After Vaccination – Unsolicited Safety Set

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=601	N=100
Any SAE	5 (1%)	3 (3%)
At least possibly related SAE	0	0
Medically attended AEs	181 (30%)	19 (19%)
Possibly related medically attended AEs	4 (1%)	1 (1%)
AE leading to premature withdrawal	0	0
Death	0	0

Source: Table 14.3.2.1; Table 14.3.2.2; Table 14.3.2.3; Table 14.3.2.4; Table 14.3.2.6; Table 14.3.2.7.5.
Abbreviations: AEs, adverse events; SAEs, serious adverse events.

12.2.2 Display of Adverse Events

An overview of subjects experiencing solicited local and systemic AEs is presented in Table 12.2.1-1. Detailed summaries of individuals with solicited local and systemic AEs are presented in Table 12.2.3-1 and Table 12.2.3-2.

A summary of subjects with unsolicited AEs is presented in Table 12.2.3-3. A summary of subjects with possibly or probably related unsolicited AEs are summarized in Table 12.2.3-4. Subjects SAEs leading to deaths and with other SAEs are summarized in Table 12.2.1-3. Subjects with unsolicited AEs leading to premature withdrawal are summarized in Table 12.2.1-3.

12.2.3 Analysis of Adverse Events

Solicited Local AEs

From 6 hours through day 7 after vaccination, the most frequently reported solicited local AEs in both primed and vaccine-naive subjects was injection site pain, reported in 36% of primed subjects and 41% of subjects in the Naive group (Table 12.2.3-1). In primed subjects, injection site erythema was reported in 3% of subjects, and injection site induration in 4%, while in the Naive group, injection site erythema was reported in 11% of subjects and injection site induration in 9%.

Severe injection site pain was reported in 11 (2%) primed subjects and 2 (2%) subjects in the Naive group (Table 12.2.3-1). Severe injection site induration was not reported by any subject, while severe injection site erythema was only reported by 2 (2%) subjects in the Naive group.

Most of the solicited local AEs had their onset between 6 hours and day 3 after vaccination (Table 14.3.1.7) and resolved within 3 days from onset (Table 14.3.1.5).

Table 12.2.3-1 Numbers and Percentages of Subjects With Any and Severe Solicited Local AEs with Onset from 6 hours through day 7 After Vaccination – Solicited Safety Set (6 hours – day 7)

Study Groups		Pooled Menveo/ Menactra-Menveo	Naive
		N=592	N=97
Injection site erythema (mm)	Any	20 (3%) N=573	10 (11%) N=92
	> 100 mm	0 N=573	2 (2%) N=92
Injection site induration (mm)	Any	24 (4%) N=572	8 (9%) N=92
	> 100 mm	0 N=572	0 N=92
Injection site pain	Any	210 (36%) N=588	40 (41%)
	Severe	11 (2%) N=588	2 (2%)

Source: Table 14.3.1.1; Table 14.3.1.2.
Abbreviation: AEs, adverse events.

Solicited Systemic AEs

From 6 hours through day 7 after vaccination, the most frequently reported solicited systemic AEs were fatigue (38% in primed subjects and 20% of subject in the Naive group) and headache (31% and 22%) (Table 12.2.3-2). Reporting for all other solicited systemic AEs ranged between 6%-18% of subjects across the pooled Menveo/Menactra-Menveo and Naive groups.

Severe solicited systemic AEs were reported in 2% of subjects or less in primed and vaccine-naive subjects except for severe headache (4%) and severe fatigue (3%) in the pooled Menveo/Menactra-Menveo group (Table 12.2.3-2).

Most of the solicited systemic AEs had their onset between 6 hours and day 3 after vaccination (Table 14.3.1.7) and resolved within 3 days from onset (Table 14.3.1.5).

Fever (body temperature ≥ 38.0°C) was reported in 7 (1%) primed subjects and by none of the subjects in the Naive group (Table 12.2.3-2). All cases of fever resolved within 2 days after vaccination (Table 14.3.1.5). Fever with a body temperature ≥ 40.0°C was not reported by any subject in the study (Table 12.2.3-2).

Both in the pooled Menveo/Menactra-Menveo and in the Naive group, 5% of subjects used antipyretics and/or analgesics for prevention of pain and/or fever; 7% and 10% of primed and vaccine-naive subjects, respectively, used antipyretics and/or analgesics for the treatment of pain and/or fever (Table 12.2.3-2).

Table 12.2.3-2 Numbers and Percentages of Subjects With Any Or Severe Solicited Systemic AEs and Other Indicators of Reactogenicity with Onset from 6 hours up to day 7 After Vaccination – Solicited Safety Set (6 hours – day 7)

Study Groups		Pooled Menveo/ Menactra-Menveo	Naive
		N=592	N=97
	Systemic AEs		
Chills	Any	69 (12%) N=589	10 (10%)
	Severe	2 (< 1%) N=589	1 (1%)
Nausea	Any	92 (16%) N=588	13 (13%)
	Severe	6 (1%) N=588	2 (2%)
Myalgia	Any	109 (18%) N=590	15 (15%)
	Severe	11 (2%) N=590	2 (2%)
Arthralgia	Any	82 (14%) N=589	13 (14%) N=96
	Severe	6 (1%) N=589	2 (2%) N=96
Headache	Any	182 (31%) N=589	21 (22%)
	Severe	21 (4%) N=589	2 (2%)
Fatigue	Any	223 (38%) N=591	19 (20%)
	Severe	19 (3%) N=591	2 (2%)
Loss of appetite	Any	83 (14%) N=590	6 (6%)
	Severe	6 (1%) N=590	2 (2%)

Study Groups		Pooled Menveo/ Menactra-Menveo	Naive
		N=592	N=97
Other indicators of reactogenicity			
Use of antipyretics/analgesics	Yes (Prevention)	28 (5%) N=589	5 (5%) N=96
	Yes (Treatment)	42 (7%) N=588	10 (10%) N=96
Fever	≥ 38.0°C	7 (1%)	0
	≥ 40.0°C	0	0

Source: Table 14.3.1.2.
Abbreviation: AEs, adverse events.

Unsolicited AEs

Unsolicited AEs With Onset Within 30 Minutes After Vaccination

Overall, 9 subjects (8 primed subjects and 1 in the Naive group) reported at least 1 unsolicited AE within 30 minutes after vaccination (Table 14.3.1.13.2). In primed subjects, injection site pain was reported in 2 subjects, and chills, dizziness, fatigue, myalgia, rash macular, and syncope all reported by 1 subject each. One subject in the Naive group reported injection site erythema.

Unsolicited AEs With Onset Between day 1 and day 29After Vaccination

Overall, 25% of primed subjects and 22% of vaccine-naive subjects reported at least 1 unsolicited AE between day 1 and day 29 after vaccination (Table 12.2.1-2). The most frequently reported unsolicited AEs were classified in the MedDRA SOC "infections and infestations" (9% and 6% of primed and vaccine-naive subjects, respectively), followed by "general disorders and administration site conditions" (6% and 9%, respectively) and "respiratory, thoracic and mediastinal disorders" (5% and 3%, respectively) Table 14.3.1.13.1).

The most frequently reported unsolicited AE between day 1 and day 29 after vaccination, by preferred term, was headache (reported in 3% of primed and vaccine-naive subjects), followed by fatigue (3% in primed subjects and none of the subjects in the Naive group), and nasopharyngitis (2% of primed and vaccine-naive subjects; Table 14.3.1.12.1). Most of the cases of headache and fatigue were solicited AEs that were ongoing after day 7 (Appendix 16.2.7.1.1 and Appendix 16.2.7.2).

Overall, 8% of primed subjects and 11% of subjects in the Naive group reported at least 1 possibly related unsolicited AE between day 1 and day 29 after vaccination (Table 12.2.3-3). The only at least possibly related AEs reported in more than 1% of subjects in either the pooled Menveo/Menactra-Menveo or the Naïve group were fatigue (reported in 2% of primed subjects), injection site erythema (4% in the Naive group), and injection site pruritus (2% in the Naive group).

Table 12.2.3-3 Numbers and Percentages of Subjects With Possibly or Probably Related Unsolicited AEs with Onset from day 1 up to 29 Days After Vaccination by System Organ Class and Preferred Term – Unsolicited Safety Set

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=601	N=100
Any Adverse Event	**50 (8%)**	**11 (11%)**
Blood and lymphatic system disorders	**1 (< 1%)**	**0**
Lymphadenopathy	1 (< 1%)	0
Eye disorders	**2 (< 1%)**	**0**
Oculogyric crisis	1 (< 1%)	0
Vision blurred	1 (< 1%)	0
Gastrointestinal disorders	**6 (1%)**	**2 (2%)**
Diarrhoea	3 (< 1%)	1 (1%)
Nausea	3 (< 1%)	1 (1%)
Abdominal pain upper	1 (< 1%)	0
Vomiting	1 (< 1%)	0
General disorders and administration site conditions	**22 (4%)**	**8 (8%)**
Fatigue	12 (2%)	0
Injection site erythema	3 (< 1%)	4 (4%)
Injection site induration	2 (< 1%)	1 (1%)
Injection site pain	3 (< 1%)	0
Injection site pruritus	1 (< 1%)	2 (2%)
Chills	1 (< 1%)	0
Injection site bruising	0	1 (1%)
Injection site swelling	1 (< 1%)	0
Pyrexia	0	1 (1%)
Vaccination site pruritus	1 (< 1%)	0
Infections and infestations	**1 (< 1%)**	**2 (2%)**
Nasopharyngitis	0	1 (1%)
Upper respiratory tract infection	0	1 (1%)
Viral rash	1 (< 1%)	0
Metabolism and nutrition disorders	**2 (< 1%)**	**0**
Decreased appetite	2 (< 1%)	0
Musculoskeletal and connective tissue disorders	**13 (2%)**	**0**

Study Groups	Pooled Menveo/ Menactra-Menveo	Naive
	N=601	N=100
Myalgia	8 (1%)	0
Arthralgia	6 (1%)	0
Joint stiffness	1 (< 1%)	0
Nervous system disorders	**12 (2%)**	**1 (1%)**
Headache	8 (1%)	1 (1%)
Dizziness	3 (< 1%)	0
Syncope	1 (< 1%)	0
Psychiatric disorders	**1 (< 1%)**	**0**
Anxiety	1 (< 1%)	0
Respiratory, thoracic and mediastinal disorders	**7 (1%)**	**1 (1%)**
Nasal congestion	5 (1%)	1 (1%)
Cough	2 (< 1%)	0
Oropharyngeal pain	1 (< 1%)	0
Sinus congestion	1 (< 1%)	0
Skin and subcutaneous tissue disorders	**3 (< 1%)**	**0**
Ecchymosis	1 (< 1%)	0
Pruritus	1 (< 1%)	0
Urticaria	1 (< 1%)	0
Vascular disorders	**1 (< 1%)**	**0**
Hot flush	1 (< 1%)	0

Source: Table 14.3.1.16.1.
Abbreviations: AEs, adverse events

12.2.4 Listing of Adverse Events by Subject

Solicited AEs are listed by subject in Appendix 16.2.7.1.

Unsolicited AEs are listed by subject in Appendix 16.2.7.2.

12.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

12.3.1 Listing of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

12.3.1.1 Deaths

No deaths were reported in this study (Table 14.3.2.7).

An overview of subjects with SAEs that did not lead to death is presented in section 12.3.1.2.

Detailed subject narratives for all SAEs are provided in Appendix 14.3.3.

12.3.1.2 Other Serious Adverse Events

An overview of subjects with SAEs that did not lead to death is presented here. Detailed subject narratives for all SAEs are provided in Appendix 14.3.3.

In total, 8 subjects reported 13 SAEs, none of which were assessed as possibly or probably related to the study vaccine (Table 12.3.1.2-1). SAEs were reported by 3 subjects in the Menveo-Menveo group, 2 subjects in the Menactra-Menveo group, and 3 subjects in the Naive group.

Most SAEs (8/13) started after the treatment period (> day 29). The other 4 SAEs (all in 1 subject in the Menveo-Menveo group) started within day 29: abdominal pain, tonsillitis (both at day 12), respiratory disorder, and septic shock (both at day 15). For 1 SAE (abortion spontaneous in the Naive group), only the month and year of the onset of the event was collected.

The majority of SAEs (8/13) lasted for 6 days or less and resolved completely. The other 4 SAEs lasted longer before the events resolved: major depression in the Menveo-Menveo group (16 days), suicide attempt in the Menactra-Menveo group (10 days), diverticulitis in the Naive group (13 days), and suicidal ideation in the Menactra-Menveo group (15 days). Last SAE was a spontaneous abortion.

Table 12.3.1.2-1 Listing of Subjects With Serious Adverse Events

Subject No.	Vaccine Group	Preferred Term	Onset (Study Day)	Duration (days)	Outcome	Hospitalization	Relatedness
PPD	Menveo-Menveo	Major depression	PPD (67)	16	Recovered/Resolved	Yes	None
		PPD	PPD (67)	1	Recovered/Resolved	No	None
	Menactra-Menveo	PPD	PPD (73)	10	Recovered/Resolved	Yes	None
	Naive	Diabetic ketoacidotic hyperglycaemic coma	PPD (32)	6	Recovered/Resolved	Yes	None
	Naive	Diverticulitis	PPD (168)	13	Recovered/Resolved	Yes	None
	Menveo-Menveo	PPD	PPD (125)	1	Recovered/Resolved	No	None
		PPD	PPD (125)	1	Recovered/Resolved	No	None
	Naive	PPD	FEB17	NK	Recovered/Resolved	No	None
	Menactra-Menveo	PPD	PPD (33)	15	Recovered/Resolved	Yes	None
	Menveo-Menveo	Abdominal pain	PPD (12)	6	Recovered/Resolved	Yes	None
		Tonsillitis	PPD (13)	5	Recovered/Resolved	Yes	None
		Respiratory disorder	PPD (15)	1	Recovered/Resolved	Yes	None
		Septic shock	PPD (15)	1	Recovered/Resolved	Yes	None

Source: Table 14.3.2.7.1.
Abbreviation: NK, not known.

12.3.1.3 Other Significant Adverse Events

A brief summary of medically attended AEs is provided in section 12.2.1. The listing of all medically attended AEs is provided in Table 14.3.2.7.5. No AEs leading to premature withdrawal from the study were reported in this study (Table 14.3.2.7.3).

12.3.2 Narratives of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

All SAE narratives are provided in Appendix 14.3.3. The listing of all SAEs is provided in Table 14.3.2.7.1.

12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

All SAE narratives are provided in Appendix 14.3.3.

12.4 Clinical Laboratory Evaluation

12.4.1 Listing of Individual Laboratory Measurements by Subject and Each Abnormal Laboratory Value

No safety laboratory tests were performed in this clinical study.

12.4.2 Evaluation of Each Laboratory Parameter

No safety laboratory tests were performed in this clinical study.

12.4.2.1 Laboratory Values Over Time

No safety laboratory tests were performed in this clinical study.

12.4.2.2 Individual Subject Changes

No safety laboratory tests were performed in this clinical study.

12.4.2.3 Individual Clinically Significant Abnormalities

No safety laboratory tests were performed in this clinical study.

12.5 Vital Signs, Physical Findings, and Other Observations Related to Safety

Not applicable.

12.6 Safety Conclusions

Solicited AEs And Other Indicators of Reactogenicity

- Between 6 hours through day 7, at least 1 solicited AE was reported in 65% of primed subjects (pooled Menveo/Menactra-Menveo group) and 55% subjects in the Naive group (Table 12.2.1-1). Solicited local AEs were reported by 36% of primed subjects and 42% of vaccine-naive subjects, and solicited systemic AEs by 52% of primed subjects and 36% of vaccine-naive subjects.
- The most frequently reported solicited local AEs was injection site pain, both for primed subjects (36%) and vaccine-naive subjects (41%; Table 12.2.3-1) and the most frequently reported systemic reactions was fatigue (38% of primed subjects and 20% of vaccine-naive subjects; Table 12.2.3-2).
- Most of the solicited AEs were mild to moderate in intensity, had their onset between 6 hours and day 3 after vaccination (Table 14.3.1.7) and resolved within 3 days from onset (Table 14.3.1.5).
- Fever (body temperature $\geq$ 38.0°C) was reported in 7 (1%) primed subjects and by none of the subjects in the Naive group (Table 12.2.3-2). All cases of fever resolved within 2 days after vaccination (Table 14.3.1.5). Fever with a body temperature $\geq$ 40.0°C was not reported by any subject in the study (Table 12.2.3-2).
- Both in the pooled Menveo/Menactra-Menveo and in the Naive group, 5% of subjects used antipyretics and/or analgesics for prevention of pain and/or fever; 7% and 10% of primed and vaccine-naive subjects, respectively, used antipyretics and/or analgesics for the treatment of pain and/or fever (Table 12.2.3-2).

Unsolicited AEs

- Overall, 9 subjects (8 primed subjects [pooled Menveo/Menactra-Menveo group] and 1 in the Naive group) reported at least 1 unsolicited AE within 30 minutes after vaccination (Table 14.3.1.13.2).
- Overall, 25% of primed subjects and 22% of subjects in the Naive group reported any unsolicited AE between day 1 and day 29 after vaccination (Table 12.2.1-2). The most frequently reported unsolicited AE between day 1 and day 29 after vaccination, by preferred term, was headache (reported in 3% of primed and vaccine-naive subjects; Table 14.3.1.12.1).
- Overall, 8% of primed subjects and 11% of subjects in the Naive group reported at least 1 possibly related unsolicited AE between day 1 and day 29 after vaccination (Table 12.2.3-3). The only at least possibly related AEs reported in more than 1% of subjects in either the pooled Menveo/Menactra-Menveo or the Naïve group were fatigue (reported in 2% of primed subjects), injection site erythema (4% in the Naive group), and injection site pruritus (2% in the Naive group).

- Medically attended AEs were reported in 30% of primed subjects and 19% of vaccine-naive subjects, respectively (Table 12.2.1-3). Overall, across primed and vaccine-naive subjects, 5 subjects reported medically attended AEs that were considered at least possibly related to the study vaccine by the investigator (Table 12.2.1-3; more details are provided in Table 14.3.2.7.5).
- Few SAEs were reported during the study: 5 (1%) primed subjects and 3 (3%) vaccine-naive subjects reported at least 1 SAE; none of the SAEs reported in this study was considered at least possibly related to the study vaccine (Table 12.2.1-3).
- There were no AEs leading to premature withdrawal from the study or deaths reported in this study (Table 12.2.1-3).

13. DISCUSSION AND OVERALL CONCLUSIONS

This was a phase 3b study that enrolled 704 subjects to evaluate the response to a single booster dose of Menveo administered to healthy adolescents and adults 15 through 55 years of age approximately 4-6 years after primary vaccination with meningococcal ACWY vaccine (either Menveo or Menactra).

The study was successful in demonstrating that a single booster dose of Menveo induced a sufficient immune response (the lower limit of the one-sided 97.5% CI for the percentage of subject with hSBA seroresponse at day 29 against serogroups A, C, W, and Y was greater than 75%), irrespective of the meningococcal quadrivalent conjugated vaccine used for priming (Menveo or Menactra). The response to the booster dose was anamnestic, as evidenced by exponentially higher hSBA titers after a booster dose in primed subjects (GMRs at day 29 compared to day 1 ranging 63.63-123.41 across serogroups) compared with Naive individuals given a first dose of meningococcal vaccine (GMRs at day 29 compared to day 1 ranging 4.57-14.14). Percentages of primed subjects with hSBA titer ≥ 8 ranged from 47.14%-97.86% already at study day 6.

Persistence of immune responses at 4-6 years after primary vaccination was measured by percentages of subjects with hSBA ≥ 8 and GMTs at day 1 (pre-vaccination). Percentages of subjects with hSBA ≥ 8 were 12.46% (Menveo-Menveo) and 15.46% (Menactra-Menveo) for serogroup A, 61.82% and 53.63% for serogroup C, 76.09% and 76.63% for serogroup W, and 53.90% and 47.24% for serogroup Y. GMTs were higher in primed subjects compared to vaccine-naive controls, especially against serogroup C, W and Y.

Overall, the safety profile of the vaccine was similar in subjects who were primed compared to subject were given a first dose in this study.

The frequencies of unsolicited AEs reported within 1 month after vaccination were also balanced between all study groups, and few at least possibly related unsolicited AEs were reported across groups. All reported SAEs (13 in 8 subjects) were considered not related to study vaccination. No deaths or AEs leading to withdrawal from the study were reported.

In conclusion, Menveo induced an anamnestic response within 5 days after vaccination in individuals primed with a quadrivalent conjugate meningococcal vaccine 4-6 years earlier. The vaccine was generally well tolerated and was not associated with any safety concern.

14.0 TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

14.1 Demographic Data

14.1.1 Summary Tables

Table 14.1.1.1
Overview of Sets Analyzed
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
All Enrolled Set	301 (100%)	301 (100%)	102 (100%)	704 (100%)
All Exposed Set	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)
FAS (Day 29, visit 4)	297 (99%)	296 (98%)	96 (94%)	689 (98%)
Serogroup A	297 (99%)	296 (98%)	96 (94%)	689 (98%)
Serogroup C	297 (99%)	294 (98%)	96 (94%)	687 (98%)
Serogroup W	297 (99%)	294 (98%)	95 (93%)	686 (97%)
Serogroup Y	297 (99%)	294 (98%)	96 (94%)	687 (98%)
FAS (Day 1, visit 1)	301 (100%)	298 (99%)	97 (95%)	696 (99%)
Serogroup A	300 (>99%)	298 (99%)	97 (95%)	695 (99%)
Serogroup C	299 (99%)	296 (98%)	97 (95%)	692 (98%)
Serogroup W	300 (>99%)	298 (99%)	97 (95%)	695 (99%)
Serogroup Y	298 (99%)	297 (99%)	97 (95%)	692 (98%)
PPS (Day 29, visit 4)	290 (96%)	282 (94%)	93 (91%)	665 (94%)
Serogroup A	290 (96%)	282 (94%)	93 (91%)	665 (94%)
Serogroup C	290 (96%)	281 (93%)	93 (91%)	664 (94%)
Serogroup W	290 (96%)	281 (93%)	92 (90%)	663 (94%)
Serogroup Y	290 (96%)	281 (93%)	93 (91%)	664 (94%)
PPS (Day 1, visit 1)	298 (99%)	291 (97%)	96 (94%)	685 (97%)
Serogroup A	297 (99%)	291 (97%)	96 (94%)	684 (97%)
Serogroup C	296 (98%)	289 (96%)	96 (94%)	681 (97%)
Serogroup W	297 (99%)	291 (97%)	96 (94%)	684 (97%)
Serogroup Y	295 (98%)	290 (96%)	96 (94%)	681 (97%)
Solicited Safety Set				
30 min	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)
6h - Day 3	296 (98%)	296 (98%)	97 (95%)	689 (98%)
Day 4 - Day 7	296 (98%)	296 (98%)	97 (95%)	689 (98%)
6h - Day 7	296 (98%)	296 (98%)	97 (95%)	689 (98%)
Unsolicited Safety Set	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)
Overall Safety set: Solicited and Unsolicited AEs	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)

PPD

Table 14.1.1.2
Study Terminations Throughout the Study
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects Enrolled	301 (100%)	301 (100%)	102 (100%)	704 (100%)
Total Number of Subjects Exposed	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)
Completed Protocol	298 (99%)	288 (96%)	97 (95%)	683 (97%)
Primary Reason For Discontinuation From Study	3 (1%)	13 (4%)	5 (5%)	21 (3%)
Withdrawal by Subject	0	1 (< 1%)	1 (1%)	2 (< 1%)
Lost to Follow-up	3 (1%)	11 (4%)	2 (2%)	16 (2%)
Other	0	1 (< 1%)	2 (2%)	3 (< 1%)
ENROLLMENT GROUP CLOSED PRIOR TO SUBJECT BEING RANDOMIZED	0	0	1 (1%)	1 (< 1%)
SITE UNABLE TO RANDOMIZE SUBJECT IN SBIR DUE TO ENROLMENT TARGET FOR VACCINE NAIVE GROUP BEING	0	0	1 (1%)	1 (< 1%)
SUBJECT WAS NOT RANDOMIZED DUE TO MENACTRA ARM CLOSED	0	1 (< 1%)	0	1 (< 1%)

PPD

Table 14.1.1.2.1
Study Terminations (From Day 1 Through Day 29)
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects Enrolled	301 (100%)	301 (100%)	102 (100%)	704 (100%)
Total Number of Subjects Exposed	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)
Completed Study Period	300 (>99%)	298 (99%)	98 (96%)	696 (99%)
Primary Reason For Discontinuation From Study	1 (< 1%)	3 (1%)	4 (4%)	8 (1%)
Withdrawal by Subject	0	1 (< 1%)	1 (1%)	2 (< 1%)
Lost to Follow-up	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Other	0	1 (< 1%)	2 (2%)	3 (< 1%)
ENROLLMENT GROUP CLOSED PRIOR TO SUBJECT BEING RANDOMIZED	0	0	1 (1%)	1 (< 1%)
SITE UNABLE TO RANDOMIZE SUBJECT IN SBIR DUE TO ENROLMENT TARGET FOR VACCINE NAIVE GROUP BEING	0	0	1 (1%)	1 (< 1%)
SUBJECT WAS NOT RANDOMIZED DUE TO MENACTRA ARM CLOSED	0	1 (< 1%)	0	1 (< 1%)

PPD

Table 14.1.1.2.2
Study Terminations (From Day 30 Through End of Study)
Overall Safety Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Total Number of Subjects Enrolled	301 (100%)	300 (100%)	100 (100%)	701 (100%)
Total Number of Subjects Exposed	301 (100%)	300 (100%)	100 (100%)	701 (100%)
Completed Study Period	298 (99%)	288 (96%)	97 (97%)	683 (97%)
Primary Reason For Discontinuation From Study	2 (1%)	10 (3%)	1 (1%)	13 (2%)
Lost to Follow-up	2 (1%)	10 (3%)	1 (1%)	13 (2%)

PPD

Table 14.1.1.3
Demography and Baseline Characteristics
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Pooled Menveo/ Menactra-Menveo (N=602)	Naive (N=102)	Total (N=704)
Age (years)					
Mean, Std.Dev	17.1,3.66	17.8,4.53	17.5,4.13	38.8,10.49	20.6,9.32
Median	16.0	16.0	16.0	38.0	16.0
Min	15	15	15	15	15
Max	51	51	51	55	55
N	301	301	602	102	704
Age Group (EudraCT)					
Adolescents (12-17 years)	247 (82%)	229 (76%)	476 (79%)	4 (4%)	480 (68%)
Adults (18-64 years)	54 (18%)	72 (24%)	126 (21%)	98 (96%)	224 (32%)
Sex					
Female	144 (48%)	156 (52%)	300 (50%)	68 (67%)	368 (52%)
Male	157 (52%)	145 (48%)	302 (50%)	34 (33%)	336 (48%)
Country of Enrollment					
PRI	10 (3%)	0	10 (2%)	0	10 (1%)
USA	291 (97%)	301 (100%)	592 (98%)	102 (100%)	694 (99%)
Center					
PPD	33 (11%)	3 (1%)	36 (6%)	5 (5%)	41 (6%)
	0	13 (4%)	13 (2%)	5 (5%)	18 (3%)
	1 (< 1%)	10 (3%)	11 (2%)	8 (8%)	19 (3%)
	31 (10%)	25 (8%)	56 (9%)	5 (5%)	61 (9%)
	1 (< 1%)	12 (4%)	13 (2%)	0	13 (2%)
	0	3 (1%)	3 (< 1%)	5 (5%)	8 (1%)
	5 (2%)	21 (7%)	26 (4%)	5 (5%)	31 (4%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	5 (5%)	7 (1%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	5 (5%)	7 (1%)
	21 (7%)	6 (2%)	27 (4%)	0	27 (4%)
	1 (< 1%)	12 (4%)	13 (2%)	5 (5%)	18 (3%)
	0	20 (7%)	20 (3%)	0	20 (3%)
	0	6 (2%)	6 (1%)	0	6 (1%)
	48 (16%)	1 (< 1%)	49 (8%)	0	49 (7%)
	10 (3%)	0	10 (2%)	0	10 (1%)
	15 (5%)	0	15 (2%)	0	15 (2%)
	0	11 (4%)	11 (2%)	0	11 (2%)
	3 (1%)	18 (6%)	21 (3%)	5 (5%)	26 (4%)
	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3
Demography and Baseline Characteristics
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Pooled Menveo/ Menactra-Menveo (N=602)	Naive (N=102)	Total (N=704)
PPD	0	8 (3%)	8 (1%)	5 (5%)	13 (2%)
	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)
	52 (17%)	2 (1%)	54 (9%)	0	54 (8%)
	0	0	0	1 (1%)	1 (< 1%)
	1 (< 1%)	17 (6%)	18 (3%)	5 (5%)	23 (3%)
	0	0	0	5 (5%)	5 (1%)
	11 (4%)	19 (6%)	30 (5%)	5 (5%)	35 (5%)
	2 (1%)	5 (2%)	7 (1%)	5 (5%)	12 (2%)
	0	2 (1%)	2 (< 1%)	2 (2%)	4 (1%)
	4 (1%)	8 (3%)	12 (2%)	5 (5%)	17 (2%)
	1 (< 1%)	4 (1%)	5 (1%)	0	5 (1%)
	0	17 (6%)	17 (3%)	2 (2%)	19 (3%)
	4 (1%)	20 (7%)	24 (4%)	4 (4%)	28 (4%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	8 (3%)	0	8 (1%)	0	8 (1%)
	16 (5%)	0	16 (3%)	0	16 (2%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	9 (3%)	0	9 (1%)	0	9 (1%)
Race					
American Indian or Alaska Native	2 (1%)	6 (2%)	8 (1%)	1 (1%)	9 (1%)
Asian	4 (1%)	14 (5%)	18 (3%)	3 (3%)	21 (3%)
Black or African American	24 (8%)	23 (8%)	47 (8%)	12 (12%)	59 (8%)
Native Hawaiian or other Pacific Islander	3 (1%)	1 (< 1%)	4 (1%)	0	4 (1%)
Other	17 (6%)	23 (8%)	40 (7%)	5 (5%)	45 (6%)
White	251 (83%)	234 (78%)	485 (81%)	81 (79%)	566 (80%)
Ethnic Origin					
Hispanic or Latino	40 (13%)	75 (25%)	115 (19%)	11 (11%)	126 (18%)
Not Hispanic or Latino	258 (86%)	223 (74%)	481 (80%)	91 (89%)	572 (81%)
Not reported	3 (1%)	3 (1%)	6 (1%)	0	6 (1%)
Weight (kg)					
Mean, Std.Dev	72.8,21.61	72.6,20.00	72.7,20.80	89.4,25.41	75.2,22.30
Median	67.1	68.6	68.0	87.5	69.6
Min	37	39	37	43	37
Max	177	157	177	164	177
N	301	301	602	102	704

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3
Demography and Baseline Characteristics
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Pooled Menveo/ Menactra-Menveo (N=602)	Naive (N=102)	Total (N=704)
Height (cm)					
Mean, Std.Dev	171.2,9.21	169.8,10.35	170.5,9.81	169.2,9.78	170.3,9.81
Median	170.2	170.0	170.2	167.6	170.2
Min	152	141	141	145	141
Max	211	196	211	193	211
N	301	301	602	102	704
BMI (kg/m²)					
Mean, Std.Dev	24.8,6.50	25.1,6.24	24.9,6.37	31.1,8.00	25.8,6.96
Median	23.0	23.3	23.1	30.7	23.9
Min	15	15	15	18	15
Max	50	47	50	66	66
N	301	301	602	102	704
Met Protocol Criteria					
No	3 (1%)	5 (2%)	8 (1%)	1 (1%)	9 (1%)
Yes	298 (99%)	296 (98%)	594 (99%)	101 (99%)	695 (99%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=33)	Menactra-Menveo (N=3)	Pooled Menveo/ Menactra-Menveo (N=36)	Naive (N=5)	Total (N=41)
Age (years)					
Mean, Std.Dev	16.4,1.75	15.7,1.15	16.4,1.71	36.6,5.77	18.8,7.13
Median	16.0	15.0	16.0	36.0	16.0
Min	15	15	15	29	15
Max	23	17	23	45	45
N	33	3	36	5	41
Sex					
Female	14 (42%)	2 (67%)	16 (44%)	3 (60%)	19 (46%)
Male	19 (58%)	1 (33%)	20 (56%)	2 (40%)	22 (54%)
Race					
Black or African American	3 (9%)	0	3 (8%)	0	3 (7%)
White	30 (91%)	3 (100%)	33 (92%)	5 (100%)	38 (93%)
Ethnic Origin					
Not Hispanic or Latino	33 (100%)	3 (100%)	36 (100%)	5 (100%)	41 (100%)
Weight (kg)					
Mean, Std.Dev	78.9,26.03	62.8,23.59	77.5,25.92	73.6,22.90	77.0,25.34
Median	69.9	52.0	69.5	66.2	69.2
Min	49	46	46	54	46
Max	154	90	154	111	154
N	33	3	36	5	41
Height (cm)					
Mean, Std.Dev	171.7,9.99	161.0,7.96	170.8,10.19	168.4,13.08	170.5,10.42
Median	170.2	158.0	170.0	164.0	170.0
Min	152	155	152	157	152
Max	196	170	196	188	196
N	33	3	36	5	41
BMI (kg/m²)					
Mean, Std.Dev	26.6,7.57	23.8,6.38	26.4,7.44	25.7,5.76	26.3,7.20
Median	24.4	20.8	24.0	24.6	24.4

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=33)	Menactra-Menveo (N=3)	Pooled Menveo/ Menactra-Menveo (N=36)	Naive (N=5)	Total (N=41)
Min	18	19	18	19	18
Max	46	31	46	32	46
N	33	3	36	5	41
Met Protocol Criteria					
Yes	33 (100%)	3 (100%)	36 (100%)	5 (100%)	41 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=13)	Pooled Menveo/ Menactra-Menveo (N=13)	Naive (N=5)	Total (N=18)
Age (years)					
Mean, Std.Dev		17.7,2.32	17.7,2.32	41.0,4.53	24.2,11.14
Median		17.0	17.0	42.0	18.0
Min		16	16	36	16
Max		25	25	47	47
N		13	13	5	18
Sex					
Female		6 (46%)	6 (46%)	3 (60%)	9 (50%)
Male		7 (54%)	7 (54%)	2 (40%)	9 (50%)
Race					
White		13 (100%)	13 (100%)	5 (100%)	18 (100%)
Ethnic Origin					
Hispanic or Latino		3 (23%)	3 (23%)	1 (20%)	4 (22%)
Not Hispanic or Latino		10 (77%)	10 (77%)	4 (80%)	14 (78%)
Weight (kg)					
Mean, Std.Dev		71.4,15.94	71.4,15.94	106.6,24.77	81.2,24.24
Median		71.7	71.7	104.1	76.9
Min		49	49	83	49
Max		109	109	148	148
N		13	13	5	18
Height (cm)					
Mean, Std.Dev		172.1,10.93	172.1,10.93	173.2,11.13	172.4,10.67
Median		172.7	172.7	172.7	172.7
Min		152	152	157	152
Max		191	191	188	191
N		13	13	5	18
BMI (kg/m²)					
Mean, Std.Dev		24.0,4.60	24.0,4.60	35.2,4.22	27.1,6.75
Median		23.4	23.4	33.4	24.1

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=13)	Pooled Menveo/ Menactra-Menveo (N=13)	Naive (N=5)	Total (N=18)
Min		19	19	31	19
Max		36	36	42	42
N		13	13	5	18
Met Protocol Criteria					
Yes		13 (100%)	13 (100%)	5 (100%)	18 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=10)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=8)	Total (N=19)
Age (years)					
Mean, Std.Dev	23.0	21.7,7.69	21.8,7.31	40.9,11.84	29.8,13.33
Median	23.0	19.5	21.0	41.5	24.0
Min	23	15	15	20	15
Max	23	41	41	54	54
N	1	10	11	8	19
Sex					
Female	1 (100%)	6 (60%)	7 (64%)	4 (50%)	11 (58%)
Male	0	4 (40%)	4 (36%)	4 (50%)	8 (42%)
Race					
American Indian or Alaska Native	0	1 (10%)	1 (9%)	0	1 (5%)
Asian	0	1 (10%)	1 (9%)	0	1 (5%)
Other	0	1 (10%)	1 (9%)	0	1 (5%)
White	1 (100%)	7 (70%)	8 (73%)	8 (100%)	16 (84%)
Ethnic Origin					
Hispanic or Latino	0	2 (20%)	2 (18%)	0	2 (11%)
Not Hispanic or Latino	1 (100%)	8 (80%)	9 (82%)	8 (100%)	17 (89%)
Weight (kg)					
Mean, Std.Dev	55.8	72.3,19.90	70.8,19.52	87.4,24.25	77.8,22.62
Median	55.8	67.3	66.9	90.9	67.8
Min	56	53	53	56	53
Max	56	124	124	117	124
N	1	10	11	8	19
Height (cm)					
Mean, Std.Dev	161.0	171.0,7.68	170.1,7.88	175.0,10.23	172.1,9.03
Median	161.0	175.0	174.0	173.0	174.0
Min	161	160	160	165	160
Max	161	180	180	193	193
N	1	10	11	8	19

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=10)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=8)	Total (N=19)
BMI (kg/m²)					
Mean, Std.Dev	21.5	24.8,6.53	24.5,6.27	28.3,6.27	26.1,6.39
Median	21.5	22.3	21.6	28.7	24.1
Min	22	18	18	19	18
Max	22	39	39	36	39
N	1	10	11	8	19
Met Protocol Criteria					
No	0	1 (10%)	1 (9%)	0	1 (5%)
Yes	1 (100%)	9 (90%)	10 (91%)	8 (100%)	18 (95%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=31)	Menactra-Menveo (N=25)	Pooled Menveo/ Menactra-Menveo (N=56)	Naive (N=5)	Total (N=61)
Age (years)					
Mean, Std.Dev	15.3,0.63	16.3,1.75	15.7,1.36	40.2,7.85	17.7,7.18
Median	15.0	16.0	15.0	43.0	15.0
Min	15	15	15	28	15
Max	17	24	24	47	47
N	31	25	56	5	61
Sex					
Female	14 (45%)	10 (40%)	24 (43%)	5 (100%)	29 (48%)
Male	17 (55%)	15 (60%)	32 (57%)	0	32 (52%)
Race					
Black or African American	2 (6%)	3 (12%)	5 (9%)	1 (20%)	6 (10%)
Other	1 (3%)	2 (8%)	3 (5%)	0	3 (5%)
White	28 (90%)	20 (80%)	48 (86%)	4 (80%)	52 (85%)
Ethnic Origin					
Hispanic or Latino	0	1 (4%)	1 (2%)	1 (20%)	2 (3%)
Not Hispanic or Latino	31 (100%)	24 (96%)	55 (98%)	4 (80%)	59 (97%)
Weight (kg)					
Mean, Std.Dev	66.8,16.08	71.8,17.50	69.1,16.76	97.0,19.20	71.4,18.48
Median	63.2	67.1	65.8	92.5	66.7
Min	39	45	39	78	39
Max	111	130	130	128	130
N	31	25	56	5	61
Height (cm)					
Mean, Std.Dev	169.9,8.93	174.5,9.64	172.0,9.44	166.1,2.83	171.5,9.21
Median	170.2	177.8	173.4	165.1	172.0
Min	152	152	152	163	152
Max	188	193	193	170	193
N	31	25	56	5	61
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=31)	Menactra-Menveo (N=25)	Pooled Menveo/ Menactra-Menveo (N=56)	Naive (N=5)	Total (N=61)
Mean, Std.Dev	23.1,4.88	23.6,5.21	23.3,4.99	35.2,7.26	24.3,6.10
Median	21.3	21.7	21.6	35.0	22.8
Min	16	17	16	28	16
Max	36	41	41	47	47
N	31	25	56	5	61
Met Protocol Criteria					
No	0	1 (4%)	1 (2%)	0	1 (2%)
Yes	31 (100%)	24 (96%)	55 (98%)	5 (100%)	60 (98%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=12)	Pooled Menveo/ Menactra-Menveo (N=13)	Naive (N=0)	Total (N=13)
Age (years)					
Mean, Std.Dev	16.0	18.3,3.55	18.2,3.46		18.2,3.46
Median	16.0	17.0	17.0		17.0
Min	16	15	15		15
Max	16	26	26		26
N	1	12	13		13
Sex					
Female	0	9 (75%)	9 (69%)		9 (69%)
Male	1 (100%)	3 (25%)	4 (31%)		4 (31%)
Race					
Asian	0	2 (17%)	2 (15%)		2 (15%)
Black or African American	0	2 (17%)	2 (15%)		2 (15%)
Other	0	1 (8%)	1 (8%)		1 (8%)
White	1 (100%)	7 (58%)	8 (62%)		8 (62%)
Ethnic Origin					
Not Hispanic or Latino	1 (100%)	12 (100%)	13 (100%)		13 (100%)
Weight (kg)					
Mean, Std.Dev	75.5	65.4,13.89	66.2,13.59		66.2,13.59
Median	75.5	62.8	64.4		64.4
Min	76	48	48		48
Max	76	97	97		97
N	1	12	13		13
Height (cm)					
Mean, Std.Dev	180.3	164.5,9.32	165.7,9.95		165.7,9.95
Median	180.3	162.6	162.6		162.6
Min	180	147	147		147
Max	180	180	180		180
N	1	12	13		13
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=12)	Pooled Menveo/ Menactra-Menveo (N=13)	Naive (N=0)	Total (N=13)
Mean, Std.Dev	23.2	24.4,5.73	24.3,5.49		24.3,5.49
Median	23.2	23.3	23.2		23.2
Min	23	16	16		16
Max	23	37	37		37
N	1	12	13		13
Met Protocol Criteria					
No	0	1 (8%)	1 (8%)		1 (8%)
Yes	1 (100%)	11 (92%)	12 (92%)		12 (92%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=3)	Pooled Menveo/ Menactra-Menveo (N=3)	Naive (N=5)	Total (N=8)
Age (years)					
Mean, Std.Dev		15.7,0.58	15.7,0.58	42.0,7.04	32.1,14.63
Median		16.0	16.0	41.0	37.0
Min		15	15	36	15
Max		16	16	54	54
N		3	3	5	8
Sex					
Female		2 (67%)	2 (67%)	2 (40%)	4 (50%)
Male		1 (33%)	1 (33%)	3 (60%)	4 (50%)
Race					
Black or African American		0	0	4 (80%)	4 (50%)
White		3 (100%)	3 (100%)	1 (20%)	4 (50%)
Ethnic Origin					
Hispanic or Latino		1 (33%)	1 (33%)	0	1 (13%)
Not Hispanic or Latino		2 (67%)	2 (67%)	5 (100%)	7 (88%)
Weight (kg)					
Mean, Std.Dev		70.2,26.19	70.2,26.19	108.3,35.03	94.0,35.85
Median		56.2	56.2	90.8	87.4
Min		54	54	75	54
Max		100	100	152	152
N		3	3	5	8
Height (cm)					
Mean, Std.Dev		164.3,8.16	164.3,8.16	172.1,13.28	169.1,11.67
Median		167.6	167.6	178.0	168.9
Min		155	155	157	155
Max		170	170	184	184
N		3	3	5	8
BMI (kg/m²)					
Mean, Std.Dev		25.9,8.67	25.9,8.67	35.8,7.16	32.1,8.80

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=3)	Pooled Menveo/ Menactra-Menveo (N=3)	Naive (N=5)	Total (N=8)
Median		22.5	22.5	33.7	31.9
Min		19	19	29	19
Max		36	36	45	45
N		3	3	5	8
Met Protocol Criteria					
Yes		3 (100%)	3 (100%)	5 (100%)	8 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=5)	Menactra-Menveo (N=21)	Pooled Menveo/ Menactra-Menveo (N=26)	Naive (N=5)	Total (N=31)
Age (years)					
Mean, Std.Dev	16.0,0.71	16.6,2.13	16.5,1.94	49.8,7.85	21.9,12.90
Median	16.0	16.0	16.0	53.0	16.0
Min	15	15	15	36	15
Max	17	25	25	55	55
N	5	21	26	5	31
Sex					
Female	2 (40%)	13 (62%)	15 (58%)	4 (80%)	19 (61%)
Male	3 (60%)	8 (38%)	11 (42%)	1 (20%)	12 (39%)
Race					
American Indian or Alaska Native	0	1 (5%)	1 (4%)	0	1 (3%)
Black or African American	0	1 (5%)	1 (4%)	0	1 (3%)
White	5 (100%)	19 (90%)	24 (92%)	5 (100%)	29 (94%)
Ethnic Origin					
Hispanic or Latino	1 (20%)	4 (19%)	5 (19%)	0	5 (16%)
Not Hispanic or Latino	4 (80%)	17 (81%)	21 (81%)	5 (100%)	26 (84%)
Weight (kg)					
Mean, Std.Dev	75.4,18.39	74.5,24.05	74.7,22.73	76.2,24.86	74.9,22.66
Median	78.9	67.1	67.8	63.4	67.6
Min	49	46	46	56	46
Max	98	120	120	115	120
N	5	21	26	5	31
Height (cm)					
Mean, Std.Dev	172.1,7.09	170.0,9.67	170.4,9.15	166.7,8.67	169.8,9.03
Median	170.2	170.2	170.2	167.6	170.2
Min	164	155	155	153	153
Max	181	193	193	175	193
N	5	21	26	5	31
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=5)	Menactra-Menveo (N=21)	Pooled Menveo/ Menactra-Menveo (N=26)	Naive (N=5)	Total (N=31)
Mean, Std.Dev	25.5,5.91	25.4,6.34	25.4,6.14	27.1,6.96	25.7,6.19
Median	27.3	23.7	24.8	24.1	24.2
Min	15	18	15	21	15
Max	30	42	42	38	42
N	5	21	26	5	31
Met Protocol Criteria					
Yes	5 (100%)	21 (100%)	26 (100%)	5 (100%)	31 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=1)	Pooled Menveo/ Menactra-Menveo (N=2)	Naive (N=5)	Total (N=7)
Age (years)					
Mean, Std.Dev	15.0	23.0	19.0,5.66	32.8,7.40	28.9,9.34
Median	15.0	23.0	19.0	31.0	30.0
Min	15	23	15	24	15
Max	15	23	23	44	44
N	1	1	2	5	7
Sex					
Female	1 (100%)	0	1 (50%)	3 (60%)	4 (57%)
Male	0	1 (100%)	1 (50%)	2 (40%)	3 (43%)
Race					
Black or African American	0	1 (100%)	1 (50%)	1 (20%)	2 (29%)
White	1 (100%)	0	1 (50%)	4 (80%)	5 (71%)
Ethnic Origin					
Not Hispanic or Latino	1 (100%)	1 (100%)	2 (100%)	5 (100%)	7 (100%)
Weight (kg)					
Mean, Std.Dev	51.3	71.7	61.5,14.43	116.5,37.42	100.8,41.10
Median	51.3	71.7	61.5	125.2	115.2
Min	51	72	51	54	51
Max	51	72	72	153	153
N	1	1	2	5	7
Height (cm)					
Mean, Std.Dev	160.0	177.8	168.9,12.57	172.7,10.92	171.6,10.46
Median	160.0	177.8	168.9	172.7	172.7
Min	160	178	160	157	157
Max	160	178	178	188	188
N	1	1	2	5	7
BMI (kg/m²)					
Mean, Std.Dev	20.0	22.7	21.3,1.88	38.2,9.54	33.4,11.36
Median	20.0	22.7	21.3	40.8	38.6

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=1)	Pooled Menveo/ Menactra-Menveo (N=2)	Naive (N=5)	Total (N=7)
Min	20	23	20	22	20
Max	20	23	23	46	46
N	1	1	2	5	7
Met Protocol Criteria					
Yes	1 (100%)	1 (100%)	2 (100%)	5 (100%)	7 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=1)	Pooled Menveo/ Menactra-Menveo (N=2)	Naive (N=5)	Total (N=7)
Age (years)					
Mean, Std.Dev	31.0	16.0	23.5,10.61	45.2,9.52	39.0,13.83
Median	31.0	16.0	23.5	50.0	36.0
Min	31	16	16	34	16
Max	31	16	31	55	55
N	1	1	2	5	7
Sex					
Female	1 (100%)	0	1 (50%)	1 (20%)	2 (29%)
Male	0	1 (100%)	1 (50%)	4 (80%)	5 (71%)
Race					
Black or African American	1 (100%)	0	1 (50%)	2 (40%)	3 (43%)
White	0	1 (100%)	1 (50%)	3 (60%)	4 (57%)
Ethnic Origin					
Not Hispanic or Latino	1 (100%)	1 (100%)	2 (100%)	5 (100%)	7 (100%)
Weight (kg)					
Mean, Std.Dev	130.0	93.6	111.8,25.74	119.2,30.62	117.1,27.36
Median	130.0	93.6	111.8	98.6	98.6
Min	130	94	94	97	94
Max	130	94	130	164	164
N	1	1	2	5	7
Height (cm)					
Mean, Std.Dev	170.2	193.0	181.6,16.16	174.8,9.74	176.7,10.86
Median	170.2	193.0	181.6	177.8	177.8
Min	170	193	170	157	157
Max	170	193	193	180	193
N	1	1	2	5	7
BMI (kg/m²)					
Mean, Std.Dev	44.9	25.1	35.0,13.98	40.1,15.43	38.7,14.05
Median	44.9	25.1	35.0	31.2	31.2

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=1)	Pooled Menveo/ Menactra-Menveo (N=2)	Naive (N=5)	Total (N=7)
Min	45	25	25	30	25
Max	45	25	45	66	66
N	1	1	2	5	7
Met Protocol Criteria					
Yes	1 (100%)	1 (100%)	2 (100%)	5 (100%)	7 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=21)	Menactra-Menveo (N=6)	Pooled Menveo/ Menactra-Menveo (N=27)	Naive (N=0)	Total (N=27)
Age (years)					
Mean, Std.Dev	17.7,2.71	15.8,0.41	17.3,2.51		17.3,2.51
Median	16.0	16.0	16.0		16.0
Min	15	15	15		15
Max	24	16	24		24
N	21	6	27		27
Sex					
Female	13 (62%)	4 (67%)	17 (63%)		17 (63%)
Male	8 (38%)	2 (33%)	10 (37%)		10 (37%)
Race					
Black or African American	1 (5%)	0	1 (4%)		1 (4%)
Other	1 (5%)	0	1 (4%)		1 (4%)
White	19 (90%)	6 (100%)	25 (93%)		25 (93%)
Ethnic Origin					
Hispanic or Latino	1 (5%)	0	1 (4%)		1 (4%)
Not Hispanic or Latino	18 (86%)	6 (100%)	24 (89%)		24 (89%)
Not reported	2 (10%)	0	2 (7%)		2 (7%)
Weight (kg)					
Mean, Std.Dev	73.5,23.05	65.1,12.65	71.6,21.26		71.6,21.26
Median	68.0	61.0	66.7		66.7
Min	49	55	49		49
Max	148	89	148		148
N	21	6	27		27
Height (cm)					
Mean, Std.Dev	168.3,8.47	162.0,13.84	166.9,9.96		166.9,9.96
Median	165.0	165.0	165.0		165.0
Min	155	141	141		141
Max	182	181	182		182
N	21	6	27		27

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=21)	Menactra-Menveo (N=6)	Pooled Menveo/ Menactra-Menveo (N=27)	Naive (N=0)	Total (N=27)
BMI (kg/m²)					
Mean, Std.Dev	25.9,7.12	24.9,4.49	25.6,6.56		25.6,6.56
Median	25.1	24.5	24.5		24.5
Min	18	20	18		18
Max	46	32	46		46
N	21	6	27		27
Met Protocol Criteria					
Yes	21 (100%)	6 (100%)	27 (100%)		27 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=12)	Pooled Menveo/ Menactra-Menveo (N=13)	Naive (N=5)	Total (N=18)
Age (years)					
Mean, Std.Dev	15.0	21.3,3.85	20.8,4.08	25.2,8.76	22.1,5.82
Median	15.0	23.5	23.0	27.0	23.5
Min	15	16	15	16	15
Max	15	27	27	38	38
N	1	12	13	5	18
Sex					
Female	0	4 (33%)	4 (31%)	4 (80%)	8 (44%)
Male	1 (100%)	8 (67%)	9 (69%)	1 (20%)	10 (56%)
Race					
Asian	1 (100%)	0	1 (8%)	0	1 (6%)
White	0	12 (100%)	12 (92%)	5 (100%)	17 (94%)
Ethnic Origin					
Not Hispanic or Latino	1 (100%)	12 (100%)	13 (100%)	5 (100%)	18 (100%)
Weight (kg)					
Mean, Std.Dev	47.6	83.8,22.25	81.0,23.54	62.7,10.26	75.9,22.07
Median	47.6	76.0	72.6	63.5	72.6
Min	48	61	48	50	48
Max	48	132	132	73	132
N	1	12	13	5	18
Height (cm)					
Mean, Std.Dev	160.0	179.7,10.17	178.2,11.16	167.6,5.96	175.3,10.95
Median	160.0	180.3	180.3	165.1	176.5
Min	160	157	157	163	157
Max	160	193	193	178	193
N	1	12	13	5	18
BMI (kg/m²)					
Mean, Std.Dev	18.6	26.0,6.53	25.4,6.58	22.3,3.02	24.5,5.90
Median	18.6	23.9	23.4	23.0	23.2

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=12)	Pooled Menveo/ Menactra-Menveo (N=13)	Naive (N=5)	Total (N=18)
Min	19	18	18	18	18
Max	19	37	37	26	37
N	1	12	13	5	18
Met Protocol Criteria					
Yes	1 (100%)	12 (100%)	13 (100%)	5 (100%)	18 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=20)	Pooled Menveo/ Menactra-Menveo (N=20)	Naive (N=0)	Total (N=20)
Age (years)					
Mean, Std.Dev		16.8,1.77	16.8,1.77		16.8,1.77
Median		16.0	16.0		16.0
Min		15	15		15
Max		21	21		21
N		20	20		20
Sex					
Female		9 (45%)	9 (45%)		9 (45%)
Male		11 (55%)	11 (55%)		11 (55%)
Race					
Asian		3 (15%)	3 (15%)		3 (15%)
White		17 (85%)	17 (85%)		17 (85%)
Ethnic Origin					
Hispanic or Latino		16 (80%)	16 (80%)		16 (80%)
Not Hispanic or Latino		4 (20%)	4 (20%)		4 (20%)
Weight (kg)					
Mean, Std.Dev		76.8,20.05	76.8,20.05		76.8,20.05
Median		74.4	74.4		74.4
Min		47	47		47
Max		109	109		109
N		20	20		20
Height (cm)					
Mean, Std.Dev		166.1,8.50	166.1,8.50		166.1,8.50
Median		167.6	167.6		167.6
Min		152	152		152
Max		183	183		183
N		20	20		20
BMI (kg/m²)					
Mean, Std.Dev		27.6,6.25	27.6,6.25		27.6,6.25

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=20)	Pooled Menveo/ Menactra-Menveo (N=20)	Naive (N=0)	Total (N=20)
Median		27.7	27.7		27.7
Min		20	20		20
Max		39	39		39
N		20	20		20
Met Protocol Criteria					
Yes		20 (100%)	20 (100%)		20 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=6)	Pooled Menveo/ Menactra-Menveo (N=6)	Naive (N=0)	Total (N=6)
Age (years)					
Mean, Std.Dev		15.8,0.75	15.8,0.75		15.8,0.75
Median		16.0	16.0		16.0
Min		15	15		15
Max		17	17		17
N		6	6		6
Sex					
Female		3 (50%)	3 (50%)		3 (50%)
Male		3 (50%)	3 (50%)		3 (50%)
Race					
American Indian or Alaska Native		2 (33%)	2 (33%)		2 (33%)
White		4 (67%)	4 (67%)		4 (67%)
Ethnic Origin					
Hispanic or Latino		4 (67%)	4 (67%)		4 (67%)
Not Hispanic or Latino		2 (33%)	2 (33%)		2 (33%)
Weight (kg)					
Mean, Std.Dev		72.4,15.00	72.4,15.00		72.4,15.00
Median		76.2	76.2		76.2
Min		47	47		47
Max		90	90		90
N		6	6		6
Height (cm)					
Mean, Std.Dev		165.9,6.15	165.9,6.15		165.9,6.15
Median		167.6	167.6		167.6
Min		157	157		157
Max		173	173		173
N		6	6		6
BMI (kg/m²)					
Mean, Std.Dev		26.1,4.59	26.1,4.59		26.1,4.59

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=6)	Pooled Menveo/ Menactra-Menveo (N=6)	Naive (N=0)	Total (N=6)
Median		26.2	26.2		26.2
Min		19	19		19
Max		33	33		33
N		6	6		6
Met Protocol Criteria					
Yes		6 (100%)	6 (100%)		6 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=48)	Menactra-Menveo (N=1)	Pooled Menveo/ Menactra-Menveo (N=49)	Naive (N=0)	Total (N=49)
Age (years)					
Mean, Std.Dev	16.2,0.79	18.0	16.2,0.82		16.2,0.82
Median	16.0	18.0	16.0		16.0
Min	15	18	15		15
Max	19	18	19		19
N	48	1	49		49
Sex					
Female	17 (35%)	0	17 (35%)		17 (35%)
Male	31 (65%)	1 (100%)	32 (65%)		32 (65%)
Race					
Black or African American	11 (23%)	0	11 (22%)		11 (22%)
Other	7 (15%)	0	7 (14%)		7 (14%)
White	30 (63%)	1 (100%)	31 (63%)		31 (63%)
Ethnic Origin					
Hispanic or Latino	3 (6%)	0	3 (6%)		3 (6%)
Not Hispanic or Latino	45 (94%)	1 (100%)	46 (94%)		46 (94%)
Weight (kg)					
Mean, Std.Dev	66.6,16.84	79.4	66.9,16.76		66.9,16.76
Median	64.0	79.4	64.2		64.2
Min	37	79	37		37
Max	154	79	154		154
N	48	1	49		49
Height (cm)					
Mean, Std.Dev	172.5,8.82	182.9	172.7,8.85		172.7,8.85
Median	172.7	182.9	172.7		172.7
Min	152	183	152		152
Max	193	183	193		193
N	48	1	49		49
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=48)	Menactra-Menveo (N=1)	Pooled Menveo/ Menactra-Menveo (N=49)	Naive (N=0)	Total (N=49)
Mean, Std.Dev	22.3,4.94	23.7	22.4,4.89		22.4,4.89
Median	21.4	23.7	21.4		21.4
Min	15	24	15		15
Max	49	24	49		49
N	48	1	49		49
Met Protocol Criteria					
No	1 (2%)	0	1 (2%)		1 (2%)
Yes	47 (98%)	1 (100%)	48 (98%)		48 (98%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=10)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=10)	Naive (N=0)	Total (N=10)
Age (years)					
Mean, Std.Dev	15.7,0.48		15.7,0.48		15.7,0.48
Median	16.0		16.0		16.0
Min	15		15		15
Max	16		16		16
N	10		10		10
Sex					
Female	8 (80%)		8 (80%)		8 (80%)
Male	2 (20%)		2 (20%)		2 (20%)
Race					
Other	3 (30%)		3 (30%)		3 (30%)
White	7 (70%)		7 (70%)		7 (70%)
Ethnic Origin					
Hispanic or Latino	10 (100%)		10 (100%)		10 (100%)
Weight (kg)					
Mean, Std.Dev	73.2,25.74		73.2,25.74		73.2,25.74
Median	63.9		63.9		63.9
Min	47		47		47
Max	130		130		130
N	10		10		10
Height (cm)					
Mean, Std.Dev	167.3,8.63		167.3,8.63		167.3,8.63
Median	164.5		164.5		164.5
Min	157		157		157
Max	187		187		187
N	10		10		10
BMI (kg/m²)					
Mean, Std.Dev	25.9,7.54		25.9,7.54		25.9,7.54
Median	23.7		23.7		23.7

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=10)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=10)	Naive (N=0)	Total (N=10)
Min	17		17		17
Max	38		38		38
N	10		10		10
Met Protocol Criteria					
Yes	10 (100%)		10 (100%)		10 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=15)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=15)	Naive (N=0)	Total (N=15)
Age (years)					
Mean, Std.Dev	15.6,0.74		15.6,0.74		15.6,0.74
Median	15.0		15.0		15.0
Min	15		15		15
Max	17		17		17
N	15		15		15
Sex					
Female	10 (67%)		10 (67%)		10 (67%)
Male	5 (33%)		5 (33%)		5 (33%)
Race					
Black or African American	1 (7%)		1 (7%)		1 (7%)
White	14 (93%)		14 (93%)		14 (93%)
Ethnic Origin					
Not Hispanic or Latino	14 (93%)		14 (93%)		14 (93%)
Not reported	1 (7%)		1 (7%)		1 (7%)
Weight (kg)					
Mean, Std.Dev	59.7,10.00		59.7,10.00		59.7,10.00
Median	59.4		59.4		59.4
Min	41		41		41
Max	81		81		81
N	15		15		15
Height (cm)					
Mean, Std.Dev	167.1,6.39		167.1,6.39		167.1,6.39
Median	166.0		166.0		166.0
Min	159		159		159
Max	180		180		180
N	15		15		15
BMI (kg/m²)					
Mean, Std.Dev	21.4,3.40		21.4,3.40		21.4,3.40

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=15)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=15)	Naive (N=0)	Total (N=15)
Median	20.9		20.9		20.9
Min	15		15		15
Max	26		26		26
N	15		15		15
Met Protocol Criteria					
Yes	15 (100%)		15 (100%)		15 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=11)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=0)	Total (N=11)
Age (years)					
Mean, Std.Dev		15.8,0.40	15.8,0.40		15.8,0.40
Median		16.0	16.0		16.0
Min		15	15		15
Max		16	16		16
N		11	11		11
Sex					
Female		4 (36%)	4 (36%)		4 (36%)
Male		7 (64%)	7 (64%)		7 (64%)
Race					
Black or African American		4 (36%)	4 (36%)		4 (36%)
White		7 (64%)	7 (64%)		7 (64%)
Ethnic Origin					
Not Hispanic or Latino		11 (100%)	11 (100%)		11 (100%)
Weight (kg)					
Mean, Std.Dev		65.4,14.89	65.4,14.89		65.4,14.89
Median		59.9	59.9		59.9
Min		48	48		48
Max		99	99		99
N		11	11		11
Height (cm)					
Mean, Std.Dev		176.2,8.13	176.2,8.13		176.2,8.13
Median		180.3	180.3		180.3
Min		160	160		160
Max		185	185		185
N		11	11		11
BMI (kg/m²)					
Mean, Std.Dev		20.9,3.67	20.9,3.67		20.9,3.67
Median		20.3	20.3		20.3

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=11)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=0)	Total (N=11)
Min		17	17		17
Max		31	31		31
N		11	11		11
Met Protocol Criteria					
Yes		11 (100%)	11 (100%)		11 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=3)	Menactra-Menveo (N=18)	Pooled Menveo/ Menactra-Menveo (N=21)	Naive (N=5)	Total (N=26)
Age (years)					
Mean, Std.Dev	16.0,1.00	16.5,1.86	16.4,1.75	21.2,9.28	17.3,4.46
Median	16.0	16.0	16.0	17.0	16.0
Min	15	15	15	15	15
Max	17	22	22	37	37
N	3	18	21	5	26
Sex					
Female	0	12 (67%)	12 (57%)	3 (60%)	15 (58%)
Male	3 (100%)	6 (33%)	9 (43%)	2 (40%)	11 (42%)
Race					
Black or African American	0	0	0	1 (20%)	1 (4%)
White	3 (100%)	18 (100%)	21 (100%)	4 (80%)	25 (96%)
Ethnic Origin					
Hispanic or Latino	2 (67%)	12 (67%)	14 (67%)	2 (40%)	16 (62%)
Not Hispanic or Latino	1 (33%)	6 (33%)	7 (33%)	3 (60%)	10 (38%)
Weight (kg)					
Mean, Std.Dev	87.6,30.97	79.2,20.73	80.4,21.69	90.2,15.10	82.3,20.69
Median	78.8	81.4	81.1	98.3	81.4
Min	62	51	51	73	51
Max	122	115	122	105	122
N	3	18	21	5	26
Height (cm)					
Mean, Std.Dev	177.0,2.93	164.4,6.68	166.2,7.69	168.7,10.87	166.7,8.19
Median	175.3	163.8	165.1	162.6	165.1
Min	175	155	155	160	155
Max	180	180	180	183	183
N	3	18	21	5	26
BMI (kg/m²)					
Mean, Std.Dev	28.1,10.56	29.3,7.40	29.2,7.61	32.1,6.89	29.7,7.43

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=3)	Menactra-Menveo (N=18)	Pooled Menveo/ Menactra-Menveo (N=21)	Naive (N=5)	Total (N=26)
Median	25.7	29.9	29.1	33.1	30.0
Min	19	17	17	22	17
Max	40	39	40	38	40
N	3	18	21	5	26
Met Protocol Criteria					
Yes	3 (100%)	18 (100%)	21 (100%)	5 (100%)	26 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=18)	Pooled Menveo/ Menactra-Menveo (N=18)	Naive (N=5)	Total (N=23)
Age (years)					
Mean, Std.Dev		15.7,0.91	15.7,0.91	35.4,3.36	20.0,8.48
Median		15.0	15.0	33.0	16.0
Min		15	15	33	15
Max		17	17	40	40
N		18	18	5	23
Sex					
Female		9 (50%)	9 (50%)	3 (60%)	12 (52%)
Male		9 (50%)	9 (50%)	2 (40%)	11 (48%)
Race					
Asian		1 (6%)	1 (6%)	0	1 (4%)
Black or African American		3 (17%)	3 (17%)	0	3 (13%)
White		14 (78%)	14 (78%)	5 (100%)	19 (83%)
Ethnic Origin					
Hispanic or Latino		1 (6%)	1 (6%)	0	1 (4%)
Not Hispanic or Latino		17 (94%)	17 (94%)	5 (100%)	22 (96%)
Weight (kg)					
Mean, Std.Dev		63.1,9.88	63.1,9.88	77.1,20.23	66.2,13.58
Median		63.1	63.1	70.3	64.1
Min		46	46	55	46
Max		81	81	108	108
N		18	18	5	23
Height (cm)					
Mean, Std.Dev		168.7,10.25	168.7,10.25	165.6,7.49	168.0,9.65
Median		168.1	168.1	170.2	170.2
Min		152	152	157	152
Max		185	185	173	185
N		18	18	5	23
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=18)	Pooled Menveo/ Menactra-Menveo (N=18)	Naive (N=5)	Total (N=23)
Mean, Std.Dev		22.3,4.12	22.3,4.12	27.8,5.41	23.5,4.88
Median		21.0	21.0	27.3	22.2
Min		15	15	22	15
Max		31	31	36	36
N		18	18	5	23
Met Protocol Criteria					
No		0	0	1 (20%)	1 (4%)
Yes		18 (100%)	18 (100%)	4 (80%)	22 (96%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=8)	Pooled Menveo/ Menactra-Menveo (N=8)	Naive (N=5)	Total (N=13)
Age (years)					
Mean, Std.Dev		19.8,3.20	19.8,3.20	42.2,6.76	28.4,12.26
Median		19.0	19.0	42.0	23.0
Min		16	16	33	16
Max		24	24	52	52
N		8	8	5	13
Sex					
Female		6 (75%)	6 (75%)	4 (80%)	10 (77%)
Male		2 (25%)	2 (25%)	1 (20%)	3 (23%)
Race					
Native Hawaiian or other Pacific Islander		1 (13%)	1 (13%)	0	1 (8%)
White		7 (88%)	7 (88%)	5 (100%)	12 (92%)
Ethnic Origin					
Hispanic or Latino		2 (25%)	2 (25%)	1 (20%)	3 (23%)
Not Hispanic or Latino		5 (63%)	5 (63%)	4 (80%)	9 (69%)
Not reported		1 (13%)	1 (13%)	0	1 (8%)
Weight (kg)					
Mean, Std.Dev		72.4,23.30	72.4,23.30	93.9,20.39	80.6,23.95
Median		68.3	68.3	102.6	70.3
Min		48	48	58	48
Max		126	126	108	126
N		8	8	5	13
Height (cm)					
Mean, Std.Dev		171.8,7.67	171.8,7.67	167.6,6.48	170.2,7.26
Median		174.0	174.0	167.6	167.6
Min		160	160	160	160
Max		180	180	178	180
N		8	8	5	13
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=8)	Pooled Menveo/ Menactra-Menveo (N=8)	Naive (N=5)	Total (N=13)
Mean, Std.Dev		24.4,7.07	24.4,7.07	33.3,6.70	27.8,8.03
Median		22.1	22.1	37.0	23.8
Min		19	19	23	19
Max		41	41	39	41
N		8	8	5	13
Met Protocol Criteria					
Yes		8 (100%)	8 (100%)	5 (100%)	13 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=18)	Pooled Menveo/ Menactra-Menveo (N=18)	Naive (N=5)	Total (N=23)
Age (years)					
Mean, Std.Dev		26.5,10.11	26.5,10.11	41.0,10.82	29.7,11.73
Median		23.0	23.0	40.0	24.0
Min		15	15	29	15
Max		51	51	52	52
N		18	18	5	23
Sex					
Female		9 (50%)	9 (50%)	2 (40%)	11 (48%)
Male		9 (50%)	9 (50%)	3 (60%)	12 (52%)
Race					
White		18 (100%)	18 (100%)	5 (100%)	23 (100%)
Ethnic Origin					
Hispanic or Latino		2 (11%)	2 (11%)	0	2 (9%)
Not Hispanic or Latino		16 (89%)	16 (89%)	5 (100%)	21 (91%)
Weight (kg)					
Mean, Std.Dev		81.5,21.61	81.5,21.61	86.9,23.16	82.7,21.53
Median		74.5	74.5	91.3	78.8
Min		54	54	51	51
Max		127	127	111	127
N		18	18	5	23
Height (cm)					
Mean, Std.Dev		175.5,12.51	175.5,12.51	173.2,11.42	175.0,12.06
Median		175.3	175.3	172.7	175.3
Min		152	152	157	152
Max		196	196	185	196
N		18	18	5	23
BMI (kg/m²)					
Mean, Std.Dev		26.4,6.13	26.4,6.13	28.6,5.97	26.8,6.03
Median		23.9	23.9	28.1	25.8

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=18)	Pooled Menveo/ Menactra-Menveo (N=18)	Naive (N=5)	Total (N=23)
Min		20	20	21	20
Max		43	43	37	43
N		18	18	5	23
Met Protocol Criteria					
Yes		18 (100%)	18 (100%)	5 (100%)	23 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=52)	Menactra-Menveo (N=2)	Pooled Menveo/ Menactra-Menveo (N=54)	Naive (N=0)	Total (N=54)
Age (years)					
Mean, Std.Dev	19.0,6.35	16.5,0.71	18.9,6.25		18.9,6.25
Median	17.0	16.5	17.0		17.0
Min	15	16	15		15
Max	51	17	51		51
N	52	2	54		54
Sex					
Female	23 (44%)	2 (100%)	25 (46%)		25 (46%)
Male	29 (56%)	0	29 (54%)		29 (54%)
Race					
Asian	2 (4%)	1 (50%)	3 (6%)		3 (6%)
Black or African American	1 (2%)	0	1 (2%)		1 (2%)
Native Hawaiian or other Pacific Islander	3 (6%)	0	3 (6%)		3 (6%)
Other	2 (4%)	0	2 (4%)		2 (4%)
White	44 (85%)	1 (50%)	45 (83%)		45 (83%)
Ethnic Origin					
Hispanic or Latino	8 (15%)	0	8 (15%)		8 (15%)
Not Hispanic or Latino	44 (85%)	2 (100%)	46 (85%)		46 (85%)
Weight (kg)					
Mean, Std.Dev	76.4,19.79	49.4,7.25	75.4,20.11		75.4,20.11
Median	72.8	49.4	71.7		71.7
Min	44	44	44		44
Max	151	55	151		151
N	52	2	54		54
Height (cm)					
Mean, Std.Dev	172.9,10.79	154.9,7.18	172.2,11.17		172.2,11.17
Median	172.7	154.9	172.7		172.7
Min	152	150	150		150
Max	211	160	211		211
N	52	2	54		54

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=52)	Menactra-Menveo (N=2)	Pooled Menveo/ Menactra-Menveo (N=54)	Naive (N=0)	Total (N=54)
BMI (kg/m²)					
Mean, Std.Dev	25.5,5.81	20.5,1.12	25.3,5.78		25.3,5.78
Median	24.3	20.5	24.1		24.1
Min	16	20	16		16
Max	42	21	42		42
N	52	2	54		54
Met Protocol Criteria					
Yes	52 (100%)	2 (100%)	54 (100%)		54 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=0)	Naive (N=1)	Total (N=1)
Age (years)					
Mean, Std.Dev				47.0	47.0
Median				47.0	47.0
Min				47	47
Max				47	47
N				1	1
Sex					
Female			0	1 (100%)	1 (100%)
Race					
Black or African American			0	1 (100%)	1 (100%)
Ethnic Origin					
Not Hispanic or Latino			0	1 (100%)	1 (100%)
Weight (kg)					
Mean, Std.Dev				77.2	77.2
Median				77.2	77.2
Min				77	77
Max				77	77
N				1	1
Height (cm)					
Mean, Std.Dev				165.1	165.1
Median				165.1	165.1
Min				165	165
Max				165	165
N				1	1
BMI (kg/m²)					
Mean, Std.Dev				28.3	28.3
Median				28.3	28.3
Min				28	28
Max				28	28

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=0)	Naive (N=1)	Total (N=1)
N				1	1
Met Protocol Criteria					
Yes			0	1 (100%)	1 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=17)	Pooled Menveo/ Menactra-Menveo (N=18)	Naive (N=5)	Total (N=23)
Age (years)					
Mean, Std.Dev	27.0	16.6,1.12	17.2,2.68	37.8,13.97	21.7,10.81
Median	27.0	17.0	17.0	30.0	17.0
Min	27	15	15	26	15
Max	27	19	27	54	54
N	1	17	18	5	23
Sex					
Female	1 (100%)	10 (59%)	11 (61%)	4 (80%)	15 (65%)
Male	0	7 (41%)	7 (39%)	1 (20%)	8 (35%)
Race					
Other	0	8 (47%)	8 (44%)	1 (20%)	9 (39%)
White	1 (100%)	9 (53%)	10 (56%)	4 (80%)	14 (61%)
Ethnic Origin					
Hispanic or Latino	1 (100%)	8 (47%)	9 (50%)	1 (20%)	10 (43%)
Not Hispanic or Latino	0	8 (47%)	8 (44%)	4 (80%)	12 (52%)
Not reported	0	1 (6%)	1 (6%)	0	1 (4%)
Weight (kg)					
Mean, Std.Dev	72.6	71.2,26.02	71.2,25.24	81.7,11.85	73.5,23.18
Median	72.6	68.0	69.0	86.5	71.6
Min	73	46	46	61	46
Max	73	157	157	89	157
N	1	17	18	5	23
Height (cm)					
Mean, Std.Dev	162.6	167.4,7.20	167.1,7.08	168.7,9.94	167.5,7.55
Median	162.6	167.6	167.6	162.6	167.6
Min	163	155	155	163	155
Max	163	183	183	185	185
N	1	17	18	5	23
BMI (kg/m²)					
Mean, Std.Dev	27.5	25.1,7.40	25.2,7.20	29.0,5.33	26.1,6.90

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=17)	Pooled Menveo/ Menactra-Menveo (N=18)	Naive (N=5)	Total (N=23)
Median	27.5	24.2	24.5	31.6	25.5
Min	27	17	17	21	17
Max	27	47	47	33	47
N	1	17	18	5	23
Met Protocol Criteria					
Yes	1 (100%)	17 (100%)	18 (100%)	5 (100%)	23 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=0)	Naive (N=5)	Total (N=5)
Age (years)					
Mean, Std.Dev				46.8,9.01	46.8,9.01
Median				52.0	52.0
Min				36	36
Max				54	54
N				5	5
Sex					
Female			0	4 (80%)	4 (80%)
Male			0	1 (20%)	1 (20%)
Race					
Black or African American			0	1 (20%)	1 (20%)
Other			0	1 (20%)	1 (20%)
White			0	3 (60%)	3 (60%)
Ethnic Origin					
Not Hispanic or Latino			0	5 (100%)	5 (100%)
Weight (kg)					
Mean, Std.Dev				79.3,22.03	79.3,22.03
Median				70.3	70.3
Min				59	59
Max				115	115
N				5	5
Height (cm)					
Mean, Std.Dev				165.7,8.61	165.7,8.61
Median				167.0	167.0
Min				154	154
Max				178	178
N				5	5
BMI (kg/m²)					
Mean, Std.Dev				29.2,8.89	29.2,8.89

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=0)	Naive (N=5)	Total (N=5)
Median				26.6	26.6
Min				21	21
Max				41	41
N				5	5
Met Protocol Criteria					
Yes			0	5 (100%)	5 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=11)	Menactra-Menveo (N=19)	Pooled Menveo/ Menactra-Menveo (N=30)	Naive (N=5)	Total (N=35)
Age (years)					
Mean, Std.Dev	17.9,3.59	18.5,3.99	18.3,3.80	42.0,12.31	21.7,10.06
Median	16.0	17.0	17.0	47.0	17.0
Min	15	16	15	26	15
Max	25	30	30	54	54
N	11	19	30	5	35
Sex					
Female	6 (55%)	9 (47%)	15 (50%)	4 (80%)	19 (54%)
Male	5 (45%)	10 (53%)	15 (50%)	1 (20%)	16 (46%)
Race					
Asian	0	3 (16%)	3 (10%)	1 (20%)	4 (11%)
Black or African American	3 (27%)	0	3 (10%)	1 (20%)	4 (11%)
White	8 (73%)	16 (84%)	24 (80%)	3 (60%)	27 (77%)
Ethnic Origin					
Hispanic or Latino	2 (18%)	4 (21%)	6 (20%)	1 (20%)	7 (20%)
Not Hispanic or Latino	9 (82%)	15 (79%)	24 (80%)	4 (80%)	28 (80%)
Weight (kg)					
Mean, Std.Dev	74.2,20.96	74.6,26.36	74.5,24.14	79.7,28.51	75.2,24.42
Median	66.7	69.6	67.1	78.0	67.5
Min	55	39	39	43	39
Max	116	130	130	116	130
N	11	19	30	5	35
Height (cm)					
Mean, Std.Dev	170.7,6.15	172.9,10.39	172.1,9.01	167.1,13.25	171.4,9.64
Median	172.7	175.3	172.7	175.3	172.7
Min	160	155	155	145	145
Max	180	188	188	175	188
N	11	19	30	5	35
BMI (kg/m²)					

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=11)	Menactra-Menveo (N=19)	Pooled Menveo/ Menactra-Menveo (N=30)	Naive (N=5)	Total (N=35)
Mean, Std.Dev	25.6,7.55	24.7,7.67	25.0,7.51	27.8,6.97	25.4,7.40
Median	21.9	22.1	22.0	25.4	22.1
Min	19	16	16	20	16
Max	41	41	41	38	41
N	11	19	30	5	35
Met Protocol Criteria					
Yes	11 (100%)	19 (100%)	30 (100%)	5 (100%)	35 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=2)	Menactra-Menveo (N=5)	Pooled Menveo/ Menactra-Menveo (N=7)	Naive (N=5)	Total (N=12)
Age (years)					
Mean, Std.Dev	19.0,4.24	17.0,1.22	17.6,2.23	37.0,9.27	25.7,11.58
Median	19.0	17.0	17.0	37.0	20.0
Min	16	15	15	27	15
Max	22	18	22	49	49
N	2	5	7	5	12
Sex					
Female	1 (50%)	3 (60%)	4 (57%)	3 (60%)	7 (58%)
Male	1 (50%)	2 (40%)	3 (43%)	2 (40%)	5 (42%)
Race					
American Indian or Alaska Native	0	0	0	1 (20%)	1 (8%)
Asian	0	1 (20%)	1 (14%)	1 (20%)	2 (17%)
Black or African American	0	1 (20%)	1 (14%)	0	1 (8%)
White	2 (100%)	3 (60%)	5 (71%)	3 (60%)	8 (67%)
Ethnic Origin					
Hispanic or Latino	1 (50%)	0	1 (14%)	0	1 (8%)
Not Hispanic or Latino	1 (50%)	5 (100%)	6 (86%)	5 (100%)	11 (92%)
Weight (kg)					
Mean, Std.Dev	117.3,84.48	63.0,10.07	78.5,44.24	97.6,16.76	86.5,35.58
Median	117.3	65.9	65.9	101.7	71.8
Min	58	48	48	70	48
Max	177	72	177	115	177
N	2	5	7	5	12
Height (cm)					
Mean, Std.Dev	179.1,12.57	174.2,12.52	175.6,11.68	174.2,14.21	175.0,12.18
Median	179.1	177.8	177.8	170.2	174.0
Min	170	155	155	160	155
Max	188	188	188	191	191
N	2	5	7	5	12

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=2)	Menactra-Menveo (N=5)	Pooled Menveo/ Menactra-Menveo (N=7)	Naive (N=5)	Total (N=12)
BMI (kg/m²)					
Mean, Std.Dev	35.0,21.38	20.6,0.89	24.7,11.21	32.2,5.38	27.9,9.70
Median	35.0	20.3	20.3	31.6	24.2
Min	20	20	20	26	20
Max	50	22	50	40	50
N	2	5	7	5	12
Met Protocol Criteria					
Yes	2 (100%)	5 (100%)	7 (100%)	5 (100%)	12 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=2)	Pooled Menveo/ Menactra-Menveo (N=2)	Naive (N=2)	Total (N=4)
Age (years)					
Mean, Std.Dev		33.5,2.12	33.5,2.12	35.5,7.78	34.5,4.80
Median		33.5	33.5	35.5	33.5
Min		32	32	30	30
Max		35	35	41	41
N		2	2	2	4
Sex					
Female		1 (50%)	1 (50%)	1 (50%)	2 (50%)
Male		1 (50%)	1 (50%)	1 (50%)	2 (50%)
Race					
White		2 (100%)	2 (100%)	2 (100%)	4 (100%)
Ethnic Origin					
Hispanic or Latino		0	0	1 (50%)	1 (25%)
Not Hispanic or Latino		2 (100%)	2 (100%)	1 (50%)	3 (75%)
Weight (kg)					
Mean, Std.Dev		78.9,11.55	78.9,11.55	92.9,19.37	85.9,15.32
Median		78.9	78.9	92.9	83.1
Min		71	71	79	71
Max		87	87	107	107
N		2	2	2	4
Height (cm)					
Mean, Std.Dev		170.3,10.92	170.3,10.92	166.0,12.73	168.1,9.99
Median		170.3	170.3	166.0	168.8
Min		163	163	157	157
Max		178	178	175	178
N		2	2	2	4
BMI (kg/m²)					
Mean, Std.Dev		27.1,0.50	27.1,0.50	33.5,1.89	30.3,3.83
Median		27.1	27.1	33.5	29.8

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=2)	Pooled Menveo/ Menactra-Menveo (N=2)	Naive (N=2)	Total (N=4)
Min		27	27	32	27
Max		27	27	35	35
N		2	2	2	4
Met Protocol Criteria					
No		1 (50%)	1 (50%)	0	1 (25%)
Yes		1 (50%)	1 (50%)	2 (100%)	3 (75%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=4)	Menactra-Menveo (N=8)	Pooled Menveo/ Menactra-Menveo (N=12)	Naive (N=5)	Total (N=17)
Age (years)					
Mean, Std.Dev	17.0,2.00	18.4,2.92	17.9,2.64	32.6,9.18	22.2,8.57
Median	16.0	17.0	17.0	31.0	20.0
Min	16	15	15	23	15
Max	20	23	23	44	44
N	4	8	12	5	17
Sex					
Female	1 (25%)	4 (50%)	5 (42%)	4 (80%)	9 (53%)
Male	3 (75%)	4 (50%)	7 (58%)	1 (20%)	8 (47%)
Race					
Black or African American	0	2 (25%)	2 (17%)	0	2 (12%)
White	4 (100%)	6 (75%)	10 (83%)	5 (100%)	15 (88%)
Ethnic Origin					
Hispanic or Latino	0	2 (25%)	2 (17%)	0	2 (12%)
Not Hispanic or Latino	4 (100%)	6 (75%)	10 (83%)	5 (100%)	15 (88%)
Weight (kg)					
Mean, Std.Dev	73.4,15.88	77.2,22.74	75.9,20.03	71.7,10.76	74.7,17.57
Median	75.1	72.4	72.4	76.3	74.4
Min	56	50	50	54	50
Max	87	126	126	79	126
N	4	8	12	5	17
Height (cm)					
Mean, Std.Dev	171.5,8.68	175.6,8.20	174.2,8.21	168.1,7.05	172.4,8.18
Median	170.2	174.0	172.7	165.1	170.2
Min	163	165	163	163	163
Max	183	188	188	180	188
N	4	8	12	5	17
BMI (kg/m²)					
Mean, Std.Dev	25.1,5.78	24.8,5.88	24.9,5.58	25.5,4.54	25.1,5.16

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=4)	Menactra-Menveo (N=8)	Pooled Menveo/ Menactra-Menveo (N=12)	Naive (N=5)	Total (N=17)
Median	25.2	23.7	23.7	28.0	23.8
Min	19	18	18	20	18
Max	31	38	38	30	38
N	4	8	12	5	17
Met Protocol Criteria					
No	0	1 (13%)	1 (8%)	0	1 (6%)
Yes	4 (100%)	7 (88%)	11 (92%)	5 (100%)	16 (94%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=4)	Pooled Menveo/ Menactra-Menveo (N=5)	Naive (N=0)	Total (N=5)
Age (years)					
Mean, Std.Dev	16.0	15.5,1.00	15.6,0.89		15.6,0.89
Median	16.0	15.0	15.0		15.0
Min	16	15	15		15
Max	16	17	17		17
N	1	4	5		5
Sex					
Female	0	2 (50%)	2 (40%)		2 (40%)
Male	1 (100%)	2 (50%)	3 (60%)		3 (60%)
Race					
Black or African American	0	1 (25%)	1 (20%)		1 (20%)
White	1 (100%)	3 (75%)	4 (80%)		4 (80%)
Ethnic Origin					
Hispanic or Latino	1 (100%)	2 (50%)	3 (60%)		3 (60%)
Not Hispanic or Latino	0	2 (50%)	2 (40%)		2 (40%)
Weight (kg)					
Mean, Std.Dev	62.6	55.4,10.33	56.9,9.50		56.9,9.50
Median	62.6	54.7	61.9		61.9
Min	63	46	46		46
Max	63	67	67		67
N	1	4	5		5
Height (cm)					
Mean, Std.Dev	165.0	165.3,7.89	165.2,6.83		165.2,6.83
Median	165.0	165.5	165.0		165.0
Min	165	156	156		156
Max	165	174	174		174
N	1	4	5		5
BMI (kg/m²)					
Mean, Std.Dev	23.0	20.2,2.10	20.7,2.22		20.7,2.22

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=1)	Menactra-Menveo (N=4)	Pooled Menveo/ Menactra-Menveo (N=5)	Naive (N=0)	Total (N=5)
Median	23.0	20.6	21.7		21.7
Min	23	17	17		17
Max	23	22	23		23
N	1	4	5		5
Met Protocol Criteria					
Yes	1 (100%)	4 (100%)	5 (100%)		5 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=17)	Pooled Menveo/ Menactra-Menveo (N=17)	Naive (N=2)	Total (N=19)
Age (years)					
Mean, Std.Dev		16.7,1.69	16.7,1.69	50.0,2.83	20.2,10.64
Median		16.0	16.0	50.0	16.0
Min		16	16	48	16
Max		23	23	52	52
N		17	17	2	19
Sex					
Female		8 (47%)	8 (47%)	2 (100%)	10 (53%)
Male		9 (53%)	9 (53%)	0	9 (47%)
Race					
American Indian or Alaska Native		2 (12%)	2 (12%)	0	2 (11%)
Asian		2 (12%)	2 (12%)	0	2 (11%)
Black or African American		3 (18%)	3 (18%)	0	3 (16%)
White		10 (59%)	10 (59%)	2 (100%)	12 (63%)
Ethnic Origin					
Hispanic or Latino		2 (12%)	2 (12%)	0	2 (11%)
Not Hispanic or Latino		15 (88%)	15 (88%)	2 (100%)	17 (89%)
Weight (kg)					
Mean, Std.Dev		62.6,11.78	62.6,11.78	90.9,18.28	65.6,14.90
Median		61.9	61.9	90.9	62.5
Min		46	46	78	46
Max		92	92	104	104
N		17	17	2	19
Height (cm)					
Mean, Std.Dev		164.2,8.37	164.2,8.37	163.8,5.39	164.2,8.00
Median		162.6	162.6	163.8	162.6
Min		152	152	160	152
Max		180	180	168	180
N		17	17	2	19

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=0)	Menactra-Menveo (N=17)	Pooled Menveo/ Menactra-Menveo (N=17)	Naive (N=2)	Total (N=19)
BMI (kg/m²)					
Mean, Std.Dev		23.2,4.25	23.2,4.25	33.7,4.59	24.3,5.30
Median		22.6	22.6	33.7	23.3
Min		18	18	30	18
Max		34	34	37	37
N		17	17	2	19
Met Protocol Criteria					
Yes		17 (100%)	17 (100%)	2 (100%)	19 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=4)	Menactra-Menveo (N=20)	Pooled Menveo/ Menactra-Menveo (N=24)	Naive (N=4)	Total (N=28)
Age (years)					
Mean, Std.Dev	24.0,2.94	15.9,0.59	17.2,3.32	42.3,6.13	20.8,9.65
Median	23.5	16.0	16.0	42.5	16.0
Min	21	15	15	36	15
Max	28	17	28	48	48
N	4	20	24	4	28
Sex					
Female	3 (75%)	9 (45%)	12 (50%)	4 (100%)	16 (57%)
Male	1 (25%)	11 (55%)	12 (50%)	0	12 (43%)
Race					
Asian	0	0	0	1 (25%)	1 (4%)
Black or African American	0	2 (10%)	2 (8%)	0	2 (7%)
Other	2 (50%)	11 (55%)	13 (54%)	3 (75%)	16 (57%)
White	2 (50%)	7 (35%)	9 (38%)	0	9 (32%)
Ethnic Origin					
Hispanic or Latino	2 (50%)	9 (45%)	11 (46%)	3 (75%)	14 (50%)
Not Hispanic or Latino	2 (50%)	10 (50%)	12 (50%)	1 (25%)	13 (46%)
Not reported	0	1 (5%)	1 (4%)	0	1 (4%)
Weight (kg)					
Mean, Std.Dev	96.4,32.54	81.1,19.85	83.7,22.31	97.0,23.53	85.6,22.54
Median	97.3	75.7	76.7	95.1	80.5
Min	61	45	45	71	45
Max	130	110	130	127	130
N	4	20	24	4	28
Height (cm)					
Mean, Std.Dev	167.0,5.63	165.5,9.97	165.7,9.30	157.5,2.07	164.6,9.10
Median	165.1	165.1	165.1	157.5	163.8
Min	163	152	152	155	152
Max	175	183	183	160	183
N	4	20	24	4	28

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=4)	Menactra-Menveo (N=20)	Pooled Menveo/ Menactra-Menveo (N=24)	Naive (N=4)	Total (N=28)
BMI (kg/m²)					
Mean, Std.Dev	34.4,10.70	29.7,7.49	30.5,8.03	39.1,9.33	31.7,8.59
Median	35.3	29.6	29.6	37.8	30.0
Min	22	18	18	30	18
Max	44	45	45	51	51
N	4	20	24	4	28
Met Protocol Criteria					
Yes	4 (100%)	20 (100%)	24 (100%)	4 (100%)	28 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=11)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=0)	Total (N=11)
Age (years)					
Mean, Std.Dev	15.5,0.69		15.5,0.69		15.5,0.69
Median	15.0		15.0		15.0
Min	15		15		15
Max	17		17		17
N	11		11		11
Sex					
Female	6 (55%)		6 (55%)		6 (55%)
Male	5 (45%)		5 (45%)		5 (45%)
Race					
American Indian or Alaska Native	2 (18%)		2 (18%)		2 (18%)
Black or African American	1 (9%)		1 (9%)		1 (9%)
Other	1 (9%)		1 (9%)		1 (9%)
White	7 (64%)		7 (64%)		7 (64%)
Ethnic Origin					
Hispanic or Latino	3 (27%)		3 (27%)		3 (27%)
Not Hispanic or Latino	8 (73%)		8 (73%)		8 (73%)
Weight (kg)					
Mean, Std.Dev	71.7,24.50		71.7,24.50		71.7,24.50
Median	61.2		61.2		61.2
Min	55		55		55
Max	135		135		135
N	11		11		11
Height (cm)					
Mean, Std.Dev	170.4,9.33		170.4,9.33		170.4,9.33
Median	167.6		167.6		167.6
Min	160		160		160
Max	191		191		191
N	11		11		11

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=11)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=0)	Total (N=11)
BMI (kg/m²)					
Mean, Std.Dev	24.7,8.06		24.7,8.06		24.7,8.06
Median	21.8		21.8		21.8
Min	17		17		17
Max	44		44		44
N	11		11		11
Met Protocol Criteria					
Yes	11 (100%)		11 (100%)		11 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=8)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=8)	Naive (N=0)	Total (N=8)
Age (years)					
Mean, Std.Dev	18.4,3.46		18.4,3.46		18.4,3.46
Median	17.0		17.0		17.0
Min	15		15		15
Max	25		25		25
N	8		8		8
Sex					
Female	2 (25%)		2 (25%)		2 (25%)
Male	6 (75%)		6 (75%)		6 (75%)
Race					
Asian	1 (13%)		1 (13%)		1 (13%)
White	7 (88%)		7 (88%)		7 (88%)
Ethnic Origin					
Not Hispanic or Latino	8 (100%)		8 (100%)		8 (100%)
Weight (kg)					
Mean, Std.Dev	73.0,8.64		73.0,8.64		73.0,8.64
Median	70.5		70.5		70.5
Min	61		61		61
Max	89		89		89
N	8		8		8
Height (cm)					
Mean, Std.Dev	176.4,6.25		176.4,6.25		176.4,6.25
Median	179.0		179.0		179.0
Min	164		164		164
Max	182		182		182
N	8		8		8
BMI (kg/m²)					
Mean, Std.Dev	23.5,2.72		23.5,2.72		23.5,2.72
Median	23.7		23.7		23.7

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=8)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=8)	Naive (N=0)	Total (N=8)
Min	18		18		18
Max	27		27		27
N	8		8		8
Met Protocol Criteria					
Yes	8 (100%)		8 (100%)		8 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=16)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=16)	Naive (N=0)	Total (N=16)
Age (years)					
Mean, Std.Dev	16.2,0.83		16.2,0.83		16.2,0.83
Median	16.0		16.0		16.0
Min	15		15		15
Max	18		18		18
N	16		16		16
Sex					
Female	7 (44%)		7 (44%)		7 (44%)
Male	9 (56%)		9 (56%)		9 (56%)
Race					
White	16 (100%)		16 (100%)		16 (100%)
Ethnic Origin					
Hispanic or Latino	2 (13%)		2 (13%)		2 (13%)
Not Hispanic or Latino	14 (88%)		14 (88%)		14 (88%)
Weight (kg)					
Mean, Std.Dev	64.7,10.56		64.7,10.56		64.7,10.56
Median	60.1		60.1		60.1
Min	49		49		49
Max	82		82		82
N	16		16		16
Height (cm)					
Mean, Std.Dev	170.1,9.80		170.1,9.80		170.1,9.80
Median	169.0		169.0		169.0
Min	154		154		154
Max	183		183		183
N	16		16		16
BMI (kg/m²)					
Mean, Std.Dev	22.4,3.20		22.4,3.20		22.4,3.20
Median	22.5		22.5		22.5

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=16)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=16)	Naive (N=0)	Total (N=16)
Min	18		18		18
Max	29		29		29
N	16		16		16
Met Protocol Criteria					
No	1 (6%)		1 (6%)		1 (6%)
Yes	15 (94%)		15 (94%)		15 (94%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=11)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=0)	Total (N=11)
Age (years)					
Mean, Std.Dev	17.7,2.37		17.7,2.37		17.7,2.37
Median	17.0		17.0		17.0
Min	16		16		16
Max	24		24		24
N	11		11		11
Sex					
Female	7 (64%)		7 (64%)		7 (64%)
Male	4 (36%)		4 (36%)		4 (36%)
Race					
White	11 (100%)		11 (100%)		11 (100%)
Ethnic Origin					
Not Hispanic or Latino	11 (100%)		11 (100%)		11 (100%)
Weight (kg)					
Mean, Std.Dev	74.8,14.99		74.8,14.99		74.8,14.99
Median	71.4		71.4		71.4
Min	55		55		55
Max	99		99		99
N	11		11		11
Height (cm)					
Mean, Std.Dev	170.9,10.29		170.9,10.29		170.9,10.29
Median	170.2		170.2		170.2
Min	157		157		157
Max	191		191		191
N	11		11		11
BMI (kg/m²)					
Mean, Std.Dev	25.7,5.55		25.7,5.55		25.7,5.55
Median	23.4		23.4		23.4
Min	20		20		20

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=11)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=11)	Naive (N=0)	Total (N=11)
Max	36		36		36
N	11		11		11
Met Protocol Criteria					
Yes	11 (100%)		11 (100%)		11 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=9)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=9)	Naive (N=0)	Total (N=9)
Age (years)					
Mean, Std.Dev	18.3,5.89		18.3,5.89		18.3,5.89
Median	16.0		16.0		16.0
Min	16		16		16
Max	34		34		34
N	9		9		9
Sex					
Female	6 (67%)		6 (67%)		6 (67%)
Male	3 (33%)		3 (33%)		3 (33%)
Race					
White	9 (100%)		9 (100%)		9 (100%)
Ethnic Origin					
Hispanic or Latino	3 (33%)		3 (33%)		3 (33%)
Not Hispanic or Latino	6 (67%)		6 (67%)		6 (67%)
Weight (kg)					
Mean, Std.Dev	90.3,30.06		90.3,30.06		90.3,30.06
Median	91.4		91.4		91.4
Min	58		58		58
Max	147		147		147
N	9		9		9
Height (cm)					
Mean, Std.Dev	174.7,10.22		174.7,10.22		174.7,10.22
Median	173.0		173.0		173.0
Min	158		158		158
Max	191		191		191
N	9		9		9
BMI (kg/m²)					
Mean, Std.Dev	29.2,7.43		29.2,7.43		29.2,7.43
Median	28.9		28.9		28.9

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.1
Demography by Center
All Enrolled Set

Center: PPD

	Menveo-Menveo (N=9)	Menactra-Menveo (N=0)	Pooled Menveo/ Menactra-Menveo (N=9)	Naive (N=0)	Total (N=9)
Min	20		20		20
Max	40		40		40
N	9		9		9
Met Protocol Criteria					
No	1 (11%)		1 (11%)		1 (11%)
Yes	8 (89%)		8 (89%)		8 (89%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.2
Demography and Baseline Characteristics
Per Protocol Set (Day 29)

	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Pooled Menveo/ Menactra-Menveo (N=572)	Naive (N=93)	Total (N=665)
Age (years)					
Mean, Std.Dev	17.1,3.68	17.8,4.54	17.5,4.14	38.8,10.43	20.4,9.19
Median	16.0	16.0	16.0	38.0	16.0
Min	15	15	15	15	15
Max	51	51	51	55	55
N	290	282	572	93	665
Age Group (EudraCT)					
Adolescents (12-17 years)	238 (82%)	215 (76%)	453 (79%)	4 (4%)	457 (69%)
Adults (18-64 years)	52 (18%)	67 (24%)	119 (21%)	89 (96%)	208 (31%)
Sex					
Female	136 (47%)	146 (52%)	282 (49%)	63 (68%)	345 (52%)
Male	154 (53%)	136 (48%)	290 (51%)	30 (32%)	320 (48%)
Country of Enrollment					
PRI	10 (3%)	0	10 (2%)	0	10 (2%)
USA	280 (97%)	282 (100%)	562 (98%)	93 (100%)	655 (98%)
Center					
PPD	31 (11%)	3 (1%)	34 (6%)	5 (5%)	39 (6%)
	0	13 (5%)	13 (2%)	5 (5%)	18 (3%)
	1 (< 1%)	8 (3%)	9 (2%)	6 (6%)	15 (2%)
	30 (10%)	20 (7%)	50 (9%)	5 (5%)	55 (8%)
	1 (< 1%)	11 (4%)	12 (2%)	0	12 (2%)
	0	3 (1%)	3 (1%)	5 (5%)	8 (1%)
	5 (2%)	21 (7%)	26 (5%)	5 (5%)	31 (5%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	4 (4%)	6 (1%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	4 (4%)	6 (1%)
	21 (7%)	6 (2%)	27 (5%)	0	27 (4%)
	1 (< 1%)	11 (4%)	12 (2%)	5 (5%)	17 (3%)
	0	20 (7%)	20 (3%)	0	20 (3%)
	0	6 (2%)	6 (1%)	0	6 (1%)
	47 (16%)	1 (< 1%)	48 (8%)	0	48 (7%)
	10 (3%)	0	10 (2%)	0	10 (2%)
	15 (5%)	0	15 (3%)	0	15 (2%)
	0	11 (4%)	11 (2%)	0	11 (2%)
	3 (1%)	18 (6%)	21 (4%)	5 (5%)	26 (4%)
	0	16 (6%)	16 (3%)	4 (4%)	20 (3%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

Table 14.1.1.3.2
Demography and Baseline Characteristics
Per Protocol Set (Day 29)

	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Pooled Menveo/ Menactra-Menveo (N=572)	Naive (N=93)	Total (N=665)
PPD	0	7 (2%)	7 (1%)	5 (5%)	12 (2%)
	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)
	52 (18%)	2 (1%)	54 (9%)	0	54 (8%)
	0	0	0	1 (1%)	1 (< 1%)
	1 (< 1%)	17 (6%)	18 (3%)	5 (5%)	23 (3%)
	0	0	0	5 (5%)	5 (1%)
	11 (4%)	17 (6%)	28 (5%)	4 (4%)	32 (5%)
	0	5 (2%)	5 (1%)	4 (4%)	9 (1%)
	0	1 (< 1%)	1 (< 1%)	1 (1%)	2 (< 1%)
	4 (1%)	7 (2%)	11 (2%)	5 (5%)	16 (2%)
	1 (< 1%)	4 (1%)	5 (1%)	0	5 (1%)
	0	14 (5%)	14 (2%)	1 (1%)	15 (2%)
	4 (1%)	20 (7%)	24 (4%)	4 (4%)	28 (4%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	8 (3%)	0	8 (1%)	0	8 (1%)
	14 (5%)	0	14 (2%)	0	14 (2%)
	9 (3%)	0	9 (2%)	0	9 (1%)
	8 (3%)	0	8 (1%)	0	8 (1%)
Race					
American Indian or Alaska Native	2 (1%)	6 (2%)	8 (1%)	0	8 (1%)
Asian	4 (1%)	13 (5%)	17 (3%)	3 (3%)	20 (3%)
Black or African American	24 (8%)	22 (8%)	46 (8%)	12 (13%)	58 (9%)
Native Hawaiian or other Pacific Islander	3 (1%)	0	3 (1%)	0	3 (< 1%)
Other	17 (6%)	23 (8%)	40 (7%)	5 (5%)	45 (7%)
White	240 (83%)	218 (77%)	458 (80%)	73 (78%)	531 (80%)
Ethnic Origin					
Hispanic or Latino	37 (13%)	74 (26%)	111 (19%)	11 (12%)	122 (18%)
Not Hispanic or Latino	250 (86%)	205 (73%)	455 (80%)	82 (88%)	537 (81%)
Not reported	3 (1%)	3 (1%)	6 (1%)	0	6 (1%)
Weight (kg)					
Mean, Std.Dev	72.8,20.92	72.8,20.05	72.8,20.48	88.8,24.99	75.0,21.87
Median	67.7	68.8	68.2	86.6	69.9
Min	37	39	37	43	37
Max	154	157	157	164	164
N	290	282	572	93	665

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.2
Demography and Baseline Characteristics
Per Protocol Set (Day 29)

	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Pooled Menveo/ Menactra-Menveo (N=572)	Naive (N=93)	Total (N=665)
Height (cm)					
Mean, Std.Dev	171.2,9.18	169.8,10.18	170.5,9.70	168.7,9.56	170.3,9.69
Median	170.2	169.0	170.2	167.6	170.2
Min	152	141	141	145	141
Max	211	196	211	191	211
N	290	282	572	93	665
BMI (kg/m²)					
Mean, Std.Dev	24.8,6.40	25.2,6.27	25.0,6.34	31.1,8.10	25.8,6.94
Median	23.1	23.4	23.2	30.6	23.9
Min	15	15	15	18	15
Max	49	47	49	66	66
N	290	282	572	93	665
Met Protocol Criteria					
Yes	290 (100%)	282 (100%)	572 (100%)	93 (100%)	665 (100%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.3
Demography and Baseline Characteristics
Overall Safety Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
Age (years)					
Mean, Std.Dev	17.1,3.66	17.9,4.54	17.5,4.13	38.8,10.47	20.5,9.25
Median	16.0	16.0	16.0	38.0	16.0
Min	15	15	15	15	15
Max	51	51	51	55	55
N	301	300	601	100	701
Age Group (EudraCT)					
Adolescents (12-17 years)	247 (82%)	228 (76%)	475 (79%)	4 (4%)	479 (68%)
Adults (18-64 years)	54 (18%)	72 (24%)	126 (21%)	96 (96%)	222 (32%)
Sex					
Female	144 (48%)	156 (52%)	300 (50%)	68 (68%)	368 (52%)
Male	157 (52%)	144 (48%)	301 (50%)	32 (32%)	333 (48%)
Country of Enrollment					
PRI	10 (3%)	0	10 (2%)	0	10 (1%)
USA	291 (97%)	300 (100%)	591 (98%)	100 (100%)	691 (99%)
Center					
PPD	33 (11%)	3 (1%)	36 (6%)	5 (5%)	41 (6%)
	0	13 (4%)	13 (2%)	5 (5%)	18 (3%)
	1 (< 1%)	10 (3%)	11 (2%)	7 (7%)	18 (3%)
	31 (10%)	24 (8%)	55 (9%)	5 (5%)	60 (9%)
	1 (< 1%)	12 (4%)	13 (2%)	0	13 (2%)
	0	3 (1%)	3 (< 1%)	5 (5%)	8 (1%)
	5 (2%)	21 (7%)	26 (4%)	5 (5%)	31 (4%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	4 (4%)	6 (1%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	5 (5%)	7 (1%)
	21 (7%)	6 (2%)	27 (4%)	0	27 (4%)
	1 (< 1%)	12 (4%)	13 (2%)	5 (5%)	18 (3%)
	0	20 (7%)	20 (3%)	0	20 (3%)
	0	6 (2%)	6 (1%)	0	6 (1%)
	48 (16%)	1 (< 1%)	49 (8%)	0	49 (7%)
	10 (3%)	0	10 (2%)	0	10 (1%)
	15 (5%)	0	15 (2%)	0	15 (2%)
	0	11 (4%)	11 (2%)	0	11 (2%)
	3 (1%)	18 (6%)	21 (3%)	5 (5%)	26 (4%)
	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.3
Demography and Baseline Characteristics
Overall Safety Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
PPD	0	8 (3%)	8 (1%)	5 (5%)	13 (2%)
	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)
	52 (17%)	2 (1%)	54 (9%)	0	54 (8%)
	0	0	0	1 (1%)	1 (< 1%)
	1 (< 1%)	17 (6%)	18 (3%)	5 (5%)	23 (3%)
	0	0	0	5 (5%)	5 (1%)
	11 (4%)	19 (6%)	30 (5%)	5 (5%)	35 (5%)
	2 (1%)	5 (2%)	7 (1%)	5 (5%)	12 (2%)
	0	2 (1%)	2 (< 1%)	2 (2%)	4 (1%)
	4 (1%)	8 (3%)	12 (2%)	5 (5%)	17 (2%)
	1 (< 1%)	4 (1%)	5 (1%)	0	5 (1%)
	0	17 (6%)	17 (3%)	2 (2%)	19 (3%)
	4 (1%)	20 (7%)	24 (4%)	4 (4%)	28 (4%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	8 (3%)	0	8 (1%)	0	8 (1%)
	16 (5%)	0	16 (3%)	0	16 (2%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	9 (3%)	0	9 (1%)	0	9 (1%)
Race					
American Indian or Alaska Native	2 (1%)	6 (2%)	8 (1%)	1 (1%)	9 (1%)
Asian	4 (1%)	14 (5%)	18 (3%)	3 (3%)	21 (3%)
Black or African American	24 (8%)	23 (8%)	47 (8%)	12 (12%)	59 (8%)
Native Hawaiian or other Pacific Islander	3 (1%)	1 (< 1%)	4 (1%)	0	4 (1%)
Other	17 (6%)	23 (8%)	40 (7%)	5 (5%)	45 (6%)
White	251 (83%)	233 (78%)	484 (81%)	79 (79%)	563 (80%)
Ethnic Origin					
Hispanic or Latino	40 (13%)	75 (25%)	115 (19%)	11 (11%)	126 (18%)
Not Hispanic or Latino	258 (86%)	222 (74%)	480 (80%)	89 (89%)	569 (81%)
Not reported	3 (1%)	3 (1%)	6 (1%)	0	6 (1%)
Weight (kg)					
Mean, Std.Dev	72.8,21.61	72.7,20.01	72.8,20.81	88.5,24.68	75.0,22.08
Median	67.1	68.6	68.0	87.1	69.6
Min	37	39	37	43	37
Max	177	157	177	164	177
N	301	300	601	100	701

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.3
Demography and Baseline Characteristics
Overall Safety Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
Height (cm)					
Mean, Std.Dev	171.2,9.21	169.8,10.34	170.5,9.81	168.8,9.39	170.2,9.76
Median	170.2	169.5	170.2	167.6	170.2
Min	152	141	141	145	141
Max	211	196	211	191	211
N	301	300	601	100	701
BMI (kg/m²)					
Mean, Std.Dev	24.8,6.50	25.1,6.23	25.0,6.36	31.0,7.98	25.8,6.94
Median	23.0	23.3	23.1	30.5	23.8
Min	15	15	15	18	15
Max	50	47	50	66	66
N	301	300	601	100	701
Met Protocol Criteria					
No	3 (1%)	5 (2%)	8 (1%)	1 (1%)	9 (1%)
Yes	298 (99%)	295 (98%)	593 (99%)	99 (99%)	692 (99%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.4
Demography and Baseline Characteristics
[table created for posting purposes]
Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
Age (years)					
Mean, Std.Dev	17.1,3.66	17.9,4.54	17.5,4.13	38.8,10.47	20.5,9.25
Median	16.0	16.0	16.0	38.0	16.0
Min	15	15	15	15	15
Max	51	51	51	55	55
N	301	300	601	100	701
Age Group (EudraCT)					
Adolescents (12-17 years)	247 (82%)	228 (76%)	475 (79%)	4 (4%)	479 (68%)
Adults (18-64 years)	54 (18%)	72 (24%)	126 (21%)	96 (96%)	222 (32%)
Sex					
Female	144 (48%)	156 (52%)	300 (50%)	68 (68%)	368 (52%)
Male	157 (52%)	144 (48%)	301 (50%)	32 (32%)	333 (48%)
Country of Enrollment					
PRI	10 (3%)	0	10 (2%)	0	10 (1%)
USA	291 (97%)	300 (100%)	591 (98%)	100 (100%)	691 (99%)
Center					
PPD	33 (11%)	3 (1%)	36 (6%)	5 (5%)	41 (6%)
	0	13 (4%)	13 (2%)	5 (5%)	18 (3%)
	1 (< 1%)	10 (3%)	11 (2%)	7 (7%)	18 (3%)
	31 (10%)	24 (8%)	55 (9%)	5 (5%)	60 (9%)
	1 (< 1%)	12 (4%)	13 (2%)	0	13 (2%)
	0	3 (1%)	3 (< 1%)	5 (5%)	8 (1%)
	5 (2%)	21 (7%)	26 (4%)	5 (5%)	31 (4%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	4 (4%)	6 (1%)
	1 (< 1%)	1 (< 1%)	2 (< 1%)	5 (5%)	7 (1%)
	21 (7%)	6 (2%)	27 (4%)	0	27 (4%)
	1 (< 1%)	12 (4%)	13 (2%)	5 (5%)	18 (3%)
	0	20 (7%)	20 (3%)	0	20 (3%)
	0	6 (2%)	6 (1%)	0	6 (1%)
	48 (16%)	1 (< 1%)	49 (8%)	0	49 (7%)
	10 (3%)	0	10 (2%)	0	10 (1%)
	15 (5%)	0	15 (2%)	0	15 (2%)
	0	11 (4%)	11 (2%)	0	11 (2%)
	3 (1%)	18 (6%)	21 (3%)	5 (5%)	26 (4%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.4
Demography and Baseline Characteristics
[table created for posting purposes]
Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
PPD	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)
	0	8 (3%)	8 (1%)	5 (5%)	13 (2%)
	0	18 (6%)	18 (3%)	5 (5%)	23 (3%)
	52 (17%)	2 (1%)	54 (9%)	0	54 (8%)
	0	0	0	1 (1%)	1 (< 1%)
	1 (< 1%)	17 (6%)	18 (3%)	5 (5%)	23 (3%)
	0	0	0	5 (5%)	5 (1%)
	11 (4%)	19 (6%)	30 (5%)	5 (5%)	35 (5%)
	2 (1%)	5 (2%)	7 (1%)	5 (5%)	12 (2%)
	0	2 (1%)	2 (< 1%)	2 (2%)	4 (1%)
	4 (1%)	8 (3%)	12 (2%)	5 (5%)	17 (2%)
	1 (< 1%)	4 (1%)	5 (1%)	0	5 (1%)
	0	17 (6%)	17 (3%)	2 (2%)	19 (3%)
	4 (1%)	20 (7%)	24 (4%)	4 (4%)	28 (4%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	8 (3%)	0	8 (1%)	0	8 (1%)
	16 (5%)	0	16 (3%)	0	16 (2%)
	11 (4%)	0	11 (2%)	0	11 (2%)
	9 (3%)	0	9 (1%)	0	9 (1%)
Race					
American Indian or Alaska Native	2 (1%)	6 (2%)	8 (1%)	1 (1%)	9 (1%)
Asian	4 (1%)	14 (5%)	18 (3%)	3 (3%)	21 (3%)
Black or African American	24 (8%)	23 (8%)	47 (8%)	12 (12%)	59 (8%)
Native Hawaiian or other Pacific Islander	3 (1%)	1 (< 1%)	4 (1%)	0	4 (1%)
Other	17 (6%)	23 (8%)	40 (7%)	5 (5%)	45 (6%)
White	251 (83%)	233 (78%)	484 (81%)	79 (79%)	563 (80%)
Ethnic Origin					
Hispanic or Latino	40 (13%)	75 (25%)	115 (19%)	11 (11%)	126 (18%)
Not Hispanic or Latino	258 (86%)	222 (74%)	480 (80%)	89 (89%)	569 (81%)
Not reported	3 (1%)	3 (1%)	6 (1%)	0	6 (1%)
Weight (kg)					
Mean, Std.Dev	72.8,21.61	72.7,20.01	72.8,20.81	88.5,24.68	75.0,22.08
Median	67.1	68.6	68.0	87.1	69.6
Min	37	39	37	43	37
Max	177	157	177	164	177

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.3.4
Demography and Baseline Characteristics
[table created for posting purposes]
Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
N	301	300	601	100	701
Height (cm)					
Mean, Std.Dev	171.2,9.21	169.8,10.34	170.5,9.81	168.8,9.39	170.2,9.76
Median	170.2	169.5	170.2	167.6	170.2
Min	152	141	141	145	141
Max	211	196	211	191	211
N	301	300	601	100	701
BMI (kg/m²)					
Mean, Std.Dev	24.8,6.50	25.1,6.23	25.0,6.36	31.0,7.98	25.8,6.94
Median	23.0	23.3	23.1	30.5	23.8
Min	15	15	15	18	15
Max	50	47	50	66	66
N	301	300	601	100	701
Met Protocol Criteria					
No	3 (1%)	5 (2%)	8 (1%)	1 (1%)	9 (1%)
Yes	298 (99%)	295 (98%)	593 (99%)	99 (99%)	692 (99%)

Total column is a summation of Menve-Menveo, Menactra-Menveo and Naive columns

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Blood and lymphatic system disorders	3 (1%)	3 (1%)	8 (8%)	14 (2%)
Anaemia	3 (1%)	0	5 (5%)	8 (1%)
Iron deficiency anaemia	0	0	2 (2%)	2 (< 1%)
Leukocytosis	0	1 (< 1%)	0	1 (< 1%)
Lymphadenitis	0	1 (< 1%)	0	1 (< 1%)
Lymphadenopathy	0	0	1 (1%)	1 (< 1%)
Microcytic anaemia	0	1 (< 1%)	0	1 (< 1%)
Cardiac disorders	7 (2%)	5 (2%)	2 (2%)	14 (2%)
Aortic valve disease	0	1 (< 1%)	0	1 (< 1%)
Arrhythmia	0	1 (< 1%)	0	1 (< 1%)
Bradycardia	0	1 (< 1%)	0	1 (< 1%)
Cardiac failure congestive	0	0	1 (1%)	1 (< 1%)
Left ventricular hypertrophy	1 (< 1%)	0	0	1 (< 1%)
Myocardial ischaemia	1 (< 1%)	0	1 (1%)	2 (< 1%)
Palpitations	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Pulmonary valve stenosis	1 (< 1%)	0	0	1 (< 1%)
Sinus bradycardia	0	1 (< 1%)	0	1 (< 1%)
Supraventricular tachycardia	1 (< 1%)	0	0	1 (< 1%)
Tachycardia	0	0	1 (1%)	1 (< 1%)
Ventricular extrasystoles	1 (< 1%)	0	0	1 (< 1%)
Wolff-Parkinson-White syndrome	1 (< 1%)	0	0	1 (< 1%)
Congenital, familial and genetic disorders	10 (3%)	10 (3%)	2 (2%)	22 (3%)
Aniridia	1 (< 1%)	0	0	1 (< 1%)
Arnold-Chiari malformation	1 (< 1%)	0	0	1 (< 1%)
Arteriovenous malformation	0	1 (< 1%)	0	1 (< 1%)
Atrial septal defect	1 (< 1%)	0	0	1 (< 1%)
Congenital cardiovascular anomaly	0	1 (< 1%)	0	1 (< 1%)
Congenital hiatus hernia	0	1 (< 1%)	0	1 (< 1%)
Congenital jaw malformation	0	1 (< 1%)	0	1 (< 1%)
Congenital oesophageal anomaly	0	1 (< 1%)	0	1 (< 1%)
Congenital uterine anomaly	0	0	1 (1%)	1 (< 1%)
Cryptorchism	1 (< 1%)	0	0	1 (< 1%)
Developmental hip dysplasia	1 (< 1%)	0	0	1 (< 1%)
External auditory canal atresia	0	1 (< 1%)	0	1 (< 1%)
Factor V deficiency	0	0	1 (1%)	1 (< 1%)
Gilbert's syndrome	1 (< 1%)	0	0	1 (< 1%)
Intestinal malrotation	0	1 (< 1%)	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Macrocephaly	1 (< 1%)	0	0	1 (< 1%)
Microtia	0	1 (< 1%)	0	1 (< 1%)
Neurofibromatosis	1 (< 1%)	0	0	1 (< 1%)
Pectus excavatum	0	1 (< 1%)	0	1 (< 1%)
Sickle cell trait	1 (< 1%)	0	0	1 (< 1%)
Syringomyelia	1 (< 1%)	0	0	1 (< 1%)
Tourette's disorder	2 (1%)	2 (1%)	0	4 (1%)
Von Willebrand's disease	0	1 (< 1%)	0	1 (< 1%)
Ear and labyrinth disorders	3 (1%)	9 (3%)	3 (3%)	15 (2%)
Cerumen impaction	1 (< 1%)	3 (1%)	0	4 (1%)
Conductive deafness	0	1 (< 1%)	0	1 (< 1%)
Deafness	0	0	2 (2%)	2 (< 1%)
Deafness unilateral	0	1 (< 1%)	0	1 (< 1%)
Ear pain	1 (< 1%)	2 (1%)	0	3 (< 1%)
Eustachian tube dysfunction	1 (< 1%)	0	0	1 (< 1%)
Hypoacusis	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Tinnitus	0	1 (< 1%)	1 (1%)	2 (< 1%)
Endocrine disorders	5 (2%)	7 (2%)	7 (7%)	19 (3%)
Autoimmune thyroiditis	0	0	1 (1%)	1 (< 1%)
Goitre	1 (< 1%)	0	1 (1%)	2 (< 1%)
Hyperandrogenism	1 (< 1%)	0	0	1 (< 1%)
Hyperparathyroidism	0	1 (< 1%)	0	1 (< 1%)
Hypogonadism	0	0	1 (1%)	1 (< 1%)
Hypogonadism male	0	1 (< 1%)	0	1 (< 1%)
Hypothyroidism	3 (1%)	5 (2%)	4 (4%)	12 (2%)
Eye disorders	11 (4%)	10 (3%)	6 (6%)	27 (4%)
Amblyopia	0	1 (< 1%)	0	1 (< 1%)
Astigmatism	0	0	1 (1%)	1 (< 1%)
Blepharitis	0	0	1 (1%)	1 (< 1%)
Blepharospasm	0	1 (< 1%)	0	1 (< 1%)
Cataract	0	0	1 (1%)	1 (< 1%)
Conjunctivitis allergic	0	3 (1%)	0	3 (< 1%)
Dry eye	0	0	2 (2%)	2 (< 1%)
Eyelid ptosis	0	0	1 (1%)	1 (< 1%)
Glaucoma	0	1 (< 1%)	0	1 (< 1%)
Hypermetropia	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Myopia	6 (2%)	3 (1%)	0	9 (1%)
Optic atrophy	1 (< 1%)	0	0	1 (< 1%)
Presbyopia	2 (1%)	0	1 (1%)	3 (< 1%)
Strabismus	3 (1%)	2 (1%)	1 (1%)	6 (1%)
Gastrointestinal disorders	36 (12%)	29 (10%)	18 (18%)	83 (12%)
Abdominal discomfort	0	1 (< 1%)	0	1 (< 1%)
Abdominal pain	5 (2%)	3 (1%)	1 (1%)	9 (1%)
Abdominal pain upper	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Abdominal rebound tenderness	0	1 (< 1%)	0	1 (< 1%)
Abdominal tenderness	0	1 (< 1%)	0	1 (< 1%)
Anal fissure	0	1 (< 1%)	0	1 (< 1%)
Anal pruritus	1 (< 1%)	0	0	1 (< 1%)
Anal skin tags	0	1 (< 1%)	0	1 (< 1%)
Coeliac disease	3 (1%)	0	0	3 (< 1%)
Constipation	4 (1%)	4 (1%)	1 (1%)	9 (1%)
Dental caries	0	0	1 (1%)	1 (< 1%)
Diarrhoea	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Diverticulum	0	0	1 (1%)	1 (< 1%)
Dyspepsia	2 (1%)	1 (< 1%)	0	3 (< 1%)
Eosinophilic oesophagitis	0	1 (< 1%)	0	1 (< 1%)
Epigastric discomfort	0	0	1 (1%)	1 (< 1%)
Gastric ulcer	2 (1%)	2 (1%)	0	4 (1%)
Gastritis	2 (1%)	0	0	2 (< 1%)
Gastrooesophageal reflux disease	11 (4%)	10 (3%)	11 (11%)	32 (5%)
Haemorrhoids	2 (1%)	1 (< 1%)	2 (2%)	5 (1%)
Inguinal hernia	2 (1%)	0	0	2 (< 1%)
Intestinal obstruction	1 (< 1%)	0	0	1 (< 1%)
Intussusception	1 (< 1%)	0	0	1 (< 1%)
Irritable bowel syndrome	0	2 (1%)	0	2 (< 1%)
Large intestine polyp	0	0	2 (2%)	2 (< 1%)
Lumbar hernia	0	1 (< 1%)	0	1 (< 1%)
Nausea	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Tooth disorder	1 (< 1%)	0	0	1 (< 1%)
Tooth impacted	3 (1%)	0	0	3 (< 1%)
Vomiting	1 (< 1%)	2 (1%)	0	3 (< 1%)
General disorders and administration site conditions	9 (3%)	9 (3%)	6 (6%)	24 (3%)
Chest pain	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Developmental delay	0	1 (< 1%)	0	1 (< 1%)
Drug intolerance	0	2 (1%)	0	2 (< 1%)
Fatigue	3 (1%)	5 (2%)	0	8 (1%)
Malaise	0	1 (< 1%)	0	1 (< 1%)
Medical device pain	1 (< 1%)	0	0	1 (< 1%)
Oedema peripheral	0	0	2 (2%)	2 (< 1%)
Pain	4 (1%)	2 (1%)	2 (2%)	8 (1%)
Pyrexia	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Retention cyst	0	0	1 (1%)	1 (< 1%)
Hepatobiliary disorders	0	3 (1%)	1 (1%)	4 (1%)
Cholecystitis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Hepatic steatosis	0	2 (1%)	0	2 (< 1%)
Immune system disorders	90 (30%)	83 (28%)	38 (37%)	211 (30%)
Allergy to animal	4 (1%)	2 (1%)	1 (1%)	7 (1%)
Allergy to metals	0	1 (< 1%)	1 (1%)	2 (< 1%)
Contrast media allergy	0	0	1 (1%)	1 (< 1%)
Drug hypersensitivity	13 (4%)	25 (8%)	19 (19%)	57 (8%)
Dust allergy	1 (< 1%)	0	0	1 (< 1%)
Food allergy	10 (3%)	5 (2%)	4 (4%)	19 (3%)
Hypersensitivity	7 (2%)	2 (1%)	1 (1%)	10 (1%)
Iodine allergy	0	0	3 (3%)	3 (< 1%)
Milk allergy	4 (1%)	0	0	4 (1%)
Multiple allergies	2 (1%)	0	0	2 (< 1%)
Mycotic allergy	1 (< 1%)	0	0	1 (< 1%)
Perennial allergy	0	1 (< 1%)	0	1 (< 1%)
Reaction to food colouring	0	1 (< 1%)	0	1 (< 1%)
Rubber sensitivity	1 (< 1%)	3 (1%)	0	4 (1%)
Seasonal allergy	67 (22%)	62 (21%)	18 (18%)	147 (21%)
Infections and infestations	43 (14%)	26 (9%)	11 (11%)	80 (11%)
Abscess	0	0	1 (1%)	1 (< 1%)
Acute sinusitis	3 (1%)	1 (< 1%)	1 (1%)	5 (1%)
Angular cheilitis	1 (< 1%)	0	0	1 (< 1%)
Appendicitis	7 (2%)	3 (1%)	1 (1%)	11 (2%)
Appendicitis perforated	1 (< 1%)	0	0	1 (< 1%)
Body tinea	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Bronchitis	0	1 (< 1%)	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Cellulitis	0	0	1 (1%)	1 (< 1%)
Chronic sinusitis	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Chronic tonsillitis	1 (< 1%)	0	0	1 (< 1%)
Conjunctivitis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Cystitis	0	0	1 (1%)	1 (< 1%)
Diverticulitis	0	0	1 (1%)	1 (< 1%)
Ear infection	1 (< 1%)	2 (1%)	0	3 (< 1%)
Folliculitis	1 (< 1%)	0	0	1 (< 1%)
Gastroenteritis	0	1 (< 1%)	0	1 (< 1%)
Genital herpes	0	0	1 (1%)	1 (< 1%)
Helicobacter infection	1 (< 1%)	0	0	1 (< 1%)
Herpes ophthalmic	1 (< 1%)	0	0	1 (< 1%)
Herpes simplex	2 (1%)	0	2 (2%)	4 (1%)
Herpes zoster	0	1 (< 1%)	0	1 (< 1%)
Impetigo	2 (1%)	0	0	2 (< 1%)
Infectious colitis	0	1 (< 1%)	0	1 (< 1%)
Infectious mononucleosis	0	1 (< 1%)	0	1 (< 1%)
Influenza	1 (< 1%)	2 (1%)	0	3 (< 1%)
Kidney infection	0	0	1 (1%)	1 (< 1%)
Nasopharyngitis	1 (< 1%)	0	0	1 (< 1%)
Onychomycosis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Oral candidiasis	0	0	1 (1%)	1 (< 1%)
Oral herpes	0	3 (1%)	0	3 (< 1%)
Otitis externa	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Otitis media	0	2 (1%)	0	2 (< 1%)
Otitis media chronic	1 (< 1%)	0	1 (1%)	2 (< 1%)
Paronychia	1 (< 1%)	0	0	1 (< 1%)
Pharyngitis	3 (1%)	1 (< 1%)	1 (1%)	5 (1%)
Pharyngitis streptococcal	4 (1%)	2 (1%)	0	6 (1%)
Pilonidal cyst	1 (< 1%)	0	0	1 (< 1%)
Pneumonia	1 (< 1%)	0	0	1 (< 1%)
Respiratory tract infection viral	0	1 (< 1%)	0	1 (< 1%)
Rhinitis	1 (< 1%)	0	0	1 (< 1%)
Salmonella bacteraemia	0	1 (< 1%)	0	1 (< 1%)
Scarlet fever	0	1 (< 1%)	0	1 (< 1%)
Scrotal abscess	1 (< 1%)	0	0	1 (< 1%)
Sinusitis	4 (1%)	0	0	4 (1%)
Streptococcal infection	0	1 (< 1%)	0	1 (< 1%)
Tinea pedis	0	1 (< 1%)	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Tinea versicolour	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Tonsillitis	5 (2%)	1 (< 1%)	0	6 (1%)
Tracheobronchitis mycoplasmal	1 (< 1%)	0	0	1 (< 1%)
Upper respiratory tract infection	3 (1%)	3 (1%)	1 (1%)	7 (1%)
Urinary tract infection	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Varicella	2 (1%)	0	0	2 (< 1%)
Viral infection	0	1 (< 1%)	0	1 (< 1%)
Viral pharyngitis	1 (< 1%)	0	0	1 (< 1%)
Viral upper respiratory tract infection	2 (1%)	0	0	2 (< 1%)
Injury, poisoning and procedural complications	17 (6%)	19 (6%)	10 (10%)	46 (7%)
Ankle fracture	1 (< 1%)	0	0	1 (< 1%)
Cartilage injury	0	1 (< 1%)	0	1 (< 1%)
Clavicle fracture	0	1 (< 1%)	0	1 (< 1%)
Concussion	5 (2%)	4 (1%)	0	9 (1%)
Contusion	0	2 (1%)	0	2 (< 1%)
Eye contusion	1 (< 1%)	0	0	1 (< 1%)
Femur fracture	1 (< 1%)	0	0	1 (< 1%)
Foot fracture	0	0	1 (1%)	1 (< 1%)
Forearm fracture	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Hand fracture	1 (< 1%)	0	0	1 (< 1%)
Joint dislocation	0	1 (< 1%)	1 (1%)	2 (< 1%)
Joint injury	0	1 (< 1%)	0	1 (< 1%)
Ligament rupture	1 (< 1%)	1 (< 1%)	3 (3%)	5 (1%)
Ligament sprain	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Lower limb fracture	1 (< 1%)	0	0	1 (< 1%)
Lumbar vertebral fracture	0	0	1 (1%)	1 (< 1%)
Meniscus injury	1 (< 1%)	0	1 (1%)	2 (< 1%)
Multiple fractures	0	0	1 (1%)	1 (< 1%)
Muscle strain	0	1 (< 1%)	0	1 (< 1%)
Post concussion syndrome	0	1 (< 1%)	0	1 (< 1%)
Procedural pain	0	0	1 (1%)	1 (< 1%)
Radius fracture	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Rib fracture	0	0	1 (1%)	1 (< 1%)
Road traffic accident	0	1 (< 1%)	0	1 (< 1%)
Tendon rupture	0	0	1 (1%)	1 (< 1%)
Tibia fracture	0	1 (< 1%)	0	1 (< 1%)
Upper limb fracture	2 (1%)	1 (< 1%)	0	3 (< 1%)
Wrist fracture	2 (1%)	2 (1%)	0	4 (1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Investigations	14 (5%)	8 (3%)	3 (3%)	25 (4%)
Arthroscopy	1 (< 1%)	0	0	1 (< 1%)
Blood glucose abnormal	0	1 (< 1%)	0	1 (< 1%)
Blood pressure increased	1 (< 1%)	0	1 (1%)	2 (< 1%)
Blood triglycerides increased	1 (< 1%)	0	0	1 (< 1%)
Body height below normal	2 (1%)	0	0	2 (< 1%)
Body mass index increased	2 (1%)	0	0	2 (< 1%)
Cardiac murmur	3 (1%)	4 (1%)	0	7 (1%)
Cardiac murmur functional	1 (< 1%)	0	0	1 (< 1%)
Colposcopy	0	0	1 (1%)	1 (< 1%)
Endoscopy	0	1 (< 1%)	0	1 (< 1%)
Full blood count abnormal	0	1 (< 1%)	0	1 (< 1%)
Hepatic enzyme abnormal	1 (< 1%)	0	0	1 (< 1%)
Liver function test increased	0	1 (< 1%)	0	1 (< 1%)
Weight decreased	0	0	1 (1%)	1 (< 1%)
Weight increased	1 (< 1%)	0	0	1 (< 1%)
White blood cell count decreased	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	26 (9%)	17 (6%)	19 (19%)	62 (9%)
Decreased appetite	2 (1%)	0	0	2 (< 1%)
Dyslipidaemia	2 (1%)	0	2 (2%)	4 (1%)
Glucose tolerance impaired	1 (< 1%)	1 (< 1%)	2 (2%)	4 (1%)
Gluten sensitivity	1 (< 1%)	0	0	1 (< 1%)
Gout	0	0	2 (2%)	2 (< 1%)
Haemochromatosis	0	0	1 (1%)	1 (< 1%)
Hypercholesterolaemia	0	0	3 (3%)	3 (< 1%)
Hyperglycaemia	0	0	2 (2%)	2 (< 1%)
Hyperlipidaemia	1 (< 1%)	2 (1%)	6 (6%)	9 (1%)
Hypertriglyceridaemia	0	1 (< 1%)	3 (3%)	4 (1%)
Hypoglycaemia	0	1 (< 1%)	1 (1%)	2 (< 1%)
Insulin resistance syndrome	1 (< 1%)	0	0	1 (< 1%)
Iron deficiency	0	0	1 (1%)	1 (< 1%)
Lactose intolerance	0	1 (< 1%)	0	1 (< 1%)
Obesity	9 (3%)	8 (3%)	7 (7%)	24 (3%)
Overweight	7 (2%)	0	0	7 (1%)
Type 1 diabetes mellitus	2 (1%)	2 (1%)	1 (1%)	5 (1%)
Type 2 diabetes mellitus	0	0	5 (5%)	5 (1%)
Vitamin B12 deficiency	0	1 (< 1%)	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Vitamin D deficiency	4 (1%)	2 (1%)	2 (2%)	8 (1%)
Musculoskeletal and connective tissue disorders	42 (14%)	29 (10%)	18 (18%)	89 (13%)
Arthralgia	8 (3%)	6 (2%)	5 (5%)	19 (3%)
Arthritis	0	0	2 (2%)	2 (< 1%)
Back pain	10 (3%)	7 (2%)	5 (5%)	22 (3%)
Femoroacetabular impingement	0	1 (< 1%)	0	1 (< 1%)
Fibromyalgia	0	0	1 (1%)	1 (< 1%)
Foot deformity	1 (< 1%)	0	0	1 (< 1%)
Intervertebral disc protrusion	0	0	2 (2%)	2 (< 1%)
Joint stiffness	0	1 (< 1%)	0	1 (< 1%)
Juvenile idiopathic arthritis	0	1 (< 1%)	0	1 (< 1%)
Kyphosis	1 (< 1%)	0	0	1 (< 1%)
Ligament laxity	1 (< 1%)	0	0	1 (< 1%)
Lordosis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Muscle spasms	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Muscle twitching	0	1 (< 1%)	0	1 (< 1%)
Muscular weakness	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Musculoskeletal pain	2 (1%)	3 (1%)	5 (5%)	10 (1%)
Myalgia	2 (1%)	2 (1%)	4 (4%)	8 (1%)
Myositis	0	0	1 (1%)	1 (< 1%)
Neck pain	0	2 (1%)	2 (2%)	4 (1%)
Osteoarthritis	0	1 (< 1%)	3 (3%)	4 (1%)
Osteochondrosis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Osteopenia	0	0	2 (2%)	2 (< 1%)
Pain in extremity	2 (1%)	2 (1%)	2 (2%)	6 (1%)
Patellofemoral pain syndrome	1 (< 1%)	0	0	1 (< 1%)
Periarthritis	0	0	1 (1%)	1 (< 1%)
Scoliosis	10 (3%)	4 (1%)	1 (1%)	15 (2%)
Shoulder deformity	0	1 (< 1%)	0	1 (< 1%)
Soft tissue mass	0	0	1 (1%)	1 (< 1%)
Spinal deformity	1 (< 1%)	0	0	1 (< 1%)
Spinal osteoarthritis	1 (< 1%)	0	1 (1%)	2 (< 1%)
Spinal pain	0	1 (< 1%)	0	1 (< 1%)
Spondylolisthesis	1 (< 1%)	0	0	1 (< 1%)
Synovial cyst	0	2 (1%)	0	2 (< 1%)
Temporomandibular joint syndrome	1 (< 1%)	0	0	1 (< 1%)
Tendon disorder	1 (< 1%)	0	0	1 (< 1%)
Tendonitis	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (2%)	3 (1%)	11 (11%)	20 (3%)
Breast cancer	0	0	1 (1%)	1 (< 1%)
Lipoma	0	0	1 (1%)	1 (< 1%)
Malignant melanoma	0	0	2 (2%)	2 (< 1%)
Melanocytic naevus	1 (< 1%)	0	3 (3%)	4 (1%)
Neoplasm skin	1 (< 1%)	0	0	1 (< 1%)
Non-Hodgkin's lymphoma stage III	0	0	1 (1%)	1 (< 1%)
Osteochondroma	1 (< 1%)	0	0	1 (< 1%)
Seborrhoeic keratosis	0	0	2 (2%)	2 (< 1%)
Skin papilloma	3 (1%)	2 (1%)	1 (1%)	6 (1%)
Thyroid cancer	0	0	1 (1%)	1 (< 1%)
Uterine leiomyoma	0	1 (< 1%)	3 (3%)	4 (1%)
Nervous system disorders	46 (15%)	42 (14%)	20 (20%)	108 (15%)
Cerebral cyst	0	1 (< 1%)	0	1 (< 1%)
Cervical radiculopathy	0	0	1 (1%)	1 (< 1%)
Cluster headache	2 (1%)	0	0	2 (< 1%)
Diabetic neuropathy	0	0	1 (1%)	1 (< 1%)
Disturbance in attention	0	1 (< 1%)	0	1 (< 1%)
Dizziness	0	1 (< 1%)	0	1 (< 1%)
Dyslexia	2 (1%)	0	0	2 (< 1%)
Essential tremor	1 (< 1%)	0	0	1 (< 1%)
Febrile convulsion	1 (< 1%)	0	0	1 (< 1%)
Headache	20 (7%)	19 (6%)	9 (9%)	48 (7%)
Memory impairment	0	1 (< 1%)	0	1 (< 1%)
Migraine	11 (4%)	17 (6%)	9 (9%)	37 (5%)
Migraine with aura	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Migraine without aura	5 (2%)	0	0	5 (1%)
Myelopathy	0	0	1 (1%)	1 (< 1%)
Restless legs syndrome	0	0	1 (1%)	1 (< 1%)
Seizure	0	1 (< 1%)	1 (1%)	2 (< 1%)
Sinus headache	0	3 (1%)	0	3 (< 1%)
Speech disorder developmental	0	2 (1%)	0	2 (< 1%)
Spinal cord disorder	1 (< 1%)	0	0	1 (< 1%)
Syncope	3 (1%)	1 (< 1%)	0	4 (1%)
Tension headache	4 (1%)	3 (1%)	0	7 (1%)
Tethered cord syndrome	1 (< 1%)	0	0	1 (< 1%)
Thoracic outlet syndrome	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Tremor	0	1 (< 1%)	0	1 (< 1%)
Pregnancy, puerperium and perinatal conditions	2 (1%)	1 (< 1%)	0	3 (< 1%)
Abortion	0	1 (< 1%)	0	1 (< 1%)
Abortion spontaneous	1 (< 1%)	0	0	1 (< 1%)
Delivery	1 (< 1%)	0	0	1 (< 1%)
Psychiatric disorders	95 (32%)	73 (24%)	38 (37%)	206 (29%)
Abnormal behaviour	1 (< 1%)	0	0	1 (< 1%)
Affective disorder	5 (2%)	1 (< 1%)	1 (1%)	7 (1%)
Alcohol abuse	0	0	1 (1%)	1 (< 1%)
Anger	2 (1%)	0	0	2 (< 1%)
Anxiety	34 (11%)	26 (9%)	14 (14%)	74 (11%)
Anxiety disorder	2 (1%)	1 (< 1%)	0	3 (< 1%)
Attention deficit/hyperactivity disorder	47 (16%)	39 (13%)	7 (7%)	93 (13%)
Autism spectrum disorder	2 (1%)	1 (< 1%)	0	3 (< 1%)
Binge eating	0	0	1 (1%)	1 (< 1%)
Bipolar disorder	0	3 (1%)	1 (1%)	4 (1%)
Bulimia nervosa	1 (< 1%)	0	0	1 (< 1%)
Depression	29 (10%)	23 (8%)	20 (20%)	72 (10%)
Drug abuse	2 (1%)	0	1 (1%)	3 (< 1%)
Eating disorder	0	1 (< 1%)	0	1 (< 1%)
Emotional distress	1 (< 1%)	0	0	1 (< 1%)
Generalised anxiety disorder	2 (1%)	0	1 (1%)	3 (< 1%)
Insomnia	7 (2%)	8 (3%)	7 (7%)	22 (3%)
Learning disorder	1 (< 1%)	0	0	1 (< 1%)
Major depression	4 (1%)	0	1 (1%)	5 (1%)
Obsessive-compulsive disorder	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Oppositional defiant disorder	1 (< 1%)	0	0	1 (< 1%)
Panic attack	0	0	1 (1%)	1 (< 1%)
Persistent depressive disorder	1 (< 1%)	0	0	1 (< 1%)
Post-traumatic stress disorder	1 (< 1%)	0	1 (1%)	2 (< 1%)
Psychotic disorder	0	0	1 (1%)	1 (< 1%)
Schizophrenia	0	0	1 (1%)	1 (< 1%)
Sleep disorder	0	1 (< 1%)	0	1 (< 1%)
Social anxiety disorder	2 (1%)	0	0	2 (< 1%)
Stress	1 (< 1%)	0	0	1 (< 1%)
Substance abuse	0	0	1 (1%)	1 (< 1%)
Suicidal ideation	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Tic	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Renal and urinary disorders	7 (2%)	2 (1%)	4 (4%)	13 (2%)
Chronic kidney disease	0	0	1 (1%)	1 (< 1%)
Dysuria	1 (< 1%)	0	0	1 (< 1%)
Glomerulonephritis acute	1 (< 1%)	0	0	1 (< 1%)
Haematuria	1 (< 1%)	0	0	1 (< 1%)
Hypertonic bladder	1 (< 1%)	0	1 (1%)	2 (< 1%)
Nephrolithiasis	1 (< 1%)	2 (1%)	0	3 (< 1%)
Pollakiuria	1 (< 1%)	0	0	1 (< 1%)
Polyuria	0	0	1 (1%)	1 (< 1%)
Urinary incontinence	0	0	1 (1%)	1 (< 1%)
Vesicoureteric reflux	2 (1%)	0	0	2 (< 1%)
Reproductive system and breast disorders	30 (10%)	21 (7%)	10 (10%)	61 (9%)
Amenorrhoea	1 (< 1%)	0	0	1 (< 1%)
Benign prostatic hyperplasia	0	0	1 (1%)	1 (< 1%)
Breast mass	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Cervical dysplasia	0	0	1 (1%)	1 (< 1%)
Dysmenorrhoea	12 (4%)	10 (3%)	1 (1%)	23 (3%)
Endometriosis	0	0	2 (2%)	2 (< 1%)
Erectile dysfunction	0	1 (< 1%)	1 (1%)	2 (< 1%)
Menometrorrhagia	2 (1%)	0	0	2 (< 1%)
Menopausal symptoms	0	0	1 (1%)	1 (< 1%)
Menorrhagia	8 (3%)	1 (< 1%)	0	9 (1%)
Menstruation irregular	3 (1%)	5 (2%)	1 (1%)	9 (1%)
Metrorrhagia	0	0	1 (1%)	1 (< 1%)
Ovarian cyst	3 (1%)	1 (< 1%)	0	4 (1%)
Polycystic ovaries	1 (< 1%)	3 (1%)	0	4 (1%)
Polymenorrhoea	2 (1%)	0	0	2 (< 1%)
Prostatomegaly	0	0	1 (1%)	1 (< 1%)
Scrotal varicose veins	1 (< 1%)	0	0	1 (< 1%)
Testicular torsion	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Uterine haemorrhage	0	1 (< 1%)	0	1 (< 1%)
Vaginal discharge	0	1 (< 1%)	0	1 (< 1%)
Vaginal disorder	0	0	1 (1%)	1 (< 1%)
Vulvovaginal discomfort	0	1 (< 1%)	0	1 (< 1%)
Vulvovaginal dryness	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Respiratory, thoracic and mediastinal disorders	70 (23%)	58 (19%)	14 (14%)	142 (20%)
Adenoidal hypertrophy	2 (1%)	0	0	2 (< 1%)
Asthma	32 (11%)	36 (12%)	3 (3%)	71 (10%)
Asthma exercise induced	10 (3%)	3 (1%)	0	13 (2%)
Bronchial hyperreactivity	3 (1%)	0	1 (1%)	4 (1%)
Bronchitis chronic	0	0	1 (1%)	1 (< 1%)
Bronchospasm	2 (1%)	3 (1%)	0	5 (1%)
Cough	2 (1%)	2 (1%)	3 (3%)	7 (1%)
Dyspnoea	0	0	1 (1%)	1 (< 1%)
Epistaxis	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Nasal congestion	1 (< 1%)	3 (1%)	0	4 (1%)
Nasal inflammation	0	0	1 (1%)	1 (< 1%)
Nasal obstruction	0	1 (< 1%)	0	1 (< 1%)
Nasal septum deviation	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Nasal turbinate hypertrophy	0	0	1 (1%)	1 (< 1%)
Oropharyngeal pain	3 (1%)	1 (< 1%)	0	4 (1%)
Pleurisy	0	1 (< 1%)	0	1 (< 1%)
Pulmonary thrombosis	0	0	1 (1%)	1 (< 1%)
Rhinitis allergic	25 (8%)	8 (3%)	3 (3%)	36 (5%)
Rhinitis perennial	0	3 (1%)	0	3 (< 1%)
Rhinorrhoea	0	0	1 (1%)	1 (< 1%)
Sinus congestion	0	1 (< 1%)	0	1 (< 1%)
Sleep apnoea syndrome	2 (1%)	2 (1%)	6 (6%)	10 (1%)
Snoring	0	1 (< 1%)	0	1 (< 1%)
Tonsillar hypertrophy	2 (1%)	3 (1%)	0	5 (1%)
Velopharyngeal incompetence	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	73 (24%)	39 (13%)	10 (10%)	122 (17%)
Acanthosis nigricans	4 (1%)	0	0	4 (1%)
Acne	46 (15%)	24 (8%)	1 (1%)	71 (10%)
Actinic keratosis	0	0	1 (1%)	1 (< 1%)
Alopecia	1 (< 1%)	0	0	1 (< 1%)
Cafe au lait spots	1 (< 1%)	0	0	1 (< 1%)
Chronic spontaneous urticaria	1 (< 1%)	0	0	1 (< 1%)
Dandruff	0	1 (< 1%)	0	1 (< 1%)
Dermatitis	1 (< 1%)	0	1 (1%)	2 (< 1%)
Dermatitis atopic	5 (2%)	2 (1%)	0	7 (1%)
Dermatitis contact	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Dry skin	2 (1%)	0	0	2 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Ecchymosis	0	1 (< 1%)	0	1 (< 1%)
Eczema	18 (6%)	10 (3%)	2 (2%)	30 (4%)
Hidradenitis	0	1 (< 1%)	0	1 (< 1%)
Hyperhidrosis	2 (1%)	0	0	2 (< 1%)
Keloid scar	1 (< 1%)	0	0	1 (< 1%)
Keratosis pilaris	1 (< 1%)	0	0	1 (< 1%)
Mechanical urticaria	1 (< 1%)	0	0	1 (< 1%)
Night sweats	0	0	1 (1%)	1 (< 1%)
Pityriasis rosea	0	1 (< 1%)	0	1 (< 1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Psoriasis	1 (< 1%)	0	1 (1%)	2 (< 1%)
Rash	1 (< 1%)	0	0	1 (< 1%)
Rosacea	0	1 (< 1%)	2 (2%)	3 (< 1%)
Sebaceous hyperplasia	0	0	1 (1%)	1 (< 1%)
Seborrhoeic dermatitis	0	1 (< 1%)	0	1 (< 1%)
Skin ulcer	0	0	1 (1%)	1 (< 1%)
Urticaria	0	2 (1%)	1 (1%)	3 (< 1%)
Social circumstances	0	2 (1%)	5 (5%)	7 (1%)
Menopause	0	0	2 (2%)	2 (< 1%)
Postmenopause	0	0	3 (3%)	3 (< 1%)
Tobacco user	0	2 (1%)	0	2 (< 1%)
Surgical and medical procedures	24 (8%)	18 (6%)	30 (29%)	72 (10%)
Adenoidectomy	4 (1%)	1 (< 1%)	0	5 (1%)
Adenotonsillectomy	2 (1%)	0	0	2 (< 1%)
Appendicectomy	6 (2%)	2 (1%)	0	8 (1%)
Brain operation	1 (< 1%)	0	0	1 (< 1%)
Caesarean section	1 (< 1%)	0	2 (2%)	3 (< 1%)
Catheter placement	0	1 (< 1%)	0	1 (< 1%)
Cautery to nose	1 (< 1%)	0	0	1 (< 1%)
Cholecystectomy	0	1 (< 1%)	2 (2%)	3 (< 1%)
Circumcision	0	1 (< 1%)	0	1 (< 1%)
Closed fracture manipulation	1 (< 1%)	0	0	1 (< 1%)
Contraception	0	1 (< 1%)	0	1 (< 1%)
Cryotherapy	0	0	1 (1%)	1 (< 1%)
Dental operation	1 (< 1%)	0	0	1 (< 1%)
Ear tube insertion	0	1 (< 1%)	0	1 (< 1%)
Female sterilisation	0	0	7 (7%)	7 (1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4
Medical History by Body System Organ Class and Preferred Term
All Enrolled Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Fracture treatment	0	1 (< 1%)	0	1 (< 1%)
Haemorrhoid operation	1 (< 1%)	0	0	1 (< 1%)
Hormone replacement therapy	0	0	1 (1%)	1 (< 1%)
Hysterectomy	0	0	7 (7%)	7 (1%)
Implantable defibrillator insertion	0	0	1 (1%)	1 (< 1%)
Inguinal hernia repair	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Intervertebral disc operation	0	0	1 (1%)	1 (< 1%)
Knee operation	1 (< 1%)	0	0	1 (< 1%)
Ligament operation	0	1 (< 1%)	0	1 (< 1%)
Lymphadenectomy	0	0	1 (1%)	1 (< 1%)
Mammoplasty	0	0	2 (2%)	2 (< 1%)
Mastectomy	0	0	1 (1%)	1 (< 1%)
Meniscus operation	1 (< 1%)	0	0	1 (< 1%)
Myringotomy	1 (< 1%)	3 (1%)	0	4 (1%)
Ovarian cystectomy	0	0	1 (1%)	1 (< 1%)
Papilloma excision	1 (< 1%)	0	0	1 (< 1%)
Plastic surgery to the face	0	0	1 (1%)	1 (< 1%)
Splint application	0	1 (< 1%)	0	1 (< 1%)
Strabismus correction	0	0	1 (1%)	1 (< 1%)
Thyroidectomy	0	0	1 (1%)	1 (< 1%)
Tonsillectomy	7 (2%)	6 (2%)	0	13 (2%)
Umbilical hernia repair	0	1 (< 1%)	0	1 (< 1%)
Vasectomy	0	0	1 (1%)	1 (< 1%)
Venous operation	0	0	1 (1%)	1 (< 1%)
Wisdom teeth removal	4 (1%)	0	0	4 (1%)
Vascular disorders	8 (3%)	2 (1%)	17 (17%)	27 (4%)
Essential hypertension	0	1 (< 1%)	1 (1%)	2 (< 1%)
Hot flush	0	0	1 (1%)	1 (< 1%)
Hypertension	4 (1%)	1 (< 1%)	14 (14%)	19 (3%)
Orthostatic hypotension	1 (< 1%)	0	0	1 (< 1%)
Peripheral venous disease	0	0	1 (1%)	1 (< 1%)
Prehypertension	2 (1%)	0	0	2 (< 1%)
Raynaud's phenomenon	1 (< 1%)	0	0	1 (< 1%)
Varicose vein	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Blood and lymphatic system disorders	3 (1%)	2 (1%)	7 (8%)	12 (2%)
Anaemia	3 (1%)	0	4 (4%)	7 (1%)
Iron deficiency anaemia	0	0	2 (2%)	2 (< 1%)
Leukocytosis	0	1 (< 1%)	0	1 (< 1%)
Lymphadenitis	0	1 (< 1%)	0	1 (< 1%)
Lymphadenopathy	0	0	1 (1%)	1 (< 1%)
Cardiac disorders	7 (2%)	5 (2%)	2 (2%)	14 (2%)
Aortic valve disease	0	1 (< 1%)	0	1 (< 1%)
Arrhythmia	0	1 (< 1%)	0	1 (< 1%)
Bradycardia	0	1 (< 1%)	0	1 (< 1%)
Cardiac failure congestive	0	0	1 (1%)	1 (< 1%)
Left ventricular hypertrophy	1 (< 1%)	0	0	1 (< 1%)
Myocardial ischaemia	1 (< 1%)	0	1 (1%)	2 (< 1%)
Palpitations	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Pulmonary valve stenosis	1 (< 1%)	0	0	1 (< 1%)
Sinus bradycardia	0	1 (< 1%)	0	1 (< 1%)
Supraventricular tachycardia	1 (< 1%)	0	0	1 (< 1%)
Tachycardia	0	0	1 (1%)	1 (< 1%)
Ventricular extrasystoles	1 (< 1%)	0	0	1 (< 1%)
Wolff-Parkinson-White syndrome	1 (< 1%)	0	0	1 (< 1%)
Congenital, familial and genetic disorders	10 (3%)	10 (4%)	2 (2%)	22 (3%)
Aniridia	1 (< 1%)	0	0	1 (< 1%)
Arnold-Chiari malformation	1 (< 1%)	0	0	1 (< 1%)
Arteriovenous malformation	0	1 (< 1%)	0	1 (< 1%)
Atrial septal defect	1 (< 1%)	0	0	1 (< 1%)
Congenital cardiovascular anomaly	0	1 (< 1%)	0	1 (< 1%)
Congenital hiatus hernia	0	1 (< 1%)	0	1 (< 1%)
Congenital jaw malformation	0	1 (< 1%)	0	1 (< 1%)
Congenital oesophageal anomaly	0	1 (< 1%)	0	1 (< 1%)
Congenital uterine anomaly	0	0	1 (1%)	1 (< 1%)
Cryptorchism	1 (< 1%)	0	0	1 (< 1%)
Developmental hip dysplasia	1 (< 1%)	0	0	1 (< 1%)
External auditory canal atresia	0	1 (< 1%)	0	1 (< 1%)
Factor V deficiency	0	0	1 (1%)	1 (< 1%)
Gilbert's syndrome	1 (< 1%)	0	0	1 (< 1%)
Intestinal malrotation	0	1 (< 1%)	0	1 (< 1%)
Macrocephaly	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Microtia	0	1 (< 1%)	0	1 (< 1%)
Neurofibromatosis	1 (< 1%)	0	0	1 (< 1%)
Pectus excavatum	0	1 (< 1%)	0	1 (< 1%)
Sickle cell trait	1 (< 1%)	0	0	1 (< 1%)
Syringomyelia	1 (< 1%)	0	0	1 (< 1%)
Tourette's disorder	2 (1%)	2 (1%)	0	4 (1%)
Von Willebrand's disease	0	1 (< 1%)	0	1 (< 1%)
Ear and labyrinth disorders	3 (1%)	9 (3%)	2 (2%)	14 (2%)
Cerumen impaction	1 (< 1%)	3 (1%)	0	4 (1%)
Conductive deafness	0	1 (< 1%)	0	1 (< 1%)
Deafness	0	0	1 (1%)	1 (< 1%)
Deafness unilateral	0	1 (< 1%)	0	1 (< 1%)
Ear pain	1 (< 1%)	2 (1%)	0	3 (< 1%)
Eustachian tube dysfunction	1 (< 1%)	0	0	1 (< 1%)
Hypoacusis	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Tinnitus	0	1 (< 1%)	1 (1%)	2 (< 1%)
Endocrine disorders	4 (1%)	6 (2%)	4 (4%)	14 (2%)
Goitre	1 (< 1%)	0	1 (1%)	2 (< 1%)
Hyperandrogenism	1 (< 1%)	0	0	1 (< 1%)
Hyperparathyroidism	0	1 (< 1%)	0	1 (< 1%)
Hypogonadism male	0	1 (< 1%)	0	1 (< 1%)
Hypothyroidism	2 (1%)	4 (1%)	3 (3%)	9 (1%)
Eye disorders	11 (4%)	10 (4%)	4 (4%)	25 (4%)
Amblyopia	0	1 (< 1%)	0	1 (< 1%)
Astigmatism	0	0	1 (1%)	1 (< 1%)
Blepharitis	0	0	1 (1%)	1 (< 1%)
Blepharospasm	0	1 (< 1%)	0	1 (< 1%)
Conjunctivitis allergic	0	3 (1%)	0	3 (< 1%)
Dry eye	0	0	2 (2%)	2 (< 1%)
Glaucoma	0	1 (< 1%)	0	1 (< 1%)
Hypermetropia	0	0	1 (1%)	1 (< 1%)
Myopia	6 (2%)	3 (1%)	0	9 (1%)
Optic atrophy	1 (< 1%)	0	0	1 (< 1%)
Presbyopia	2 (1%)	0	1 (1%)	3 (< 1%)
Strabismus	3 (1%)	2 (1%)	1 (1%)	6 (1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Gastrointestinal disorders	36 (12%)	28 (10%)	15 (16%)	79 (12%)
Abdominal discomfort	0	1 (< 1%)	0	1 (< 1%)
Abdominal pain	5 (2%)	3 (1%)	1 (1%)	9 (1%)
Abdominal pain upper	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Abdominal rebound tenderness	0	1 (< 1%)	0	1 (< 1%)
Abdominal tenderness	0	1 (< 1%)	0	1 (< 1%)
Anal fissure	0	1 (< 1%)	0	1 (< 1%)
Anal pruritus	1 (< 1%)	0	0	1 (< 1%)
Coeliac disease	3 (1%)	0	0	3 (< 1%)
Constipation	4 (1%)	4 (1%)	1 (1%)	9 (1%)
Dental caries	0	0	1 (1%)	1 (< 1%)
Diarrhoea	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Diverticulum	0	0	1 (1%)	1 (< 1%)
Dyspepsia	2 (1%)	1 (< 1%)	0	3 (< 1%)
Eosinophilic oesophagitis	0	1 (< 1%)	0	1 (< 1%)
Epigastric discomfort	0	0	1 (1%)	1 (< 1%)
Gastric ulcer	2 (1%)	2 (1%)	0	4 (1%)
Gastritis	2 (1%)	0	0	2 (< 1%)
Gastrooesophageal reflux disease	11 (4%)	10 (4%)	8 (9%)	29 (4%)
Haemorrhoids	2 (1%)	0	2 (2%)	4 (1%)
Inguinal hernia	2 (1%)	0	0	2 (< 1%)
Intestinal obstruction	1 (< 1%)	0	0	1 (< 1%)
Intussusception	1 (< 1%)	0	0	1 (< 1%)
Irritable bowel syndrome	0	2 (1%)	0	2 (< 1%)
Large intestine polyp	0	0	1 (1%)	1 (< 1%)
Lumbar hernia	0	1 (< 1%)	0	1 (< 1%)
Nausea	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Tooth disorder	1 (< 1%)	0	0	1 (< 1%)
Tooth impacted	3 (1%)	0	0	3 (< 1%)
Vomiting	1 (< 1%)	2 (1%)	0	3 (< 1%)
General disorders and administration site conditions	9 (3%)	8 (3%)	4 (4%)	21 (3%)
Chest pain	0	0	1 (1%)	1 (< 1%)
Developmental delay	0	1 (< 1%)	0	1 (< 1%)
Drug intolerance	0	2 (1%)	0	2 (< 1%)
Fatigue	3 (1%)	5 (2%)	0	8 (1%)
Malaise	0	1 (< 1%)	0	1 (< 1%)
Medical device pain	1 (< 1%)	0	0	1 (< 1%)
Oedema peripheral	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Pain	4 (1%)	1 (< 1%)	1 (1%)	6 (1%)
Pyrexia	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Retention cyst	0	0	1 (1%)	1 (< 1%)
Hepatobiliary disorders	0	3 (1%)	1 (1%)	4 (1%)
Cholecystitis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Hepatic steatosis	0	2 (1%)	0	2 (< 1%)
Immune system disorders	86 (30%)	79 (28%)	34 (37%)	199 (30%)
Allergy to animal	3 (1%)	2 (1%)	1 (1%)	6 (1%)
Allergy to metals	0	1 (< 1%)	1 (1%)	2 (< 1%)
Contrast media allergy	0	0	1 (1%)	1 (< 1%)
Drug hypersensitivity	13 (4%)	24 (9%)	16 (17%)	53 (8%)
Dust allergy	1 (< 1%)	0	0	1 (< 1%)
Food allergy	10 (3%)	5 (2%)	3 (3%)	18 (3%)
Hypersensitivity	6 (2%)	2 (1%)	1 (1%)	9 (1%)
Iodine allergy	0	0	3 (3%)	3 (< 1%)
Milk allergy	4 (1%)	0	0	4 (1%)
Multiple allergies	2 (1%)	0	0	2 (< 1%)
Mycotic allergy	1 (< 1%)	0	0	1 (< 1%)
Perennial allergy	0	1 (< 1%)	0	1 (< 1%)
Reaction to food colouring	0	1 (< 1%)	0	1 (< 1%)
Rubber sensitivity	1 (< 1%)	3 (1%)	0	4 (1%)
Seasonal allergy	64 (22%)	58 (21%)	16 (17%)	138 (21%)
Infections and infestations	43 (15%)	26 (9%)	11 (12%)	80 (12%)
Abscess	0	0	1 (1%)	1 (< 1%)
Acute sinusitis	3 (1%)	1 (< 1%)	1 (1%)	5 (1%)
Angular cheilitis	1 (< 1%)	0	0	1 (< 1%)
Appendicitis	7 (2%)	3 (1%)	1 (1%)	11 (2%)
Appendicitis perforated	1 (< 1%)	0	0	1 (< 1%)
Body tinea	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Bronchitis	0	1 (< 1%)	0	1 (< 1%)
Cellulitis	0	0	1 (1%)	1 (< 1%)
Chronic sinusitis	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Chronic tonsillitis	1 (< 1%)	0	0	1 (< 1%)
Conjunctivitis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Cystitis	0	0	1 (1%)	1 (< 1%)
Diverticulitis	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Ear infection	1 (< 1%)	2 (1%)	0	3 (< 1%)
Folliculitis	1 (< 1%)	0	0	1 (< 1%)
Gastroenteritis	0	1 (< 1%)	0	1 (< 1%)
Genital herpes	0	0	1 (1%)	1 (< 1%)
Helicobacter infection	1 (< 1%)	0	0	1 (< 1%)
Herpes ophthalmic	1 (< 1%)	0	0	1 (< 1%)
Herpes simplex	2 (1%)	0	2 (2%)	4 (1%)
Herpes zoster	0	1 (< 1%)	0	1 (< 1%)
Impetigo	2 (1%)	0	0	2 (< 1%)
Infectious colitis	0	1 (< 1%)	0	1 (< 1%)
Infectious mononucleosis	0	1 (< 1%)	0	1 (< 1%)
Influenza	1 (< 1%)	2 (1%)	0	3 (< 1%)
Kidney infection	0	0	1 (1%)	1 (< 1%)
Nasopharyngitis	1 (< 1%)	0	0	1 (< 1%)
Onychomycosis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Oral candidiasis	0	0	1 (1%)	1 (< 1%)
Oral herpes	0	3 (1%)	0	3 (< 1%)
Otitis externa	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Otitis media	0	2 (1%)	0	2 (< 1%)
Otitis media chronic	1 (< 1%)	0	1 (1%)	2 (< 1%)
Paronychia	1 (< 1%)	0	0	1 (< 1%)
Pharyngitis	3 (1%)	1 (< 1%)	1 (1%)	5 (1%)
Pharyngitis streptococcal	4 (1%)	2 (1%)	0	6 (1%)
Pilonidal cyst	1 (< 1%)	0	0	1 (< 1%)
Pneumonia	1 (< 1%)	0	0	1 (< 1%)
Respiratory tract infection viral	0	1 (< 1%)	0	1 (< 1%)
Rhinitis	1 (< 1%)	0	0	1 (< 1%)
Salmonella bacteraemia	0	1 (< 1%)	0	1 (< 1%)
Scarlet fever	0	1 (< 1%)	0	1 (< 1%)
Scrotal abscess	1 (< 1%)	0	0	1 (< 1%)
Sinusitis	4 (1%)	0	0	4 (1%)
Streptococcal infection	0	1 (< 1%)	0	1 (< 1%)
Tinea pedis	0	1 (< 1%)	0	1 (< 1%)
Tinea versicolour	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Tonsillitis	5 (2%)	1 (< 1%)	0	6 (1%)
Tracheobronchitis mycoplasmal	1 (< 1%)	0	0	1 (< 1%)
Upper respiratory tract infection	3 (1%)	3 (1%)	1 (1%)	7 (1%)
Urinary tract infection	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Varicella	2 (1%)	0	0	2 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Viral infection	0	1 (< 1%)	0	1 (< 1%)
Viral pharyngitis	1 (< 1%)	0	0	1 (< 1%)
Viral upper respiratory tract infection	2 (1%)	0	0	2 (< 1%)
Injury, poisoning and procedural complications	17 (6%)	19 (7%)	10 (11%)	46 (7%)
Ankle fracture	1 (< 1%)	0	0	1 (< 1%)
Cartilage injury	0	1 (< 1%)	0	1 (< 1%)
Clavicle fracture	0	1 (< 1%)	0	1 (< 1%)
Concussion	5 (2%)	4 (1%)	0	9 (1%)
Contusion	0	2 (1%)	0	2 (< 1%)
Eye contusion	1 (< 1%)	0	0	1 (< 1%)
Femur fracture	1 (< 1%)	0	0	1 (< 1%)
Foot fracture	0	0	1 (1%)	1 (< 1%)
Forearm fracture	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Hand fracture	1 (< 1%)	0	0	1 (< 1%)
Joint dislocation	0	1 (< 1%)	1 (1%)	2 (< 1%)
Joint injury	0	1 (< 1%)	0	1 (< 1%)
Ligament rupture	1 (< 1%)	1 (< 1%)	3 (3%)	5 (1%)
Ligament sprain	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Lower limb fracture	1 (< 1%)	0	0	1 (< 1%)
Lumbar vertebral fracture	0	0	1 (1%)	1 (< 1%)
Meniscus injury	1 (< 1%)	0	1 (1%)	2 (< 1%)
Multiple fractures	0	0	1 (1%)	1 (< 1%)
Muscle strain	0	1 (< 1%)	0	1 (< 1%)
Post concussion syndrome	0	1 (< 1%)	0	1 (< 1%)
Procedural pain	0	0	1 (1%)	1 (< 1%)
Radius fracture	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Rib fracture	0	0	1 (1%)	1 (< 1%)
Road traffic accident	0	1 (< 1%)	0	1 (< 1%)
Tendon rupture	0	0	1 (1%)	1 (< 1%)
Tibia fracture	0	1 (< 1%)	0	1 (< 1%)
Upper limb fracture	2 (1%)	1 (< 1%)	0	3 (< 1%)
Wrist fracture	2 (1%)	2 (1%)	0	4 (1%)
Investigations	14 (5%)	8 (3%)	3 (3%)	25 (4%)
Arthroscopy	1 (< 1%)	0	0	1 (< 1%)
Blood glucose abnormal	0	1 (< 1%)	0	1 (< 1%)
Blood pressure increased	1 (< 1%)	0	1 (1%)	2 (< 1%)
Blood triglycerides increased	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Body height below normal	2 (1%)	0	0	2 (< 1%)
Body mass index increased	2 (1%)	0	0	2 (< 1%)
Cardiac murmur	3 (1%)	4 (1%)	0	7 (1%)
Cardiac murmur functional	1 (< 1%)	0	0	1 (< 1%)
Colposcopy	0	0	1 (1%)	1 (< 1%)
Endoscopy	0	1 (< 1%)	0	1 (< 1%)
Full blood count abnormal	0	1 (< 1%)	0	1 (< 1%)
Hepatic enzyme abnormal	1 (< 1%)	0	0	1 (< 1%)
Liver function test increased	0	1 (< 1%)	0	1 (< 1%)
Weight decreased	0	0	1 (1%)	1 (< 1%)
Weight increased	1 (< 1%)	0	0	1 (< 1%)
White blood cell count decreased	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	24 (8%)	17 (6%)	16 (17%)	57 (9%)
Decreased appetite	2 (1%)	0	0	2 (< 1%)
Dyslipidaemia	2 (1%)	0	2 (2%)	4 (1%)
Glucose tolerance impaired	1 (< 1%)	1 (< 1%)	2 (2%)	4 (1%)
Gluten sensitivity	1 (< 1%)	0	0	1 (< 1%)
Gout	0	0	2 (2%)	2 (< 1%)
Haemochromatosis	0	0	1 (1%)	1 (< 1%)
Hypercholesterolaemia	0	0	1 (1%)	1 (< 1%)
Hyperglycaemia	0	0	2 (2%)	2 (< 1%)
Hyperlipidaemia	1 (< 1%)	2 (1%)	5 (5%)	8 (1%)
Hypertriglyceridaemia	0	1 (< 1%)	2 (2%)	3 (< 1%)
Hypoglycaemia	0	1 (< 1%)	1 (1%)	2 (< 1%)
Insulin resistance syndrome	1 (< 1%)	0	0	1 (< 1%)
Iron deficiency	0	0	1 (1%)	1 (< 1%)
Lactose intolerance	0	1 (< 1%)	0	1 (< 1%)
Obesity	8 (3%)	8 (3%)	6 (6%)	22 (3%)
Overweight	7 (2%)	0	0	7 (1%)
Type 1 diabetes mellitus	2 (1%)	2 (1%)	1 (1%)	5 (1%)
Type 2 diabetes mellitus	0	0	4 (4%)	4 (1%)
Vitamin B12 deficiency	0	1 (< 1%)	0	1 (< 1%)
Vitamin D deficiency	3 (1%)	2 (1%)	2 (2%)	7 (1%)
Musculoskeletal and connective tissue disorders	41 (14%)	27 (10%)	15 (16%)	83 (12%)
Arthralgia	8 (3%)	6 (2%)	5 (5%)	19 (3%)
Arthritis	0	0	2 (2%)	2 (< 1%)
Back pain	10 (3%)	6 (2%)	4 (4%)	20 (3%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Femoroacetabular impingement	0	1 (< 1%)	0	1 (< 1%)
Foot deformity	1 (< 1%)	0	0	1 (< 1%)
Intervertebral disc protrusion	0	0	1 (1%)	1 (< 1%)
Joint stiffness	0	1 (< 1%)	0	1 (< 1%)
Kyphosis	1 (< 1%)	0	0	1 (< 1%)
Ligament laxity	1 (< 1%)	0	0	1 (< 1%)
Lordosis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Muscle spasms	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Muscle twitching	0	1 (< 1%)	0	1 (< 1%)
Muscular weakness	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Musculoskeletal pain	2 (1%)	3 (1%)	5 (5%)	10 (2%)
Myalgia	2 (1%)	2 (1%)	4 (4%)	8 (1%)
Myositis	0	0	1 (1%)	1 (< 1%)
Neck pain	0	2 (1%)	1 (1%)	3 (< 1%)
Osteoarthritis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Osteochondrosis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Osteopenia	0	0	2 (2%)	2 (< 1%)
Pain in extremity	2 (1%)	2 (1%)	1 (1%)	5 (1%)
Patellofemoral pain syndrome	1 (< 1%)	0	0	1 (< 1%)
Periarthritis	0	0	1 (1%)	1 (< 1%)
Scoliosis	9 (3%)	4 (1%)	1 (1%)	14 (2%)
Shoulder deformity	0	1 (< 1%)	0	1 (< 1%)
Soft tissue mass	0	0	1 (1%)	1 (< 1%)
Spinal deformity	1 (< 1%)	0	0	1 (< 1%)
Spinal osteoarthritis	1 (< 1%)	0	0	1 (< 1%)
Spinal pain	0	1 (< 1%)	0	1 (< 1%)
Spondylolisthesis	1 (< 1%)	0	0	1 (< 1%)
Synovial cyst	0	2 (1%)	0	2 (< 1%)
Temporomandibular joint syndrome	1 (< 1%)	0	0	1 (< 1%)
Tendon disorder	1 (< 1%)	0	0	1 (< 1%)
Tendonitis	1 (< 1%)	0	0	1 (< 1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (2%)	2 (1%)	9 (10%)	17 (3%)
Breast cancer	0	0	1 (1%)	1 (< 1%)
Malignant melanoma	0	0	2 (2%)	2 (< 1%)
Melanocytic naevus	1 (< 1%)	0	3 (3%)	4 (1%)
Neoplasm skin	1 (< 1%)	0	0	1 (< 1%)
Non-Hodgkin's lymphoma stage III	0	0	1 (1%)	1 (< 1%)
Osteochondroma	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Seborrhoeic keratosis	0	0	2 (2%)	2 (< 1%)
Skin papilloma	3 (1%)	1 (< 1%)	0	4 (1%)
Thyroid cancer	0	0	1 (1%)	1 (< 1%)
Uterine leiomyoma	0	1 (< 1%)	3 (3%)	4 (1%)
Nervous system disorders	44 (15%)	39 (14%)	19 (20%)	102 (15%)
Cerebral cyst	0	1 (< 1%)	0	1 (< 1%)
Cervical radiculopathy	0	0	1 (1%)	1 (< 1%)
Cluster headache	1 (< 1%)	0	0	1 (< 1%)
Diabetic neuropathy	0	0	1 (1%)	1 (< 1%)
Disturbance in attention	0	1 (< 1%)	0	1 (< 1%)
Dizziness	0	1 (< 1%)	0	1 (< 1%)
Dyslexia	2 (1%)	0	0	2 (< 1%)
Essential tremor	1 (< 1%)	0	0	1 (< 1%)
Febrile convulsion	1 (< 1%)	0	0	1 (< 1%)
Headache	20 (7%)	17 (6%)	9 (10%)	46 (7%)
Memory impairment	0	1 (< 1%)	0	1 (< 1%)
Migraine	10 (3%)	15 (5%)	9 (10%)	34 (5%)
Migraine with aura	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Migraine without aura	4 (1%)	0	0	4 (1%)
Restless legs syndrome	0	0	1 (1%)	1 (< 1%)
Seizure	0	1 (< 1%)	1 (1%)	2 (< 1%)
Sinus headache	0	3 (1%)	0	3 (< 1%)
Speech disorder developmental	0	2 (1%)	0	2 (< 1%)
Spinal cord disorder	1 (< 1%)	0	0	1 (< 1%)
Syncope	3 (1%)	1 (< 1%)	0	4 (1%)
Tension headache	4 (1%)	3 (1%)	0	7 (1%)
Tethered cord syndrome	1 (< 1%)	0	0	1 (< 1%)
Thoracic outlet syndrome	1 (< 1%)	0	0	1 (< 1%)
Tremor	0	1 (< 1%)	0	1 (< 1%)
Pregnancy, puerperium and perinatal conditions	2 (1%)	1 (< 1%)	0	3 (< 1%)
Abortion	0	1 (< 1%)	0	1 (< 1%)
Abortion spontaneous	1 (< 1%)	0	0	1 (< 1%)
Delivery	1 (< 1%)	0	0	1 (< 1%)
Psychiatric disorders	91 (31%)	68 (24%)	34 (37%)	193 (29%)
Abnormal behaviour	1 (< 1%)	0	0	1 (< 1%)
Affective disorder	4 (1%)	1 (< 1%)	1 (1%)	6 (1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Alcohol abuse	0	0	1 (1%)	1 (< 1%)
Anger	2 (1%)	0	0	2 (< 1%)
Anxiety	33 (11%)	24 (9%)	12 (13%)	69 (10%)
Anxiety disorder	2 (1%)	1 (< 1%)	0	3 (< 1%)
Attention deficit/hyperactivity disorder	45 (16%)	36 (13%)	7 (8%)	88 (13%)
Autism spectrum disorder	2 (1%)	1 (< 1%)	0	3 (< 1%)
Binge eating	0	0	1 (1%)	1 (< 1%)
Bipolar disorder	0	3 (1%)	0	3 (< 1%)
Bulimia nervosa	1 (< 1%)	0	0	1 (< 1%)
Depression	28 (10%)	22 (8%)	19 (20%)	69 (10%)
Drug abuse	2 (1%)	0	1 (1%)	3 (< 1%)
Eating disorder	0	1 (< 1%)	0	1 (< 1%)
Emotional distress	1 (< 1%)	0	0	1 (< 1%)
Generalised anxiety disorder	2 (1%)	0	1 (1%)	3 (< 1%)
Insomnia	7 (2%)	8 (3%)	7 (8%)	22 (3%)
Learning disorder	1 (< 1%)	0	0	1 (< 1%)
Major depression	4 (1%)	0	1 (1%)	5 (1%)
Obsessive-compulsive disorder	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Panic attack	0	0	1 (1%)	1 (< 1%)
Persistent depressive disorder	1 (< 1%)	0	0	1 (< 1%)
Post-traumatic stress disorder	1 (< 1%)	0	1 (1%)	2 (< 1%)
Psychotic disorder	0	0	1 (1%)	1 (< 1%)
Schizophrenia	0	0	1 (1%)	1 (< 1%)
Sleep disorder	0	1 (< 1%)	0	1 (< 1%)
Social anxiety disorder	1 (< 1%)	0	0	1 (< 1%)
Stress	1 (< 1%)	0	0	1 (< 1%)
Substance abuse	0	0	1 (1%)	1 (< 1%)
Suicidal ideation	0	0	1 (1%)	1 (< 1%)
Tic	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Renal and urinary disorders	7 (2%)	2 (1%)	4 (4%)	13 (2%)
Chronic kidney disease	0	0	1 (1%)	1 (< 1%)
Dysuria	1 (< 1%)	0	0	1 (< 1%)
Glomerulonephritis acute	1 (< 1%)	0	0	1 (< 1%)
Haematuria	1 (< 1%)	0	0	1 (< 1%)
Hypertonic bladder	1 (< 1%)	0	1 (1%)	2 (< 1%)
Nephrolithiasis	1 (< 1%)	2 (1%)	0	3 (< 1%)
Pollakiuria	1 (< 1%)	0	0	1 (< 1%)
Polyuria	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Urinary incontinence	0	0	1 (1%)	1 (< 1%)
Vesicoureteric reflux	2 (1%)	0	0	2 (< 1%)
Reproductive system and breast disorders	30 (10%)	19 (7%)	8 (9%)	57 (9%)
Amenorrhoea	1 (< 1%)	0	0	1 (< 1%)
Benign prostatic hyperplasia	0	0	1 (1%)	1 (< 1%)
Breast mass	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Cervical dysplasia	0	0	1 (1%)	1 (< 1%)
Dysmenorrhoea	12 (4%)	10 (4%)	1 (1%)	23 (3%)
Endometriosis	0	0	2 (2%)	2 (< 1%)
Erectile dysfunction	0	1 (< 1%)	0	1 (< 1%)
Menometrorrhagia	2 (1%)	0	0	2 (< 1%)
Menopausal symptoms	0	0	1 (1%)	1 (< 1%)
Menorrhagia	8 (3%)	1 (< 1%)	0	9 (1%)
Menstruation irregular	3 (1%)	4 (1%)	1 (1%)	8 (1%)
Metrorrhagia	0	0	1 (1%)	1 (< 1%)
Ovarian cyst	3 (1%)	0	0	3 (< 1%)
Polycystic ovaries	1 (< 1%)	3 (1%)	0	4 (1%)
Polymenorrhoea	2 (1%)	0	0	2 (< 1%)
Scrotal varicose veins	1 (< 1%)	0	0	1 (< 1%)
Testicular torsion	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Uterine haemorrhage	0	1 (< 1%)	0	1 (< 1%)
Vaginal discharge	0	1 (< 1%)	0	1 (< 1%)
Vaginal disorder	0	0	1 (1%)	1 (< 1%)
Vulvovaginal discomfort	0	1 (< 1%)	0	1 (< 1%)
Vulvovaginal dryness	0	0	1 (1%)	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	69 (24%)	56 (20%)	12 (13%)	137 (21%)
Adenoidal hypertrophy	2 (1%)	0	0	2 (< 1%)
Asthma	31 (11%)	34 (12%)	2 (2%)	67 (10%)
Asthma exercise induced	10 (3%)	3 (1%)	0	13 (2%)
Bronchial hyperreactivity	3 (1%)	0	0	3 (< 1%)
Bronchitis chronic	0	0	1 (1%)	1 (< 1%)
Bronchospasm	2 (1%)	3 (1%)	0	5 (1%)
Cough	2 (1%)	2 (1%)	2 (2%)	6 (1%)
Dyspnoea	0	0	1 (1%)	1 (< 1%)
Epistaxis	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Nasal congestion	1 (< 1%)	3 (1%)	0	4 (1%)
Nasal inflammation	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Nasal obstruction	0	1 (< 1%)	0	1 (< 1%)
Nasal septum deviation	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Nasal turbinate hypertrophy	0	0	1 (1%)	1 (< 1%)
Oropharyngeal pain	3 (1%)	1 (< 1%)	0	4 (1%)
Pleurisy	0	1 (< 1%)	0	1 (< 1%)
Pulmonary thrombosis	0	0	1 (1%)	1 (< 1%)
Rhinitis allergic	25 (9%)	8 (3%)	3 (3%)	36 (5%)
Rhinitis perennial	0	3 (1%)	0	3 (< 1%)
Rhinorrhoea	0	0	1 (1%)	1 (< 1%)
Sinus congestion	0	1 (< 1%)	0	1 (< 1%)
Sleep apnoea syndrome	2 (1%)	2 (1%)	5 (5%)	9 (1%)
Snoring	0	1 (< 1%)	0	1 (< 1%)
Tonsillar hypertrophy	2 (1%)	3 (1%)	0	5 (1%)
Velopharyngeal incompetence	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	69 (24%)	37 (13%)	8 (9%)	114 (17%)
Acanthosis nigricans	4 (1%)	0	0	4 (1%)
Acne	44 (15%)	22 (8%)	1 (1%)	67 (10%)
Actinic keratosis	0	0	1 (1%)	1 (< 1%)
Alopecia	1 (< 1%)	0	0	1 (< 1%)
Cafe au lait spots	1 (< 1%)	0	0	1 (< 1%)
Chronic spontaneous urticaria	1 (< 1%)	0	0	1 (< 1%)
Dandruff	0	1 (< 1%)	0	1 (< 1%)
Dermatitis	1 (< 1%)	0	1 (1%)	2 (< 1%)
Dermatitis atopic	5 (2%)	2 (1%)	0	7 (1%)
Dermatitis contact	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Dry skin	2 (1%)	0	0	2 (< 1%)
Ecchymosis	0	1 (< 1%)	0	1 (< 1%)
Eczema	16 (6%)	10 (4%)	1 (1%)	27 (4%)
Hidradenitis	0	1 (< 1%)	0	1 (< 1%)
Hyperhidrosis	2 (1%)	0	0	2 (< 1%)
Keloid scar	1 (< 1%)	0	0	1 (< 1%)
Keratosis pilaris	1 (< 1%)	0	0	1 (< 1%)
Mechanical urticaria	1 (< 1%)	0	0	1 (< 1%)
Night sweats	0	0	1 (1%)	1 (< 1%)
Pityriasis rosea	0	1 (< 1%)	0	1 (< 1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Psoriasis	0	0	1 (1%)	1 (< 1%)
Rash	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Rosacea	0	1 (< 1%)	1 (1%)	2 (< 1%)
Sebaceous hyperplasia	0	0	1 (1%)	1 (< 1%)
Seborrhoeic dermatitis	0	1 (< 1%)	0	1 (< 1%)
Skin ulcer	0	0	1 (1%)	1 (< 1%)
Urticaria	0	2 (1%)	1 (1%)	3 (< 1%)
Social circumstances	0	2 (1%)	5 (5%)	7 (1%)
Menopause	0	0	2 (2%)	2 (< 1%)
Postmenopause	0	0	3 (3%)	3 (< 1%)
Tobacco user	0	2 (1%)	0	2 (< 1%)
Surgical and medical procedures	23 (8%)	16 (6%)	29 (31%)	68 (10%)
Adenoidectomy	3 (1%)	1 (< 1%)	0	4 (1%)
Adenotonsillectomy	2 (1%)	0	0	2 (< 1%)
Appendicectomy	6 (2%)	1 (< 1%)	0	7 (1%)
Brain operation	1 (< 1%)	0	0	1 (< 1%)
Caesarean section	1 (< 1%)	0	2 (2%)	3 (< 1%)
Catheter placement	0	1 (< 1%)	0	1 (< 1%)
Cautery to nose	1 (< 1%)	0	0	1 (< 1%)
Cholecystectomy	0	1 (< 1%)	2 (2%)	3 (< 1%)
Circumcision	0	1 (< 1%)	0	1 (< 1%)
Closed fracture manipulation	1 (< 1%)	0	0	1 (< 1%)
Contraception	0	1 (< 1%)	0	1 (< 1%)
Cryotherapy	0	0	1 (1%)	1 (< 1%)
Dental operation	1 (< 1%)	0	0	1 (< 1%)
Ear tube insertion	0	1 (< 1%)	0	1 (< 1%)
Female sterilisation	0	0	7 (8%)	7 (1%)
Fracture treatment	0	1 (< 1%)	0	1 (< 1%)
Haemorrhoid operation	1 (< 1%)	0	0	1 (< 1%)
Hysterectomy	0	0	7 (8%)	7 (1%)
Implantable defibrillator insertion	0	0	1 (1%)	1 (< 1%)
Inguinal hernia repair	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Intervertebral disc operation	0	0	1 (1%)	1 (< 1%)
Knee operation	1 (< 1%)	0	0	1 (< 1%)
Ligament operation	0	1 (< 1%)	0	1 (< 1%)
Lymphadenectomy	0	0	1 (1%)	1 (< 1%)
Mammoplasty	0	0	2 (2%)	2 (< 1%)
Mastectomy	0	0	1 (1%)	1 (< 1%)
Meniscus operation	1 (< 1%)	0	0	1 (< 1%)
Myringotomy	1 (< 1%)	2 (1%)	0	3 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.1
Medical History by Body System Organ Class and Preferred Term
Per Protocol Set (Day 29)

System Organ Class Preferred Term	Menveo-Menveo (N=290)	Menactra-Menveo (N=282)	Naive (N=93)	Total (N=665)
Ovarian cystectomy	0	0	1 (1%)	1 (< 1%)
Papilloma excision	1 (< 1%)	0	0	1 (< 1%)
Plastic surgery to the face	0	0	1 (1%)	1 (< 1%)
Splint application	0	1 (< 1%)	0	1 (< 1%)
Strabismus correction	0	0	1 (1%)	1 (< 1%)
Thyroidectomy	0	0	1 (1%)	1 (< 1%)
Tonsillectomy	6 (2%)	6 (2%)	0	12 (2%)
Umbilical hernia repair	0	1 (< 1%)	0	1 (< 1%)
Vasectomy	0	0	1 (1%)	1 (< 1%)
Venous operation	0	0	1 (1%)	1 (< 1%)
Wisdom teeth removal	4 (1%)	0	0	4 (1%)
Vascular disorders	7 (2%)	2 (1%)	14 (15%)	23 (3%)
Essential hypertension	0	1 (< 1%)	0	1 (< 1%)
Hot flush	0	0	1 (1%)	1 (< 1%)
Hypertension	4 (1%)	1 (< 1%)	12 (13%)	17 (3%)
Peripheral venous disease	0	0	1 (1%)	1 (< 1%)
Prehypertension	2 (1%)	0	0	2 (< 1%)
Raynaud's phenomenon	1 (< 1%)	0	0	1 (< 1%)
Varicose vein	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Blood and lymphatic system disorders	3 (1%)	3 (1%)	8 (8%)	14 (2%)
Anaemia	3 (1%)	0	5 (5%)	8 (1%)
Iron deficiency anaemia	0	0	2 (2%)	2 (< 1%)
Leukocytosis	0	1 (< 1%)	0	1 (< 1%)
Lymphadenitis	0	1 (< 1%)	0	1 (< 1%)
Lymphadenopathy	0	0	1 (1%)	1 (< 1%)
Microcytic anaemia	0	1 (< 1%)	0	1 (< 1%)
Cardiac disorders	7 (2%)	5 (2%)	2 (2%)	14 (2%)
Aortic valve disease	0	1 (< 1%)	0	1 (< 1%)
Arrhythmia	0	1 (< 1%)	0	1 (< 1%)
Bradycardia	0	1 (< 1%)	0	1 (< 1%)
Cardiac failure congestive	0	0	1 (1%)	1 (< 1%)
Left ventricular hypertrophy	1 (< 1%)	0	0	1 (< 1%)
Myocardial ischaemia	1 (< 1%)	0	1 (1%)	2 (< 1%)
Palpitations	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Pulmonary valve stenosis	1 (< 1%)	0	0	1 (< 1%)
Sinus bradycardia	0	1 (< 1%)	0	1 (< 1%)
Supraventricular tachycardia	1 (< 1%)	0	0	1 (< 1%)
Tachycardia	0	0	1 (1%)	1 (< 1%)
Ventricular extrasystoles	1 (< 1%)	0	0	1 (< 1%)
Wolff-Parkinson-White syndrome	1 (< 1%)	0	0	1 (< 1%)
Congenital, familial and genetic disorders	10 (3%)	10 (3%)	2 (2%)	22 (3%)
Aniridia	1 (< 1%)	0	0	1 (< 1%)
Arnold-Chiari malformation	1 (< 1%)	0	0	1 (< 1%)
Arteriovenous malformation	0	1 (< 1%)	0	1 (< 1%)
Atrial septal defect	1 (< 1%)	0	0	1 (< 1%)
Congenital cardiovascular anomaly	0	1 (< 1%)	0	1 (< 1%)
Congenital hiatus hernia	0	1 (< 1%)	0	1 (< 1%)
Congenital jaw malformation	0	1 (< 1%)	0	1 (< 1%)
Congenital oesophageal anomaly	0	1 (< 1%)	0	1 (< 1%)
Congenital uterine anomaly	0	0	1 (1%)	1 (< 1%)
Cryptorchism	1 (< 1%)	0	0	1 (< 1%)
Developmental hip dysplasia	1 (< 1%)	0	0	1 (< 1%)
External auditory canal atresia	0	1 (< 1%)	0	1 (< 1%)
Factor V deficiency	0	0	1 (1%)	1 (< 1%)
Gilbert's syndrome	1 (< 1%)	0	0	1 (< 1%)
Intestinal malrotation	0	1 (< 1%)	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Macrocephaly	1 (< 1%)	0	0	1 (< 1%)
Microtia	0	1 (< 1%)	0	1 (< 1%)
Neurofibromatosis	1 (< 1%)	0	0	1 (< 1%)
Pectus excavatum	0	1 (< 1%)	0	1 (< 1%)
Sickle cell trait	1 (< 1%)	0	0	1 (< 1%)
Syringomyelia	1 (< 1%)	0	0	1 (< 1%)
Tourette's disorder	2 (1%)	2 (1%)	0	4 (1%)
Von Willebrand's disease	0	1 (< 1%)	0	1 (< 1%)
Ear and labyrinth disorders	3 (1%)	9 (3%)	2 (2%)	14 (2%)
Cerumen impaction	1 (< 1%)	3 (1%)	0	4 (1%)
Conductive deafness	0	1 (< 1%)	0	1 (< 1%)
Deafness	0	0	1 (1%)	1 (< 1%)
Deafness unilateral	0	1 (< 1%)	0	1 (< 1%)
Ear pain	1 (< 1%)	2 (1%)	0	3 (< 1%)
Eustachian tube dysfunction	1 (< 1%)	0	0	1 (< 1%)
Hypoacusis	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Tinnitus	0	1 (< 1%)	1 (1%)	2 (< 1%)
Endocrine disorders	5 (2%)	7 (2%)	6 (6%)	18 (3%)
Autoimmune thyroiditis	0	0	1 (1%)	1 (< 1%)
Goitre	1 (< 1%)	0	1 (1%)	2 (< 1%)
Hyperandrogenism	1 (< 1%)	0	0	1 (< 1%)
Hyperparathyroidism	0	1 (< 1%)	0	1 (< 1%)
Hypogonadism male	0	1 (< 1%)	0	1 (< 1%)
Hypothyroidism	3 (1%)	5 (2%)	4 (4%)	12 (2%)
Eye disorders	11 (4%)	10 (3%)	5 (5%)	26 (4%)
Amblyopia	0	1 (< 1%)	0	1 (< 1%)
Astigmatism	0	0	1 (1%)	1 (< 1%)
Blepharitis	0	0	1 (1%)	1 (< 1%)
Blepharospasm	0	1 (< 1%)	0	1 (< 1%)
Cataract	0	0	1 (1%)	1 (< 1%)
Conjunctivitis allergic	0	3 (1%)	0	3 (< 1%)
Dry eye	0	0	2 (2%)	2 (< 1%)
Glaucoma	0	1 (< 1%)	0	1 (< 1%)
Hypermetropia	0	0	1 (1%)	1 (< 1%)
Myopia	6 (2%)	3 (1%)	0	9 (1%)
Optic atrophy	1 (< 1%)	0	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Presbyopia	2 (1%)	0	1 (1%)	3 (< 1%)
Strabismus	3 (1%)	2 (1%)	1 (1%)	6 (1%)
Gastrointestinal disorders	36 (12%)	29 (10%)	17 (17%)	82 (12%)
Abdominal discomfort	0	1 (< 1%)	0	1 (< 1%)
Abdominal pain	5 (2%)	3 (1%)	1 (1%)	9 (1%)
Abdominal pain upper	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Abdominal rebound tenderness	0	1 (< 1%)	0	1 (< 1%)
Abdominal tenderness	0	1 (< 1%)	0	1 (< 1%)
Anal fissure	0	1 (< 1%)	0	1 (< 1%)
Anal pruritus	1 (< 1%)	0	0	1 (< 1%)
Anal skin tags	0	1 (< 1%)	0	1 (< 1%)
Coeliac disease	3 (1%)	0	0	3 (< 1%)
Constipation	4 (1%)	4 (1%)	1 (1%)	9 (1%)
Dental caries	0	0	1 (1%)	1 (< 1%)
Diarrhoea	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Diverticulum	0	0	1 (1%)	1 (< 1%)
Dyspepsia	2 (1%)	1 (< 1%)	0	3 (< 1%)
Eosinophilic oesophagitis	0	1 (< 1%)	0	1 (< 1%)
Epigastric discomfort	0	0	1 (1%)	1 (< 1%)
Gastric ulcer	2 (1%)	2 (1%)	0	4 (1%)
Gastritis	2 (1%)	0	0	2 (< 1%)
Gastrooesophageal reflux disease	11 (4%)	10 (3%)	10 (10%)	31 (4%)
Haemorrhoids	2 (1%)	1 (< 1%)	2 (2%)	5 (1%)
Inguinal hernia	2 (1%)	0	0	2 (< 1%)
Intestinal obstruction	1 (< 1%)	0	0	1 (< 1%)
Intussusception	1 (< 1%)	0	0	1 (< 1%)
Irritable bowel syndrome	0	2 (1%)	0	2 (< 1%)
Large intestine polyp	0	0	1 (1%)	1 (< 1%)
Lumbar hernia	0	1 (< 1%)	0	1 (< 1%)
Nausea	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Tooth disorder	1 (< 1%)	0	0	1 (< 1%)
Tooth impacted	3 (1%)	0	0	3 (< 1%)
Vomiting	1 (< 1%)	2 (1%)	0	3 (< 1%)
General disorders and administration site conditions	9 (3%)	9 (3%)	5 (5%)	23 (3%)
Chest pain	0	0	1 (1%)	1 (< 1%)
Developmental delay	0	1 (< 1%)	0	1 (< 1%)
Drug intolerance	0	2 (1%)	0	2 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Fatigue	3 (1%)	5 (2%)	0	8 (1%)
Malaise	0	1 (< 1%)	0	1 (< 1%)
Medical device pain	1 (< 1%)	0	0	1 (< 1%)
Oedema peripheral	0	0	1 (1%)	1 (< 1%)
Pain	4 (1%)	2 (1%)	2 (2%)	8 (1%)
Pyrexia	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Retention cyst	0	0	1 (1%)	1 (< 1%)
Hepatobiliary disorders	0	3 (1%)	1 (1%)	4 (1%)
Cholecystitis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Hepatic steatosis	0	2 (1%)	0	2 (< 1%)
Immune system disorders	90 (30%)	83 (28%)	37 (37%)	210 (30%)
Allergy to animal	4 (1%)	2 (1%)	1 (1%)	7 (1%)
Allergy to metals	0	1 (< 1%)	1 (1%)	2 (< 1%)
Contrast media allergy	0	0	1 (1%)	1 (< 1%)
Drug hypersensitivity	13 (4%)	25 (8%)	18 (18%)	56 (8%)
Dust allergy	1 (< 1%)	0	0	1 (< 1%)
Food allergy	10 (3%)	5 (2%)	4 (4%)	19 (3%)
Hypersensitivity	7 (2%)	2 (1%)	1 (1%)	10 (1%)
Iodine allergy	0	0	3 (3%)	3 (< 1%)
Milk allergy	4 (1%)	0	0	4 (1%)
Multiple allergies	2 (1%)	0	0	2 (< 1%)
Mycotic allergy	1 (< 1%)	0	0	1 (< 1%)
Perennial allergy	0	1 (< 1%)	0	1 (< 1%)
Reaction to food colouring	0	1 (< 1%)	0	1 (< 1%)
Rubber sensitivity	1 (< 1%)	3 (1%)	0	4 (1%)
Seasonal allergy	67 (22%)	62 (21%)	18 (18%)	147 (21%)
Infections and infestations	43 (14%)	26 (9%)	11 (11%)	80 (11%)
Abscess	0	0	1 (1%)	1 (< 1%)
Acute sinusitis	3 (1%)	1 (< 1%)	1 (1%)	5 (1%)
Angular cheilitis	1 (< 1%)	0	0	1 (< 1%)
Appendicitis	7 (2%)	3 (1%)	1 (1%)	11 (2%)
Appendicitis perforated	1 (< 1%)	0	0	1 (< 1%)
Body tinea	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Bronchitis	0	1 (< 1%)	0	1 (< 1%)
Cellulitis	0	0	1 (1%)	1 (< 1%)
Chronic sinusitis	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Chronic tonsillitis	1 (< 1%)	0	0	1 (< 1%)
Conjunctivitis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Cystitis	0	0	1 (1%)	1 (< 1%)
Diverticulitis	0	0	1 (1%)	1 (< 1%)
Ear infection	1 (< 1%)	2 (1%)	0	3 (< 1%)
Folliculitis	1 (< 1%)	0	0	1 (< 1%)
Gastroenteritis	0	1 (< 1%)	0	1 (< 1%)
Genital herpes	0	0	1 (1%)	1 (< 1%)
Helicobacter infection	1 (< 1%)	0	0	1 (< 1%)
Herpes ophthalmic	1 (< 1%)	0	0	1 (< 1%)
Herpes simplex	2 (1%)	0	2 (2%)	4 (1%)
Herpes zoster	0	1 (< 1%)	0	1 (< 1%)
Impetigo	2 (1%)	0	0	2 (< 1%)
Infectious colitis	0	1 (< 1%)	0	1 (< 1%)
Infectious mononucleosis	0	1 (< 1%)	0	1 (< 1%)
Influenza	1 (< 1%)	2 (1%)	0	3 (< 1%)
Kidney infection	0	0	1 (1%)	1 (< 1%)
Nasopharyngitis	1 (< 1%)	0	0	1 (< 1%)
Onychomycosis	0	1 (< 1%)	1 (1%)	2 (< 1%)
Oral candidiasis	0	0	1 (1%)	1 (< 1%)
Oral herpes	0	3 (1%)	0	3 (< 1%)
Otitis externa	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Otitis media	0	2 (1%)	0	2 (< 1%)
Otitis media chronic	1 (< 1%)	0	1 (1%)	2 (< 1%)
Paronychia	1 (< 1%)	0	0	1 (< 1%)
Pharyngitis	3 (1%)	1 (< 1%)	1 (1%)	5 (1%)
Pharyngitis streptococcal	4 (1%)	2 (1%)	0	6 (1%)
Pilonidal cyst	1 (< 1%)	0	0	1 (< 1%)
Pneumonia	1 (< 1%)	0	0	1 (< 1%)
Respiratory tract infection viral	0	1 (< 1%)	0	1 (< 1%)
Rhinitis	1 (< 1%)	0	0	1 (< 1%)
Salmonella bacteraemia	0	1 (< 1%)	0	1 (< 1%)
Scarlet fever	0	1 (< 1%)	0	1 (< 1%)
Scrotal abscess	1 (< 1%)	0	0	1 (< 1%)
Sinusitis	4 (1%)	0	0	4 (1%)
Streptococcal infection	0	1 (< 1%)	0	1 (< 1%)
Tinea pedis	0	1 (< 1%)	0	1 (< 1%)
Tinea versicolour	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Tonsillitis	5 (2%)	1 (< 1%)	0	6 (1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Tracheobronchitis mycoplasmal	1 (< 1%)	0	0	1 (< 1%)
Upper respiratory tract infection	3 (1%)	3 (1%)	1 (1%)	7 (1%)
Urinary tract infection	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Varicella	2 (1%)	0	0	2 (< 1%)
Viral infection	0	1 (< 1%)	0	1 (< 1%)
Viral pharyngitis	1 (< 1%)	0	0	1 (< 1%)
Viral upper respiratory tract infection	2 (1%)	0	0	2 (< 1%)
Injury, poisoning and procedural complications	17 (6%)	19 (6%)	10 (10%)	46 (7%)
Ankle fracture	1 (< 1%)	0	0	1 (< 1%)
Cartilage injury	0	1 (< 1%)	0	1 (< 1%)
Clavicle fracture	0	1 (< 1%)	0	1 (< 1%)
Concussion	5 (2%)	4 (1%)	0	9 (1%)
Contusion	0	2 (1%)	0	2 (< 1%)
Eye contusion	1 (< 1%)	0	0	1 (< 1%)
Femur fracture	1 (< 1%)	0	0	1 (< 1%)
Foot fracture	0	0	1 (1%)	1 (< 1%)
Forearm fracture	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Hand fracture	1 (< 1%)	0	0	1 (< 1%)
Joint dislocation	0	1 (< 1%)	1 (1%)	2 (< 1%)
Joint injury	0	1 (< 1%)	0	1 (< 1%)
Ligament rupture	1 (< 1%)	1 (< 1%)	3 (3%)	5 (1%)
Ligament sprain	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Lower limb fracture	1 (< 1%)	0	0	1 (< 1%)
Lumbar vertebral fracture	0	0	1 (1%)	1 (< 1%)
Meniscus injury	1 (< 1%)	0	1 (1%)	2 (< 1%)
Multiple fractures	0	0	1 (1%)	1 (< 1%)
Muscle strain	0	1 (< 1%)	0	1 (< 1%)
Post concussion syndrome	0	1 (< 1%)	0	1 (< 1%)
Procedural pain	0	0	1 (1%)	1 (< 1%)
Radius fracture	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Rib fracture	0	0	1 (1%)	1 (< 1%)
Road traffic accident	0	1 (< 1%)	0	1 (< 1%)
Tendon rupture	0	0	1 (1%)	1 (< 1%)
Tibia fracture	0	1 (< 1%)	0	1 (< 1%)
Upper limb fracture	2 (1%)	1 (< 1%)	0	3 (< 1%)
Wrist fracture	2 (1%)	2 (1%)	0	4 (1%)
Investigations	14 (5%)	8 (3%)	3 (3%)	25 (4%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Arthroscopy	1 (< 1%)	0	0	1 (< 1%)
Blood glucose abnormal	0	1 (< 1%)	0	1 (< 1%)
Blood pressure increased	1 (< 1%)	0	1 (1%)	2 (< 1%)
Blood triglycerides increased	1 (< 1%)	0	0	1 (< 1%)
Body height below normal	2 (1%)	0	0	2 (< 1%)
Body mass index increased	2 (1%)	0	0	2 (< 1%)
Cardiac murmur	3 (1%)	4 (1%)	0	7 (1%)
Cardiac murmur functional	1 (< 1%)	0	0	1 (< 1%)
Colposcopy	0	0	1 (1%)	1 (< 1%)
Endoscopy	0	1 (< 1%)	0	1 (< 1%)
Full blood count abnormal	0	1 (< 1%)	0	1 (< 1%)
Hepatic enzyme abnormal	1 (< 1%)	0	0	1 (< 1%)
Liver function test increased	0	1 (< 1%)	0	1 (< 1%)
Weight decreased	0	0	1 (1%)	1 (< 1%)
Weight increased	1 (< 1%)	0	0	1 (< 1%)
White blood cell count decreased	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	26 (9%)	17 (6%)	18 (18%)	61 (9%)
Decreased appetite	2 (1%)	0	0	2 (< 1%)
Dyslipidaemia	2 (1%)	0	2 (2%)	4 (1%)
Glucose tolerance impaired	1 (< 1%)	1 (< 1%)	2 (2%)	4 (1%)
Gluten sensitivity	1 (< 1%)	0	0	1 (< 1%)
Gout	0	0	2 (2%)	2 (< 1%)
Haemochromatosis	0	0	1 (1%)	1 (< 1%)
Hypercholesterolaemia	0	0	2 (2%)	2 (< 1%)
Hyperglycaemia	0	0	2 (2%)	2 (< 1%)
Hyperlipidaemia	1 (< 1%)	2 (1%)	6 (6%)	9 (1%)
Hypertriglyceridaemia	0	1 (< 1%)	2 (2%)	3 (< 1%)
Hypoglycaemia	0	1 (< 1%)	1 (1%)	2 (< 1%)
Insulin resistance syndrome	1 (< 1%)	0	0	1 (< 1%)
Iron deficiency	0	0	1 (1%)	1 (< 1%)
Lactose intolerance	0	1 (< 1%)	0	1 (< 1%)
Obesity	9 (3%)	8 (3%)	6 (6%)	23 (3%)
Overweight	7 (2%)	0	0	7 (1%)
Type 1 diabetes mellitus	2 (1%)	2 (1%)	1 (1%)	5 (1%)
Type 2 diabetes mellitus	0	0	4 (4%)	4 (1%)
Vitamin B12 deficiency	0	1 (< 1%)	0	1 (< 1%)
Vitamin D deficiency	4 (1%)	2 (1%)	2 (2%)	8 (1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Musculoskeletal and connective tissue disorders	42 (14%)	29 (10%)	17 (17%)	88 (13%)
Arthralgia	8 (3%)	6 (2%)	5 (5%)	19 (3%)
Arthritis	0	0	2 (2%)	2 (< 1%)
Back pain	10 (3%)	7 (2%)	4 (4%)	21 (3%)
Femoroacetabular impingement	0	1 (< 1%)	0	1 (< 1%)
Fibromyalgia	0	0	1 (1%)	1 (< 1%)
Foot deformity	1 (< 1%)	0	0	1 (< 1%)
Intervertebral disc protrusion	0	0	1 (1%)	1 (< 1%)
Joint stiffness	0	1 (< 1%)	0	1 (< 1%)
Juvenile idiopathic arthritis	0	1 (< 1%)	0	1 (< 1%)
Kyphosis	1 (< 1%)	0	0	1 (< 1%)
Ligament laxity	1 (< 1%)	0	0	1 (< 1%)
Lordosis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Muscle spasms	1 (< 1%)	1 (< 1%)	1 (1%)	3 (< 1%)
Muscle twitching	0	1 (< 1%)	0	1 (< 1%)
Muscular weakness	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Musculoskeletal pain	2 (1%)	3 (1%)	5 (5%)	10 (1%)
Myalgia	2 (1%)	2 (1%)	4 (4%)	8 (1%)
Myositis	0	0	1 (1%)	1 (< 1%)
Neck pain	0	2 (1%)	1 (1%)	3 (< 1%)
Osteoarthritis	0	1 (< 1%)	3 (3%)	4 (1%)
Osteochondrosis	2 (1%)	1 (< 1%)	0	3 (< 1%)
Osteopenia	0	0	2 (2%)	2 (< 1%)
Pain in extremity	2 (1%)	2 (1%)	1 (1%)	5 (1%)
Patellofemoral pain syndrome	1 (< 1%)	0	0	1 (< 1%)
Periarthritis	0	0	1 (1%)	1 (< 1%)
Scoliosis	10 (3%)	4 (1%)	1 (1%)	15 (2%)
Shoulder deformity	0	1 (< 1%)	0	1 (< 1%)
Soft tissue mass	0	0	1 (1%)	1 (< 1%)
Spinal deformity	1 (< 1%)	0	0	1 (< 1%)
Spinal osteoarthritis	1 (< 1%)	0	0	1 (< 1%)
Spinal pain	0	1 (< 1%)	0	1 (< 1%)
Spondylolisthesis	1 (< 1%)	0	0	1 (< 1%)
Synovial cyst	0	2 (1%)	0	2 (< 1%)
Temporomandibular joint syndrome	1 (< 1%)	0	0	1 (< 1%)
Tendon disorder	1 (< 1%)	0	0	1 (< 1%)
Tendonitis	1 (< 1%)	0	0	1 (< 1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (2%)	3 (1%)	10 (10%)	19 (3%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Breast cancer	0	0	1 (1%)	1 (< 1%)
Malignant melanoma	0	0	2 (2%)	2 (< 1%)
Melanocytic naevus	1 (< 1%)	0	3 (3%)	4 (1%)
Neoplasm skin	1 (< 1%)	0	0	1 (< 1%)
Non-Hodgkin's lymphoma stage III	0	0	1 (1%)	1 (< 1%)
Osteochondroma	1 (< 1%)	0	0	1 (< 1%)
Seborrhoeic keratosis	0	0	2 (2%)	2 (< 1%)
Skin papilloma	3 (1%)	2 (1%)	1 (1%)	6 (1%)
Thyroid cancer	0	0	1 (1%)	1 (< 1%)
Uterine leiomyoma	0	1 (< 1%)	3 (3%)	4 (1%)
Nervous system disorders	46 (15%)	42 (14%)	19 (19%)	107 (15%)
Cerebral cyst	0	1 (< 1%)	0	1 (< 1%)
Cervical radiculopathy	0	0	1 (1%)	1 (< 1%)
Cluster headache	2 (1%)	0	0	2 (< 1%)
Diabetic neuropathy	0	0	1 (1%)	1 (< 1%)
Disturbance in attention	0	1 (< 1%)	0	1 (< 1%)
Dizziness	0	1 (< 1%)	0	1 (< 1%)
Dyslexia	2 (1%)	0	0	2 (< 1%)
Essential tremor	1 (< 1%)	0	0	1 (< 1%)
Febrile convulsion	1 (< 1%)	0	0	1 (< 1%)
Headache	20 (7%)	19 (6%)	9 (9%)	48 (7%)
Memory impairment	0	1 (< 1%)	0	1 (< 1%)
Migraine	11 (4%)	17 (6%)	9 (9%)	37 (5%)
Migraine with aura	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Migraine without aura	5 (2%)	0	0	5 (1%)
Restless legs syndrome	0	0	1 (1%)	1 (< 1%)
Seizure	0	1 (< 1%)	1 (1%)	2 (< 1%)
Sinus headache	0	3 (1%)	0	3 (< 1%)
Speech disorder developmental	0	2 (1%)	0	2 (< 1%)
Spinal cord disorder	1 (< 1%)	0	0	1 (< 1%)
Syncope	3 (1%)	1 (< 1%)	0	4 (1%)
Tension headache	4 (1%)	3 (1%)	0	7 (1%)
Tethered cord syndrome	1 (< 1%)	0	0	1 (< 1%)
Thoracic outlet syndrome	1 (< 1%)	0	0	1 (< 1%)
Tremor	0	1 (< 1%)	0	1 (< 1%)
Pregnancy, puerperium and perinatal conditions	2 (1%)	1 (< 1%)	0	3 (< 1%)
Abortion	0	1 (< 1%)	0	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Abortion spontaneous	1 (< 1%)	0	0	1 (< 1%)
Delivery	1 (< 1%)	0	0	1 (< 1%)
Psychiatric disorders	95 (32%)	73 (24%)	36 (36%)	204 (29%)
Abnormal behaviour	1 (< 1%)	0	0	1 (< 1%)
Affective disorder	5 (2%)	1 (< 1%)	1 (1%)	7 (1%)
Alcohol abuse	0	0	1 (1%)	1 (< 1%)
Anger	2 (1%)	0	0	2 (< 1%)
Anxiety	34 (11%)	26 (9%)	14 (14%)	74 (11%)
Anxiety disorder	2 (1%)	1 (< 1%)	0	3 (< 1%)
Attention deficit/hyperactivity disorder	47 (16%)	39 (13%)	7 (7%)	93 (13%)
Autism spectrum disorder	2 (1%)	1 (< 1%)	0	3 (< 1%)
Binge eating	0	0	1 (1%)	1 (< 1%)
Bipolar disorder	0	3 (1%)	0	3 (< 1%)
Bulimia nervosa	1 (< 1%)	0	0	1 (< 1%)
Depression	29 (10%)	23 (8%)	19 (19%)	71 (10%)
Drug abuse	2 (1%)	0	1 (1%)	3 (< 1%)
Eating disorder	0	1 (< 1%)	0	1 (< 1%)
Emotional distress	1 (< 1%)	0	0	1 (< 1%)
Generalised anxiety disorder	2 (1%)	0	1 (1%)	3 (< 1%)
Insomnia	7 (2%)	8 (3%)	7 (7%)	22 (3%)
Learning disorder	1 (< 1%)	0	0	1 (< 1%)
Major depression	4 (1%)	0	1 (1%)	5 (1%)
Obsessive-compulsive disorder	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Oppositional defiant disorder	1 (< 1%)	0	0	1 (< 1%)
Panic attack	0	0	1 (1%)	1 (< 1%)
Persistent depressive disorder	1 (< 1%)	0	0	1 (< 1%)
Post-traumatic stress disorder	1 (< 1%)	0	1 (1%)	2 (< 1%)
Psychotic disorder	0	0	1 (1%)	1 (< 1%)
Schizophrenia	0	0	1 (1%)	1 (< 1%)
Sleep disorder	0	1 (< 1%)	0	1 (< 1%)
Social anxiety disorder	2 (1%)	0	0	2 (< 1%)
Stress	1 (< 1%)	0	0	1 (< 1%)
Substance abuse	0	0	1 (1%)	1 (< 1%)
Suicidal ideation	0	0	1 (1%)	1 (< 1%)
Tic	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Renal and urinary disorders	7 (2%)	2 (1%)	4 (4%)	13 (2%)
Chronic kidney disease	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Dysuria	1 (< 1%)	0	0	1 (< 1%)
Glomerulonephritis acute	1 (< 1%)	0	0	1 (< 1%)
Haematuria	1 (< 1%)	0	0	1 (< 1%)
Hypertonic bladder	1 (< 1%)	0	1 (1%)	2 (< 1%)
Nephrolithiasis	1 (< 1%)	2 (1%)	0	3 (< 1%)
Pollakiuria	1 (< 1%)	0	0	1 (< 1%)
Polyuria	0	0	1 (1%)	1 (< 1%)
Urinary incontinence	0	0	1 (1%)	1 (< 1%)
Vesicoureteric reflux	2 (1%)	0	0	2 (< 1%)
Reproductive system and breast disorders	30 (10%)	21 (7%)	9 (9%)	60 (9%)
Amenorrhoea	1 (< 1%)	0	0	1 (< 1%)
Benign prostatic hyperplasia	0	0	1 (1%)	1 (< 1%)
Breast mass	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Cervical dysplasia	0	0	1 (1%)	1 (< 1%)
Dysmenorrhoea	12 (4%)	10 (3%)	1 (1%)	23 (3%)
Endometriosis	0	0	2 (2%)	2 (< 1%)
Erectile dysfunction	0	1 (< 1%)	0	1 (< 1%)
Menometrorrhagia	2 (1%)	0	0	2 (< 1%)
Menopausal symptoms	0	0	1 (1%)	1 (< 1%)
Menorrhagia	8 (3%)	1 (< 1%)	0	9 (1%)
Menstruation irregular	3 (1%)	5 (2%)	1 (1%)	9 (1%)
Metrorrhagia	0	0	1 (1%)	1 (< 1%)
Ovarian cyst	3 (1%)	1 (< 1%)	0	4 (1%)
Polycystic ovaries	1 (< 1%)	3 (1%)	0	4 (1%)
Polymenorrhoea	2 (1%)	0	0	2 (< 1%)
Prostatomegaly	0	0	1 (1%)	1 (< 1%)
Scrotal varicose veins	1 (< 1%)	0	0	1 (< 1%)
Testicular torsion	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Uterine haemorrhage	0	1 (< 1%)	0	1 (< 1%)
Vaginal discharge	0	1 (< 1%)	0	1 (< 1%)
Vaginal disorder	0	0	1 (1%)	1 (< 1%)
Vulvovaginal discomfort	0	1 (< 1%)	0	1 (< 1%)
Vulvovaginal dryness	0	0	1 (1%)	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	70 (23%)	58 (19%)	13 (13%)	141 (20%)
Adenoidal hypertrophy	2 (1%)	0	0	2 (< 1%)
Asthma	32 (11%)	36 (12%)	2 (2%)	70 (10%)
Asthma exercise induced	10 (3%)	3 (1%)	0	13 (2%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Bronchial hyperreactivity	3 (1%)	0	1 (1%)	4 (1%)
Bronchitis chronic	0	0	1 (1%)	1 (< 1%)
Bronchospasm	2 (1%)	3 (1%)	0	5 (1%)
Cough	2 (1%)	2 (1%)	2 (2%)	6 (1%)
Dyspnoea	0	0	1 (1%)	1 (< 1%)
Epistaxis	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Nasal congestion	1 (< 1%)	3 (1%)	0	4 (1%)
Nasal inflammation	0	0	1 (1%)	1 (< 1%)
Nasal obstruction	0	1 (< 1%)	0	1 (< 1%)
Nasal septum deviation	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Nasal turbinate hypertrophy	0	0	1 (1%)	1 (< 1%)
Oropharyngeal pain	3 (1%)	1 (< 1%)	0	4 (1%)
Pleurisy	0	1 (< 1%)	0	1 (< 1%)
Pulmonary thrombosis	0	0	1 (1%)	1 (< 1%)
Rhinitis allergic	25 (8%)	8 (3%)	3 (3%)	36 (5%)
Rhinitis perennial	0	3 (1%)	0	3 (< 1%)
Rhinorrhoea	0	0	1 (1%)	1 (< 1%)
Sinus congestion	0	1 (< 1%)	0	1 (< 1%)
Sleep apnoea syndrome	2 (1%)	2 (1%)	5 (5%)	9 (1%)
Snoring	0	1 (< 1%)	0	1 (< 1%)
Tonsillar hypertrophy	2 (1%)	3 (1%)	0	5 (1%)
Velopharyngeal incompetence	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	73 (24%)	39 (13%)	10 (10%)	122 (17%)
Acanthosis nigricans	4 (1%)	0	0	4 (1%)
Acne	46 (15%)	24 (8%)	1 (1%)	71 (10%)
Actinic keratosis	0	0	1 (1%)	1 (< 1%)
Alopecia	1 (< 1%)	0	0	1 (< 1%)
Cafe au lait spots	1 (< 1%)	0	0	1 (< 1%)
Chronic spontaneous urticaria	1 (< 1%)	0	0	1 (< 1%)
Dandruff	0	1 (< 1%)	0	1 (< 1%)
Dermatitis	1 (< 1%)	0	1 (1%)	2 (< 1%)
Dermatitis atopic	5 (2%)	2 (1%)	0	7 (1%)
Dermatitis contact	1 (< 1%)	1 (< 1%)	0	2 (< 1%)
Dry skin	2 (1%)	0	0	2 (< 1%)
Ecchymosis	0	1 (< 1%)	0	1 (< 1%)
Eczema	18 (6%)	10 (3%)	2 (2%)	30 (4%)
Hidradenitis	0	1 (< 1%)	0	1 (< 1%)
Hyperhidrosis	2 (1%)	0	0	2 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Keloid scar	1 (< 1%)	0	0	1 (< 1%)
Keratosis pilaris	1 (< 1%)	0	0	1 (< 1%)
Mechanical urticaria	1 (< 1%)	0	0	1 (< 1%)
Night sweats	0	0	1 (1%)	1 (< 1%)
Pityriasis rosea	0	1 (< 1%)	0	1 (< 1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Psoriasis	1 (< 1%)	0	1 (1%)	2 (< 1%)
Rash	1 (< 1%)	0	0	1 (< 1%)
Rosacea	0	1 (< 1%)	2 (2%)	3 (< 1%)
Sebaceous hyperplasia	0	0	1 (1%)	1 (< 1%)
Seborrhoeic dermatitis	0	1 (< 1%)	0	1 (< 1%)
Skin ulcer	0	0	1 (1%)	1 (< 1%)
Urticaria	0	2 (1%)	1 (1%)	3 (< 1%)
Social circumstances	0	2 (1%)	5 (5%)	7 (1%)
Menopause	0	0	2 (2%)	2 (< 1%)
Postmenopause	0	0	3 (3%)	3 (< 1%)
Tobacco user	0	2 (1%)	0	2 (< 1%)
Surgical and medical procedures	24 (8%)	18 (6%)	30 (30%)	72 (10%)
Adenoidectomy	4 (1%)	1 (< 1%)	0	5 (1%)
Adenotonsillectomy	2 (1%)	0	0	2 (< 1%)
Appendicectomy	6 (2%)	2 (1%)	0	8 (1%)
Brain operation	1 (< 1%)	0	0	1 (< 1%)
Caesarean section	1 (< 1%)	0	2 (2%)	3 (< 1%)
Catheter placement	0	1 (< 1%)	0	1 (< 1%)
Cautery to nose	1 (< 1%)	0	0	1 (< 1%)
Cholecystectomy	0	1 (< 1%)	2 (2%)	3 (< 1%)
Circumcision	0	1 (< 1%)	0	1 (< 1%)
Closed fracture manipulation	1 (< 1%)	0	0	1 (< 1%)
Contraception	0	1 (< 1%)	0	1 (< 1%)
Cryotherapy	0	0	1 (1%)	1 (< 1%)
Dental operation	1 (< 1%)	0	0	1 (< 1%)
Ear tube insertion	0	1 (< 1%)	0	1 (< 1%)
Female sterilisation	0	0	7 (7%)	7 (1%)
Fracture treatment	0	1 (< 1%)	0	1 (< 1%)
Haemorrhoid operation	1 (< 1%)	0	0	1 (< 1%)
Hormone replacement therapy	0	0	1 (1%)	1 (< 1%)
Hysterectomy	0	0	7 (7%)	7 (1%)
Implantable defibrillator insertion	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.4.2
Medical History by Body System Organ Class and Preferred Term
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)	Total (N=701)
Inguinal hernia repair	2 (1%)	1 (< 1%)	1 (1%)	4 (1%)
Intervertebral disc operation	0	0	1 (1%)	1 (< 1%)
Knee operation	1 (< 1%)	0	0	1 (< 1%)
Ligament operation	0	1 (< 1%)	0	1 (< 1%)
Lymphadenectomy	0	0	1 (1%)	1 (< 1%)
Mammoplasty	0	0	2 (2%)	2 (< 1%)
Mastectomy	0	0	1 (1%)	1 (< 1%)
Meniscus operation	1 (< 1%)	0	0	1 (< 1%)
Myringotomy	1 (< 1%)	3 (1%)	0	4 (1%)
Ovarian cystectomy	0	0	1 (1%)	1 (< 1%)
Papilloma excision	1 (< 1%)	0	0	1 (< 1%)
Plastic surgery to the face	0	0	1 (1%)	1 (< 1%)
Splint application	0	1 (< 1%)	0	1 (< 1%)
Strabismus correction	0	0	1 (1%)	1 (< 1%)
Thyroidectomy	0	0	1 (1%)	1 (< 1%)
Tonsillectomy	7 (2%)	6 (2%)	0	13 (2%)
Umbilical hernia repair	0	1 (< 1%)	0	1 (< 1%)
Vasectomy	0	0	1 (1%)	1 (< 1%)
Venous operation	0	0	1 (1%)	1 (< 1%)
Wisdom teeth removal	4 (1%)	0	0	4 (1%)
Vascular disorders	8 (3%)	2 (1%)	16 (16%)	26 (4%)
Essential hypertension	0	1 (< 1%)	0	1 (< 1%)
Hot flush	0	0	1 (1%)	1 (< 1%)
Hypertension	4 (1%)	1 (< 1%)	14 (14%)	19 (3%)
Orthostatic hypotension	1 (< 1%)	0	0	1 (< 1%)
Peripheral venous disease	0	0	1 (1%)	1 (< 1%)
Prehypertension	2 (1%)	0	0	2 (< 1%)
Raynaud's phenomenon	1 (< 1%)	0	0	1 (< 1%)
Varicose vein	0	0	1 (1%)	1 (< 1%)

Note: Mappings done using MedDRA coding 20.1

PPD

Table 14.1.1.5
Vaccine Administration
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Prevaccination Temperature (C)				
Mean, Std	36.6,0.40	36.6,0.39	36.6,0.30	36.6,0.38
Median	36.7	36.7	36.6	36.7
Min	35.1	35.1	35.8	35.1
Max	37.7	37.6	37.2	37.7
n	301	301	101	703
Temperature Location				
AXILLARY	0	1 (< 1%)	0	1 (< 1%)
EAR	1 (< 1%)	0	4 (4%)	5 (1%)
ORAL	300 (>99%)	300 (>99%)	97 (95%)	697 (99%)
Vaccination Given				
No	0	1 (< 1%)	2 (2%)	3 (< 1%)
Yes	301 (100%)	300 (>99%)	100 (98%)	701 (>99%)
Vaccination Site				
LEFT DELTOID	194 (64%)	212 (70%)	73 (72%)	479 (68%)
LOWER LEFT DELTOID	2 (1%)	1 (< 1%)	0	3 (< 1%)
RIGHT DELTOID	41 (14%)	61 (20%)	17 (17%)	119 (17%)
UPPER LEFT ARM	2 (1%)	0	1 (1%)	3 (< 1%)
UPPER LEFT DELTOID	51 (17%)	19 (6%)	3 (3%)	73 (10%)
UPPER RIGHT ARM	1 (< 1%)	0	0	1 (< 1%)
UPPER RIGHT DELTOID	10 (3%)	7 (2%)	6 (6%)	23 (3%)

PPD

Table 14.1.1.5.1
Days on Which Safety Assessments Occurred
Safety Calls and Clinic Visits
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Timing of Study Day 1 Safety Assessment (Clinic Visit)				
No safety assessment on Day 1	0	1 (< 1%)	2 (2%)	3 (< 1%)
Safety assessed between Day 1 and Day 1	298 (99%)	297 (99%)	100 (98%)	695 (99%)
Safety assessed out of window Day 1 and Day 1	3 (1%)	3 (1%)	0	6 (1%)
Timing of Study Day 4 Safety Assessment (Clinic Visit)				
Safety assessed between Day 3 and Day 5	149 (50%)	142 (47%)	50 (49%)	341 (48%)
Safety assessed out of window Day 3 and Day 5	2 (1%)	7 (2%)	2 (2%)	11 (2%)
Not Available	0	1 (< 1%)	0	1 (< 1%)
Not Planned	150 (50%)	151 (50%)	50 (49%)	351 (50%)
Timing of Study Day 6 Safety Assessment (Clinic Visit)				
Safety assessed between Day 5 and Day 7	148 (49%)	147 (49%)	45 (44%)	340 (48%)
Safety assessed out of window Day 5 and Day 7	1 (< 1%)	3 (1%)	2 (2%)	6 (1%)
Not Available	1 (< 1%)	1 (< 1%)	3 (3%)	5 (1%)
Not Planned	151 (50%)	150 (50%)	52 (51%)	353 (50%)
Timing of Study Day15 Safety Assessment (Phone Call)				
No safety assessment on Day 15	6 (2%)	3 (1%)	2 (2%)	11 (2%)
Safety assessed between Day 13 and Day 17	274 (91%)	288 (96%)	93 (91%)	655 (93%)
Safety assessed out of window Day 13 and Day 17	20 (7%)	7 (2%)	4 (4%)	31 (4%)
Not Available	1 (< 1%)	3 (1%)	3 (3%)	7 (1%)
Timing of Study Day29 Safety Assessment (Clinic Visit)				
Safety assessed between Day 22 and Day 43	297 (99%)	292 (97%)	96 (94%)	685 (97%)
Safety assessed out of window Day 22 and Day 43	3 (1%)	6 (2%)	2 (2%)	11 (2%)
Not Available	1 (< 1%)	3 (1%)	4 (4%)	8 (1%)
Timing of Study Day 91 Safety Assessment (Phone Call)				
No safety assessment on Day 91	1 (< 1%)	2 (1%)	0	3 (< 1%)
Safety assessed between Day 77 and Day 105	296 (98%)	293 (97%)	97 (95%)	686 (97%)
Safety assessed out of window Day 77 and Day 105	2 (1%)	2 (1%)	1 (1%)	5 (1%)
Not Available	2 (1%)	4 (1%)	4 (4%)	10 (1%)
Timing of Study Day 181 Safety Assessment (Phone Call)				
Safety assessed between Day 167 and Day 195	293 (97%)	282 (94%)	96 (94%)	671 (95%)
Safety assessed out of window Day 167 and Day 195	5 (2%)	6 (2%)	1 (1%)	12 (2%)
Not Available	3 (1%)	13 (4%)	5 (5%)	21 (3%)

PPD

Table 14.1.1.6
Days of Blood Samples
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Blood Sample prior to Vaccination 1				
No Day 1 Blood Sample	0	1 (< 1%)	2 (2%)	3 (< 1%)
Sample drawn on Day 1	301 (100%)	297 (99%)	99 (97%)	697 (99%)
Sample not drawn on Day 1	0	3 (1%)	1 (1%)	4 (1%)
Timing of Study Day 4 Blood Sample				
No Day 4 Blood Sample	0	2 (1%)	0	2 (< 1%)
Sample drawn between Day 3 and Day 5	149 (50%)	141 (47%)	50 (49%)	340 (48%)
Sample drawn out of window Day 3 and Day 5	2 (1%)	6 (2%)	2 (2%)	10 (1%)
Not Available	0	1 (< 1%)	0	1 (< 1%)
Not Planned	150 (50%)	151 (50%)	50 (49%)	351 (50%)
Timing of Study Day 6 Blood Sample				
No Day 6 Blood Sample	1 (< 1%)	2 (1%)	0	3 (< 1%)
Sample drawn between Day 5 and Day 7	147 (49%)	145 (48%)	45 (44%)	337 (48%)
Sample drawn out of window Day 5 and Day 7	1 (< 1%)	3 (1%)	2 (2%)	6 (1%)
Not Available	1 (< 1%)	1 (< 1%)	3 (3%)	5 (1%)
Not Planned	151 (50%)	150 (50%)	52 (51%)	353 (50%)
Timing of Study Day 29 Blood Sample				
No Day 29 Blood Sample	2 (1%)	0	0	2 (< 1%)
Sample drawn between Day 22 and Day 43	295 (98%)	292 (97%)	96 (94%)	683 (97%)
Sample drawn out of window Day 22 and Day 43	3 (1%)	6 (2%)	2 (2%)	11 (2%)
Not Available	1 (< 1%)	3 (1%)	4 (4%)	8 (1%)

PPD

Table 14.1.1.7
Duration (Number of Days) of Subject Participation in the Study
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Duration of Subject Participation: Overall Study (days)				
Mean, Std	176.1, 16.55	173.9, 26.79	165.8, 33.93	173.6, 24.49
Median	179	176	169	176
Min	1	1	1	1
Max	252	270	212	270
n	301	301	102	704
Duration of Subject Participation: Overall Study (days)				
1 day	1 (< 1%)	2 (1%)	1 (1%)	4 (1%)
2 - 4 days	0	1 (< 1%)	0	1 (< 1%)
5 - 6 days	0	0	2 (2%)	2 (< 1%)
16 - 29 days	0	0	1 (1%)	1 (< 1%)
30 - 91 days	2 (1%)	6 (2%)	0	8 (1%)
92 - 181 days	188 (62%)	190 (63%)	82 (80%)	460 (65%)
> 181 days	110 (37%)	102 (34%)	16 (16%)	228 (32%)

PPD

Table 14.1.1.8
Protocol Deviations
All Enrolled Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Any Protocol Deviation	10 (3%)	19 (6%)	8 (8%)	37 (5%)
Key study procedures missed or performed out of window	6 (2%)	10 (3%)	6 (6%)	22 (3%)
Serological results not available postvaccination	3 (1%)	2 (1%)	4 (4%)	9 (1%)
Subject did not comply with blood draw schedule	3 (1%)	8 (3%)	2 (2%)	13 (2%)
Subject randomized and did not satisfy the entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)
Subject did not meet entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)
Subject received the wrong treatment or incorrect dose	0	1 (< 1%)	2 (2%)	3 (< 1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)
Subject took an excluded concomitant medication	1 (< 1%)	3 (1%)	0	4 (1%)
Administration of any medication forbidden by the protocol	1 (< 1%)	3 (1%)	0	4 (1%)

PPD

Table 14.1.1.9
Exclusions from Immunogenicity Sets
All Enrolled Set

Type of Population: FAS (Day 1, visit 1)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	3 (1%)	5 (5%)	8 (1%)
Reasons:				
Serological results not available postvaccination	0	2 (1%)	4 (4%)	6 (1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.9
Exclusions from Immunogenicity Sets
All Enrolled Set

Type of Population: FAS (Day 29, visit 4)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	4 (1%)	5 (2%)	6 (6%)	15 (2%)
Reasons:				
Serological results not available postvaccination	4 (1%)	5 (2%)	6 (6%)	15 (2%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.9
Exclusions from Immunogenicity Sets
All Enrolled Set

Type of Population: PPS (Primary Objective, Day 1, visit 1)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	3 (1%)	10 (3%)	6 (6%)	19 (3%)
Reasons:				
Serological results not available postvaccination	0	2 (1%)	4 (4%)	6 (1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)
Subject did not comply with blood draw schedule	0	2 (1%)	0	2 (< 1%)
Subject did not meet entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)

PPD

Table 14.1.1.9
Exclusions from Immunogenicity Sets
All Enrolled Set

Type of Population: PPS (Primary Objective, Day 29, visit 4)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	11 (4%)	19 (6%)	9 (9%)	39 (6%)
Reasons:				
Administration of any medication forbidden by the protocol	1 (< 1%)	3 (1%)	0	4 (1%)
Serological results not available postvaccination	4 (1%)	5 (2%)	6 (6%)	15 (2%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)
Subject did not comply with blood draw schedule	3 (1%)	6 (2%)	2 (2%)	11 (2%)
Subject did not meet entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)

PPD

Table 14.1.1.9.1
Exclusions from Immunogenicity Sets Due to Protocol Deviations
All Enrolled Set

Type of Population: FAS (Day 1, visit 1)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	3 (1%)	5 (5%)	8 (1%)
Reasons:				
Serological results not available postvaccination	0	2 (1%)	4 (4%)	6 (1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.9.1
Exclusions from Immunogenicity Sets Due to Protocol Deviations
All Enrolled Set

Type of Population: FAS (Day 29, visit 4)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	3 (1%)	3 (1%)	5 (5%)	11 (2%)
Reasons:				
Serological results not available postvaccination	3 (1%)	2 (1%)	4 (4%)	9 (1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.9.1
Exclusions from Immunogenicity Sets Due to Protocol Deviations
All Enrolled Set

Type of Population: PPS (Primary Objective, Day 1, visit 1)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	3 (1%)	10 (3%)	6 (6%)	19 (3%)
Reasons:				
Serological results not available postvaccination	0	2 (1%)	4 (4%)	6 (1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)
Subject did not comply with blood draw schedule	0	2 (1%)	0	2 (< 1%)
Subject did not meet entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)

PPD

Table 14.1.1.9.1
Exclusions from Immunogenicity Sets Due to Protocol Deviations
All Enrolled Set

Type of Population: PPS (Primary Objective, Day 29, visit 4)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	10 (3%)	17 (6%)	8 (8%)	35 (5%)
Reasons:				
Administration of any medication forbidden by the protocol	1 (< 1%)	3 (1%)	0	4 (1%)
Serological results not available postvaccination	3 (1%)	2 (1%)	4 (4%)	9 (1%)
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)
Subject did not comply with blood draw schedule	3 (1%)	6 (2%)	2 (2%)	11 (2%)
Subject did not meet entry criteria	3 (1%)	5 (2%)	1 (1%)	9 (1%)

PPD

Table 14.1.1.9.2
Exclusions from Immunogenicity Sets Due to Other Reasons Than Protocol Deviations
All Enrolled Set

Type of Population: FAS (Day 29, visit 4)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	1 (< 1%)	3 (1%)	4 (4%)	8 (1%)
Reasons:				
Serological results are not available on visit 4 Early study termination visit: 1.	1 (< 1%)	2 (1%)	3 (3%)	6 (1%)
Serological results are not available on visit 4 Early study termination visit: 2.	0	1 (< 1%)	0	1 (< 1%)
Serological results are not available on visit 4 Early study termination visit: 3.	0	0	1 (1%)	1 (< 1%)

PPD

Table 14.1.1.9.2
Exclusions from Immunogenicity Sets Due to Other Reasons Than Protocol Deviations
All Enrolled Set

Type of Population: PPS (Primary Objective, Day 29, visit 4)

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	1 (< 1%)	3 (1%)	4 (4%)	8 (1%)
Reasons:				
Serological results are not available on visit 4 Early study termination visit: 1.	1 (< 1%)	2 (1%)	3 (3%)	6 (1%)
Serological results are not available on visit 4 Early study termination visit: 2.	0	1 (< 1%)	0	1 (< 1%)
Serological results are not available on visit 4 Early study termination visit: 3.	0	0	1 (1%)	1 (< 1%)

PPD

Table 14.1.1.10
Exclusions from Safety Sets
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: All Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	1 (< 1%)	2 (2%)	3 (< 1%)
Reasons:				
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.10
Exclusions from Safety Sets
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: Unsolicited Safety Set Overall

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	1 (< 1%)	2 (2%)	3 (< 1%)
Reasons:				
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.10
Exclusions from Safety Sets
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: Solicited Safety Set Overall

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	1 (< 1%)	2 (2%)	3 (< 1%)
Reasons:				
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.10.1
Exclusions from Safety Sets due to Protocol deviations
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: All Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	1 (< 1%)	2 (2%)	3 (< 1%)
Reasons:				
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.10.1
Exclusions from Safety Sets due to Protocol deviations
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: Unsolicited Safety Set Overall

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	1 (< 1%)	2 (2%)	3 (< 1%)
Reasons:				
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.10.1
Exclusions from Safety Sets due to Protocol deviations
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: Solicited Safety Set Overall

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
Total Number of Subjects With Exclusions:				
Any Exclusion	0	1 (< 1%)	2 (2%)	3 (< 1%)
Reasons:				
Study vaccine not administered AT ALL but subject number allocated	0	1 (< 1%)	2 (2%)	3 (< 1%)

PPD

Table 14.1.1.10.2
Exclusions from Safety Sets due to Other Reasons Than Protocol deviations
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: All Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
None Reported				

PPD

Table 14.1.1.10.2
Exclusions from Safety Sets due to Other Reasons Than Protocol deviations
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: Unsolicited Safety Set Overall

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
None Reported				

PPD

Table 14.1.1.10.2
Exclusions from Safety Sets due to Other Reasons Than Protocol deviations
Solicited and Unsolicited Safety Sets
All Enrolled Set

Type of Population: Solicited Safety Set Overall

	Menveo-Menveo (N=301)	Menactra-Menveo (N=301)	Naive (N=102)	Total (N=704)
None Reported				

PPD

14.2 Immunogenicity Data

14.2.1 Summary Tables

Table 14.2.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	1	3	4	0
Percentage	0.81%	2.56%	1.67%	0%
95% Conf Int	0.02%-4.45%	0.53%-7.31%	0.46%-4.21%	0%-7.87%
N	123	117	240	45
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	1	0	1	0
Percentage	4.76%	0%	2.38%	0%
95% Conf Int	0.12%-23.82%	0%-16.11%	0.06%-12.57%	0%-70.76%
N	21	21	42	3
DAY 4 : Total seroresponse				
Number	2	3	5	0
Percentage	1.39%	2.17%	1.77%	0%
95% Conf Int	0.17%-4.93%	0.45%-6.22%	0.58%-4.09%	0%-7.40%
N	144	138	282	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	49	38	87	1
Percentage	39.84%	33.63%	36.86%	2.56%
95% Conf Int	31.12%-49.05%	25.01%-43.12%	30.70%-43.37%	0.06%-13.48%
N	123	113	236	39
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	8	6	14	1
Percentage	36.36%	22.22%	28.57%	20.00%
95% Conf Int	17.20%-59.34%	8.62%-42.26%	16.58%-43.26%	0.51%-71.64%
N	22	27	49	5
DAY 6 : Total seroresponse				
Number	57	44	101	2
Percentage	39.31%	31.43%	35.44%	4.55%
95% Conf Int	31.31%-47.76%	23.85%-39.81%	29.89%-41.30%	0.56%-15.47%
N	145	140	285	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	241	227	468	55
Percentage	97.97%	97.01%	97.50%	64.71%
95% Conf Int	95.32%-99.34%	93.93%-98.79%	95.67%-98.70%	53.59%-74.77%
N	246	234	480	85
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	38	45	83	6
Percentage	88.37%	93.75%	91.21%	75.00%
95% Conf Int	74.92%-96.11%	82.80%-98.69%	83.41%-96.13%	34.91%-96.81%
N	43	48	91	8
DAY 29 : Total seroresponse				
Number	279	272	551	61
Percentage	96.54%	96.45%	96.50%	65.59%
95% Conf Int	93.73%-98.33%	93.58%-98.29%	94.64%-97.85%	55.02%-75.14%
N	289	282	571	93
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				1.39%
95% Conf Int				-6.08%-4.94%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				2.17%
95% Conf Int				-5.32%-6.21%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				1.77%
95% Conf Int				-5.68%-4.09%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.79%		
95% Conf Int		-4.98%-3.01%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				34.76%
95% Conf Int				22.38%-44.07%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				26.88%
95% Conf Int				14.67%-36.13%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				30.89%
95% Conf Int				19.42%-37.97%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		7.88%		
95% Conf Int		-3.25%-18.81%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				30.95%
95% Conf Int				21.76%-41.25%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				30.86%
95% Conf Int				21.66%-41.17%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				30.91%
95% Conf Int				21.89%-41.12%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.09%		
95% Conf Int		-3.15%-3.36%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	0	5	5	1
Percentage	0%	9.80%	5.75%	5.00%
95% Conf Int	0%-9.74%	3.26%-21.41%	1.89%-12.90%	0.13%-24.87%
N	36	51	87	20
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	4	7	11	2
Percentage	3.74%	8.14%	5.70%	7.14%
95% Conf Int	1.03%-9.30%	3.34%-16.05%	2.88%-9.97%	0.88%-23.50%
N	107	86	193	28
DAY 4 : Total seroresponse				
Number	4	12	16	3
Percentage	2.80%	8.76%	5.71%	6.25%
95% Conf Int	0.77%-7.01%	4.61%-14.80%	3.30%-9.11%	1.31%-17.20%
N	143	137	280	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	32	33	65	3
Percentage	65.31%	64.71%	65.00%	13.04%
95% Conf Int	50.36%-78.33%	50.07%-77.57%	54.82%-74.27%	2.78%-33.59%
N	49	51	100	23
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	42	34	76	2
Percentage	44.21%	38.64%	41.53%	9.52%
95% Conf Int	34.02%-54.77%	28.44%-49.62%	34.31%-49.03%	1.17%-30.38%
N	95	88	183	21
DAY 6 : Total seroresponse				
Number	74	67	141	5
Percentage	51.39%	48.20%	49.82%	11.36%
95% Conf Int	42.92%-59.80%	39.65%-56.83%	43.85%-55.80%	3.79%-24.56%
N	144	139	283	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	85	103	188	24
Percentage	100%	100%	100%	55.81%
95% Conf Int	95.75%-100%	96.48%-100%	98.06%-100%	39.88%-70.92%
N	85	103	188	43
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	190	166	356	29
Percentage	93.60%	93.79%	93.68%	58.00%
95% Conf Int	89.30%-96.55%	89.15%-96.86%	90.75%-95.91%	43.21%-71.81%
N	203	177	380	50
DAY 29 : Total seroresponse				
Number	275	269	544	53
Percentage	95.49%	96.07%	95.77%	56.99%
95% Conf Int	92.40%-97.57%	93.08%-98.02%	93.78%-97.27%	46.31%-67.22%
N	288	280	568	93
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				-3.45%
95% Conf Int				-14.26%-2.35%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				2.51%
95% Conf Int				-8.70%-9.98%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				-0.54%
95% Conf Int				-11.35%-4.90%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-5.96%		
95% Conf Int		-12.25%--0.57%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				40.03%
95% Conf Int				25.37%-50.92%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				36.84%
95% Conf Int				22.14%-47.90%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				38.46%
95% Conf Int				24.79%-47.57%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		3.19%		
95% Conf Int		-8.44%-14.73%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				38.50%
95% Conf Int				28.54%-48.90%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				39.08%
95% Conf Int				29.16%-49.46%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				38.79%
95% Conf Int				29.03%-49.06%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.59%		
95% Conf Int		-4.12%-2.92%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	2	9	11	2
Percentage	9.52%	30.00%	21.57%	11.76%
95% Conf Int	1.17%-30.38%	14.73%-49.40%	11.29%-35.32%	1.46%-36.44%
N	21	30	51	17
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	2	5	7	1
Percentage	1.63%	4.63%	3.03%	3.23%
95% Conf Int	0.20%-5.75%	1.52%-10.47%	1.23%-6.14%	0.08%-16.70%
N	123	108	231	31
DAY 4 : Total seroresponse				
Number	4	14	18	3
Percentage	2.78%	10.14%	6.38%	6.25%
95% Conf Int	0.76%-6.96%	5.66%-16.44%	3.83%-9.90%	1.31%-17.20%
N	144	138	282	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	20	21	41	4
Percentage	64.52%	75.00%	69.49%	25.00%
95% Conf Int	45.37%-80.77%	55.13%-89.31%	56.13%-80.81%	7.27%-52.38%
N	31	28	59	16
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	53	48	101	1
Percentage	46.49%	42.86%	44.69%	3.57%
95% Conf Int	37.10%-56.07%	33.55%-52.55%	38.09%-51.43%	0.09%-18.35%
N	114	112	226	28
DAY 6 : Total seroresponse				
Number	73	69	142	5
Percentage	50.34%	49.29%	49.82%	11.36%
95% Conf Int	41.93%-58.75%	40.74%-57.86%	43.87%-55.78%	3.79%-24.56%
N	145	140	285	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	52	58	110	18
Percentage	100%	100%	100%	54.55%
95% Conf Int	93.15%-100%	93.84%-100%	96.70%-100%	36.35%-71.89%
N	52	58	110	33
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	225	204	429	15
Percentage	94.94%	91.48%	93.26%	25.42%
95% Conf Int	91.32%-97.36%	87.01%-94.79%	90.57%-95.38%	14.98%-38.44%
N	237	223	460	59
DAY 29 : Total seroresponse				
Number	277	262	539	33
Percentage	95.85%	93.24%	94.56%	35.87%
95% Conf Int	92.86%-97.84%	89.64%-95.88%	92.37%-96.28%	26.13%-46.54%
N	289	281	570	92
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				-3.47%
95% Conf Int				-14.28%-2.31%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				3.89%
95% Conf Int				-7.40%-11.60%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				0.13%
95% Conf Int				-10.70%-5.66%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-7.37%		
95% Conf Int		-13.89%--1.80%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				38.98%
95% Conf Int				24.35%-49.88%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				37.92%
95% Conf Int				23.23%-48.95%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				38.46%
95% Conf Int				24.80%-47.56%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.06%		
95% Conf Int		-10.51%-12.60%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				59.98%
95% Conf Int				49.49%-69.32%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				57.37%
95% Conf Int				46.71%-66.88%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				58.69%
95% Conf Int				48.32%-67.94%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		2.61%		
95% Conf Int		-1.17%-6.62%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	5	4	9	0
Percentage	8.06%	6.67%	7.38%	0%
95% Conf Int	2.67%-17.83%	1.85%-16.20%	3.43%-13.54%	0%-12.77%
N	62	60	122	27
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	6	2	8	0
Percentage	7.50%	2.60%	5.10%	0%
95% Conf Int	2.80%-15.61%	0.32%-9.07%	2.23%-9.79%	0%-16.11%
N	80	77	157	21
DAY 4 : Total seroresponse				
Number	11	6	17	0
Percentage	7.75%	4.38%	6.09%	0%
95% Conf Int	3.93%-13.44%	1.62%-9.29%	3.59%-9.58%	0%-7.40%
N	142	137	279	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	33	47	80	3
Percentage	63.46%	75.81%	70.18%	11.11%
95% Conf Int	48.96%-76.38%	63.26%-85.78%	60.89%-78.38%	2.35%-29.16%
N	52	62	114	27
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	37	33	70	1
Percentage	40.66%	42.31%	41.42%	5.88%
95% Conf Int	30.48%-51.47%	31.19%-54.02%	33.91%-49.24%	0.15%-28.69%
N	91	78	169	17
DAY 6 : Total seroresponse				
Number	70	80	150	4
Percentage	48.95%	57.14%	53.00%	9.09%
95% Conf Int	40.51%-57.44%	48.51%-65.47%	47.01%-58.94%	2.53%-21.67%
N	143	140	283	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

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Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	115	120	235	30
Percentage	100%	97.56%	98.74%	55.56%
95% Conf Int	96.84%-100%	93.04%-99.49%	96.36%-99.74%	41.40%-69.08%
N	115	123	238	54
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	163	144	307	18
Percentage	94.77%	91.72%	93.31%	46.15%
95% Conf Int	90.30%-97.58%	86.26%-95.52%	90.05%-95.76%	30.09%-62.82%
N	172	157	329	39
DAY 29 : Total seroresponse				
Number	278	264	542	48
Percentage	96.86%	94.29%	95.59%	51.61%
95% Conf Int	94.13%-98.56%	90.89%-96.70%	93.56%-97.13%	41.01%-62.11%
N	287	280	567	93
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				7.75%
95% Conf Int				0.15%-13.36%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				4.38%
95% Conf Int				-3.15%-9.24%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				6.09%
95% Conf Int				-1.41%-9.55%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		3.37%		
95% Conf Int		-2.48%-9.54%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				39.86%
95% Conf Int				25.76%-50.29%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				48.05%
95% Conf Int				33.89%-58.34%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				43.91%
95% Conf Int				30.79%-52.37%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-8.19%		
95% Conf Int		-19.61%-3.45%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				45.25%
95% Conf Int				35.11%-55.47%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				42.67%
95% Conf Int				32.34%-53.04%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				43.98%
95% Conf Int				33.92%-54.14%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		2.58%		
95% Conf Int		-0.86%-6.30%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	2	0
Percentage	1.64%	3.08%	0%
95% Conf Int	0.04%-8.80%	0.37%-10.68%	0%-23.16%
N	61	65	14
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	0	
Percentage	11.11%	0%	
95% Conf Int	0.28%-48.25%	0%-36.94%	
N	9	8	
DAY 4 : Total seroresponse			
Number	2	2	0
Percentage	2.86%	2.74%	0%
95% Conf Int	0.35%-9.94%	0.33%-9.55%	0%-23.16%
N	70	73	14
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	30	13	0
Percentage	40.54%	28.26%	0%
95% Conf Int	29.27%-52.59%	15.99%-43.46%	0%-23.16%
N	74	46	14
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	2	1
Percentage	22.22%	13.33%	50.00%
95% Conf Int	2.81%-60.01%	1.66%-40.46%	1.26%-98.74%
N	9	15	2
DAY 6 : Total seroresponse			
Number	32	15	1
Percentage	38.55%	24.59%	6.25%
95% Conf Int	28.07%-49.88%	14.46%-37.29%	0.16%-30.23%
N	83	61	16
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	132	109	18

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	97.78%	96.46%	64.29%
95% Conf Int	93.64%-99.54%	91.18%-99.03%	44.07%-81.36%
N	135	113	28
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	14	22	1
Percentage	77.78%	95.65%	50.00%
95% Conf Int	52.36%-93.59%	78.05%-99.89%	1.26%-98.74%
N	18	23	2
DAY 29 : Total seroresponse			
Number	146	131	19
Percentage	95.42%	96.32%	63.33%
95% Conf Int	90.80%-98.14%	91.63%-98.80%	43.86%-80.07%
N	153	136	30
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			2.86%
95% Conf Int			-19.00%-9.89%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			2.74%
95% Conf Int			-19.10%-9.51%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0.12%	
95% Conf Int		-6.99%-7.46%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			32.30%
95% Conf Int			8.47%-45.31%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			18.34%
95% Conf Int			-5.50%-32.49%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		13.96%	
95% Conf Int		-1.63%-28.45%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			32.09%
95% Conf Int			16.76%-50.24%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			32.99%
95% Conf Int			17.68%-51.11%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-0.90%	
95% Conf Int		-5.99%-4.30%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	1	0
Percentage	0%	4.00%	0%
95% Conf Int	0%-17.65%	0.10%-20.35%	0%-52.18%
N	19	25	5
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	4	0
Percentage	4.00%	8.51%	0%
95% Conf Int	0.49%-13.71%	2.37%-20.38%	0%-33.63%
N	50	47	9
DAY 4 : Total seroresponse			
Number	2	5	0
Percentage	2.90%	6.94%	0%
95% Conf Int	0.35%-10.08%	2.29%-15.47%	0%-23.16%
N	69	72	14
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	22	13	0
Percentage	61.11%	61.90%	0%
95% Conf Int	43.46%-76.86%	38.44%-81.89%	0%-52.18%
N	36	21	5
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	21	13	2
Percentage	44.68%	32.50%	18.18%
95% Conf Int	30.17%-59.88%	18.57%-49.13%	2.28%-51.78%
N	47	40	11
DAY 6 : Total seroresponse			
Number	43	26	2
Percentage	51.81%	42.62%	12.50%
95% Conf Int	40.56%-62.92%	30.04%-55.94%	1.55%-38.35%
N	83	61	16
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	55	47	6

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	60.00%
95% Conf Int	93.51%-100%	92.45%-100%	26.24%-87.84%
N	55	47	10
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	92	81	11
Percentage	93.88%	93.10%	55.00%
95% Conf Int	87.15%-97.72%	85.59%-97.43%	31.53%-76.94%
N	98	87	20
DAY 29 : Total seroresponse			
Number	147	128	17
Percentage	96.08%	95.52%	56.67%
95% Conf Int	91.66%-98.55%	90.51%-98.34%	37.43%-74.54%
N	153	134	30
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			2.90%
95% Conf Int			-18.96%-10.03%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			6.94%
95% Conf Int			-15.07%-15.31%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-4.05%	
95% Conf Int		-12.81%-3.94%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			39.31%
95% Conf Int			13.66%-54.36%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			30.12%
95% Conf Int			3.92%-46.87%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		9.18%	
95% Conf Int		-7.35%-25.14%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			39.41%
95% Conf Int			23.03%-57.18%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			38.86%
95% Conf Int			22.34%-56.70%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0.56%	
95% Conf Int		-4.46%-5.98%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	4	0
Percentage	0%	25.00%	0%
95% Conf Int	0%-36.94%	7.27%-52.38%	0%-70.76%
N	8	16	3
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	3	1
Percentage	1.61%	5.26%	9.09%
95% Conf Int	0.04%-8.66%	1.10%-14.62%	0.23%-41.28%
N	62	57	11
DAY 4 : Total seroresponse			
Number	1	7	1
Percentage	1.43%	9.59%	7.14%
95% Conf Int	0.04%-7.70%	3.94%-18.76%	0.18%-33.87%
N	70	73	14
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	12	12	1
Percentage	57.14%	85.71%	50.00%
95% Conf Int	34.02%-78.18%	57.19%-98.22%	1.26%-98.74%
N	21	14	2
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	27	15	1
Percentage	43.55%	31.91%	7.14%
95% Conf Int	30.99%-56.74%	19.09%-47.12%	0.18%-33.87%
N	62	47	14
DAY 6 : Total seroresponse			
Number	39	27	2
Percentage	46.99%	44.26%	12.50%
95% Conf Int	35.93%-58.26%	31.55%-57.55%	1.55%-38.35%
N	83	61	16
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	29	30	2

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	40.00%
95% Conf Int	88.06%-100%	88.43%-100%	5.27%-85.34%
N	29	30	5
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	117	97	10
Percentage	94.35%	92.38%	40.00%
95% Conf Int	88.71%-97.70%	85.54%-96.65%	21.13%-61.33%
N	124	105	25
DAY 29 : Total seroresponse			
Number	146	127	12
Percentage	95.42%	94.07%	40.00%
95% Conf Int	90.80%-98.14%	88.66%-97.41%	22.66%-59.40%
N	153	135	30
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			-5.71%
95% Conf Int			-30.32%-2.46%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			2.45%
95% Conf Int			-22.64%-13.77%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-8.16%	
95% Conf Int		-17.32%--0.77%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			34.49%
95% Conf Int			8.88%-49.66%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			31.76%
95% Conf Int			5.52%-48.49%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		2.73%	
95% Conf Int		-13.69%-18.87%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			55.42%
95% Conf Int			37.33%-71.23%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			54.07%
95% Conf Int			35.80%-70.03%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		1.35%	
95% Conf Int		-4.07%-7.24%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	2	0
Percentage	6.45%	5.71%	0%
95% Conf Int	0.79%-21.42%	0.70%-19.16%	0%-45.93%
N	31	35	6
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	5	2	0
Percentage	13.51%	5.41%	0%
95% Conf Int	4.54%-28.77%	0.66%-18.19%	0%-36.94%
N	37	37	8
DAY 4 : Total seroresponse			
Number	7	4	0
Percentage	10.29%	5.56%	0%
95% Conf Int	4.24%-20.07%	1.53%-13.62%	0%-23.16%
N	68	72	14
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	18	23	1
Percentage	60.00%	82.14%	12.50%
95% Conf Int	40.60%-77.34%	63.11%-93.94%	0.32%-52.65%
N	30	28	8
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	18	11	0
Percentage	34.62%	33.33%	0%
95% Conf Int	21.97%-49.09%	17.96%-51.83%	0%-36.94%
N	52	33	8
DAY 6 : Total seroresponse			
Number	36	34	1
Percentage	43.90%	55.74%	6.25%
95% Conf Int	32.96%-55.30%	42.45%-68.45%	0.16%-30.23%
N	82	61	16
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	62	63	7

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	98.44%	50.00%
95% Conf Int	94.22%-100%	91.60%-99.96%	23.04%-76.96%
N	62	64	14
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	86	65	6
Percentage	95.56%	92.86%	37.50%
95% Conf Int	89.01%-98.78%	84.11%-97.64%	15.20%-64.57%
N	90	70	16
DAY 29 : Total seroresponse			
Number	148	128	13
Percentage	97.37%	95.52%	43.33%
95% Conf Int	93.40%-99.28%	90.51%-98.34%	25.46%-62.57%
N	152	134	30
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			10.29%
95% Conf Int			-11.87%-19.83%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			5.56%
95% Conf Int			-16.40%-13.49%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		4.74%	
95% Conf Int		-4.68%-15.02%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			37.65%
95% Conf Int			13.71%-50.71%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			49.49%
95% Conf Int			24.81%-63.58%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Sex: Male

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-11.84%	
95% Conf Int		-27.79%-4.76%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			54.04%
95% Conf Int			36.29%-70.23%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			52.19%
95% Conf Int			34.23%-68.56%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		1.85%	
95% Conf Int		-2.74%-7.12%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	1	0
Percentage	0%	1.92%	0%
95% Conf Int	0%-5.78%	0.05%-10.26%	0%-11.22%
N	62	52	31
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-26.46%	0%-24.71%	0%-70.76%
N	12	13	3
DAY 4 : Total seroresponse			
Number	0	1	0
Percentage	0%	1.54%	0%
95% Conf Int	0%-4.86%	0.04%-8.28%	0%-10.28%
N	74	65	34
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	19	25	1
Percentage	38.78%	37.31%	4.00%
95% Conf Int	25.20%-53.76%	25.80%-49.99%	0.10%-20.35%
N	49	67	25
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	6	4	0
Percentage	46.15%	33.33%	0%
95% Conf Int	19.22%-74.87%	9.92%-65.11%	0%-70.76%
N	13	12	3
DAY 6 : Total seroresponse			
Number	25	29	1
Percentage	40.32%	36.71%	3.57%
95% Conf Int	28.05%-53.55%	26.14%-48.31%	0.09%-18.35%
N	62	79	28
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	109	118	37

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	98.20%	97.52%	64.91%
95% Conf Int	93.64%-99.78%	92.93%-99.49%	51.13%-77.09%
N	111	121	57
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	24	23	5
Percentage	96.00%	92.00%	83.33%
95% Conf Int	79.65%-99.90%	73.97%-99.02%	35.88%-99.58%
N	25	25	6
DAY 29 : Total seroresponse			
Number	133	141	42
Percentage	97.79%	96.58%	66.67%
95% Conf Int	93.69%-99.54%	92.19%-98.88%	53.66%-78.05%
N	136	146	63
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-10.24%-4.98%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			1.54%
95% Conf Int			-8.76%-8.27%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-1.54%	
95% Conf Int		-8.25%-3.47%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			36.75%
95% Conf Int			19.76%-50.19%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			33.14%
95% Conf Int			16.85%-45.18%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		3.61%	
95% Conf Int		-12.40%-19.72%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			31.13%
95% Conf Int			20.29%-43.66%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			29.91%
95% Conf Int			18.91%-42.52%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		1.22%	
95% Conf Int		-3.28%-5.86%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	4	1
Percentage	0%	15.38%	6.67%
95% Conf Int	0%-19.51%	4.36%-34.87%	0.17%-31.95%
N	17	26	15
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	3	2
Percentage	3.51%	7.69%	10.53%
95% Conf Int	0.43%-12.11%	1.62%-20.87%	1.30%-33.14%
N	57	39	19
DAY 4 : Total seroresponse			
Number	2	7	3
Percentage	2.70%	10.77%	8.82%
95% Conf Int	0.33%-9.42%	4.44%-20.94%	1.86%-23.68%
N	74	65	34
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	10	20	3
Percentage	76.92%	66.67%	16.67%
95% Conf Int	46.19%-94.96%	47.19%-82.71%	3.58%-41.42%
N	13	30	18
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	21	21	0
Percentage	43.75%	43.75%	0%
95% Conf Int	29.48%-58.82%	29.48%-58.82%	0%-30.85%
N	48	48	10
DAY 6 : Total seroresponse			
Number	31	41	3
Percentage	50.82%	52.56%	10.71%
95% Conf Int	37.70%-63.86%	40.93%-63.99%	2.27%-28.23%
N	61	78	28
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	30	56	18

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	54.55%
95% Conf Int	88.43%-100%	93.62%-100%	36.35%-71.89%
N	30	56	33
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	98	85	18
Percentage	93.33%	94.44%	60.00%
95% Conf Int	86.75%-97.28%	87.51%-98.17%	40.60%-77.34%
N	105	90	30
DAY 29 : Total seroresponse			
Number	128	141	36
Percentage	94.81%	96.58%	57.14%
95% Conf Int	89.61%-97.89%	92.19%-98.88%	44.05%-69.54%
N	135	146	63
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			-6.12%
95% Conf Int			-20.60%-2.45%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			1.95%
95% Conf Int			-13.38%-13.75%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-8.07%	
95% Conf Int		-18.31%-0.19%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			40.11%
95% Conf Int			20.07%-55.16%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			41.85%
95% Conf Int			22.52%-55.64%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-1.74%	
95% Conf Int		-18.28%-14.84%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			37.67%
95% Conf Int			25.38%-50.46%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			39.43%
95% Conf Int			27.44%-52.04%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-1.76%	
95% Conf Int		-7.33%-3.31%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	5	2
Percentage	15.38%	35.71%	14.29%
95% Conf Int	1.92%-45.45%	12.76%-64.86%	1.78%-42.81%
N	13	14	14
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	2	0
Percentage	1.64%	3.92%	0%
95% Conf Int	0.04%-8.80%	0.48%-13.46%	0%-16.84%
N	61	51	20
DAY 4 : Total seroresponse			
Number	3	7	2
Percentage	4.05%	10.77%	5.88%
95% Conf Int	0.84%-11.39%	4.44%-20.94%	0.72%-19.68%
N	74	65	34
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	8	9	3
Percentage	80.00%	64.29%	21.43%
95% Conf Int	44.39%-97.48%	35.14%-87.24%	4.66%-50.80%
N	10	14	14
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	26	33	0
Percentage	50.00%	50.77%	0%
95% Conf Int	35.81%-64.19%	38.07%-63.40%	0%-23.16%
N	52	65	14
DAY 6 : Total seroresponse			
Number	34	42	3
Percentage	54.84%	53.16%	10.71%
95% Conf Int	41.68%-67.52%	41.60%-64.49%	2.27%-28.23%
N	62	79	28
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	23	28	16

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	57.14%
95% Conf Int	85.18%-100%	87.66%-100%	37.18%-75.54%
N	23	28	28
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	108	107	5
Percentage	95.58%	90.68%	14.71%
95% Conf Int	89.98%-98.55%	83.93%-95.25%	4.95%-31.06%
N	113	118	34
DAY 29 : Total seroresponse			
Number	131	135	21
Percentage	96.32%	92.47%	33.87%
95% Conf Int	91.63%-98.80%	86.92%-96.18%	22.33%-47.01%
N	136	146	62
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			-1.83%
95% Conf Int			-15.49%-6.66%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			4.89%
95% Conf Int			-9.45%-16.05%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-6.72%	
95% Conf Int		-17.14%-2.15%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			44.12%
95% Conf Int			24.09%-58.88%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			42.45%
95% Conf Int			23.15%-56.15%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		1.67%	
95% Conf Int		-14.82%-17.98%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			62.45%
95% Conf Int			49.52%-73.43%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			58.59%
95% Conf Int			45.31%-69.93%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		3.86%	
95% Conf Int		-1.74%-9.81%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	3	2	0
Percentage	9.68%	8.00%	0%
95% Conf Int	2.04%-25.75%	0.98%-26.03%	0%-16.11%
N	31	25	21
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	0	0
Percentage	2.33%	0%	0%
95% Conf Int	0.06%-12.29%	0%-8.81%	0%-24.71%
N	43	40	13
DAY 4 : Total seroresponse			
Number	4	2	0
Percentage	5.41%	3.08%	0%
95% Conf Int	1.49%-13.27%	0.37%-10.68%	0%-10.28%
N	74	65	34
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	15	24	2
Percentage	68.18%	70.59%	10.53%
95% Conf Int	45.13%-86.14%	52.52%-84.90%	1.30%-33.14%
N	22	34	19
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	19	22	1
Percentage	48.72%	48.89%	11.11%
95% Conf Int	32.42%-65.22%	33.70%-64.23%	0.28%-48.25%
N	39	45	9
DAY 6 : Total seroresponse			
Number	34	46	3
Percentage	55.74%	58.23%	10.71%
95% Conf Int	42.45%-68.45%	46.59%-69.23%	2.27%-28.23%
N	61	79	28
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	53	57	23

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	96.61%	57.50%
95% Conf Int	93.28%-100%	88.29%-99.59%	40.89%-72.96%
N	53	59	40
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	77	79	12
Percentage	93.90%	90.80%	52.17%
95% Conf Int	86.34%-97.99%	82.68%-95.95%	30.59%-73.18%
N	82	87	23
DAY 29 : Total seroresponse			
Number	130	136	35
Percentage	96.30%	93.15%	55.56%
95% Conf Int	91.57%-98.79%	87.76%-96.67%	42.49%-68.08%
N	135	146	63
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			5.41%
95% Conf Int			-5.01%-13.14%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			3.08%
95% Conf Int			-7.28%-10.60%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		2.33%	
95% Conf Int		-5.82%-10.51%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			45.02%
95% Conf Int			24.92%-59.80%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			47.51%
95% Conf Int			28.21%-60.95%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.1
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Sex, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Sex: Female

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-2.49%	
95% Conf Int		-18.89%-13.86%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			40.74%
95% Conf Int			28.53%-53.35%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			37.60%
95% Conf Int			25.06%-50.44%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		3.15%	
95% Conf Int		-2.40%-8.96%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-60.24%	
N	1	4	
DAY 4 : Total seroresponse			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-60.24%	
N	1	4	
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		0	
Percentage		0%	
95% Conf Int		0%-84.19%	
N		2	
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1		
Percentage	100%		
95% Conf Int	2.50%-100%		
N	1		
DAY 6 : Total seroresponse			
Number	1	0	
Percentage	100%	0%	
95% Conf Int	2.50%-100%	0%-84.19%	
N	1	2	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	6	
Percentage	100%	100%	
95% Conf Int	2.50%-100%	54.07%-100%	
N	1	6	
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%		
95% Conf Int	2.50%-100%		
N	1		
DAY 29 : Total seroresponse			
Number	2	6	
Percentage	100%	100%	
95% Conf Int	15.81%-100%	54.07%-100%	
N	2	6	
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-54.55%-82.76%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		100%	
95% Conf Int		-31.52%-100.00%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-68.70%-42.25%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		0	
Percentage		0%	
95% Conf Int		0%-97.50%	
N		1	
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-70.76%	
N	1	3	
DAY 4 : Total seroresponse			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-60.24%	
N	1	4	
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	0	
Percentage	100%	0%	
95% Conf Int	2.50%-100%	0%-97.50%	
N	1	1	
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number		0	
Percentage		0%	
95% Conf Int		0%-97.50%	
N		1	
DAY 6 : Total seroresponse			
Number	1	0	
Percentage	100%	0%	
95% Conf Int	2.50%-100%	0%-84.19%	
N	1	2	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	2	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	
95% Conf Int	2.50%-100%	15.81%-100%	
N	1	2	
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	4	
Percentage	100%	100%	
95% Conf Int	2.50%-100%	39.76%-100%	
N	1	4	
DAY 29 : Total seroresponse			
Number	2	6	
Percentage	100%	100%	
95% Conf Int	15.81%-100%	54.07%-100%	
N	2	6	
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-54.55%-82.76%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		100%	
95% Conf Int		-31.52%-100.00%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-68.70%-42.25%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		0	
Percentage		0%	
95% Conf Int		0%-97.50%	
N		1	
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-70.76%	
N	1	3	
DAY 4 : Total seroresponse			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-60.24%	
N	1	4	
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		1	
Percentage		100%	
95% Conf Int		2.50%-100%	
N		1	
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	0	
Percentage	100%	0%	
95% Conf Int	2.50%-100%	0%-97.50%	
N	1	1	
DAY 6 : Total seroresponse			
Number	1	1	
Percentage	100%	50.00%	
95% Conf Int	2.50%-100%	1.26%-98.74%	
N	1	2	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		2	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage		100%	
95% Conf Int		15.81%-100%	
N		2	
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	4	
Percentage	100%	100%	
95% Conf Int	15.81%-100%	39.76%-100%	
N	2	4	
DAY 29 : Total seroresponse			
Number	2	6	
Percentage	100%	100%	
95% Conf Int	15.81%-100%	54.07%-100%	
N	2	6	
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-54.55%-82.76%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		50.00%	
95% Conf Int		-64.16%-93.08%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-68.70%-42.25%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number		0	
Percentage		0%	
95% Conf Int		0%-60.24%	
N		4	
DAY 4 : Total seroresponse			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-60.24%	
N	1	4	
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	1	
Percentage	100%	50.00%	
95% Conf Int	2.50%-100%	1.26%-98.74%	
N	1	2	
DAY 6 : Total seroresponse			
Number	1	1	
Percentage	100%	50.00%	
95% Conf Int	2.50%-100%	1.26%-98.74%	
N	1	2	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1		
Percentage	100%		
95% Conf Int	2.50%-100%		
N	1		
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	6	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: American Indian or Alaska Native

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	
95% Conf Int	2.50%-100%	54.07%-100%	
N	1	6	
DAY 29 : Total seroresponse			
Number	2	6	
Percentage	100%	100%	
95% Conf Int	15.81%-100%	54.07%-100%	
N	2	6	
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-54.55%-82.76%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		50.00%	
95% Conf Int		-64.16%-93.08%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-68.70%-42.25%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-84.19%	0%-45.93%	0%-70.76%
N	2	6	3
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number		0	
Percentage		0%	
95% Conf Int		0%-97.50%	
N		1	
DAY 4 : Total seroresponse			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-84.19%	0%-40.96%	0%-70.76%
N	2	7	3
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	1	
Percentage	100%	50.00%	
95% Conf Int	2.50%-100%	1.26%-98.74%	
N	1	2	
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	2	
Percentage	0%	66.67%	
95% Conf Int	0%-97.50%	9.43%-99.16%	
N	1	3	
DAY 6 : Total seroresponse			
Number	1	3	
Percentage	50.00%	60.00%	
95% Conf Int	1.26%-98.74%	14.66%-94.73%	
N	2	5	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	9	2

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	66.67%	100%	66.67%
95% Conf Int	9.43%-99.16%	66.37%-100%	9.43%-99.16%
N	3	9	3
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	3	
Percentage	100%	75.00%	
95% Conf Int	2.50%-100%	19.41%-99.37%	
N	1	4	
DAY 29 : Total seroresponse			
Number	3	12	2
Percentage	75.00%	92.31%	66.67%
95% Conf Int	19.41%-99.37%	63.97%-99.81%	9.43%-99.16%
N	4	13	3
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-61.55%-70.60%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-58.72%-37.88%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-38.17%-68.36%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-10.00%	
95% Conf Int		-70.30%-56.30%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			8.33%
95% Conf Int			-54.63%-68.03%

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			25.64%
95% Conf Int			-13.33%-74.50%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-17.31%	
95% Conf Int		-65.15%-17.54%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	1	0
Percentage	0%	33.33%	0%
95% Conf Int	0%-97.50%	0.84%-90.57%	0%-84.19%
N	1	3	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-97.50%	0%-60.24%	0%-97.50%
N	1	4	1
DAY 4 : Total seroresponse			
Number	0	1	0
Percentage	0%	14.29%	0%
95% Conf Int	0%-84.19%	0.36%-57.87%	0%-70.76%
N	2	7	3
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	2	
Percentage	50.00%	40.00%	
95% Conf Int	1.26%-98.74%	5.27%-85.34%	
N	2	5	
DAY 6 : Total seroresponse			
Number	1	2	
Percentage	50.00%	40.00%	
95% Conf Int	1.26%-98.74%	5.27%-85.34%	
N	2	5	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	4	1
Percentage	100%	100%	50.00%
95% Conf Int	2.50%-100%	39.76%-100%	1.26%-98.74%
N	1	4	2
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	3	8	1

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	88.89%	100%
95% Conf Int	29.24%-100%	51.75%-99.72%	2.50%-100%
N	3	9	1
DAY 29 : Total seroresponse			
Number	4	12	2
Percentage	100%	92.31%	66.67%
95% Conf Int	39.76%-100%	63.97%-99.81%	9.43%-99.16%
N	4	13	3
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-61.55%-70.60%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			14.29%
95% Conf Int			-48.41%-53.25%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-14.29%	
95% Conf Int		-53.48%-58.36%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		10.00%	
95% Conf Int		-56.30%-70.29%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			33.33%
95% Conf Int			-31.36%-81.14%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			25.64%
95% Conf Int			-13.33%-74.50%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		7.69%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
95% Conf Int		-44.23%-34.29%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-97.50%	0%-97.50%	0%-84.19%
N	1	1	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	1	0
Percentage	0%	16.67%	0%
95% Conf Int	0%-97.50%	0.42%-64.12%	0%-97.50%
N	1	6	1
DAY 4 : Total seroresponse			
Number	0	1	0
Percentage	0%	14.29%	0%
95% Conf Int	0%-84.19%	0.36%-57.87%	0%-70.76%
N	2	7	3
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	4	
Percentage	50.00%	80.00%	
95% Conf Int	1.26%-98.74%	28.36%-99.49%	
N	2	5	
DAY 6 : Total seroresponse			
Number	1	4	
Percentage	50.00%	80.00%	
95% Conf Int	1.26%-98.74%	28.36%-99.49%	
N	2	5	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	1	1
Percentage	100%	100%	50.00%
95% Conf Int	2.50%-100%	2.50%-100%	1.26%-98.74%
N	1	1	2
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	3	12	0

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	0%
95% Conf Int	29.24%-100%	73.54%-100%	0%-97.50%
N	3	12	1
DAY 29 : Total seroresponse			
Number	4	13	1
Percentage	100%	100%	33.33%
95% Conf Int	39.76%-100%	75.29%-100%	0.84%-90.57%
N	4	13	3
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-61.55%-70.60%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			14.29%
95% Conf Int			-48.41%-53.25%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-14.29%	
95% Conf Int		-53.48%-58.36%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-30.00%	
95% Conf Int		-82.00%-39.20%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			66.67%
95% Conf Int			-7.19%-94.51%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			66.67%
95% Conf Int			19.96%-94.13%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
95% Conf Int		-50.50%-23.89%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-97.50%	0%-60.24%	0%-84.19%
N	1	4	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-97.50%	0%-70.76%	0%-97.50%
N	1	3	1
DAY 4 : Total seroresponse			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-84.19%	0%-40.96%	0%-70.76%
N	2	7	3
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		2	
Percentage		100%	
95% Conf Int		15.81%-100%	
N		2	
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	2	
Percentage	50.00%	66.67%	
95% Conf Int	1.26%-98.74%	9.43%-99.16%	
N	2	3	
DAY 6 : Total seroresponse			
Number	1	4	
Percentage	50.00%	80.00%	
95% Conf Int	1.26%-98.74%	28.36%-99.49%	
N	2	5	
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	6	1

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	50.00%
95% Conf Int	2.50%-100%	54.07%-100%	1.26%-98.74%
N	1	6	2
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	3	6	0
Percentage	100%	85.71%	0%
95% Conf Int	29.24%-100%	42.13%-99.64%	0%-97.50%
N	3	7	1
DAY 29 : Total seroresponse			
Number	4	12	1
Percentage	100%	92.31%	33.33%
95% Conf Int	39.76%-100%	63.97%-99.81%	0.84%-90.57%
N	4	13	3
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-61.55%-70.60%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-58.72%-37.88%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-38.17%-68.36%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-30.00%	
95% Conf Int		-82.00%-39.20%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			66.67%
95% Conf Int			-7.19%-94.51%

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Asian

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			58.97%
95% Conf Int			6.44%-89.67%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		7.69%	
95% Conf Int		-44.23%-34.29%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-24.71%	0%-36.94%	0%-45.93%
N	13	8	6
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number		0	
Percentage		0%	
95% Conf Int		0%-84.19%	
N		2	
DAY 4 : Total seroresponse			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-24.71%	0%-30.85%	0%-45.93%
N	13	10	6
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	5	0
Percentage	18.18%	41.67%	0%
95% Conf Int	2.28%-51.78%	15.17%-72.33%	0%-52.18%
N	11	12	5
DAY 6 : Total seroresponse			
Number	2	5	0
Percentage	18.18%	41.67%	0%
95% Conf Int	2.28%-51.78%	15.17%-72.33%	0%-52.18%
N	11	12	5
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	22	20	9
Percentage	91.67%	100%	75.00%
95% Conf Int	73.00%-98.97%	83.16%-100%	42.81%-94.51%
N	24	20	12
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number		2	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage		100%	
95% Conf Int		15.81%-100%	
N		2	
DAY 29 : Total seroresponse			
Number	22	22	9
Percentage	91.67%	100%	75.00%
95% Conf Int	73.00%-98.97%	84.56%-100%	42.81%-94.51%
N	24	22	12
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-40.33%-23.77%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-40.58%-29.06%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-28.65%-23.60%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			18.18%
95% Conf Int			-30.19%-48.69%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			41.67%
95% Conf Int			-9.34%-68.71%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-23.48%	
95% Conf Int		-56.04%-15.45%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			16.67%

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
95% Conf Int			-7.43%-46.78%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			25.00%
95% Conf Int			7.35%-53.64%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-8.33%	
95% Conf Int		-26.10%-7.44%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-45.93%	0%-60.24%	0%-84.19%
N	6	4	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	1	0
Percentage	0%	16.67%	0%
95% Conf Int	0%-40.96%	0.42%-64.12%	0%-60.24%
N	7	6	4
DAY 4 : Total seroresponse			
Number	0	1	0
Percentage	0%	10.00%	0%
95% Conf Int	0%-24.71%	0.25%-44.50%	0%-45.93%
N	13	10	6
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	4	4	0
Percentage	66.67%	100%	0%
95% Conf Int	22.28%-95.67%	39.76%-100%	0%-84.19%
N	6	4	2
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	4	0
Percentage	20.00%	50.00%	0%
95% Conf Int	0.51%-71.64%	15.70%-84.30%	0%-70.76%
N	5	8	3
DAY 6 : Total seroresponse			
Number	5	8	0
Percentage	45.45%	66.67%	0%
95% Conf Int	16.75%-76.62%	34.89%-90.08%	0%-52.18%
N	11	12	5
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	12	7	2

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	50.00%
95% Conf Int	73.54%-100%	59.04%-100%	6.76%-93.24%
N	12	7	4
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	10	14	2
Percentage	83.33%	100%	25.00%
95% Conf Int	51.59%-97.91%	76.84%-100%	3.19%-65.09%
N	12	14	8
DAY 29 : Total seroresponse			
Number	22	21	4
Percentage	91.67%	100%	33.33%
95% Conf Int	73.00%-98.97%	83.89%-100%	9.92%-65.11%
N	24	21	12
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-40.33%-23.77%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			10.00%
95% Conf Int			-32.52%-41.54%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-10.00%	
95% Conf Int		-41.19%-15.03%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			45.45%
95% Conf Int			-6.42%-72.66%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			66.67%
95% Conf Int			14.41%-86.56%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-21.21%	
95% Conf Int		-55.87%-19.47%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			58.33%
95% Conf Int			26.58%-80.44%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			66.67%
95% Conf Int			38.68%-86.38%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-8.33%	
95% Conf Int		-26.10%-8.07%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-70.76%	0%-84.19%	
N	3	2	
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	1	0
Percentage	0%	12.50%	0%
95% Conf Int	0%-30.85%	0.32%-52.65%	0%-45.93%
N	10	8	6
DAY 4 : Total seroresponse			
Number	0	1	0
Percentage	0%	10.00%	0%
95% Conf Int	0%-24.71%	0.25%-44.50%	0%-45.93%
N	13	10	6
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	1	1
Percentage	50.00%	100%	50.00%
95% Conf Int	6.76%-93.24%	2.50%-100%	1.26%-98.74%
N	4	1	2
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	3	7	0
Percentage	42.86%	63.64%	0%
95% Conf Int	9.90%-81.59%	30.79%-89.07%	0%-70.76%
N	7	11	3
DAY 6 : Total seroresponse			
Number	5	8	1
Percentage	45.45%	66.67%	20.00%
95% Conf Int	16.75%-76.62%	34.89%-90.08%	0.51%-71.64%
N	11	12	5
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	7	3	1

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	50.00%
95% Conf Int	59.04%-100%	29.24%-100%	1.26%-98.74%
N	7	3	2
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	15	18	4
Percentage	88.24%	100%	44.44%
95% Conf Int	63.56%-98.54%	81.47%-100%	13.70%-78.80%
N	17	18	9
DAY 29 : Total seroresponse			
Number	22	21	5
Percentage	91.67%	100%	45.45%
95% Conf Int	73.00%-98.97%	83.89%-100%	16.75%-76.62%
N	24	21	11
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-40.33%-23.77%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			10.00%
95% Conf Int			-32.52%-41.54%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-10.00%	
95% Conf Int		-41.19%-15.03%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			25.45%
95% Conf Int			-27.35%-61.54%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			46.67%
95% Conf Int			-6.68%-77.04%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-21.21%	
95% Conf Int		-55.87%-19.47%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			46.21%
95% Conf Int			15.08%-72.68%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			54.55%
95% Conf Int			27.68%-79.00%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-8.33%	
95% Conf Int		-26.10%-8.07%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-40.96%	0%-70.76%	0%-70.76%
N	7	3	3
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-va cc titer			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-45.93%	0%-40.96%	0%-70.76%
N	6	7	3
DAY 4 : Total seroresponse			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-24.71%	0%-30.85%	0%-45.93%
N	13	10	6
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	4	0
Percentage	33.33%	80.00%	0%
95% Conf Int	0.84%-90.57%	28.36%-99.49%	0%-84.19%
N	3	5	2
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-va cc titer			
Number	3	3	1
Percentage	37.50%	42.86%	33.33%
95% Conf Int	8.52%-75.51%	9.90%-81.59%	0.84%-90.57%
N	8	7	3
DAY 6 : Total seroresponse			
Number	4	7	1
Percentage	36.36%	58.33%	20.00%
95% Conf Int	10.93%-69.21%	27.67%-84.83%	0.51%-71.64%
N	11	12	5
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=1 6			
Number	10	8	3

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	60.00%
95% Conf Int	69.15%-100%	63.06%-100%	14.66%-94.73%
N	10	8	5
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	13	11	6
Percentage	92.86%	84.62%	85.71%
95% Conf Int	66.13%-99.82%	54.55%-98.08%	42.13%-99.64%
N	14	13	7
DAY 29 : Total seroresponse			
Number	23	19	9
Percentage	95.83%	90.48%	75.00%
95% Conf Int	78.88%-99.89%	69.62%-98.83%	42.81%-94.51%
N	24	21	12
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-40.33%-23.77%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-40.58%-29.06%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-28.65%-23.60%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			16.36%
95% Conf Int			-35.18%-53.70%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			38.33%
95% Conf Int			-14.83%-70.92%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Black or African American

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-21.97%	
95% Conf Int		-56.41%-19.08%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			20.83%
95% Conf Int			-1.30%-50.22%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			15.48%
95% Conf Int			-10.35%-45.98%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		5.36%	
95% Conf Int		-12.50%-25.73%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Native Hawaiian or Other Pacific Islander

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 4 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 6 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	3		
Percentage	100%		
95% Conf Int	29.24%-100%		
N	3		
DAY 29 : Total seroresponse			
Number	3		
Percentage	100%		
95% Conf Int	29.24%-100%		
N	3		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Native Hawaiian or Other Pacific Islander

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 4 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 6 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	3		
Percentage	100%		
95% Conf Int	29.24%-100%		
N	3		
DAY 29 : Total seroresponse			
Number	3		
Percentage	100%		
95% Conf Int	29.24%-100%		
N	3		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Native Hawaiian or Other Pacific Islander

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 4 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 6 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	3		
Percentage	100%		
95% Conf Int	29.24%-100%		
N	3		
DAY 29 : Total seroresponse			
Number	3		
Percentage	100%		
95% Conf Int	29.24%-100%		
N	3		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Native Hawaiian or Other Pacific Islander

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 4 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-97.50%		
N	1		
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 6 : Total seroresponse			
Number	0		
Percentage	0%		
95% Conf Int	0%-84.19%		
N	2		
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2		
Percentage	66.67%		
95% Conf Int	9.43%-99.16%		
N	3		
DAY 29 : Total seroresponse			
Number	2		
Percentage	66.67%		
95% Conf Int	9.43%-99.16%		
N	3		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	3	0
Percentage	1.04%	3.37%	0%
95% Conf Int	0.03%-5.67%	0.70%-9.54%	0%-10.28%
N	96	89	34
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	0	0
Percentage	5.00%	0%	0%
95% Conf Int	0.13%-24.87%	0%-20.59%	0%-70.76%
N	20	16	3
DAY 4 : Total seroresponse			
Number	2	3	0
Percentage	1.72%	2.86%	0%
95% Conf Int	0.21%-6.09%	0.59%-8.12%	0%-9.49%
N	116	105	37
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	44	30	1
Percentage	42.31%	33.33%	3.23%
95% Conf Int	32.68%-52.39%	23.74%-44.05%	0.08%-16.70%
N	104	90	31
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	7	4	1
Percentage	36.84%	20.00%	20.00%
95% Conf Int	16.29%-61.64%	5.73%-43.66%	0.51%-71.64%
N	19	20	5
DAY 6 : Total seroresponse			
Number	51	34	2
Percentage	41.46%	30.91%	5.56%
95% Conf Int	32.65%-50.69%	22.45%-40.43%	0.68%-18.66%
N	123	110	36
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	198	175	41

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	99.00%	96.15%	63.08%
95% Conf Int	96.43%-99.88%	92.24%-98.44%	50.20%-74.72%
N	200	182	65
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	34	34	6
Percentage	87.18%	94.44%	75.00%
95% Conf Int	72.57%-95.70%	81.34%-99.32%	34.91%-96.81%
N	39	36	8
DAY 29 : Total seroresponse			
Number	232	209	47
Percentage	97.07%	95.87%	64.38%
95% Conf Int	94.06%-98.81%	92.31%-98.10%	52.31%-75.25%
N	239	218	73
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			1.72%
95% Conf Int			-7.78%-6.09%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			2.86%
95% Conf Int			-6.68%-8.09%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-1.13%	
95% Conf Int		-6.56%-3.58%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			35.91%
95% Conf Int			21.42%-46.27%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			25.35%
95% Conf Int			10.99%-35.97%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		10.55%	
95% Conf Int		-1.86%-22.58%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			32.69%
95% Conf Int			22.37%-44.33%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			31.49%
95% Conf Int			21.01%-43.22%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		1.20%	
95% Conf Int		-2.35%-5.07%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	3	1
Percentage	0%	7.32%	7.14%
95% Conf Int	0%-12.77%	1.54%-19.92%	0.18%-33.87%
N	27	41	14
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	6	2
Percentage	2.27%	9.52%	8.70%
95% Conf Int	0.28%-7.97%	3.58%-19.59%	1.07%-28.04%
N	88	63	23
DAY 4 : Total seroresponse			
Number	2	9	3
Percentage	1.74%	8.65%	8.11%
95% Conf Int	0.21%-6.14%	4.03%-15.79%	1.70%-21.91%
N	115	104	37
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	25	26	3
Percentage	64.10%	63.41%	15.79%
95% Conf Int	47.18%-78.80%	46.94%-77.88%	3.38%-39.58%
N	39	41	19
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	39	26	2
Percentage	46.99%	38.24%	11.76%
95% Conf Int	35.93%-58.26%	26.71%-50.82%	1.46%-36.44%
N	83	68	17
DAY 6 : Total seroresponse			
Number	64	52	5
Percentage	52.46%	47.71%	13.89%
95% Conf Int	43.22%-61.57%	38.05%-57.49%	4.67%-29.50%
N	122	109	36
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	66	83	19

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	57.58%
95% Conf Int	94.56%-100%	95.65%-100%	39.22%-74.52%
N	66	83	33
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	162	126	26
Percentage	94.19%	94.03%	65.00%
95% Conf Int	89.57%-97.18%	88.58%-97.39%	48.32%-79.37%
N	172	134	40
DAY 29 : Total seroresponse			
Number	228	209	45
Percentage	95.80%	96.31%	61.64%
95% Conf Int	92.41%-97.97%	92.87%-98.40%	49.52%-72.79%
N	238	217	73
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			-6.37%
95% Conf Int			-19.74%-0.23%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0.55%
95% Conf Int			-13.35%-9.59%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-6.91%	
95% Conf Int		-14.13%--1.28%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			38.57%
95% Conf Int			21.65%-50.95%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			33.82%
95% Conf Int			16.69%-46.69%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination

Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects

Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		4.75%	
95% Conf Int		-8.15%-17.50%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			34.15%
95% Conf Int			23.44%-45.89%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			34.67%
95% Conf Int			23.96%-46.40%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-0.52%	
95% Conf Int		-4.36%-3.40%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	9	2
Percentage	11.76%	36.00%	15.38%
95% Conf Int	1.46%-36.44%	17.97%-57.48%	1.92%-45.45%
N	17	25	13
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	3	1
Percentage	2.02%	3.75%	4.17%
95% Conf Int	0.25%-7.11%	0.78%-10.57%	0.11%-21.12%
N	99	80	24
DAY 4 : Total seroresponse			
Number	4	12	3
Percentage	3.45%	11.43%	8.11%
95% Conf Int	0.95%-8.59%	6.05%-19.11%	1.70%-21.91%
N	116	105	37
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	16	16	2
Percentage	64.00%	72.73%	18.18%
95% Conf Int	42.52%-82.03%	49.78%-89.27%	2.28%-51.78%
N	25	22	11
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	46	36	1
Percentage	46.94%	40.91%	4.00%
95% Conf Int	36.78%-57.29%	30.54%-51.91%	0.10%-20.35%
N	98	88	25
DAY 6 : Total seroresponse			
Number	62	52	3
Percentage	50.41%	47.27%	8.33%
95% Conf Int	41.25%-59.54%	37.68%-57.02%	1.75%-22.47%
N	123	110	36
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	42	47	13

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	54.17%
95% Conf Int	91.59%-100%	92.45%-100%	32.82%-74.45%
N	42	47	24
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	188	155	11
Percentage	95.43%	90.64%	22.45%
95% Conf Int	91.50%-97.89%	85.25%-94.56%	11.77%-36.62%
N	197	171	49
DAY 29 : Total seroresponse			
Number	230	202	24
Percentage	96.23%	92.66%	32.88%
95% Conf Int	92.97%-98.26%	88.35%-95.75%	22.33%-44.87%
N	239	218	73
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			-4.66%
95% Conf Int			-18.15%-2.64%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			3.32%
95% Conf Int			-10.75%-12.87%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-7.98%	
95% Conf Int		-15.92%--1.22%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			42.07%
95% Conf Int			26.50%-53.08%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			38.94%
95% Conf Int			23.17%-50.44%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		3.13%	
95% Conf Int		-9.69%-15.85%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			63.36%
95% Conf Int			51.66%-73.34%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			59.78%
95% Conf Int			47.80%-70.06%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		3.57%	
95% Conf Int		-0.63%-8.24%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	4	4	0
Percentage	8.16%	8.16%	0%
95% Conf Int	2.27%-19.60%	2.27%-19.60%	0%-16.84%
N	49	49	20
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	5	2	0
Percentage	7.69%	3.64%	0%
95% Conf Int	2.54%-17.05%	0.44%-12.53%	0%-19.51%
N	65	55	17
DAY 4 : Total seroresponse			
Number	9	6	0
Percentage	7.89%	5.77%	0%
95% Conf Int	3.67%-14.46%	2.15%-12.13%	0%-9.49%
N	114	104	37
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	30	38	3
Percentage	65.22%	74.51%	13.64%
95% Conf Int	49.75%-78.65%	60.37%-85.67%	2.91%-34.91%
N	46	51	22
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	32	27	0
Percentage	42.67%	45.76%	0%
95% Conf Int	31.31%-54.62%	32.72%-59.25%	0%-23.16%
N	75	59	14
DAY 6 : Total seroresponse			
Number	62	65	3
Percentage	51.24%	59.09%	8.33%
95% Conf Int	41.99%-60.43%	49.31%-68.37%	1.75%-22.47%
N	121	110	36
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	96	98	23

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	97.03%	54.76%
95% Conf Int	96.23%-100%	91.56%-99.38%	38.67%-70.15%
N	96	101	42
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	135	108	12
Percentage	95.74%	93.10%	38.71%
95% Conf Int	90.97%-98.42%	86.86%-96.98%	21.85%-57.81%
N	141	116	31
DAY 29 : Total seroresponse			
Number	231	206	35
Percentage	97.47%	94.93%	47.95%
95% Conf Int	94.57%-99.07%	91.11%-97.44%	36.10%-59.96%
N	237	217	73
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			7.89%
95% Conf Int			-1.75%-14.35%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			5.77%
95% Conf Int			-3.85%-12.05%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		2.13%	
95% Conf Int		-5.14%-9.39%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			42.91%
95% Conf Int			27.29%-53.95%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			50.76%
95% Conf Int			34.94%-61.85%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: White

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		-7.85%	
95% Conf Int		-20.43%-5.01%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			49.52%
95% Conf Int			38.02%-60.77%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			46.99%
95% Conf Int			35.25%-58.42%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		2.54%	
95% Conf Int		-1.04%-6.61%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-30.85%	0%-30.85%	0%-84.19%
N	10	10	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-84.19%	
N	1	2	
DAY 4 : Total seroresponse			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-28.49%	0%-26.46%	0%-84.19%
N	11	12	2
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	2	0
Percentage	40.00%	28.57%	0%
95% Conf Int	5.27%-85.34%	3.67%-70.96%	0%-70.76%
N	5	7	3
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-97.50%	0%-60.24%	
N	1	4	
DAY 6 : Total seroresponse			
Number	2	2	0
Percentage	33.33%	18.18%	0%
95% Conf Int	4.33%-77.72%	2.28%-51.78%	0%-70.76%
N	6	11	3
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	15	17	3

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	60.00%
95% Conf Int	78.20%-100%	80.49%-100%	14.66%-94.73%
N	15	17	5
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	6	
Percentage	100%	100%	
95% Conf Int	15.81%-100%	54.07%-100%	
N	2	6	
DAY 29 : Total seroresponse			
Number	17	23	3
Percentage	100%	100%	60.00%
95% Conf Int	80.49%-100%	85.18%-100%	14.66%-94.73%
N	17	23	5
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-67.54%-27.45%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-67.41%-25.64%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-25.08%-26.74%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			33.33%
95% Conf Int			-34.84%-71.60%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			18.18%
95% Conf Int			-43.47%-48.84%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		15.15%	
95% Conf Int		-26.02%-57.81%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			40.00%
95% Conf Int			11.44%-77.48%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			40.00%
95% Conf Int			11.51%-77.36%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-18.82%-14.62%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	0	1	0
Percentage	0%	50.00%	0%
95% Conf Int	0%-84.19%	1.26%-98.74%	0%-84.19%
N	2	2	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	0	
Percentage	22.22%	0%	
95% Conf Int	2.81%-60.01%	0%-30.85%	
N	9	10	
DAY 4 : Total seroresponse			
Number	2	1	0
Percentage	18.18%	8.33%	0%
95% Conf Int	2.28%-51.78%	0.21%-38.48%	0%-84.19%
N	11	12	2
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	3	0
Percentage	66.67%	60.00%	0%
95% Conf Int	9.43%-99.16%	14.66%-94.73%	0%-84.19%
N	3	5	2
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	2	0
Percentage	33.33%	33.33%	0%
95% Conf Int	0.84%-90.57%	4.33%-77.72%	0%-97.50%
N	3	6	1
DAY 6 : Total seroresponse			
Number	3	5	0
Percentage	50.00%	45.45%	0%
95% Conf Int	11.81%-88.19%	16.75%-76.62%	0%-70.76%
N	6	11	3
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	5	7	2

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	50.00%
95% Conf Int	47.82%-100%	59.04%-100%	6.76%-93.24%
N	5	7	4
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	11	14	0
Percentage	91.67%	87.50%	0%
95% Conf Int	61.52%-99.79%	61.65%-98.45%	0%-97.50%
N	12	16	1
DAY 29 : Total seroresponse			
Number	16	21	2
Percentage	94.12%	91.30%	40.00%
95% Conf Int	71.31%-99.85%	71.96%-98.93%	5.27%-85.34%
N	17	23	5
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			18.18%
95% Conf Int			-53.25%-48.93%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			8.33%
95% Conf Int			-60.87%-36.62%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		9.85%	
95% Conf Int		-21.91%-42.12%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			50.00%
95% Conf Int			-21.33%-82.35%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			45.45%
95% Conf Int			-19.86%-72.76%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		4.55%	
95% Conf Int		-40.93%-48.75%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			54.12%
95% Conf Int			12.53%-84.60%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			51.30%
95% Conf Int			10.48%-82.09%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		2.81%	
95% Conf Int		-19.92%-22.41%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number		0	0
Percentage		0%	0%
95% Conf Int		0%-97.50%	0%-84.19%
N		1	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-28.49%	0%-28.49%	
N	11	11	
DAY 4 : Total seroresponse			
Number	0	0	0
Percentage	0%	0%	0%
95% Conf Int	0%-28.49%	0%-26.46%	0%-84.19%
N	11	12	2
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	3	1
Percentage	100%	75.00%	33.33%
95% Conf Int	15.81%-100%	19.41%-99.37%	0.84%-90.57%
N	2	4	3
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	2	1	
Percentage	50.00%	14.29%	
95% Conf Int	6.76%-93.24%	0.36%-57.87%	
N	4	7	
DAY 6 : Total seroresponse			
Number	4	4	1
Percentage	66.67%	36.36%	33.33%
95% Conf Int	22.28%-95.67%	10.93%-69.21%	0.84%-90.57%
N	6	11	3
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	5	3

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	60.00%
95% Conf Int	15.81%-100%	47.82%-100%	14.66%-94.73%
N	2	5	5
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	14	15	
Percentage	93.33%	83.33%	
95% Conf Int	68.05%-99.83%	58.58%-96.42%	
N	15	18	
DAY 29 : Total seroresponse			
Number	16	20	3
Percentage	94.12%	86.96%	60.00%
95% Conf Int	71.31%-99.85%	66.41%-97.22%	14.66%-94.73%
N	17	23	5
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-67.54%-27.45%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-67.41%-25.64%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		0%	
95% Conf Int		-25.08%-26.74%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			33.33%
95% Conf Int			-33.64%-77.71%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			3.03%
95% Conf Int			-52.92%-48.06%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		30.30%	
95% Conf Int		-19.44%-67.10%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			34.12%
95% Conf Int			-0.77%-73.09%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			26.96%
95% Conf Int			-7.95%-66.85%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		7.16%	
95% Conf Int		-16.19%-27.84%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	1	0	0
Percentage	25.00%	0%	0%
95% Conf Int	0.63%-80.59%	0%-60.24%	0%-84.19%
N	4	4	2
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	1	0	
Percentage	14.29%	0%	
95% Conf Int	0.36%-57.87%	0%-36.94%	
N	7	8	
DAY 4 : Total seroresponse			
Number	2	0	0
Percentage	18.18%	0%	0%
95% Conf Int	2.28%-51.78%	0%-26.46%	0%-84.19%
N	11	12	2
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	2	3	0
Percentage	66.67%	75.00%	0%
95% Conf Int	9.43%-99.16%	19.41%-99.37%	0%-70.76%
N	3	4	3
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	0	0	
Percentage	0%	0%	
95% Conf Int	0%-70.76%	0%-40.96%	
N	3	7	
DAY 6 : Total seroresponse			
Number	2	3	0
Percentage	33.33%	27.27%	0%
95% Conf Int	4.33%-77.72%	6.02%-60.97%	0%-70.76%
N	6	11	3
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16			
Number	7	8	3

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Percentage	100%	100%	60.00%
95% Conf Int	59.04%-100%	63.06%-100%	14.66%-94.73%
N	7	8	5
DAY 29 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer			
Number	9	13	
Percentage	90.00%	86.67%	
95% Conf Int	55.50%-99.75%	59.54%-98.34%	
N	10	15	
DAY 29 : Total seroresponse			
Number	16	21	3
Percentage	94.12%	91.30%	60.00%
95% Conf Int	71.31%-99.85%	71.96%-98.93%	14.66%-94.73%
N	17	23	5
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			18.18%
95% Conf Int			-53.25%-48.93%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			0%
95% Conf Int			-67.41%-25.64%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		18.18%	
95% Conf Int		-9.39%-48.38%	
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			33.33%
95% Conf Int			-34.84%-71.60%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			27.27%
95% Conf Int			-35.87%-57.58%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.2
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Analysis by Race, Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA
Race: Other

	Menveo-Menveo	Menactra-Menveo	Naive
Difference		6.06%	
95% Conf Int		-35.65%-50.85%	
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)			
Difference			34.12%
95% Conf Int			-0.77%-73.09%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)			
Difference			31.30%
95% Conf Int			-2.33%-70.42%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)			
Difference		2.81%	
95% Conf Int		-19.92%-22.41%	

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	1	3	4	0
Percentage	0.81%	2.56%	1.67%	0%
95% Conf Int	0.11%-5.59%	0.83%-7.68%	0.62%-4.37%	0%-100%
N	123	117	240	45
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	1	0	1	0
Percentage	4.61%	0%	2.30%	0%
95% Conf Int	0.56%-29.14%	0%-100%	0.28%-16.37%	0%-100%
N	21	21	42	3
DAY 4 : Total seroresponse				
Number	2	3	5	0
Percentage	1.38%	2.16%	1.76%	0%
95% Conf Int	0.34%-5.40%	0.69%-6.54%	0.73%-4.20%	0.00%-100%
N	144	138	282	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	49	38	87	1
Percentage	39.84%	33.63%	36.86%	2.56%
95% Conf Int	31.54%-48.76%	25.50%-42.85%	30.92%-43.23%	0.36%-16.20%
N	123	113	236	39
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	8	6	14	1
Percentage	36.19%	20.74%	27.52%	8.53%
95% Conf Int	17.80%-59.77%	8.80%-41.51%	15.94%-43.18%	0.80%-51.96%
N	22	27	49	5
DAY 6 : Total seroresponse				
Number	57	44	101	2
Percentage	39.08%	31.61%	35.42%	4.29%
95% Conf Int	31.42%-47.33%	24.38%-39.85%	30.02%-41.20%	1.07%-15.73%
N	145	140	285	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	241	227	468	55
Percentage	97.97%	97.01%	97.50%	64.71%
95% Conf Int	95.20%-99.15%	93.85%-98.57%	95.65%-98.58%	54.00%-74.11%
N	246	234	480	85
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	38	45	83	6
Percentage	92.18%	96.09%	94.26%	60.51%
95% Conf Int	78.82%-97.39%	85.86%-99.00%	86.05%-97.76%	19.18%-90.82%
N	43	48	91	8
DAY 29 : Total seroresponse				
Number	279	272	551	61
Percentage	97.04%	97.08%	97.06%	63.11%
95% Conf Int	94.37%-98.46%	94.40%-98.50%	95.24%-98.19%	52.50%-72.58%
N	289	282	571	93
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				1.38%
95% Conf Int				-0.52%-3.29%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				2.16%
95% Conf Int				-0.27%-4.59%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				1.76%
95% Conf Int				0.22%-3.30%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.78%		
95% Conf Int		-3.87%-2.31%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				34.79%
95% Conf Int				24.90%-44.68%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				27.32%
95% Conf Int				17.61%-37.02%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				31.13%
95% Conf Int				23.06%-39.21%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		7.47%		
95% Conf Int		-3.66%-18.61%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				33.93%
95% Conf Int				23.61%-44.26%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				33.97%
95% Conf Int				23.65%-44.30%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				33.95%
95% Conf Int				23.71%-44.20%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.04%		
95% Conf Int		-2.76%-2.67%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	0	5	5	1
Percentage	0%	9.80%	5.75%	5.00%
95% Conf Int	0%-100%	4.10%-21.66%	2.39%-13.19%	0.68%-28.70%
N	36	51	87	20
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	4	7	11	2
Percentage	3.53%	6.32%	4.79%	3.87%
95% Conf Int	1.26%-9.49%	2.66%-14.28%	2.37%-9.44%	0.79%-16.95%
N	107	86	193	28
DAY 4 : Total seroresponse				
Number	4	12	16	3
Percentage	2.90%	8.26%	5.55%	5.41%
95% Conf Int	1.09%-7.50%	4.61%-14.35%	3.36%-9.02%	1.67%-16.16%
N	143	137	280	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	32	33	65	3
Percentage	65.31%	64.71%	65.00%	13.04%
95% Conf Int	50.96%-77.32%	50.65%-76.61%	55.08%-73.77%	4.22%-33.82%
N	49	51	100	23
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	42	34	76	2
Percentage	44.43%	37.43%	41.00%	4.85%
95% Conf Int	33.86%-55.52%	27.30%-48.79%	33.47%-48.97%	1.11%-18.86%
N	95	88	183	21
DAY 6 : Total seroresponse				
Number	74	67	141	5
Percentage	53.12%	48.30%	50.73%	7.40%
95% Conf Int	44.31%-61.73%	39.53%-57.17%	44.49%-56.96%	2.97%-17.28%
N	144	139	283	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	85	103	188	24
Percentage	100%	100%	100%	55.81%
95% Conf Int	0%-100%	0%-100%	0%-100%	40.82%-69.82%
N	85	103	188	43
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	190	166	356	29
Percentage	95.50%	94.85%	95.20%	45.98%
95% Conf Int	91.67%-97.61%	90.48%-97.28%	92.31%-97.03%	31.21%-61.50%
N	203	177	380	50
DAY 29 : Total seroresponse				
Number	275	269	544	53
Percentage	97.33%	97.09%	97.21%	46.98%
95% Conf Int	94.86%-98.63%	94.45%-98.50%	95.36%-98.34%	35.95%-58.31%
N	288	280	568	93
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				-2.51%
95% Conf Int				-9.31%-4.29%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				2.85%
95% Conf Int				-4.92%-10.62%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				0.39%
95% Conf Int				-6.14%-6.93%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-5.36%		
95% Conf Int		-10.82%-0.10%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				45.71%
95% Conf Int				34.76%-56.66%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				40.89%
95% Conf Int				29.85%-51.93%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				43.31%
95% Conf Int				34.25%-52.38%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		4.82%		
95% Conf Int		-7.66%-17.30%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				50.35%
95% Conf Int				38.86%-61.83%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				50.11%
95% Conf Int				38.61%-61.62%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				50.19%
95% Conf Int				38.76%-61.61%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.23%		
95% Conf Int		-2.36%-2.83%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	2	9	11	2
Percentage	9.52%	30.00%	21.57%	11.76%
95% Conf Int	2.33%-31.72%	16.21%-48.71%	12.23%-35.18%	2.88%-37.48%
N	21	30	51	17
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	2	5	7	1
Percentage	1.21%	4.03%	2.49%	2.32%
95% Conf Int	0.27%-5.28%	1.52%-10.23%	1.04%-5.85%	0.30%-15.98%
N	123	108	231	31
DAY 4 : Total seroresponse				
Number	4	14	18	3
Percentage	1.85%	6.60%	4.04%	2.61%
95% Conf Int	0.62%-5.36%	3.25%-12.94%	2.09%-7.68%	0.68%-9.42%
N	144	138	282	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	20	21	41	4
Percentage	64.52%	75.00%	69.49%	25.00%
95% Conf Int	46.25%-79.35%	55.69%-87.75%	56.46%-80.01%	9.54%-51.31%
N	31	28	59	16
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	53	48	101	1
Percentage	45.38%	43.46%	44.42%	2.76%
95% Conf Int	35.96%-55.14%	34.18%-53.23%	37.72%-51.33%	0.37%-17.76%
N	114	112	226	28
DAY 6 : Total seroresponse				
Number	73	69	142	5
Percentage	50.63%	51.27%	50.94%	7.62%
95% Conf Int	42.01%-59.21%	42.48%-59.97%	44.76%-57.10%	3.00%-18.06%
N	145	140	285	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	52	58	110	18
Percentage	100%	100%	100%	54.55%
95% Conf Int	0%-100%	0%-100%	0%-100%	37.55%-70.55%
N	52	58	110	33
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	225	204	429	15
Percentage	96.67%	95.02%	95.87%	18.79%
95% Conf Int	93.67%-98.27%	91.31%-97.19%	93.39%-97.44%	10.69%-30.92%
N	237	223	460	59
DAY 29 : Total seroresponse				
Number	277	262	539	33
Percentage	97.66%	96.43%	97.06%	22.56%
95% Conf Int	95.53%-98.78%	93.74%-97.99%	95.28%-98.19%	14.31%-33.71%
N	289	281	570	92
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				-0.76%
95% Conf Int				-4.73%-3.21%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				3.99%
95% Conf Int				-1.72%-9.70%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				1.55%
95% Conf Int				-2.67%-5.78%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-4.75%		
95% Conf Int		-9.73%-0.23%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				43.01%
95% Conf Int				31.95%-54.07%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				43.64%
95% Conf Int				32.46%-54.82%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				43.32%
95% Conf Int				34.06%-52.57%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.63%		
95% Conf Int		-12.98%-11.71%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				75.09%
95% Conf Int				65.26%-84.93%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				73.87%
95% Conf Int				63.95%-83.79%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				74.60%
95% Conf Int				64.80%-84.40%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.22%		
95% Conf Int		-1.31%-3.76%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	5	4	9	0
Percentage	8.06%	6.67%	7.38%	0%
95% Conf Int	3.37%-18.07%	2.50%-16.57%	3.86%-13.64%	0%-100%
N	62	60	122	27
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	6	2	8	0
Percentage	7.45%	2.63%	5.10%	0%
95% Conf Int	3.35%-15.75%	0.65%-10.00%	2.55%-9.92%	0.00%-100%
N	80	77	157	21
DAY 4 : Total seroresponse				
Number	11	6	17	0
Percentage	7.64%	4.38%	6.04%	0%
95% Conf Int	4.25%-13.37%	1.97%-9.45%	3.76%-9.57%	0.00%-100%
N	142	137	279	48
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	33	47	80	3
Percentage	63.46%	75.81%	70.18%	11.11%
95% Conf Int	49.57%-75.43%	63.55%-84.92%	61.09%-77.91%	3.59%-29.55%
N	52	62	114	27
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	37	33	70	1
Percentage	42.37%	40.11%	41.33%	4.59%
95% Conf Int	32.28%-53.15%	29.48%-51.76%	33.90%-49.17%	0.62%-27.22%
N	91	78	169	17
DAY 6 : Total seroresponse				
Number	70	80	150	4
Percentage	52.12%	56.37%	54.25%	6.32%
95% Conf Int	43.37%-60.75%	47.56%-64.79%	48.04%-60.33%	2.30%-16.22%
N	143	140	283	44

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

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Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	115	120	235	30
Percentage	100%	97.56%	98.74%	55.56%
95% Conf Int	0%-100%	92.68%-99.21%	96.15%-99.59%	42.17%-68.18%
N	115	123	238	54
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	163	144	307	18
Percentage	97.85%	96.45%	97.20%	29.65%
95% Conf Int	94.78%-99.13%	92.22%-98.42%	94.43%-98.61%	16.87%-46.68%
N	172	157	329	39
DAY 29 : Total seroresponse				
Number	278	264	542	48
Percentage	98.44%	96.91%	97.73%	40.68%
95% Conf Int	96.62%-99.29%	94.20%-98.37%	96.03%-98.71%	30.12%-52.17%
N	287	280	567	93
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				7.64%
95% Conf Int				3.26%-12.02%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				4.38%
95% Conf Int				0.94%-7.81%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				6.04%
95% Conf Int				3.23%-8.86%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		3.27%		
95% Conf Int		-2.30%-8.83%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.3

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				45.80%
95% Conf Int				35.07%-56.53%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				50.05%
95% Conf Int				39.38%-60.71%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				47.97%
95% Conf Int				39.25%-56.69%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-4.24%		
95% Conf Int		-16.56%-8.07%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				57.77%
95% Conf Int				46.52%-69.01%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				56.23%
95% Conf Int				44.88%-67.59%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				57.01%
95% Conf Int				45.77%-68.25%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.53%		
95% Conf Int		-0.78%-3.84%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers. Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	2	3	5	0
Percentage	1.57%	2.50%	2.02%	0%
95% Conf Int	0.19%-5.57%	0.52%-7.13%	0.66%-4.66%	0%-7.71%
N	127	120	247	46
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	1	0	1	0
Percentage	4.55%	0%	2.17%	0%
95% Conf Int	0.12%-22.84%	0%-14.25%	0.06%-11.53%	0%-70.76%
N	22	24	46	3
DAY 4 : Total seroresponse				
Number	3	3	6	0
Percentage	2.01%	2.08%	2.05%	0%
95% Conf Int	0.42%-5.77%	0.43%-5.97%	0.76%-4.40%	0%-7.25%
N	149	144	293	49
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	50	39	89	1
Percentage	40.00%	33.05%	36.63%	2.44%
95% Conf Int	31.34%-49.14%	24.67%-42.31%	30.56%-43.02%	0.06%-12.86%
N	125	118	243	41
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	8	7	15	1
Percentage	36.36%	23.33%	28.85%	20.00%
95% Conf Int	17.20%-59.34%	9.93%-42.28%	17.13%-43.08%	0.51%-71.64%
N	22	30	52	5
DAY 6 : Total seroresponse				
Number	58	46	104	2
Percentage	39.46%	31.08%	35.25%	4.35%
95% Conf Int	31.50%-47.84%	23.74%-39.20%	29.81%-41.00%	0.53%-14.84%
N	147	148	295	46

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	247	234	481	56
Percentage	98.02%	96.69%	97.37%	63.64%
95% Conf Int	95.43%-99.35%	93.59%-98.56%	95.54%-98.59%	52.69%-73.63%
N	252	242	494	88
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	39	50	89	6
Percentage	88.64%	92.59%	90.82%	75.00%
95% Conf Int	75.44%-96.21%	82.11%-97.94%	83.28%-95.71%	34.91%-96.81%
N	44	54	98	8
DAY 29 : Total seroresponse				
Number	286	284	570	62
Percentage	96.62%	95.95%	96.28%	64.58%
95% Conf Int	93.87%-98.37%	93.03%-97.89%	94.43%-97.66%	54.16%-74.08%
N	296	296	592	96
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				2.01%
95% Conf Int				-5.33%-5.76%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				2.08%
95% Conf Int				-5.26%-5.96%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				2.05%
95% Conf Int				-5.26%-4.40%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.07%		
95% Conf Int		-4.18%-3.94%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				35.11%
95% Conf Int				23.10%-44.28%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				26.73%
95% Conf Int				14.98%-35.68%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				30.91%
95% Conf Int				19.85%-37.80%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		8.37%		
95% Conf Int		-2.55%-19.13%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				32.04%
95% Conf Int				22.89%-42.19%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				31.36%
95% Conf Int				22.16%-41.55%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				31.70%
95% Conf Int				22.71%-41.77%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.68%		
95% Conf Int		-2.55%-3.98%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4

Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	0	6	6	1
Percentage	0%	11.32%	6.74%	5.00%
95% Conf Int	0%-9.74%	4.27%-23.03%	2.51%-14.10%	0.13%-24.87%
N	36	53	89	20
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	4	7	11	2
Percentage	3.57%	7.78%	5.45%	6.90%
95% Conf Int	0.98%-8.89%	3.18%-15.37%	2.75%-9.53%	0.85%-22.77%
N	112	90	202	29
DAY 4 : Total seroresponse				
Number	4	13	17	3
Percentage	2.70%	9.09%	5.84%	6.12%
95% Conf Int	0.74%-6.78%	4.93%-15.04%	3.44%-9.19%	1.28%-16.87%
N	148	143	291	49
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	32	35	67	3
Percentage	65.31%	64.81%	65.05%	12.50%
95% Conf Int	50.36%-78.33%	50.62%-77.32%	55.02%-74.18%	2.66%-32.36%
N	49	54	103	24
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	44	37	81	2
Percentage	45.36%	40.22%	42.86%	9.09%
95% Conf Int	35.22%-55.79%	30.12%-50.96%	35.70%-50.24%	1.12%-29.16%
N	97	92	189	22
DAY 6 : Total seroresponse				
Number	76	72	148	5
Percentage	52.05%	49.32%	50.68%	10.87%
95% Conf Int	43.64%-60.38%	40.95%-57.71%	44.80%-56.56%	3.62%-23.57%
N	146	146	292	46

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	85	108	193	25
Percentage	100%	100%	100%	56.82%
95% Conf Int	95.75%-100%	96.64%-100%	98.11%-100%	41.03%-71.65%
N	85	108	193	44
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	197	172	369	31
Percentage	93.81%	92.97%	93.42%	59.62%
95% Conf Int	89.65%-96.66%	88.28%-96.21%	90.50%-95.66%	45.10%-72.99%
N	210	185	395	52
DAY 29 : Total seroresponse				
Number	282	280	562	56
Percentage	95.59%	95.56%	95.58%	58.33%
95% Conf Int	92.58%-97.63%	92.53%-97.62%	93.59%-97.09%	47.82%-68.32%
N	295	293	588	96
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				-3.42%
95% Conf Int				-14.03%-2.23%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				2.97%
95% Conf Int				-8.06%-10.33%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				-0.28%
95% Conf Int				-10.91%-5.06%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-6.39%		
95% Conf Int		-12.58%--1.09%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				41.19%
95% Conf Int				26.95%-51.84%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				38.45%
95% Conf Int				24.23%-49.15%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				39.82%
95% Conf Int				26.60%-48.65%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		2.74%		
95% Conf Int		-8.71%-14.11%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				37.26%
95% Conf Int				27.54%-47.51%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				37.23%
95% Conf Int				27.51%-47.49%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				37.24%
95% Conf Int				27.72%-47.38%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.03%		
95% Conf Int		-3.48%-3.55%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	2	9	11	2
Percentage	9.52%	28.13%	20.75%	11.76%
95% Conf Int	1.17%-30.38%	13.75%-46.75%	10.84%-34.11%	1.46%-36.44%
N	21	32	53	17
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	2	5	7	1
Percentage	1.56%	4.46%	2.92%	3.13%
95% Conf Int	0.19%-5.53%	1.47%-10.11%	1.18%-5.92%	0.08%-16.22%
N	128	112	240	32
DAY 4 : Total seroresponse				
Number	4	14	18	3
Percentage	2.68%	9.72%	6.14%	6.12%
95% Conf Int	0.74%-6.73%	5.42%-15.77%	3.68%-9.54%	1.28%-16.87%
N	149	144	293	49
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	20	21	41	4
Percentage	64.52%	72.41%	68.33%	22.22%
95% Conf Int	45.37%-80.77%	52.76%-87.27%	55.04%-79.74%	6.41%-47.64%
N	31	29	60	18
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	53	52	105	1
Percentage	45.69%	43.70%	44.68%	3.57%
95% Conf Int	36.41%-55.19%	34.63%-53.09%	38.21%-51.28%	0.09%-18.35%
N	116	119	235	28
DAY 6 : Total seroresponse				
Number	73	73	146	5
Percentage	49.66%	49.32%	49.49%	10.87%
95% Conf Int	41.32%-58.02%	41.02%-57.66%	43.65%-55.35%	3.62%-23.57%
N	147	148	295	46

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	52	61	113	18
Percentage	100%	100%	100%	51.43%
95% Conf Int	93.15%-100%	94.13%-100%	96.79%-100%	33.99%-68.62%
N	52	61	113	35
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	228	212	440	15
Percentage	93.44%	90.99%	92.24%	25.00%
95% Conf Int	89.57%-96.21%	86.55%-94.33%	89.47%-94.48%	14.72%-37.86%
N	244	233	477	60
DAY 29 : Total seroresponse				
Number	280	273	553	33
Percentage	94.59%	92.86%	93.73%	34.74%
95% Conf Int	91.37%-96.88%	89.29%-95.52%	91.46%-95.55%	25.26%-45.20%
N	296	294	590	95
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				-3.44%
95% Conf Int				-14.05%-2.19%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				3.60%
95% Conf Int				-7.46%-11.05%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				0.02%
95% Conf Int				-10.62%-5.40%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-7.04%		
95% Conf Int		-13.31%--1.68%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				38.79%
95% Conf Int				24.58%-49.47%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				38.45%
95% Conf Int				24.26%-49.12%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				38.62%
95% Conf Int				25.41%-47.44%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.34%		
95% Conf Int		-11.02%-11.69%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				59.86%
95% Conf Int				49.49%-69.04%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				58.12%
95% Conf Int				47.64%-67.41%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				58.99%
95% Conf Int				48.79%-68.03%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.74%		
95% Conf Int		-2.26%-5.85%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	5	4	9	0
Percentage	7.94%	6.35%	7.14%	0%
95% Conf Int	2.63%-17.56%	1.76%-15.47%	3.32%-13.13%	0%-12.34%
N	63	63	126	28
DAY 4 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	6	2	8	0
Percentage	7.14%	2.50%	4.88%	0%
95% Conf Int	2.67%-14.90%	0.30%-8.74%	2.13%-9.39%	0%-16.11%
N	84	80	164	21
DAY 4 : Total seroresponse				
Number	11	6	17	0
Percentage	7.48%	4.20%	5.86%	0%
95% Conf Int	3.79%-12.99%	1.56%-8.91%	3.45%-9.22%	0%-7.25%
N	147	143	290	49
DAY 6 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	34	48	82	3
Percentage	62.96%	75.00%	69.49%	10.34%
95% Conf Int	48.74%-75.71%	62.60%-84.98%	60.34%-77.63%	2.19%-27.35%
N	54	64	118	29
DAY 6 : Pre-vacc titer >=4, post-vacc >=4*pre-vacc titer				
Number	37	36	73	1
Percentage	40.66%	42.86%	41.71%	5.88%
95% Conf Int	30.48%-51.47%	32.11%-54.12%	34.32%-49.39%	0.15%-28.69%
N	91	84	175	17
DAY 6 : Total seroresponse				
Number	71	84	155	4
Percentage	48.97%	56.76%	52.90%	8.70%
95% Conf Int	40.58%-57.39%	48.37%-64.87%	47.01%-58.73%	2.42%-20.79%
N	145	148	293	46

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 29 : Pre-vacc titer < 4, post-vacc titer >=16				
Number	118	124	242	31
Percentage	100%	96.88%	98.37%	54.39%
95% Conf Int	96.92%-100%	92.19%-99.14%	95.89%-99.56%	40.66%-67.64%
N	118	128	246	57
DAY 29 : Pre-vacc titer >=4, post-vacc >=4* pre-vacc titer				
Number	165	149	314	18
Percentage	93.75%	90.30%	92.08%	46.15%
95% Conf Int	89.09%-96.84%	84.73%-94.36%	88.69%-94.72%	30.09%-62.82%
N	176	165	341	39
DAY 29 : Total seroresponse				
Number	283	273	556	49
Percentage	96.26%	93.17%	94.72%	51.04%
95% Conf Int	93.40%-98.12%	89.65%-95.78%	92.59%-96.38%	40.63%-61.39%
N	294	293	587	96
DAY 4 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				7.48%
95% Conf Int				0.04%-12.92%
DAY 4 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				4.20%
95% Conf Int				-3.19%-8.87%
DAY 4 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				5.86%
95% Conf Int				-1.49%-9.19%
DAY 4 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		3.29%		
95% Conf Int		-2.34%-9.26%		
DAY 6 : Total seroresponse (Menveo-Menveo vs. Naive)				

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.1.4
Percentage of Subjects with hSBA Seroresponse against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Difference				40.27%
95% Conf Int				26.58%-50.51%
DAY 6 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				48.06%
95% Conf Int				34.39%-58.03%
DAY 6 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				44.21%
95% Conf Int				31.53%-52.42%
DAY 6 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-7.79%		
95% Conf Int		-19.04%-3.65%		
DAY 29 : Total seroresponse (Menveo-Menveo vs. Naive)				
Difference				45.22%
95% Conf Int				35.16%-55.29%
DAY 29 : Total seroresponse (Menactra-Menveo vs. Naive)				
Difference				42.13%
95% Conf Int				31.87%-52.38%
DAY 29 : Total seroresponse (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				43.68%
95% Conf Int				33.72%-53.69%
DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)				
Difference		3.08%		
95% Conf Int		-0.57%-6.98%		

Seroresponse is defined as follows: for subjects with pre-vaccination titers <4, post-vaccination titers >=16; for subjects with pre-vaccination titers >=4, post vaccination titers at least 4 times the pre-vaccination titers.

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	36	42	78	4
Percentage	12.46%	14.89%	13.66%	4.30%
95% Conf Int	8.88%-16.83%	10.95%-19.59%	10.95%-16.75%	1.18%-10.65%
N	289	282	571	93
DAY 4				
Number	16	18	34	2
Percentage	11.11%	13.04%	12.06%	4.17%
95% Conf Int	6.49%-17.42%	7.92%-19.83%	8.50%-16.44%	0.51%-14.25%
N	144	138	282	48
DAY 6				
Number	78	66	144	4
Percentage	53.42%	47.14%	50.35%	9.09%
95% Conf Int	44.99%-61.71%	38.66%-55.75%	44.40%-56.29%	2.53%-21.67%
N	146	140	286	44
DAY 29				
Number	286	279	565	66
Percentage	98.62%	98.94%	98.78%	70.97%
95% Conf Int	96.51%-99.62%	96.92%-99.78%	97.49%-99.51%	60.64%-79.92%
N	290	282	572	93
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				8.16%
95% Conf Int				1.23%-13.41%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				10.59%
95% Conf Int				3.54%-16.14%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				9.36%
95% Conf Int				2.72%-13.58%

PPD

Table 14.2.1.2

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-2.44%		
95% Conf Int		-8.17%-3.24%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				6.94%
95% Conf Int				-3.57%-14.15%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				8.88%
95% Conf Int				-1.77%-16.52%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				7.89%
95% Conf Int				-2.34%-13.48%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.93%		
95% Conf Int		-9.84%-5.82%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				44.33%
95% Conf Int				30.25%-54.60%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				38.05%
95% Conf Int				23.93%-48.58%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				41.26%

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				28.15%-49.72%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		6.28%		
95% Conf Int		-5.31%-17.71%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				27.65%
95% Conf Int				19.25%-37.65%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				27.97%
95% Conf Int				19.60%-37.95%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				27.81%
95% Conf Int				19.50%-37.76%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.32%		
95% Conf Int		-2.56%-1.86%		

PPD

Table 14.2.1.2

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	176	151	327	31
Percentage	61.11%	53.74%	57.47%	33.33%
95% Conf Int	55.22%-66.77%	47.72%-59.68%	53.29%-61.57%	23.89%-43.87%
N	288	281	569	93
DAY 4				
Number	102	83	185	21
Percentage	70.83%	60.14%	65.60%	43.75%
95% Conf Int	62.68%-78.10%	51.47%-68.38%	59.74%-71.13%	29.48%-58.82%
N	144	138	282	48
DAY 6				
Number	127	128	255	19
Percentage	87.59%	92.09%	89.79%	43.18%
95% Conf Int	81.09%-92.47%	86.28%-95.98%	85.66%-93.05%	28.35%-58.97%
N	145	139	284	44
DAY 29				
Number	290	280	570	81
Percentage	100%	99.64%	99.82%	87.10%
95% Conf Int	98.74%-100%	98.03%-99.99%	99.03%-100.00%	78.55%-93.15%
N	290	281	571	93
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				27.78%
95% Conf Int				16.23%-38.27%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				20.40%
95% Conf Int				8.78%-31.03%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				24.14%
95% Conf Int				13.28%-33.86%

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		7.37%		
95% Conf Int		-0.76%-15.42%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				27.08%
95% Conf Int				11.04%-42.14%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				16.39%
95% Conf Int				0.04%-31.90%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				21.85%
95% Conf Int				6.73%-36.11%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		10.69%		
95% Conf Int		-0.42%-21.60%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				44.40%
95% Conf Int				28.65%-58.93%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				48.90%
95% Conf Int				33.45%-63.13%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				46.61%

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				31.52%-60.59%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-4.50%		
95% Conf Int		-11.84%-2.69%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				12.90%
95% Conf Int				7.53%-21.22%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				12.55%
95% Conf Int				7.10%-20.89%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				12.73%
95% Conf Int				7.34%-21.05%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.36%		
95% Conf Int		-0.96%-1.99%		

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	218	217	435	57
Percentage	75.43%	76.95%	76.18%	61.29%
95% Conf Int	70.05%-80.29%	71.59%-81.74%	72.47%-79.62%	50.62%-71.22%
N	289	282	571	93
DAY 4				
Number	118	114	232	30
Percentage	81.94%	82.61%	82.27%	62.50%
95% Conf Int	74.67%-87.85%	75.24%-88.53%	77.30%-86.54%	47.35%-76.05%
N	144	138	282	48
DAY 6				
Number	137	137	274	28
Percentage	93.84%	97.86%	95.80%	63.64%
95% Conf Int	88.62%-97.14%	93.87%-99.56%	92.79%-97.81%	47.77%-77.59%
N	146	140	286	44
DAY 29				
Number	290	281	571	78
Percentage	100%	100%	100%	84.78%
95% Conf Int	98.74%-100%	98.70%-100%	99.36%-100%	75.79%-91.42%
N	290	281	571	92
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				14.14%
95% Conf Int				3.46%-25.39%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				15.66%
95% Conf Int				5.00%-26.89%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				14.89%
95% Conf Int				4.91%-25.62%

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.52%		
95% Conf Int		-8.51%-5.50%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				19.44%
95% Conf Int				5.25%-34.83%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				20.11%
95% Conf Int				5.88%-35.50%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				19.77%
95% Conf Int				6.53%-34.58%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.66%		
95% Conf Int		-9.67%-8.40%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				30.20%
95% Conf Int				16.78%-45.45%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				34.22%
95% Conf Int				21.29%-49.20%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				32.17%

PPD

Table 14.2.1.2

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				19.30%-47.13%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-4.02%		
95% Conf Int		-9.45%-0.74%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				15.22%
95% Conf Int				9.28%-23.95%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				15.22%
95% Conf Int				9.28%-23.95%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				15.22%
95% Conf Int				9.28%-23.94%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-1.31%-1.35%		

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	155	132	287	30
Percentage	54.01%	46.98%	50.53%	32.26%
95% Conf Int	48.05%-59.88%	41.02%-52.99%	46.33%-54.72%	22.93%-42.75%
N	287	281	568	93
DAY 4				
Number	79	77	156	16
Percentage	55.24%	55.80%	55.52%	33.33%
95% Conf Int	46.71%-63.56%	47.10%-64.24%	49.50%-61.42%	20.40%-48.41%
N	143	138	281	48
DAY 6				
Number	124	123	247	20
Percentage	85.52%	87.86%	86.67%	45.45%
95% Conf Int	78.72%-90.81%	81.27%-92.76%	82.16%-90.39%	30.39%-61.15%
N	145	140	285	44
DAY 29				
Number	290	280	570	72
Percentage	100%	99.64%	99.82%	77.42%
95% Conf Int	98.74%-100%	98.03%-99.99%	99.03%-100.00%	67.58%-85.45%
N	290	281	571	93
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				21.75%
95% Conf Int				10.19%-32.25%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				14.72%
95% Conf Int				3.15%-25.29%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				18.27%
95% Conf Int				7.44%-27.92%

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		7.03%		
95% Conf Int		-1.20%-15.17%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				21.91%
95% Conf Int				5.57%-36.37%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				22.46%
95% Conf Int				6.05%-37.00%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				22.18%
95% Conf Int				6.89%-35.38%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.55%		
95% Conf Int		-12.11%-11.03%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				40.06%
95% Conf Int				24.26%-54.95%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				42.40%
95% Conf Int				26.71%-57.17%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				41.21%

PPD

Table 14.2.1.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				26.12%-55.55%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-2.34%		
95% Conf Int		-10.41%-5.73%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				22.58%
95% Conf Int				15.26%-32.08%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				22.22%
95% Conf Int				14.86%-31.74%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				22.41%
95% Conf Int				15.08%-31.90%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.36%		
95% Conf Int		-0.96%-1.99%		

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	24	27	51	1
Percentage	8.30%	9.57%	8.93%	1.08%
95% Conf Int	5.39%-12.10%	6.40%-13.62%	6.72%-11.58%	0.03%-5.85%
N	289	282	571	93
DAY 4				
Number	12	12	24	1
Percentage	8.33%	8.70%	8.51%	2.08%
95% Conf Int	4.38%-14.10%	4.57%-14.70%	5.53%-12.40%	0.05%-11.07%
N	144	138	282	48
DAY 6				
Number	67	58	125	2
Percentage	45.89%	41.43%	43.71%	4.55%
95% Conf Int	37.62%-54.33%	33.17%-50.05%	37.87%-49.67%	0.56%-15.47%
N	146	140	286	44
DAY 29				
Number	285	275	560	62
Percentage	98.28%	97.52%	97.90%	66.67%
95% Conf Int	96.02%-99.44%	94.95%-99.00%	96.36%-98.91%	56.13%-76.11%
N	290	282	572	93
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				7.23%
95% Conf Int				2.08%-11.23%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				8.50%
95% Conf Int				3.28%-12.74%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				7.86%
95% Conf Int				2.87%-10.78%

PPD

Table 14.2.1.2.1
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.27%		
95% Conf Int		-6.10%-3.49%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				6.25%
95% Conf Int				-3.04%-12.44%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				6.61%
95% Conf Int				-2.71%-13.01%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				6.43%
95% Conf Int				-2.66%-10.90%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.36%		
95% Conf Int		-7.27%-6.43%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				41.34%
95% Conf Int				28.85%-50.63%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				36.88%
95% Conf Int				24.39%-46.34%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				39.16%

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				27.61%-46.33%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		4.46%		
95% Conf Int		-7.04%-15.83%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				31.61%
95% Conf Int				22.68%-41.79%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				30.85%
95% Conf Int				21.85%-41.08%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				31.24%
95% Conf Int				22.39%-41.38%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.76%		
95% Conf Int		-1.81%-3.52%		

PPD

Table 14.2.1.2.1
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	136	107	243	16
Percentage	47.22%	38.08%	42.71%	17.20%
95% Conf Int	41.34%-53.16%	32.38%-44.04%	38.60%-46.89%	10.17%-26.43%
N	288	281	569	93
DAY 4				
Number	78	62	140	14
Percentage	54.17%	44.93%	49.65%	29.17%
95% Conf Int	45.67%-62.49%	36.46%-53.62%	43.66%-55.64%	16.95%-44.06%
N	144	138	282	48
DAY 6				
Number	119	113	232	14
Percentage	82.07%	81.29%	81.69%	31.82%
95% Conf Int	74.84%-87.94%	73.81%-87.40%	76.69%-86.01%	18.61%-47.58%
N	145	139	284	44
DAY 29				
Number	289	280	569	65
Percentage	99.66%	99.64%	99.65%	69.89%
95% Conf Int	98.09%-99.99%	98.03%-99.99%	98.74%-99.96%	59.50%-78.97%
N	290	281	571	93
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				30.02%
95% Conf Int				19.55%-38.83%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				20.87%
95% Conf Int				10.48%-29.69%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				25.50%
95% Conf Int				15.79%-33.21%

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		9.14%		
95% Conf Int		1.01%-17.16%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				25.00%
95% Conf Int				8.82%-38.90%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				15.76%
95% Conf Int				-0.44%-29.86%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				20.48%
95% Conf Int				5.32%-33.08%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		9.24%		
95% Conf Int		-2.45%-20.68%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				50.25%
95% Conf Int				34.09%-63.67%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				49.48%
95% Conf Int				33.21%-63.01%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				49.87%

PPD

Table 14.2.1.2.1
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				34.42%-62.60%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.77%		
95% Conf Int		-8.30%-9.92%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				29.76%
95% Conf Int				21.34%-39.75%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				29.75%
95% Conf Int				21.32%-39.74%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				29.76%
95% Conf Int				21.35%-39.73%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.01%		
95% Conf Int		-1.60%-1.67%		

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	190	187	377	45
Percentage	65.74%	66.31%	66.02%	48.39%
95% Conf Int	59.96%-71.20%	60.47%-71.81%	61.98%-69.91%	37.89%-58.99%
N	289	282	571	93
DAY 4				
Number	99	106	205	26
Percentage	68.75%	76.81%	72.70%	54.17%
95% Conf Int	60.50%-76.21%	68.87%-83.57%	67.10%-77.81%	39.17%-68.63%
N	144	138	282	48
DAY 6				
Number	130	129	259	22
Percentage	89.04%	92.14%	90.56%	50.00%
95% Conf Int	82.81%-93.60%	86.38%-96.01%	86.56%-93.69%	34.56%-65.44%
N	146	140	286	44
DAY 29				
Number	290	281	571	74
Percentage	100%	100%	100%	80.43%
95% Conf Int	98.74%-100%	98.70%-100%	99.36%-100%	70.85%-87.97%
N	290	281	571	92
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				17.36%
95% Conf Int				5.85%-28.67%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				17.92%
95% Conf Int				6.39%-29.25%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				17.64%
95% Conf Int				6.85%-28.28%

PPD

Table 14.2.1.2.1
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.57%		
95% Conf Int		-8.32%-7.20%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				14.58%
95% Conf Int				-0.98%-30.38%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				22.64%
95% Conf Int				7.30%-38.16%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				18.53%
95% Conf Int				4.14%-33.37%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-8.06%		
95% Conf Int		-18.34%-2.38%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				39.04%
95% Conf Int				23.76%-54.07%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				42.14%
95% Conf Int				27.08%-56.98%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				40.56%

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				25.91%-55.15%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-3.10%		
95% Conf Int		-10.20%-3.89%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				19.57%
95% Conf Int				12.74%-28.83%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				19.57%
95% Conf Int				12.74%-28.83%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				19.57%
95% Conf Int				12.75%-28.83%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-1.31%-1.35%		

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	112	98	210	16
Percentage	39.02%	34.88%	36.97%	17.20%
95% Conf Int	33.35%-44.93%	29.31%-40.76%	32.99%-41.09%	10.17%-26.43%
N	287	281	568	93
DAY 4				
Number	56	54	110	10
Percentage	39.16%	39.13%	39.15%	20.83%
95% Conf Int	31.11%-47.67%	30.94%-47.80%	33.40%-45.12%	10.47%-34.99%
N	143	138	281	48
DAY 6				
Number	117	112	229	14
Percentage	80.69%	80.00%	80.35%	31.82%
95% Conf Int	73.31%-86.77%	72.41%-86.28%	75.26%-84.80%	18.61%-47.58%
N	145	140	285	44
DAY 29				
Number	290	277	567	60
Percentage	100%	98.58%	99.30%	64.52%
95% Conf Int	98.74%-100%	96.40%-99.61%	98.22%-99.81%	53.91%-74.17%
N	290	281	571	93
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				21.82%
95% Conf Int				11.44%-30.60%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				17.67%
95% Conf Int				7.34%-26.43%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				19.77%
95% Conf Int				10.09%-27.43%

PPD

Table 14.2.1.2.1
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		4.15%		
95% Conf Int		-3.80%-12.04%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				18.33%
95% Conf Int				2.92%-30.99%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				18.30%
95% Conf Int				2.83%-31.06%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				18.31%
95% Conf Int				3.83%-29.39%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.03%		
95% Conf Int		-11.35%-11.39%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				48.87%
95% Conf Int				32.64%-62.38%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				48.18%
95% Conf Int				31.87%-61.79%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				48.53%

PPD

Table 14.2.1.2.1

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				33.04%-61.31%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.69%		
95% Conf Int		-8.60%-10.04%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				35.48%
95% Conf Int				26.50%-45.62%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				34.06%
95% Conf Int				24.94%-44.28%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				34.78%
95% Conf Int				25.78%-44.93%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.42%		
95% Conf Int		0.10%-3.60%		

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	16	18	34	2
Percentage	3.21%	4.52%	3.84%	2.43%
95% Conf Int	1.17%-8.49%	1.81%-10.84%	1.82%-7.90%	0.29%-17.39%
N	144	138	282	48
DAY 6				
Number	78	66	144	4
Percentage	61.44%	51.00%	56.36%	10.77%
95% Conf Int	51.30%-70.67%	40.66%-61.25%	48.22%-64.16%	3.92%-26.31%
N	146	140	286	44
DAY 29				
Number	286	279	565	66
Percentage	98.95%	99.17%	99.06%	77.33%
95% Conf Int	96.78%-99.66%	97.11%-99.77%	97.63%-99.63%	62.54%-87.45%
N	290	282	572	93
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				0.78%
95% Conf Int				-5.18%-6.74%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				2.09%
95% Conf Int				-4.38%-8.56%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				1.41%
95% Conf Int				-4.37%-7.18%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.31%		
95% Conf Int		-6.47%-3.84%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				50.66%
95% Conf Int				36.41%-64.92%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				40.23%
95% Conf Int				25.53%-54.93%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				45.58%
95% Conf Int				32.49%-58.68%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		10.44%		
95% Conf Int		-3.83%-24.71%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				21.62%
95% Conf Int				9.06%-34.18%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				21.85%
95% Conf Int				9.30%-34.39%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				21.73%
95% Conf Int				9.20%-34.25%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.22%		
95% Conf Int		-1.80%-1.35%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	102	83	185	21
Percentage	90.60%	91.85%	91.27%	86.41%
95% Conf Int	80.56%-95.73%	83.04%-96.29%	83.74%-95.50%	70.79%-94.34%
N	144	138	282	48
DAY 6				
Number	127	128	255	19
Percentage	95.76%	97.71%	96.73%	71.45%
95% Conf Int	89.98%-98.27%	93.89%-99.16%	92.58%-98.60%	51.06%-85.72%
N	145	139	284	44
DAY 29				
Number	290	280	570	81
Percentage	100%	99.93%	99.96%	97.73%
95% Conf Int	0.00%-100%	98.92%-100.00%	99.42%-100.00%	85.52%-99.68%
N	290	281	571	93
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				4.19%
95% Conf Int				-9.18%-17.55%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				5.44%
95% Conf Int				-7.45%-18.33%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				4.93%
95% Conf Int				-7.70%-17.57%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.25%		
95% Conf Int		-10.74%-8.23%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				24.31%
95% Conf Int				6.14%-42.48%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				26.26%
95% Conf Int				8.33%-44.18%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				25.52%
95% Conf Int				7.52%-43.52%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.95%		
95% Conf Int		-6.32%-2.42%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				2.27%
95% Conf Int				-2.13%-6.67%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				2.20%
95% Conf Int				-2.20%-6.61%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				2.22%
95% Conf Int				-2.15%-6.60%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.07%		
95% Conf Int		-0.12%-0.25%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	118	114	232	30
Percentage	92.76%	96.22%	94.33%	89.25%
95% Conf Int	86.10%-96.37%	91.13%-98.44%	89.61%-96.98%	74.77%-95.88%
N	144	138	282	48
DAY 6				
Number	137	137	274	28
Percentage	98.50%	99.49%	98.98%	85.05%
95% Conf Int	95.08%-99.56%	97.60%-99.89%	96.79%-99.68%	66.21%-94.29%
N	146	140	286	44
DAY 29				
Number	290	281	571	78
Percentage	100%	100%	100%	99.18%
95% Conf Int	0%-100%	0%-100%	0%-100%	82.98%-99.97%
N	290	281	571	92
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				3.51%
95% Conf Int				-7.47%-14.49%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				6.97%
95% Conf Int				-3.41%-17.35%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				5.76%
95% Conf Int				-4.91%-16.43%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-3.46%		
95% Conf Int		-9.33%-2.41%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				13.45%
95% Conf Int				-0.16%-27.07%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				14.44%
95% Conf Int				0.92%-27.96%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				14.05%
95% Conf Int				0.50%-27.60%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.99%		
95% Conf Int		-2.95%-0.98%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				0.82%
95% Conf Int				-1.78%-3.42%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				0.82%
95% Conf Int				-1.78%-3.42%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				0.82%
95% Conf Int				-1.78%-3.42%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-0.00%-0.00%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	79	77	156	16
Percentage	71.46%	71.27%	71.37%	49.81%
95% Conf Int	58.62%-81.57%	57.47%-82.00%	61.31%-79.69%	29.03%-70.65%
N	143	138	281	48
DAY 6				
Number	124	123	247	20
Percentage	90.17%	93.81%	92.11%	62.58%
95% Conf Int	83.05%-94.49%	88.50%-96.76%	87.20%-95.24%	44.36%-77.82%
N	145	140	285	44
DAY 29				
Number	290	280	570	72
Percentage	100%	99.88%	99.94%	91.75%
95% Conf Int	0.00%-100%	98.82%-99.99%	99.40%-99.99%	77.35%-97.31%
N	290	281	571	93
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				21.65%
95% Conf Int				-3.27%-46.58%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				21.47%
95% Conf Int				-3.85%-46.78%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				21.57%
95% Conf Int				-2.36%-45.49%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.19%		
95% Conf Int		-16.77%-17.14%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.2
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				27.59%
95% Conf Int				9.44%-45.73%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				31.23%
95% Conf Int				13.51%-48.96%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				29.77%
95% Conf Int				12.05%-47.49%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-3.65%		
95% Conf Int		-10.43%-3.14%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				8.25%
95% Conf Int				-0.67%-17.17%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				8.13%
95% Conf Int				-0.80%-17.05%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				8.18%
95% Conf Int				-0.73%-17.08%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.12%		
95% Conf Int		-0.16%-0.40%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable. Two models are fitted and the results combined in one table.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	12	12	24	1
Percentage	2.11%	2.04%	2.07%	0.46%
95% Conf Int	0.69%-6.27%	0.65%-6.22%	0.81%-5.19%	0.01%-13.21%
N	144	138	282	48
DAY 6				
Number	67	58	125	2
Percentage	48.04%	40.57%	44.37%	5.21%
95% Conf Int	39.40%-56.81%	32.16%-49.57%	38.20%-50.71%	1.30%-18.72%
N	146	140	286	44
DAY 29				
Number	285	275	560	62
Percentage	98.77%	98.19%	98.49%	74.81%
95% Conf Int	96.52%-99.57%	95.43%-99.29%	96.62%-99.33%	59.26%-85.85%
N	290	282	572	93
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				1.64%
95% Conf Int				-1.18%-4.47%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				1.58%
95% Conf Int				-1.23%-4.39%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				1.61%
95% Conf Int				-0.89%-4.11%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.07%		
95% Conf Int		-3.21%-3.35%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				42.83%
95% Conf Int				31.59%-54.08%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				35.35%
95% Conf Int				24.11%-46.60%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				39.16%
95% Conf Int				29.74%-48.58%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		7.48%		
95% Conf Int		-4.91%-19.86%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				23.96%
95% Conf Int				10.47%-37.45%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				23.38%
95% Conf Int				9.84%-36.91%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				23.69%
95% Conf Int				10.19%-37.19%

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N
PPD

Table 14.2.1.2.3

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.58%		
95% Conf Int		-1.54%-2.71%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	78	62	140	14
Percentage	42.22%	58.71%	50.50%	58.29%
95% Conf Int	28.75%-56.96%	43.99%-72.02%	40.35%-60.61%	36.39%-77.34%
N	144	138	282	48
DAY 6				
Number	119	113	232	14
Percentage	89.28%	89.20%	89.24%	49.04%
95% Conf Int	82.11%-93.79%	81.95%-93.76%	83.49%-93.15%	31.26%-67.06%
N	145	139	284	44
DAY 29				
Number	289	280	569	65
Percentage	99.81%	99.84%	99.83%	85.32%
95% Conf Int	98.47%-99.98%	98.66%-99.98%	99.15%-99.96%	71.53%-93.08%
N	290	281	571	93
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				-16.06%
95% Conf Int				-42.07%-9.94%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				0.42%
95% Conf Int				-25.53%-26.37%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				-7.11%
95% Conf Int				-30.89%-16.66%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-16.49%		
95% Conf Int		-36.83%-3.86%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				40.24%
95% Conf Int				20.73%-59.74%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				40.16%
95% Conf Int				20.63%-59.68%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				40.20%
95% Conf Int				20.95%-59.45%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.08%		
95% Conf Int		-7.99%-8.15%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				14.49%
95% Conf Int				4.00%-24.98%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				14.52%
95% Conf Int				4.03%-25.01%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				14.51%
95% Conf Int				4.02%-25.00%

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N
PPD

Table 14.2.1.2.3

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects

Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.03%		
95% Conf Int		-0.55%-0.50%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	99	106	205	26
Percentage	73.82%	91.03%	81.93%	76.88%
95% Conf Int	63.33%-82.15%	83.10%-95.45%	75.11%-87.20%	57.69%-89.02%
N	144	138	282	48
DAY 6				
Number	130	129	259	22
Percentage	94.94%	96.20%	95.55%	62.31%
95% Conf Int	89.90%-97.54%	91.72%-98.30%	91.83%-97.61%	43.42%-78.08%
N	146	140	286	44
DAY 29				
Number	290	281	571	74
Percentage	100%	100%	100%	95.82%
95% Conf Int	0%-100%	0%-100%	0%-100%	84.12%-99.00%
N	290	281	571	92
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				-3.06%
95% Conf Int				-21.45%-15.33%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				14.15%
95% Conf Int				-2.70%-31.00%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				6.38%
95% Conf Int				-10.45%-23.20%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-17.21%		
95% Conf Int		-28.34%--6.09%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				32.63%
95% Conf Int				14.32%-50.94%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				33.89%
95% Conf Int				15.68%-52.09%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				33.22%
95% Conf Int				15.06%-51.39%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.26%		
95% Conf Int		-5.93%-3.41%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				4.18%
95% Conf Int				-1.68%-10.03%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				4.18%
95% Conf Int				-1.68%-10.03%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				4.18%
95% Conf Int				-1.68%-10.03%

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N
PPD

Table 14.2.1.2.3

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-0.00%-0.00%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 4				
Number	56	54	110	10
Percentage	33.65%	28.21%	31.11%	22.86%
95% Conf Int	23.37%-45.76%	18.28%-40.83%	23.52%-39.89%	10.66%-42.40%
N	143	138	281	48
DAY 6				
Number	117	112	229	14
Percentage	83.15%	85.07%	84.13%	40.16%
95% Conf Int	75.39%-88.83%	77.81%-90.26%	78.65%-88.42%	25.07%-57.38%
N	145	140	285	44
DAY 29				
Number	290	277	567	60
Percentage	100%	98.92%	99.46%	72.96%
95% Conf Int	0%-100%	96.95%-99.62%	98.46%-99.81%	60.67%-82.51%
N	290	281	571	93
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				10.80%
95% Conf Int				-8.79%-30.38%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				5.35%
95% Conf Int				-14.26%-24.96%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				8.23%
95% Conf Int				-9.74%-26.20%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		5.45%		
95% Conf Int		-10.59%-21.48%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3
Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				42.99%
95% Conf Int				25.04%-60.93%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				44.91%
95% Conf Int				27.15%-62.67%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				44.02%
95% Conf Int				26.69%-61.35%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.92%		
95% Conf Int		-10.98%-7.13%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				27.04%
95% Conf Int				16.03%-38.05%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				25.96%
95% Conf Int				14.90%-37.03%
Vaccine comparison at DAY 29 (Pooled Menveo /Menactra-Menveo vs. Naive)				
Difference				26.40%
95% Conf Int				15.40%-37.41%

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.3

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Adjusted Groups Differences at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.08%		
95% Conf Int		-0.05%-2.20%		

Statistical model used for adjusted group differences: Log-linear model with pre-vaccination titer as independent variable.
The percentage is from the model and not from the ratio Number/N

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	37	48	85	4
Percentage	12.50%	16.22%	14.36%	4.17%
95% Conf Int	8.96%-16.82%	12.21%-20.92%	11.63%-17.44%	1.15%-10.33%
N	296	296	592	96
DAY 4				
Number	18	21	39	2
Percentage	12.08%	14.58%	13.31%	4.08%
95% Conf Int	7.32%-18.42%	9.26%-21.42%	9.64%-17.74%	0.50%-13.98%
N	149	144	293	49
DAY 6				
Number	79	70	149	4
Percentage	53.38%	47.30%	50.34%	8.70%
95% Conf Int	45.01%-61.61%	39.04%-55.66%	44.49%-56.17%	2.42%-20.79%
N	148	148	296	46
DAY 29				
Number	293	292	585	67
Percentage	98.65%	98.65%	98.65%	69.79%
95% Conf Int	96.59%-99.63%	96.58%-99.63%	97.36%-99.42%	59.57%-78.75%
N	297	296	593	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				8.33%
95% Conf Int				1.59%-13.49%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				12.05%
95% Conf Int				5.13%-17.56%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				10.19%
95% Conf Int				3.72%-14.36%

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-3.72%		
95% Conf Int		-9.44%-1.96%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				8.00%
95% Conf Int				-2.38%-15.22%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				10.50%
95% Conf Int				-0.04%-18.18%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				9.23%
95% Conf Int				-0.85%-14.83%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-2.50%		
95% Conf Int		-10.54%-5.40%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				44.68%
95% Conf Int				31.01%-54.76%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				38.60%
95% Conf Int				24.97%-48.79%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				41.64%

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				28.98%-49.86%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		6.08%		
95% Conf Int		-5.31%-17.32%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				28.86%
95% Conf Int				20.44%-38.75%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				28.86%
95% Conf Int				20.43%-38.74%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				28.86%
95% Conf Int				20.51%-38.71%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-2.23%-2.24%		

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	183	158	341	33
Percentage	62.03%	53.74%	57.89%	34.38%
95% Conf Int	56.23%-67.60%	47.86%-59.55%	53.79%-61.92%	24.98%-44.77%
N	295	294	589	96
DAY 4				
Number	106	88	194	22
Percentage	71.14%	61.11%	66.21%	44.90%
95% Conf Int	63.16%-78.26%	52.64%-69.12%	60.48%-71.61%	30.67%-59.77%
N	149	144	293	49
DAY 6				
Number	129	135	264	20
Percentage	87.76%	91.84%	89.80%	43.48%
95% Conf Int	81.34%-92.58%	86.17%-95.71%	85.75%-93.01%	28.93%-58.89%
N	147	147	294	46
DAY 29				
Number	297	293	590	84
Percentage	100%	99.66%	99.83%	87.50%
95% Conf Int	98.77%-100%	98.12%-99.99%	99.06%-100.00%	79.18%-93.37%
N	297	294	591	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				27.66%
95% Conf Int				16.26%-38.07%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				19.37%
95% Conf Int				7.92%-29.90%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				23.52%
95% Conf Int				12.81%-33.19%

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		8.29%		
95% Conf Int		0.31%-16.17%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				26.24%
95% Conf Int				10.44%-41.21%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				16.21%
95% Conf Int				0.12%-31.59%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				21.31%
95% Conf Int				6.41%-35.51%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		10.03%		
95% Conf Int		-0.82%-20.71%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				44.28%
95% Conf Int				28.84%-58.56%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				48.36%
95% Conf Int				33.24%-62.34%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				46.32%

PPD

Table 14.2.1.2.4
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				31.56%-60.06%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-4.08%		
95% Conf Int		-11.35%-2.97%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				12.50%
95% Conf Int				7.29%-20.60%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				12.16%
95% Conf Int				6.88%-20.28%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				12.33%
95% Conf Int				7.11%-20.43%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.34%		
95% Conf Int		-0.94%-1.90%		

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	225	227	452	58
Percentage	76.01%	76.69%	76.35%	60.42%
95% Conf Int	70.73%-80.76%	71.45%-81.39%	72.72%-79.72%	49.92%-70.25%
N	296	296	592	96
DAY 4				
Number	123	118	241	31
Percentage	82.55%	81.94%	82.25%	63.27%
95% Conf Int	75.49%-88.27%	74.67%-87.85%	77.39%-86.45%	48.29%-76.58%
N	149	144	293	49
DAY 6				
Number	139	144	283	28
Percentage	93.92%	97.30%	95.61%	60.87%
95% Conf Int	88.77%-97.18%	93.22%-99.26%	92.61%-97.64%	45.37%-74.91%
N	148	148	296	46
DAY 29				
Number	297	294	591	80
Percentage	100%	100%	100%	84.21%
95% Conf Int	98.77%-100%	98.75%-100%	99.38%-100%	75.30%-90.88%
N	297	294	591	95
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				15.60%
95% Conf Int				5.03%-26.66%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				16.27%
95% Conf Int				5.73%-27.32%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				15.93%
95% Conf Int				6.05%-26.49%

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.68%		
95% Conf Int		-7.54%-6.19%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				19.29%
95% Conf Int				5.38%-34.46%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				18.68%
95% Conf Int				4.67%-33.93%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				18.99%
95% Conf Int				5.98%-33.64%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.61%		
95% Conf Int		-8.23%-9.50%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				33.05%
95% Conf Int				19.52%-47.95%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				36.43%
95% Conf Int				23.29%-51.08%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				34.74%

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				21.72%-49.35%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-3.38%		
95% Conf Int		-8.81%-1.47%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				15.79%
95% Conf Int				9.80%-24.44%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				15.79%
95% Conf Int				9.80%-24.44%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				15.79%
95% Conf Int				9.81%-24.44%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-1.28%-1.29%		

PPD

Table 14.2.1.2.4

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	159	141	300	30
Percentage	54.08%	47.80%	50.93%	31.25%
95% Conf Int	48.20%-59.88%	41.97%-53.66%	46.82%-55.04%	22.18%-41.52%
N	294	295	589	96
DAY 4				
Number	83	80	163	16
Percentage	56.08%	55.56%	55.82%	32.65%
95% Conf Int	47.69%-64.22%	47.05%-63.83%	49.92%-61.60%	19.95%-47.54%
N	148	144	292	49
DAY 6				
Number	125	130	255	20
Percentage	85.03%	87.84%	86.44%	43.48%
95% Conf Int	78.22%-90.38%	81.46%-92.63%	82.00%-90.13%	28.93%-58.89%
N	147	148	295	46
DAY 29				
Number	297	293	590	73
Percentage	100%	99.66%	99.83%	76.04%
95% Conf Int	98.77%-100%	98.12%-99.99%	99.06%-100.00%	66.25%-84.17%
N	297	294	591	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				22.83%
95% Conf Int				11.48%-33.10%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				16.55%
95% Conf Int				5.22%-26.84%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				19.68%
95% Conf Int				9.06%-29.09%

PPD

Table 14.2.1.2.4
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		6.29%		
95% Conf Int		-1.80%-14.28%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				23.43%
95% Conf Int				7.31%-37.62%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				22.90%
95% Conf Int				6.72%-37.17%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				23.17%
95% Conf Int				8.07%-36.12%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.53%		
95% Conf Int		-10.82%-11.86%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				41.56%
95% Conf Int				25.94%-56.02%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				44.36%
95% Conf Int				28.94%-58.63%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				42.96%

PPD

Table 14.2.1.2.4
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				28.09%-56.83%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-2.80%		
95% Conf Int		-10.84%-5.14%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				23.96%
95% Conf Int				16.52%-33.40%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				23.62%
95% Conf Int				16.14%-33.08%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				23.79%
95% Conf Int				16.35%-33.23%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.34%		
95% Conf Int		-0.94%-1.90%		

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	25	33	58	1
Percentage	8.45%	11.15%	9.80%	1.04%
95% Conf Int	5.54%-12.22%	7.80%-15.30%	7.52%-12.48%	0.03%-5.67%
N	296	296	592	96
DAY 4				
Number	14	15	29	1
Percentage	9.40%	10.42%	9.90%	2.04%
95% Conf Int	5.23%-15.26%	5.95%-16.60%	6.73%-13.90%	0.05%-10.85%
N	149	144	293	49
DAY 6				
Number	68	62	130	2
Percentage	45.95%	41.89%	43.92%	4.35%
95% Conf Int	37.73%-54.32%	33.84%-50.27%	38.18%-49.78%	0.53%-14.84%
N	148	148	296	46
DAY 29				
Number	292	288	580	63
Percentage	98.32%	97.30%	97.81%	65.63%
95% Conf Int	96.12%-99.45%	94.74%-98.83%	96.28%-98.83%	55.23%-75.02%
N	297	296	593	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				7.40%
95% Conf Int				2.39%-11.37%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				10.11%
95% Conf Int				4.95%-14.43%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				8.76%
95% Conf Int				3.90%-11.70%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-2.70%		
95% Conf Int		-7.63%-2.14%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				7.36%
95% Conf Int				-1.81%-13.62%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				8.38%
95% Conf Int				-0.86%-14.94%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				7.86%
95% Conf Int				-1.09%-12.43%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-1.02%		
95% Conf Int		-8.20%-6.03%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				41.60%
95% Conf Int				29.48%-50.75%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				37.54%
95% Conf Int				25.49%-46.71%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				39.57%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				28.43%-46.57%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		4.05%		
95% Conf Int		-7.25%-15.25%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				32.69%
95% Conf Int				23.79%-42.73%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				31.67%
95% Conf Int				22.68%-41.77%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				32.18%
95% Conf Int				23.35%-42.19%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.02%		
95% Conf Int		-1.52%-3.76%		

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	138	111	249	16
Percentage	46.78%	37.76%	42.28%	16.67%
95% Conf Int	40.97%-52.65%	32.19%-43.57%	38.25%-46.38%	9.84%-25.65%
N	295	294	589	96
DAY 4				
Number	80	66	146	14
Percentage	53.69%	45.83%	49.83%	28.57%
95% Conf Int	45.35%-61.89%	37.51%-54.33%	43.96%-55.70%	16.58%-43.26%
N	149	144	293	49
DAY 6				
Number	121	119	240	14
Percentage	82.31%	80.95%	81.63%	30.43%
95% Conf Int	75.17%-88.11%	73.66%-86.95%	76.72%-85.89%	17.74%-45.75%
N	147	147	294	46
DAY 29				
Number	296	293	589	68
Percentage	99.66%	99.66%	99.66%	70.83%
95% Conf Int	98.14%-99.99%	98.12%-99.99%	98.78%-99.96%	60.67%-79.67%
N	297	294	591	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				30.11%
95% Conf Int				19.88%-38.74%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				21.09%
95% Conf Int				10.96%-29.66%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				25.61%
95% Conf Int				16.13%-33.11%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		9.02%		
95% Conf Int		1.04%-16.90%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				25.12%
95% Conf Int				9.16%-38.78%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				17.26%
95% Conf Int				1.29%-31.09%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				21.26%
95% Conf Int				6.31%-33.63%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		7.86%		
95% Conf Int		-3.61%-19.12%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				51.88%
95% Conf Int				36.10%-64.85%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				50.52%
95% Conf Int				34.67%-63.58%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				51.20%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				36.12%-63.47%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.36%		
95% Conf Int		-7.59%-10.32%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				28.83%
95% Conf Int				20.64%-38.61%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				28.83%
95% Conf Int				20.63%-38.61%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				28.83%
95% Conf Int				20.66%-38.60%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-1.57%-1.59%		

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	195	196	391	46
Percentage	65.88%	66.22%	66.05%	47.92%
95% Conf Int	60.17%-71.27%	60.52%-71.59%	62.08%-69.86%	37.61%-58.36%
N	296	296	592	96
DAY 4				
Number	103	110	213	27
Percentage	69.13%	76.39%	72.70%	55.10%
95% Conf Int	61.05%-76.43%	68.60%-83.06%	67.21%-77.72%	40.23%-69.33%
N	149	144	293	49
DAY 6				
Number	131	136	267	22
Percentage	88.51%	91.89%	90.20%	47.83%
95% Conf Int	82.25%-93.16%	86.27%-95.74%	86.23%-93.34%	32.89%-63.05%
N	148	148	296	46
DAY 29				
Number	297	294	591	75
Percentage	100%	100%	100%	78.95%
95% Conf Int	98.77%-100%	98.75%-100%	99.38%-100%	69.38%-86.64%
N	297	294	591	95
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				17.96%
95% Conf Int				6.61%-29.09%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				18.30%
95% Conf Int				6.96%-29.42%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				18.13%
95% Conf Int				7.50%-28.59%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.34%		
95% Conf Int		-7.96%-7.28%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				14.03%
95% Conf Int				-1.27%-29.66%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				21.29%
95% Conf Int				6.19%-36.67%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				17.59%
95% Conf Int				3.45%-32.31%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-7.26%		
95% Conf Int		-17.37%-2.98%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				40.69%
95% Conf Int				25.52%-55.31%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				44.07%
95% Conf Int				29.17%-58.45%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				42.38%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				27.86%-56.51%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-3.38%		
95% Conf Int		-10.50%-3.55%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				21.05%
95% Conf Int				14.05%-30.31%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				21.05%
95% Conf Int				14.05%-30.31%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				21.05%
95% Conf Int				14.06%-30.30%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0%		
95% Conf Int		-1.28%-1.29%		

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
DAY 1				
Number	113	106	219	16
Percentage	38.44%	35.93%	37.18%	16.67%
95% Conf Int	32.85%-44.26%	30.45%-41.70%	33.27%-41.23%	9.84%-25.65%
N	294	295	589	96
DAY 4				
Number	59	57	116	10
Percentage	39.86%	39.58%	39.73%	20.41%
95% Conf Int	31.92%-48.23%	31.54%-48.06%	34.07%-45.59%	10.24%-34.34%
N	148	144	292	49
DAY 6				
Number	118	119	237	14
Percentage	80.27%	80.41%	80.34%	30.43%
95% Conf Int	72.91%-86.37%	73.09%-86.47%	75.34%-84.72%	17.74%-45.75%
N	147	148	295	46
DAY 29				
Number	297	289	586	61
Percentage	100%	98.30%	99.15%	63.54%
95% Conf Int	98.77%-100%	96.08%-99.45%	98.04%-99.72%	53.09%-73.13%
N	297	294	591	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)				
Difference				21.77%
95% Conf Int				11.63%-30.35%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)				
Difference				19.27%
95% Conf Int				9.17%-27.80%
Vaccine comparison at DAY 1 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				20.52%
95% Conf Int				11.07%-27.98%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		2.50%		
95% Conf Int		-5.30%-10.28%		
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Naive)				
Difference				19.46%
95% Conf Int				4.28%-31.89%
Vaccine comparison at DAY 4 (Menactra-Menveo vs. Naive)				
Difference				19.18%
95% Conf Int				3.95%-31.69%
Vaccine comparison at DAY 4 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				19.32%
95% Conf Int				5.05%-30.19%
Vaccine comparison at DAY 4 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		0.28%		
95% Conf Int		-10.91%-11.45%		
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Naive)				
Difference				49.84%
95% Conf Int				33.96%-62.95%
Vaccine comparison at DAY 6 (Menactra-Menveo vs. Naive)				
Difference				49.97%
95% Conf Int				34.11%-63.06%
Vaccine comparison at DAY 6 (Pooled Menveo/ Menactra-Menveo vs. Naive)				
Difference				49.90%

PPD

Table 14.2.1.2.5

Percentage of Subjects with hSBA titer >=16 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
95% Conf Int				34.80%-62.22%
Vaccine comparison at DAY 6 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		-0.13%		
95% Conf Int		-9.30%-9.02%		
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Naive)				
Difference				36.46%
95% Conf Int				27.51%-46.45%
Vaccine comparison at DAY 29 (Menactra-Menveo vs. Naive)				
Difference				34.76%
95% Conf Int				25.66%-44.84%
Vaccine comparison at DAY 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Difference				35.61%
95% Conf Int				26.64%-45.62%
Vaccine comparison at DAY 29 (Menveo-Menveo vs. Menactra-Menveo)				
Difference		1.70%		
95% Conf Int		0.41%-3.92%		

PPD

Table 14.2.1.3

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	37	45	4
Percentage	12.46%	15.46%	4.17%
95% Conf Int	8.93%-16.76%	11.51%-20.14%	1.15%-10.33%
N	297	291	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			8.29%
95% Conf Int			1.55%-13.44%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			11.30%
95% Conf Int			4.40%-16.78%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-3.01%	
95% Conf Int		-8.70%-2.63%	

PPD

Table 14.2.1.3

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	183	155	34
Percentage	61.82%	53.63%	35.42%
95% Conf Int	56.02%-67.38%	47.70%-59.49%	25.92%-45.84%
N	296	289	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			26.41%
95% Conf Int			14.99%-36.90%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			18.22%
95% Conf Int			6.72%-28.86%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		8.19%	
95% Conf Int		0.18%-16.11%	

PPD

Table 14.2.1.3

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	226	223	59
Percentage	76.09%	76.63%	61.46%
95% Conf Int	70.83%-80.83%	71.34%-81.37%	50.97%-71.22%
N	297	291	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			14.64%
95% Conf Int			4.14%-25.69%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			15.17%
95% Conf Int			4.67%-26.23%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-0.54%	
95% Conf Int		-7.42%-6.35%	

PPD

Table 14.2.1.3

Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	159	137	30
Percentage	53.90%	47.24%	31.25%
95% Conf Int	48.03%-59.69%	41.38%-53.16%	22.18%-41.52%
N	295	290	96
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			22.65%
95% Conf Int			11.30%-32.91%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			15.99%
95% Conf Int			4.64%-26.32%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		6.66%	
95% Conf Int		-1.45%-14.68%	

PPD

Table 14.2.1.3.1
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	38	48	4
Percentage	12.67%	16.11%	4.12%
95% Conf Int	9.12%-16.97%	12.12%-20.78%	1.13%-10.22%
N	300	298	97
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			8.54%
95% Conf Int			1.85%-13.68%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			11.98%
95% Conf Int			5.12%-17.45%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-3.44%	
95% Conf Int		-9.14%-2.21%	

PPD

Table 14.2.1.3.1
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	186	160	34
Percentage	62.21%	54.05%	35.05%
95% Conf Int	56.45%-67.73%	48.19%-59.83%	25.64%-45.41%
N	299	296	97
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			27.16%
95% Conf Int			15.81%-37.57%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			19.00%
95% Conf Int			7.59%-29.54%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		8.15%	
95% Conf Int		0.22%-15.99%	

PPD

Table 14.2.1.3.1
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	229	229	59
Percentage	76.33%	76.85%	60.82%
95% Conf Int	71.11%-81.03%	71.63%-81.51%	50.39%-70.58%
N	300	298	97
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			15.51%
95% Conf Int			5.03%-26.50%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			16.02%
95% Conf Int			5.55%-27.01%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		-0.51%	
95% Conf Int		-7.31%-6.29%	

PPD

Table 14.2.1.3.1
Percentage of Subjects with hSBA titer >=8 against N. Meningitidis serogroups A, C, W and Y and Groups Differences at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
DAY 1			
Number	161	142	30
Percentage	54.03%	47.81%	30.93%
95% Conf Int	48.18%-59.79%	42.01%-53.66%	21.93%-41.12%
N	298	297	97
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Naive)			
Difference			23.10%
95% Conf Int			11.83%-33.28%
Vaccine comparison at DAY 1 (Menactra-Menveo vs. Naive)			
Difference			16.88%
95% Conf Int			5.62%-27.11%
Vaccine comparison at DAY 1 (Menveo-Menveo vs. Menactra-Menveo)			
Difference		6.22%	
95% Conf Int		-1.82%-14.17%	

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	2.81	2.95	2.88	2.27
95% Conf Int	(2.54-3.11)	(2.67-3.27)	(2.68-3.09)	(1.90-2.71)
Median	2.00	2.00	2.00	2.00
Min, Max	2.00, 140	2.00, 173	2.00, 173	2.00, 71
N	289	282	571	93
Day 4				
GMT	2.83	3.00	2.91	2.25
95% Conf Int	(2.43-3.29)	(2.57-3.51)	(2.61-3.25)	(1.73-2.93)
Median	2.00	2.00	2.00	2.00
Min, Max	2.00, 244	2.00, 453	2.00, 453	2.00, 101
N	144	138	282	48
Day 6				
GMT	12.87	10.17	11.47	2.48
95% Conf Int	(9.63-17.19)	(7.57-13.66)	(9.32-14.10)	(1.46-4.20)
Median	11	2.00	8.00	2.00
Min, Max	2.00, 817	2.00, 1688	2.00, 1688	2.00, 36
N	146	140	286	44
Day 29				
GMT	210.10	236.69	222.81	32.11
95% Conf Int	(181.07-243.78)	(203.56-275.20)	(200.43-247.70)	(24.70-41.76)
Median	215	215	215	37
Min, Max	2.00, 7250	2.00, 3861	2.00, 7250	2.00, 1999
N	290	282	572	93
Day 4/Day 1				
GMR	1.02	1.07	1.04	0.99
95% Conf Int	(0.93-1.12)	(0.97-1.17)	(0.98-1.11)	(0.84-1.16)
Median	1.00	1.00	1.00	1.00
Min, Max	0.091, 122	0.11, 227	0.091, 227	0.40, 1.42
N	144	138	282	48

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	4.58	3.25	3.87	1.09
95% Conf Int	(3.49-6.00)	(2.46-4.28)	(3.19-4.70)	(0.66-1.78)
Median	1.67	1.00	1.00	1.00
Min, Max	0.071, 409	0.083, 268	0.071, 409	0.40, 18
N	145	140	285	44
Day 29/Day 1				
GMR	75.02	80.13	77.50	14.14
95% Conf Int	(63.87-88.12)	(68.09-94.30)	(69.12-86.90)	(10.65-18.77)
Median	93	90	92	18
Min, Max	1.00, 863	1.00, 1931	1.00, 1931	1.00, 1000
N	289	282	571	93
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.26
95% Conf Int				(0.93-1.70)
Ratio of GMRs				1.03
95% Conf Int				(0.86-1.24)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.34
95% Conf Int				(0.98-1.82)
Ratio of GMRs				1.08
95% Conf Int				(0.89-1.30)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.29
95% Conf Int				(0.97-1.72)
Ratio of GMRs				1.05
95% Conf Int				(0.89-1.25)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.94		
95% Conf Int		(0.76-1.17)		
Ratio of GMRs		0.96		
95% Conf Int		(0.84-1.09)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				5.19
95% Conf Int				(2.84-9.47)
Ratio of GMRs				4.21
95% Conf Int				(2.40-7.38)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				4.10
95% Conf Int				(2.24-7.50)
Ratio of GMRs				2.99
95% Conf Int				(1.70-5.25)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				4.62
95% Conf Int				(2.62-8.15)
Ratio of GMRs				3.55
95% Conf Int				(2.09-6.04)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.27		
95% Conf Int		(0.84-1.91)		
Ratio of GMRs		1.41		
95% Conf Int		(0.96-2.08)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				6.54
95% Conf Int				(4.84-8.85)
Ratio of GMRs				5.31
95% Conf Int				(3.83-7.35)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				7.37
95% Conf Int				(5.44-9.98)
Ratio of GMRs				5.67
95% Conf Int				(4.09-7.86)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				6.94
95% Conf Int				(5.23-9.21)
Ratio of GMRs				5.48
95% Conf Int				(4.04-7.44)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.89		
95% Conf Int		(0.72-1.10)		
Ratio of GMRs		0.94		
95% Conf Int		(0.74-1.18)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	16.11	10.72	13.17	5.06
95% Conf Int	(13.28-19.54)	(8.82-13.03)	(11.48-15.12)	(3.60-7.10)
Median	13	10	11	4.00
Min, Max	2.00, 1590	2.00, 1848	2.00, 1848	2.00, 208
N	288	281	569	93
Day 4				
GMT	22.96	14.29	18.21	6.69
95% Conf Int	(17.31-30.45)	(10.71-19.07)	(14.86-22.31)	(4.10-10.90)
Median	21	13	15	6.00
Min, Max	2.00, 1457	2.00, 3385	2.00, 3385	2.00, 232
N	144	138	282	48
Day 6				
GMT	92.27	90.06	91.18	6.71
95% Conf Int	(68.91-123.56)	(66.84-121.35)	(74.04-112.30)	(3.95-11.40)
Median	115	99	105	5.00
Min, Max	2.00, 3663	2.00, 3859	2.00, 3859	2.00, 351
N	145	139	284	44
Day 29				
GMT	1159.93	1057.66	1108.42	59.70
95% Conf Int	(977.33-1376.63)	(888.74-1258.68)	(981.09-1252.27)	(44.12-80.78)
Median	1425	1122	1234	50
Min, Max	13, 19263	2.00, 33272	2.00, 33272	2.00, 41043
N	290	281	571	93
Day 4/Day 1				
GMR	1.12	1.35	1.23	1.21
95% Conf Int	(0.99-1.28)	(1.19-1.54)	(1.12-1.35)	(0.97-1.51)
Median	1.00	1.00	1.00	1.00
Min, Max	0.25, 30	0.13, 178	0.13, 178	0.40, 11
N	143	137	280	48

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	7.25	7.94	7.58	1.45
95% Conf Int	(5.39-9.75)	(5.87-10.73)	(6.14-9.36)	(0.85-2.48)
Median	5.63	5.85	5.76	1.00
Min, Max	0.017, 923	0.66, 1930	0.017, 1930	0.40, 59
N	144	139	283	44
Day 29/Day 1				
GMR	71.72	97.13	83.29	11.81
95% Conf Int	(58.88-87.37)	(79.51-118.65)	(72.34-95.89)	(8.34-16.71)
Median	69	99	84	8.80
Min, Max	0.54, 3265	0.33, 8362	0.33, 8362	0.81, 4179
N	288	280	568	93
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				3.43
95% Conf Int				(1.95-6.04)
Ratio of GMRs				0.93
95% Conf Int				(0.72-1.20)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.14
95% Conf Int				(1.21-3.77)
Ratio of GMRs				1.12
95% Conf Int				(0.86-1.44)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.72
95% Conf Int				(1.60-4.64)
Ratio of GMRs				1.01
95% Conf Int				(0.80-1.29)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.61		
95% Conf Int		(1.07-2.40)		
Ratio of GMRs		0.83		
95% Conf Int		(0.69-1.00)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				13.75
95% Conf Int				(7.51-25.19)
Ratio of GMRs				5.00
95% Conf Int				(2.71-9.22)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				13.42
95% Conf Int				(7.31-24.66)
Ratio of GMRs				5.47
95% Conf Int				(2.96-10.12)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				13.59
95% Conf Int				(7.70-24.00)
Ratio of GMRs				5.23
95% Conf Int				(2.94-9.29)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.02		
95% Conf Int		(0.67-1.56)		
Ratio of GMRs		0.91		
95% Conf Int		(0.60-1.39)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				19.43
95% Conf Int				(13.73-27.51)
Ratio of GMRs				6.08
95% Conf Int				(4.07-9.06)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				17.72
95% Conf Int				(12.50-25.12)
Ratio of GMRs				8.23
95% Conf Int				(5.51-12.28)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				18.57
95% Conf Int				(13.40-25.73)
Ratio of GMRs				7.06
95% Conf Int				(4.85-10.27)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.10		
95% Conf Int		(0.86-1.40)		
Ratio of GMRs		0.74		
95% Conf Int		(0.56-0.98)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	22.07	23.46	22.75	12.21
95% Conf Int	(18.54-26.29)	(19.66-28.00)	(20.09-25.76)	(8.98-16.62)
Median	28	31	29	14
Min, Max	2.00, 761	2.00, 6726	2.00, 6726	2.00, 200
N	289	282	571	93
Day 4				
GMT	25.90	33.87	29.53	13.80
95% Conf Int	(20.13-33.32)	(26.18-43.82)	(24.66-35.37)	(8.92-21.35)
Median	33	42	36	23
Min, Max	2.00, 763	2.00, 7353	2.00, 7353	2.00, 186
N	144	138	282	48
Day 6				
GMT	112.49	143.75	126.84	15.98
95% Conf Int	(86.26-146.71)	(109.61-188.54)	(104.90-153.37)	(9.85-25.93)
Median	147	165	151	20
Min, Max	2.00, 6974	2.00, 22491	2.00, 22491	2.00, 577
N	146	140	286	44
Day 29				
GMT	1394.65	1883.96	1617.11	55.31
95% Conf Int	(1176.59-1653.11)	(1585.12-2239.15)	(1431.93-1826.23)	(40.90-74.80)
Median	1521	2057	1680	58
Min, Max	20, 87078	18, 78040	18, 87078	2.00, 29145
N	290	281	571	92
Day 4/Day 1				
GMR	1.05	1.40	1.21	1.14
95% Conf Int	(0.91-1.23)	(1.20-1.63)	(1.09-1.35)	(0.88-1.48)
Median	1.00	1.04	1.00	1.00
Min, Max	0.019, 64	0.22, 69	0.019, 69	0.091, 51
N	144	138	282	48

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	5.71	6.27	5.98	1.32
95% Conf Int	(4.37-7.45)	(4.78-8.23)	(4.95-7.23)	(0.81-2.15)
Median	4.37	5.04	4.50	1.00
Min, Max	0.24, 647	0.45, 346	0.24, 647	0.077, 289
N	145	140	285	44
Day 29/Day 1				
GMR	63.63	80.61	71.50	4.57
95% Conf Int	(51.37-78.81)	(64.88-100.14)	(61.38-83.27)	(3.13-6.68)
Median	73	83	74	2.11
Min, Max	1.69, 6383	0.44, 6902	0.44, 6902	0.33, 14573
N	289	281	570	92
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.88
95% Conf Int				(1.13-3.11)
Ratio of GMRs				0.92
95% Conf Int				(0.68-1.25)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.46
95% Conf Int				(1.48-4.08)
Ratio of GMRs				1.23
95% Conf Int				(0.90-1.66)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.14
95% Conf Int				(1.33-3.44)
Ratio of GMRs				1.06
95% Conf Int				(0.80-1.41)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.76		
95% Conf Int		(0.53-1.10)		
Ratio of GMRs		0.75		
95% Conf Int		(0.61-0.94)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				7.04
95% Conf Int				(4.05-12.22)
Ratio of GMRs				4.32
95% Conf Int				(2.48-7.50)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				8.99
95% Conf Int				(5.16-15.66)
Ratio of GMRs				4.75
95% Conf Int				(2.72-8.27)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				7.94
95% Conf Int				(4.72-13.35)
Ratio of GMRs				4.52
95% Conf Int				(2.69-7.60)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.78		
95% Conf Int		(0.54-1.14)		
Ratio of GMRs		0.91		
95% Conf Int		(0.62-1.33)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				25.21
95% Conf Int				(17.83-35.65)
Ratio of GMRs				13.91
95% Conf Int				(9.00-21.50)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				34.06
95% Conf Int				(24.06-48.23)
Ratio of GMRs				17.62
95% Conf Int				(11.38-27.27)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				29.24
95% Conf Int				(21.09-40.52)
Ratio of GMRs				15.63
95% Conf Int				(10.38-23.53)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.74		
95% Conf Int		(0.58-0.94)		
Ratio of GMRs		0.79		
95% Conf Int		(0.58-1.07)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	9.24	8.22	8.72	4.56
95% Conf Int	(7.81-10.94)	(6.93-9.75)	(7.74-9.83)	(3.39-6.13)
Median	10	6.00	8.00	2.00
Min, Max	2.00, 350	2.00, 5173	2.00, 5173	2.00, 72
N	287	281	568	93
Day 4				
GMT	10.87	12.12	11.47	4.63
95% Conf Int	(8.26-14.32)	(9.16-16.04)	(9.43-13.95)	(2.88-7.44)
Median	10	11	10	2.00
Min, Max	2.00, 381	2.00, 12288	2.00, 12288	2.00, 84
N	143	138	281	48
Day 6				
GMT	63.30	61.56	62.44	6.44
95% Conf Int	(47.73-83.95)	(46.18-82.05)	(51.06-76.34)	(3.86-10.76)
Median	80	62	72	2.00
Min, Max	2.00, 2563	2.00, 23434	2.00, 23434	2.00, 184
N	145	140	285	44
Day 29				
GMT	1066.66	1007.62	1037.19	37.40
95% Conf Int	(900.67-1263.25)	(848.53-1196.54)	(919.46-1169.98)	(27.75-50.42)
Median	879	965	912	30
Min, Max	45, 26324	2.00, 22572	2.00, 26324	2.00, 6607
N	290	281	571	93
Day 4/Day 1				
GMR	1.35	1.31	1.33	0.99
95% Conf Int	(1.15-1.59)	(1.11-1.54)	(1.19-1.49)	(0.75-1.31)
Median	1.00	1.00	1.00	1.00
Min, Max	0.095, 177	0.022, 78	0.022, 177	0.17, 2.25
N	142	137	279	48

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	6.09	8.59	7.22	1.48
95% Conf Int	(4.53-8.19)	(6.37-11.59)	(5.85-8.92)	(0.87-2.52)
Median	4.78	9.00	6.00	1.00
Min, Max	0.0062, 621	0.11, 640	0.0062, 640	0.29, 88
N	143	140	283	44
Day 29/Day 1				
GMR	116.58	123.41	119.91	8.21
95% Conf Int	(94.42-143.95)	(99.69-152.78)	(103.21-139.30)	(5.67-11.89)
Median	137	132	135	6.00
Min, Max	1.24, 5831	0.81, 7756	0.81, 7756	0.13, 3304
N	287	280	567	93
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				2.35
95% Conf Int				(1.36-4.07)
Ratio of GMRs				1.36
95% Conf Int				(0.99-1.88)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.62
95% Conf Int				(1.51-4.54)
Ratio of GMRs				1.32
95% Conf Int				(0.95-1.82)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.48
95% Conf Int				(1.48-4.14)
Ratio of GMRs				1.34
95% Conf Int				(0.99-1.81)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.90		
95% Conf Int		(0.61-1.33)		
Ratio of GMRs		1.04		
95% Conf Int		(0.82-1.30)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				9.82
95% Conf Int				(5.47-17.64)
Ratio of GMRs				4.12
95% Conf Int				(2.24-7.59)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				9.55
95% Conf Int				(5.31-17.19)
Ratio of GMRs				5.81
95% Conf Int				(3.15-10.72)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				9.69
95% Conf Int				(5.59-16.79)
Ratio of GMRs				4.89
95% Conf Int				(2.75-8.68)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.03		
95% Conf Int		(0.69-1.54)		
Ratio of GMRs		0.71		
95% Conf Int		(0.47-1.08)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				28.52
95% Conf Int				(20.23-40.20)
Ratio of GMRs				14.20
95% Conf Int				(9.28-21.75)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				26.94
95% Conf Int				(19.09-38.02)
Ratio of GMRs				15.04
95% Conf Int				(9.81-23.06)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				27.73
95% Conf Int				(20.10-38.26)
Ratio of GMRs				14.61
95% Conf Int				(9.80-21.78)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.06		
95% Conf Int		(0.83-1.35)		
Ratio of GMRs		0.94		
95% Conf Int		(0.70-1.28)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 4				
Adjusted GMT	2.77	2.90	2.83	2.64
95% Conf Int	(2.53-3.03)	(2.64-3.19)	(2.65-3.03)	(2.25-3.09)
Median	2.00	2.00	2.00	2.00
Min, Max	2.00, 244	2.00, 453	2.00, 453	2.00, 101
N	144	138	282	48
Day 6				
Adjusted GMT	13.14	9.55	11.24	2.95
95% Conf Int	(10.04-17.19)	(7.26-12.57)	(9.27-13.62)	(1.81-4.82)
Median	11	2.00	8.00	2.00
Min, Max	2.00, 817	2.00, 1688	2.00, 1688	2.00, 36
N	146	140	286	44
Day 29				
Adjusted GMT	210.22	232.35	220.86	34.25
95% Conf Int	(181.71-243.20)	(200.46-269.33)	(199.10-245.00)	(26.46-44.33)
Median	215	215	215	37
Min, Max	2.00, 7250	2.00, 3861	2.00, 7250	2.00, 1999
N	290	282	572	93
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.05
95% Conf Int				(0.87-1.26)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.10
95% Conf Int				(0.92-1.32)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.07
95% Conf Int				(0.91-1.28)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.95		
95% Conf Int		(0.84-1.09)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				4.45
95% Conf Int				(2.55-7.79)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				3.24
95% Conf Int				(1.84-5.69)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				3.82
95% Conf Int				(2.25-6.48)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.38		
95% Conf Int		(0.94-2.02)		
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				6.14
95% Conf Int				(4.56-8.25)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				6.78
95% Conf Int				(5.04-9.14)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				6.45
95% Conf Int				(4.88-8.51)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.90		
95% Conf Int		(0.74-1.11)		

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1

Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 4				
Adjusted GMT	14.98	17.01	15.95	14.43
95% Conf Int	(13.17-17.04)	(14.94-19.36)	(14.57-17.47)	(11.55-18.02)
Median	21	13	15	6.00
Min, Max	2.00, 1457	2.00, 3385	2.00, 3385	2.00, 232
N	144	138	282	48
Day 6				
Adjusted GMT	83.57	86.80	85.15	10.00
95% Conf Int	(64.26-108.67)	(66.48-113.35)	(70.62-102.66)	(6.18-16.20)
Median	115	99	105	5.00
Min, Max	2.00, 3663	2.00, 3859	2.00, 3859	2.00, 351
N	145	139	284	44
Day 29				
Adjusted GMT	1020.57	1074.39	1046.98	81.22
95% Conf Int	(871.96-1194.50)	(917.11-1258.65)	(936.67-1170.28)	(61.43-107.38)
Median	1425	1122	1234	50
Min, Max	13, 19263	2.00, 33272	2.00, 33272	2.00, 41043
N	290	281	571	93
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.04
95% Conf Int				(0.80-1.35)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.18
95% Conf Int				(0.91-1.52)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.11
95% Conf Int				(0.87-1.42)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.88		
95% Conf Int		(0.73-1.06)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				8.35
95% Conf Int				(4.81-14.50)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				8.68
95% Conf Int				(5.00-15.07)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				8.51
95% Conf Int				(5.07-14.30)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.96		
95% Conf Int		(0.66-1.40)		
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				12.57
95% Conf Int				(9.09-17.37)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				13.23
95% Conf Int				(9.60-18.22)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				12.91
95% Conf Int				(9.54-17.46)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.95		
95% Conf Int		(0.76-1.19)		

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 4				
Adjusted GMT	23.66	31.31	27.14	22.67
95% Conf Int	(20.45-27.38)	(26.97-36.34)	(24.43-30.15)	(17.56-29.27)
Median	33	42	36	23
Min, Max	2.00, 763	2.00, 7353	2.00, 7353	2.00, 186
N	144	138	282	48
Day 6				
Adjusted GMT	113.05	133.46	122.63	20.43
95% Conf Int	(89.25-143.19)	(104.87-169.83)	(103.59-145.17)	(13.26-31.47)
Median	147	165	151	20
Min, Max	2.00, 6974	2.00, 22491	2.00, 22491	2.00, 577
N	146	140	286	44
Day 29				
Adjusted GMT	1385.89	1835.20	1591.45	62.49
95% Conf Int	(1174.18-1635.76)	(1550.98-2171.51)	(1413.52-1791.78)	(46.47-84.05)
Median	1521	2057	1680	58
Min, Max	20, 87078	18, 78040	18, 87078	2.00, 29145
N	290	281	571	92
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.04
95% Conf Int				(0.78-1.40)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.38
95% Conf Int				(1.03-1.86)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.20
95% Conf Int				(0.91-1.58)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.76		
95% Conf Int		(0.61-0.93)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				5.53
95% Conf Int				(3.38-9.05)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				6.53
95% Conf Int				(3.98-10.73)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				6.00
95% Conf Int				(3.77-9.54)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.85		
95% Conf Int		(0.60-1.19)		
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				22.18
95% Conf Int				(15.78-31.16)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				29.37
95% Conf Int				(20.87-41.33)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				25.45
95% Conf Int				(18.46-35.07)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.76		
95% Conf Int		(0.60-0.96)		

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 4				
Adjusted GMT	10.80	10.59	10.70	7.47
95% Conf Int	(9.21-12.67)	(9.00-12.46)	(9.55-11.98)	(5.66-9.85)
Median	10	11	10	2.00
Min, Max	2.00, 381	2.00, 12288	2.00, 12288	2.00, 84
N	143	138	281	48
Day 6				
Adjusted GMT	56.54	64.30	60.29	8.36
95% Conf Int	(43.17-74.06)	(49.05-84.28)	(49.84-72.93)	(5.13-13.62)
Median	80	62	72	2.00
Min, Max	2.00, 2563	2.00, 23434	2.00, 23434	2.00, 184
N	145	140	285	44
Day 29				
Adjusted GMT	1041.30	1003.83	1022.58	42.46
95% Conf Int	(881.63-1229.88)	(848.48-1187.63)	(908.53-1150.96)	(31.62-57.01)
Median	879	965	912	30
Min, Max	45, 26324	2.00, 22572	2.00, 26324	2.00, 6607
N	290	281	571	93
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.45
95% Conf Int				(1.05-1.99)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.42
95% Conf Int				(1.03-1.96)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.43
95% Conf Int				(1.06-1.93)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.02		
95% Conf Int		(0.81-1.28)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				6.77
95% Conf Int				(3.85-11.88)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				7.69
95% Conf Int				(4.41-13.42)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				7.24
95% Conf Int				(4.28-12.24)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.88		
95% Conf Int		(0.60-1.29)		
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				24.53
95% Conf Int				(17.46-34.46)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				23.64
95% Conf Int				(16.84-33.21)

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.1
Adjusted Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				24.08
95% Conf Int				(17.52-33.10)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.04		
95% Conf Int		(0.82-1.31)		

Statistical model used: ANCOVA model with study group as factor and pre-vaccination titer as covariate. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	2.82	3.09	2.95	2.26
95% Conf Int	(2.55-3.13)	(2.79-3.42)	(2.75-3.18)	(1.89-2.71)
Median	2.00	2.00	2.00	2.00
Min, Max	2.00, 140	2.00, 173	2.00, 173	2.00, 71
N	296	296	592	96
Day 4				
GMT	2.92	3.14	3.02	2.24
95% Conf Int	(2.49-3.41)	(2.68-3.68)	(2.70-3.38)	(1.71-2.95)
Median	2.00	2.00	2.00	2.00
Min, Max	2.00, 244	2.00, 453	2.00, 453	2.00, 101
N	149	144	293	49
Day 6				
GMT	12.84	10.60	11.67	2.46
95% Conf Int	(9.61-17.17)	(7.93-14.17)	(9.50-14.32)	(1.46-4.14)
Median	11	2.00	8.00	2.00
Min, Max	2.00, 817	2.00, 1688	2.00, 1688	2.00, 36
N	148	148	296	46
Day 29				
GMT	207.23	235.03	220.67	30.78
95% Conf Int	(178.71-240.29)	(202.64-272.60)	(198.71-245.05)	(23.72-39.93)
Median	214	216	215	36
Min, Max	2.00, 7250	2.00, 3861	2.00, 7250	2.00, 1999
N	297	296	593	96
Day 4/Day 1				
GMR	1.04	1.06	1.05	0.99
95% Conf Int	(0.94-1.14)	(0.97-1.17)	(0.98-1.12)	(0.84-1.16)
Median	1.00	1.00	1.00	1.00
Min, Max	0.091, 122	0.11, 227	0.091, 227	0.40, 1.42
N	149	144	293	49

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	4.59	3.25	3.86	1.08
95% Conf Int	(3.50-6.01)	(2.48-4.26)	(3.19-4.67)	(0.67-1.76)
Median	1.67	1.00	1.00	1.00
Min, Max	0.071, 409	0.083, 373	0.071, 409	0.40, 18
N	147	148	295	46
Day 29/Day 1				
GMR	73.60	76.14	74.86	13.60
95% Conf Int	(62.66-86.45)	(64.82-89.43)	(66.81-83.87)	(10.25-18.04)
Median	92	89	89	17
Min, Max	1.00, 863	1.00, 1931	1.00, 1931	1.00, 1000
N	296	296	592	96
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.30
95% Conf Int				(0.95-1.78)
Ratio of GMRs				1.05
95% Conf Int				(0.87-1.26)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.40
95% Conf Int				(1.02-1.92)
Ratio of GMRs				1.07
95% Conf Int				(0.89-1.29)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				1.35
95% Conf Int				(1.00-1.81)
Ratio of GMRs				1.06
95% Conf Int				(0.89-1.26)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.93		
95% Conf Int		(0.74-1.16)		
Ratio of GMRs		0.97		
95% Conf Int		(0.85-1.11)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				5.23
95% Conf Int				(2.88-9.49)
Ratio of GMRs				4.23
95% Conf Int				(2.43-7.36)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				4.31
95% Conf Int				(2.38-7.83)
Ratio of GMRs				3.00
95% Conf Int				(1.72-5.21)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				4.75
95% Conf Int				(2.71-8.31)
Ratio of GMRs				3.56
95% Conf Int				(2.11-6.00)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.21		
95% Conf Int		(0.80-1.83)		
Ratio of GMRs		1.41		
95% Conf Int		(0.96-2.07)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				6.73
95% Conf Int				(4.99-9.08)
Ratio of GMRs				5.41
95% Conf Int				(3.91-7.49)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				7.64
95% Conf Int				(5.66-10.30)
Ratio of GMRs				5.60
95% Conf Int				(4.04-7.75)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				7.17
95% Conf Int				(5.41-9.49)
Ratio of GMRs				5.50
95% Conf Int				(4.06-7.46)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.88		
95% Conf Int		(0.72-1.09)		
Ratio of GMRs		0.97		
95% Conf Int		(0.77-1.21)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	16.12	10.66	13.11	5.09
95% Conf Int	(13.33-19.48)	(8.81-12.89)	(11.45-15.01)	(3.65-7.10)
Median	13	10	11	4.50
Min, Max	2.00, 1590	2.00, 1848	2.00, 1848	2.00, 208
N	295	294	589	96
Day 4				
GMT	22.79	14.41	18.20	6.75
95% Conf Int	(17.30-30.03)	(10.89-19.08)	(14.93-22.18)	(4.18-10.93)
Median	19	13	15	6.00
Min, Max	2.00, 1457	2.00, 3385	2.00, 3385	2.00, 232
N	149	144	293	49
Day 6				
GMT	92.13	93.03	92.58	6.62
95% Conf Int	(68.93-123.14)	(69.60-124.35)	(75.43-113.63)	(3.94-11.12)
Median	115	103	107	5.00
Min, Max	2.00, 3663	2.00, 3859	2.00, 3859	2.00, 351
N	147	147	294	46
Day 29				
GMT	1138.03	1043.82	1090.15	61.86
95% Conf Int	(960.79-1347.98)	(880.49-1237.45)	(966.90-1229.11)	(45.93-83.32)
Median	1373	1121	1197	52
Min, Max	13, 19263	2.00, 33272	2.00, 33272	2.00, 41043
N	297	294	591	96
Day 4/Day 1				
GMR	1.12	1.35	1.23	1.21
95% Conf Int	(0.99-1.27)	(1.19-1.54)	(1.12-1.34)	(0.97-1.50)
Median	1.00	1.00	1.00	1.00
Min, Max	0.25, 30	0.13, 178	0.13, 178	0.40, 11
N	148	143	291	49

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	7.25	8.30	7.75	1.43
95% Conf Int	(5.40-9.72)	(6.18-11.13)	(6.30-9.54)	(0.85-2.42)
Median	5.92	6.00	6.00	1.00
Min, Max	0.017, 923	0.66, 1930	0.017, 1930	0.40, 59
N	146	146	292	46
Day 29/Day 1				
GMR	70.34	96.47	82.33	12.15
95% Conf Int	(57.87-85.50)	(79.32-117.34)	(71.67-94.57)	(8.63-17.11)
Median	69	97	83	9.00
Min, Max	0.54, 3265	0.33, 8362	0.33, 8362	0.81, 4179
N	295	293	588	96
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				3.37
95% Conf Int				(1.94-5.87)
Ratio of GMRs				0.93
95% Conf Int				(0.72-1.19)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.13
95% Conf Int				(1.22-3.72)
Ratio of GMRs				1.12
95% Conf Int				(0.87-1.44)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.69
95% Conf Int				(1.60-4.54)
Ratio of GMRs				1.02
95% Conf Int				(0.80-1.29)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.58		
95% Conf Int		(1.07-2.34)		
Ratio of GMRs		0.83		
95% Conf Int		(0.69-0.99)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				13.92
95% Conf Int				(7.68-25.22)
Ratio of GMRs				5.07
95% Conf Int				(2.78-9.24)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				14.06
95% Conf Int				(7.76-25.47)
Ratio of GMRs				5.80
95% Conf Int				(3.18-10.58)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				13.99
95% Conf Int				(8.01-24.42)
Ratio of GMRs				5.42
95% Conf Int				(3.09-9.52)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.99		
95% Conf Int		(0.66-1.49)		
Ratio of GMRs		0.87		
95% Conf Int		(0.58-1.32)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				18.40
95% Conf Int				(13.06-25.91)
Ratio of GMRs				5.79
95% Conf Int				(3.90-8.58)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				16.87
95% Conf Int				(11.97-23.78)
Ratio of GMRs				7.94
95% Conf Int				(5.35-11.77)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				17.62
95% Conf Int				(12.78-24.29)
Ratio of GMRs				6.77
95% Conf Int				(4.68-9.81)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.09		
95% Conf Int		(0.86-1.39)		
Ratio of GMRs		0.73		
95% Conf Int		(0.55-0.96)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	22.47	23.86	23.15	11.85
95% Conf Int	(18.88-26.74)	(20.05-28.39)	(20.47-26.18)	(8.73-16.09)
Median	28	31	30	14
Min, Max	2.00, 761	2.00, 6726	2.00, 6726	2.00, 200
N	296	296	592	96
Day 4				
GMT	26.37	33.99	29.88	13.90
95% Conf Int	(20.54-33.86)	(26.36-43.83)	(24.99-35.71)	(8.99-21.49)
Median	33	42	36	23
Min, Max	2.00, 763	2.00, 7353	2.00, 7353	2.00, 186
N	149	144	293	49
Day 6				
GMT	110.31	149.10	128.24	14.60
95% Conf Int	(84.28-144.39)	(113.91-195.15)	(105.97-155.20)	(9.01-23.67)
Median	143	166	151	14
Min, Max	2.00, 6974	2.00, 22491	2.00, 22491	2.00, 577
N	148	148	296	46
Day 29				
GMT	1345.64	1838.29	1571.55	52.04
95% Conf Int	(1137.16-1592.33)	(1552.16-2177.17)	(1394.09-1771.59)	(38.65-70.08)
Median	1497	1900	1642	55
Min, Max	20, 87078	18, 78040	18, 87078	2.00, 29145
N	297	294	591	95
Day 4/Day 1				
GMR	1.05	1.37	1.20	1.13
95% Conf Int	(0.91-1.22)	(1.18-1.60)	(1.08-1.33)	(0.88-1.46)
Median	1.00	1.02	1.00	1.00
Min, Max	0.019, 64	0.22, 69	0.019, 69	0.091, 51
N	149	144	293	49

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	5.53	6.42	5.96	1.31
95% Conf Int	(4.24-7.22)	(4.92-8.38)	(4.94-7.20)	(0.81-2.11)
Median	4.33	5.04	4.40	1.00
Min, Max	0.24, 647	0.45, 346	0.24, 647	0.077, 289
N	147	148	295	46
Day 29/Day 1				
GMR	60.29	77.37	68.27	4.43
95% Conf Int	(48.74-74.59)	(62.50-95.79)	(58.71-79.39)	(3.05-6.46)
Median	72	74	72	2.09
Min, Max	1.69, 6383	0.44, 6902	0.44, 6902	0.33, 14573
N	296	294	590	95
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				1.90
95% Conf Int				(1.15-3.13)
Ratio of GMRs				0.93
95% Conf Int				(0.69-1.25)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.45
95% Conf Int				(1.48-4.05)
Ratio of GMRs				1.21
95% Conf Int				(0.90-1.63)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.15
95% Conf Int				(1.34-3.44)
Ratio of GMRs				1.06
95% Conf Int				(0.80-1.40)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.78		
95% Conf Int		(0.54-1.11)		
Ratio of GMRs		0.76		
95% Conf Int		(0.62-0.94)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				7.55
95% Conf Int				(4.35-13.13)
Ratio of GMRs				4.23
95% Conf Int				(2.45-7.32)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				10.21
95% Conf Int				(5.87-17.75)
Ratio of GMRs				4.92
95% Conf Int				(2.85-8.49)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				8.78
95% Conf Int				(5.22-14.77)
Ratio of GMRs				4.56
95% Conf Int				(2.73-7.62)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.74		
95% Conf Int		(0.51-1.08)		
Ratio of GMRs		0.86		
95% Conf Int		(0.59-1.26)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				25.86
95% Conf Int				(18.37-36.40)
Ratio of GMRs				13.60
95% Conf Int				(8.83-20.93)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				35.32
95% Conf Int				(25.08-49.74)
Ratio of GMRs				17.45
95% Conf Int				(11.33-26.87)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				30.20
95% Conf Int				(21.88-41.67)
Ratio of GMRs				15.39
95% Conf Int				(10.27-23.09)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.73		
95% Conf Int		(0.58-0.93)		
Ratio of GMRs		0.78		
95% Conf Int		(0.58-1.05)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 1				
GMT	9.29	8.60	8.93	4.44
95% Conf Int	(7.83-11.02)	(7.25-10.19)	(7.92-10.08)	(3.30-5.99)
Median	10	6.00	8.00	2.00
Min, Max	2.00, 1370	2.00, 5173	2.00, 5173	2.00, 72
N	294	295	589	96
Day 4				
GMT	11.22	12.23	11.71	4.55
95% Conf Int	(8.53-14.76)	(9.26-16.15)	(9.63-14.23)	(2.82-7.33)
Median	11	11	11	2.00
Min, Max	2.00, 1225	2.00, 12288	2.00, 12288	2.00, 84
N	148	144	292	49
Day 6				
GMT	62.06	67.00	64.49	6.12
95% Conf Int	(46.60-82.64)	(50.36-89.13)	(52.70-78.92)	(3.67-10.22)
Median	79	67	74	2.00
Min, Max	2.00, 2563	2.00, 23434	2.00, 23434	2.00, 184
N	147	148	295	46
Day 29				
GMT	1037.41	964.39	1000.42	35.24
95% Conf Int	(873.79-1231.67)	(811.57-1145.98)	(885.85-1129.80)	(26.06-47.66)
Median	869	950	908	29
Min, Max	44, 26324	2.00, 22572	2.00, 26324	2.00, 6607
N	297	294	591	96
Day 4/Day 1				
GMR	1.35	1.29	1.32	0.99
95% Conf Int	(1.15-1.58)	(1.11-1.52)	(1.18-1.48)	(0.76-1.30)
Median	1.00	1.00	1.00	1.00
Min, Max	0.095, 177	0.022, 78	0.022, 177	0.17, 2.25
N	147	143	290	49

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Day 6/Day 1				
GMR	6.11	8.69	7.30	1.45
95% Conf Int	(4.55-8.20)	(6.49-11.63)	(5.93-8.98)	(0.86-2.45)
Median	4.78	9.00	6.00	1.00
Min, Max	0.0062, 621	0.11, 958	0.0062, 958	0.29, 88
N	145	148	293	46
Day 29/Day 1				
GMR	112.79	112.98	112.88	7.93
95% Conf Int	(91.22-139.46)	(91.34-139.75)	(97.15-131.16)	(5.47-11.50)
Median	134	125	130	5.52
Min, Max	1.24, 5831	0.81, 7756	0.81, 7756	0.13, 3304
N	294	293	587	96
Vaccine comparison at Day 4 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				2.47
95% Conf Int				(1.42-4.28)
Ratio of GMRs				1.36
95% Conf Int				(0.99-1.86)
Vaccine comparison at Day 4 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.69
95% Conf Int				(1.55-4.67)
Ratio of GMRs				1.30
95% Conf Int				(0.95-1.78)
Vaccine comparison at Day 4 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				2.57
95% Conf Int				(1.54-4.31)
Ratio of GMRs				1.33
95% Conf Int				(0.99-1.78)

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 4 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.92		
95% Conf Int		(0.62-1.36)		
Ratio of GMRs		1.04		
95% Conf Int		(0.83-1.30)		
Vaccine comparison at Day 6 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				10.13
95% Conf Int				(5.64-18.22)
Ratio of GMRs				4.20
95% Conf Int				(2.31-7.66)
Vaccine comparison at Day 6 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				10.94
95% Conf Int				(6.09-19.66)
Ratio of GMRs				5.98
95% Conf Int				(3.29-10.88)
Vaccine comparison at Day 6 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				10.53
95% Conf Int				(6.08-18.25)
Ratio of GMRs				5.02
95% Conf Int				(2.86-8.83)
Vaccine comparison at Day 6 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		0.93		
95% Conf Int		(0.62-1.39)		
Ratio of GMRs		0.70		
95% Conf Int		(0.46-1.06)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.4.2
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Pooled Menveo/Menactra-Menveo	Naive
Vaccine comparison at Day 29 (Menveo-Menveo vs. Naive)				
Ratio of GMTs				29.44
95% Conf Int				(20.80-41.66)
Ratio of GMRs				14.21
95% Conf Int				(9.27-21.80)
Vaccine comparison at Day 29 (Menactra-Menveo vs. Naive)				
Ratio of GMTs				27.37
95% Conf Int				(19.33-38.75)
Ratio of GMRs				14.24
95% Conf Int				(9.28-21.84)
Vaccine comparison at Day 29 (Pooled Menveo/Menactra-Menveo vs. Naive)				
Ratio of GMTs				28.39
95% Conf Int				(20.50-39.30)
Ratio of GMRs				14.23
95% Conf Int				(9.53-21.23)
Vaccine comparison at Day 29 (Menveo-Menveo vs. Menactra-Menveo)				
Ratio of GMTs		1.08		
95% Conf Int		(0.84-1.37)		
Ratio of GMRs		1.00		
95% Conf Int		(0.74-1.35)		

Statistical model used: ANOVA model with study group as factor. Two models are fitted and the results combined in one table.
The first model includes Menveo-Menveo, Menactra-Menveo and Naive as study group. The second model includes Pooled Menveo/Menactra and Naive as study group.

PPD

Table 14.2.1.5
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	2.80	3.01	2.26
95% Conf Int	(2.53-3.09)	(2.72-3.33)	(1.90-2.70)
Median	2.00	2.00	2.00
Min, Max	2.00, 140	2.00, 173	2.00, 71
N	297	291	96
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			1.24
95% Conf Int			(1.01-1.51)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			1.33
95% Conf Int			(1.09-1.63)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		0.93	
95% Conf Int		(0.81-1.07)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	15.99	10.63	5.24
95% Conf Int	(13.23-19.31)	(8.78-12.87)	(3.76-7.30)
Median	13	10	5.00
Min, Max	2.00, 1590	2.00, 1848	2.00, 208
N	296	289	96
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			3.05
95% Conf Int			(2.08-4.47)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			2.03
95% Conf Int			(1.38-2.98)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		1.50	
95% Conf Int		(1.15-1.97)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	22.54	23.33	12.33
95% Conf Int	(18.98-26.77)	(19.61-27.75)	(9.11-16.68)
Median	28	31	14
Min, Max	2.00, 761	2.00, 6726	2.00, 200
N	297	291	96
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			1.83
95% Conf Int			(1.29-2.59)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			1.89
95% Conf Int			(1.34-2.68)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		0.97	
95% Conf Int		(0.76-1.23)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Per Protocol Set (Day 1)

Serogroup: Men Y Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	9.12	8.34	4.44
95% Conf Int	(7.72-10.77)	(7.05-9.87)	(3.32-5.95)
Median	10	6.00	2.00
Min, Max	2.00, 350	2.00, 5173	2.00, 72
N	295	290	96
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			2.05
95% Conf Int			(1.47-2.87)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			1.88
95% Conf Int			(1.34-2.63)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		1.09	
95% Conf Int		(0.86-1.39)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5.1
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men A Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	2.83	3.08	2.26
95% Conf Int	(2.55-3.13)	(2.78-3.41)	(1.89-2.70)
Median	2.00	2.00	2.00
Min, Max	2.00, 140	2.00, 173	2.00, 71
N	300	298	97
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			1.25
95% Conf Int			(1.02-1.54)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			1.36
95% Conf Int			(1.11-1.67)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		0.92	
95% Conf Int		(0.79-1.06)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5.1
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men C Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	16.06	10.75	5.19
95% Conf Int	(13.30-19.39)	(8.90-12.99)	(3.73-7.22)
Median	13	10	5.00
Min, Max	2.00, 1590	2.00, 1848	2.00, 208
N	299	296	97
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			3.10
95% Conf Int			(2.12-4.53)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			2.07
95% Conf Int			(1.42-3.03)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		1.49	
95% Conf Int		(1.14-1.95)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5.1
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men W Human Complement SBA

	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	22.75	24.02	12.10
95% Conf Int	(19.14-27.03)	(20.20-28.56)	(8.94-16.39)
Median	29	32	14
Min, Max	2.00, 761	2.00, 6726	2.00, 200
N	300	298	97
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			1.88
95% Conf Int			(1.33-2.66)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			1.98
95% Conf Int			(1.40-2.81)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		0.95	
95% Conf Int		(0.74-1.21)	

Statistical model used: ANOVA model with study group as factor.

PPD

Table 14.2.1.5.1
Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects
Full Analysis Set (Day 1)

Serogroup: Men Y Human Complement SBA

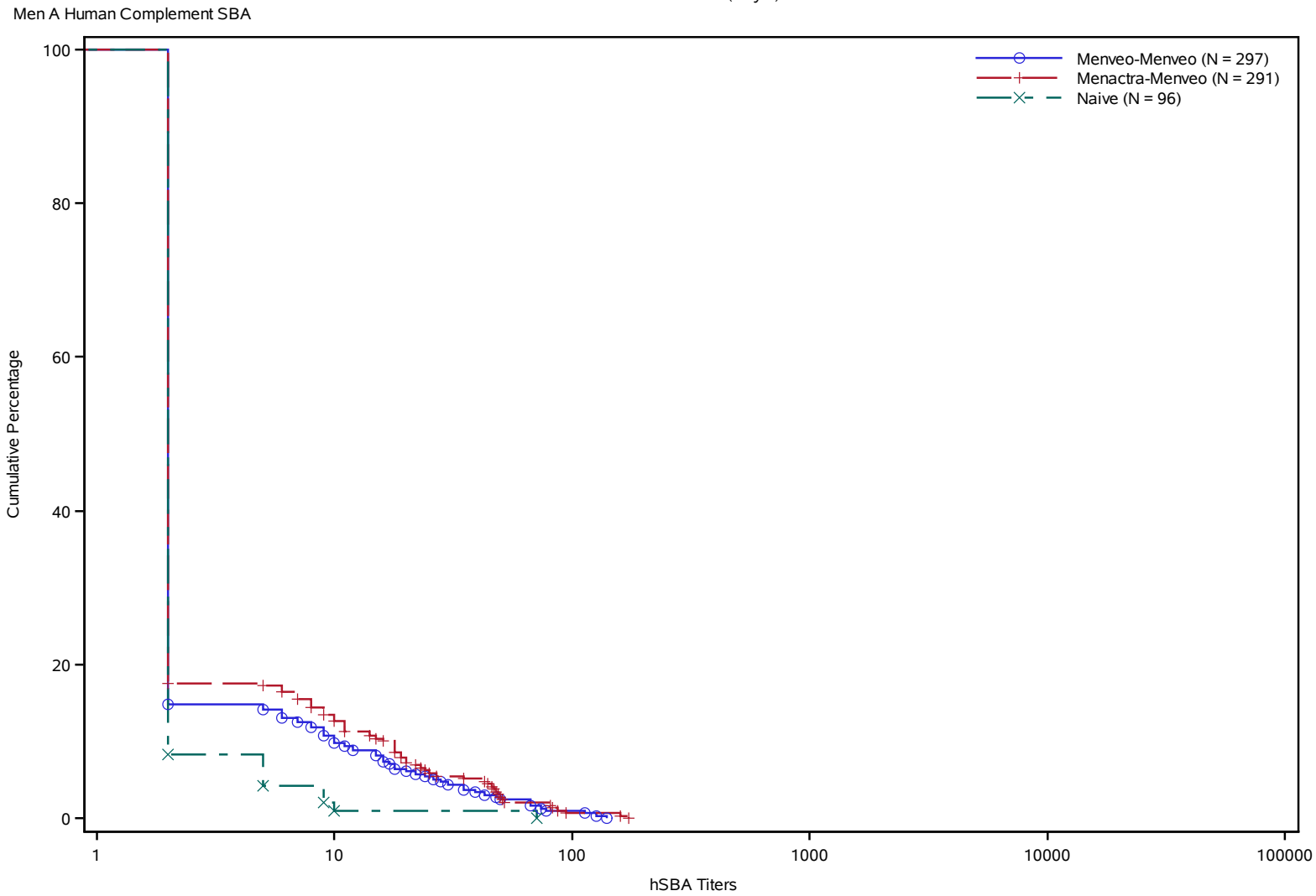
	Menveo-Menveo	Menactra-Menveo	Naive
Day 1			
GMT	9.23	8.66	4.41
95% Conf Int	(7.79-10.94)	(7.31-10.27)	(3.27-5.93)
Median	10	6.00	2.00
Min, Max	2.00, 1370	2.00, 5173	2.00, 72
N	298	297	97
Vaccine comparison at Day 1 (Menveo-Menveo vs. Naive)			
Ratio of GMTs			2.10
95% Conf Int			(1.49-2.95)
Vaccine comparison at Day 1 (Menactra-Menveo vs. Naive)			
Ratio of GMTs			1.97
95% Conf Int			(1.40-2.77)
Vaccine comparison at Day 1 (Menveo-Menveo vs. Menactra-Menveo)			
Ratio of GMTs		1.07	
95% Conf Int		(0.84-1.36)	

Statistical model used: ANOVA model with study group as factor.

PPD

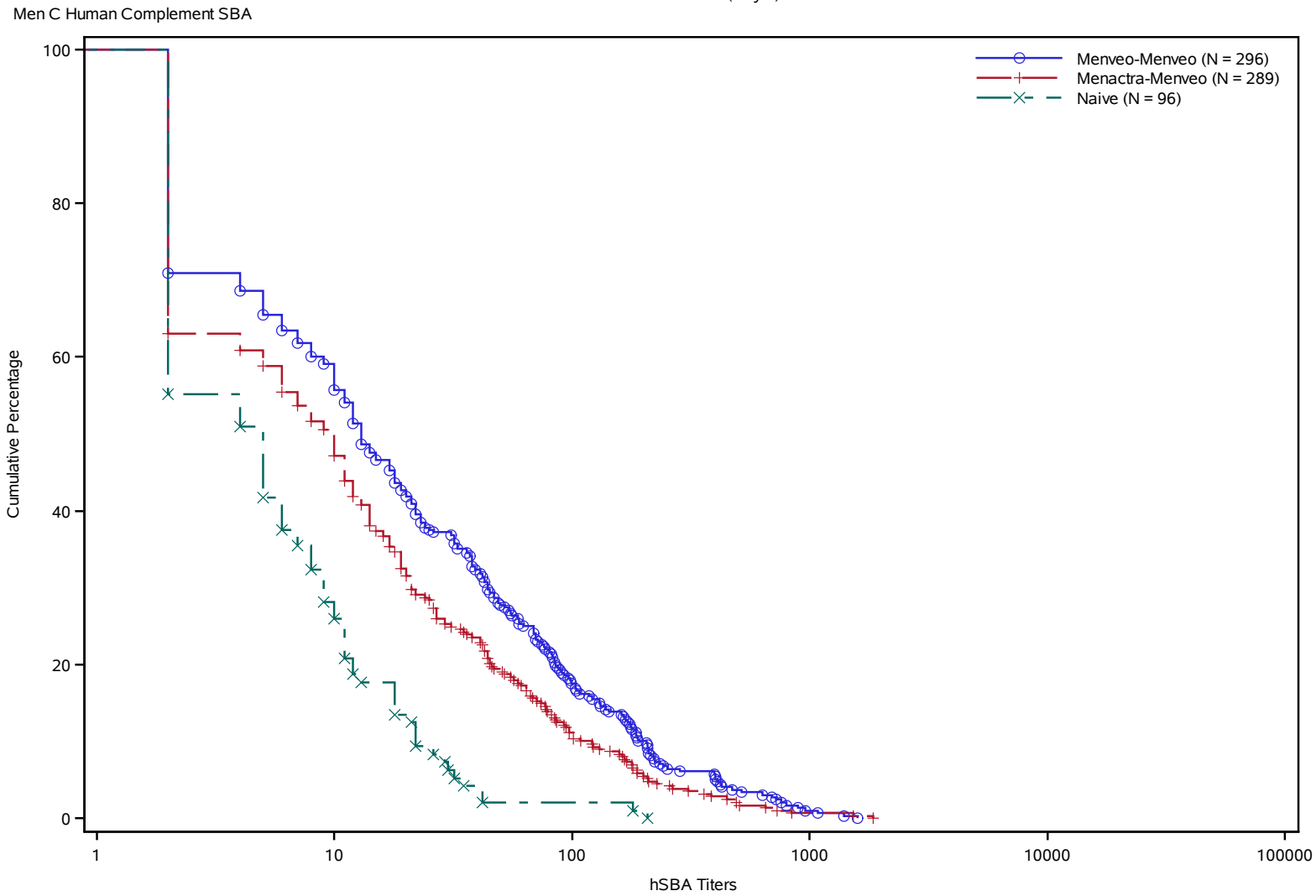
14.2.2 Figures

Figure 14.2.2.1.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 1)



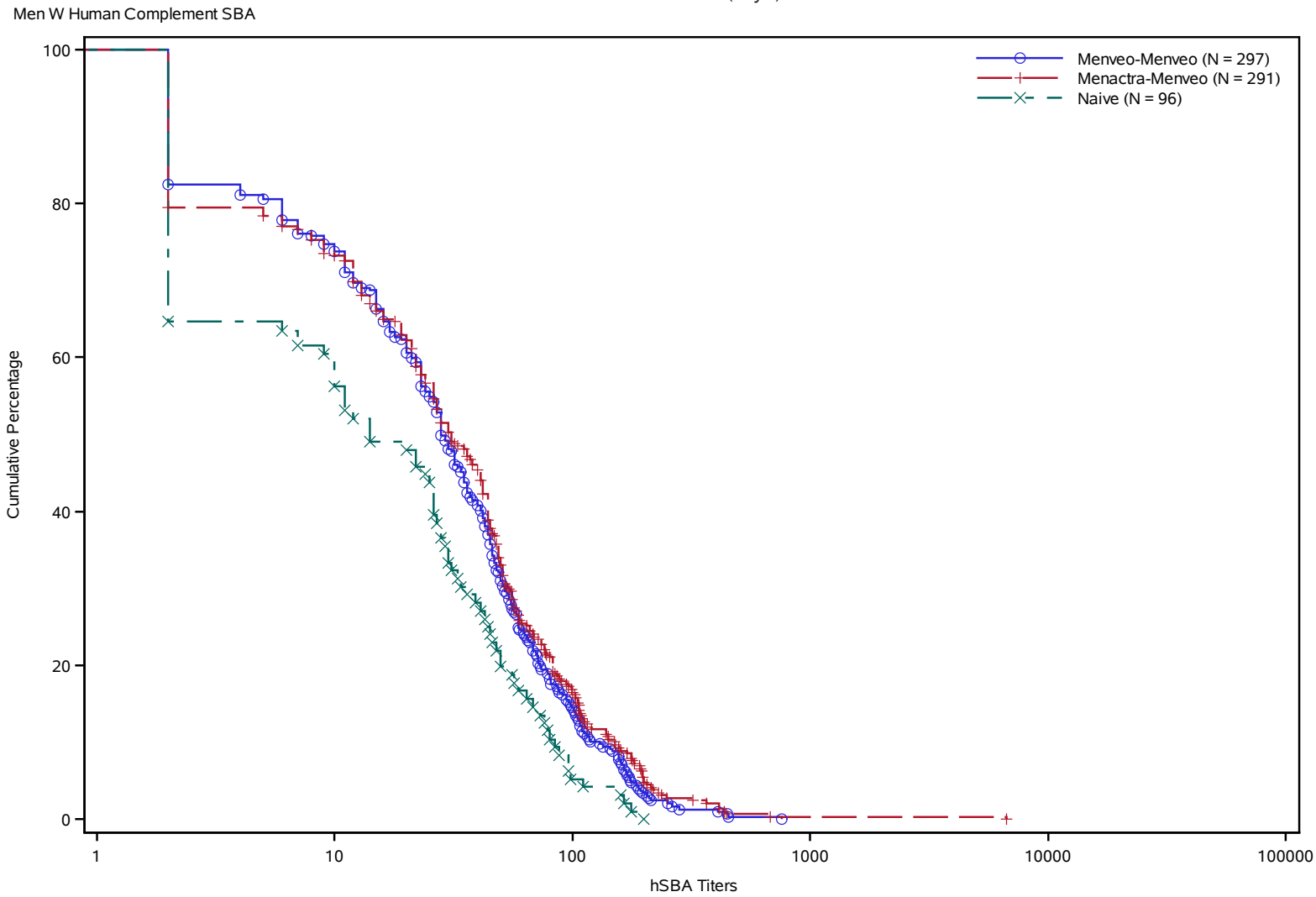
PPD

Figure 14.2.2.1.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 1)



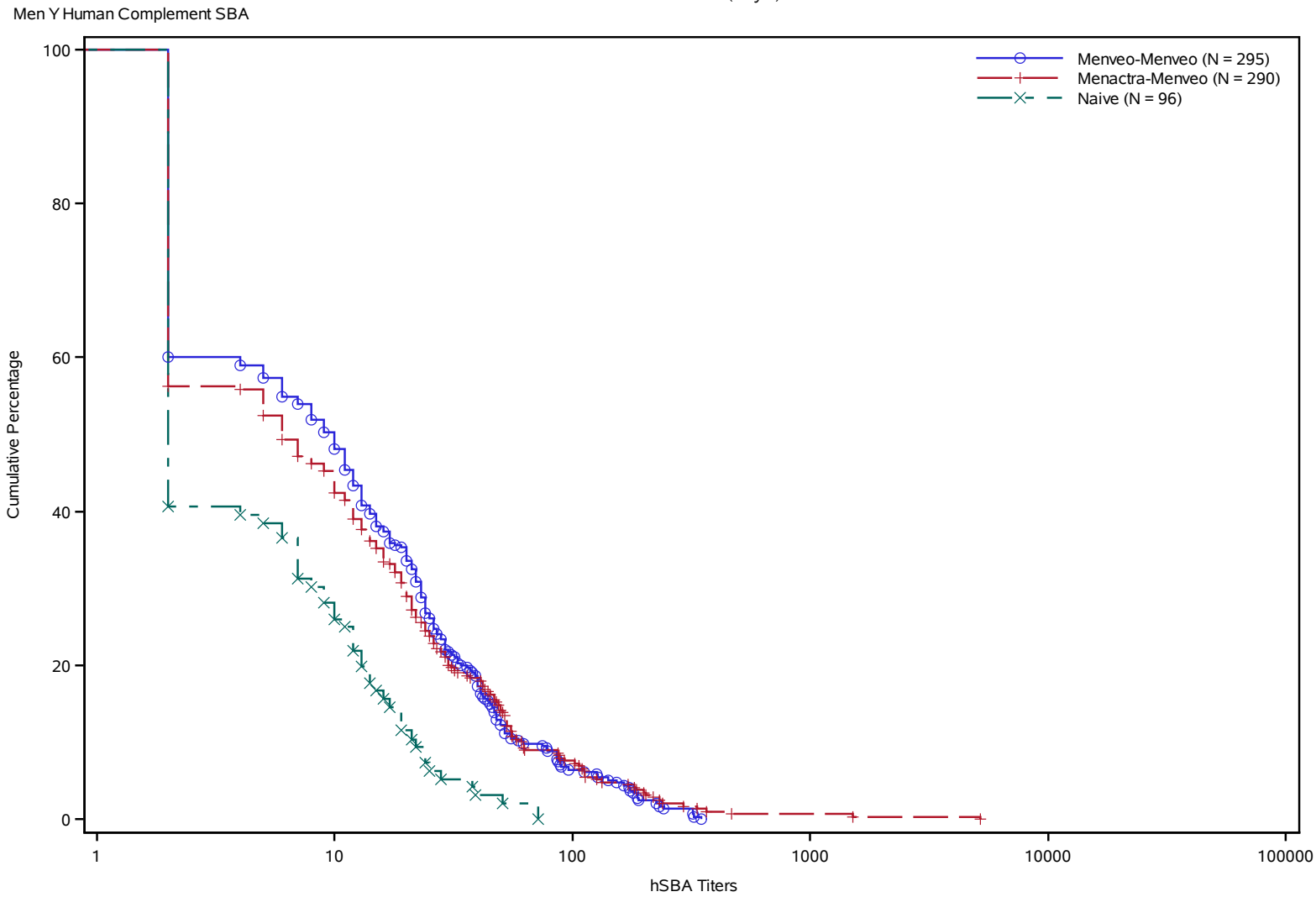
PPD

Figure 14.2.2.1.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 1)



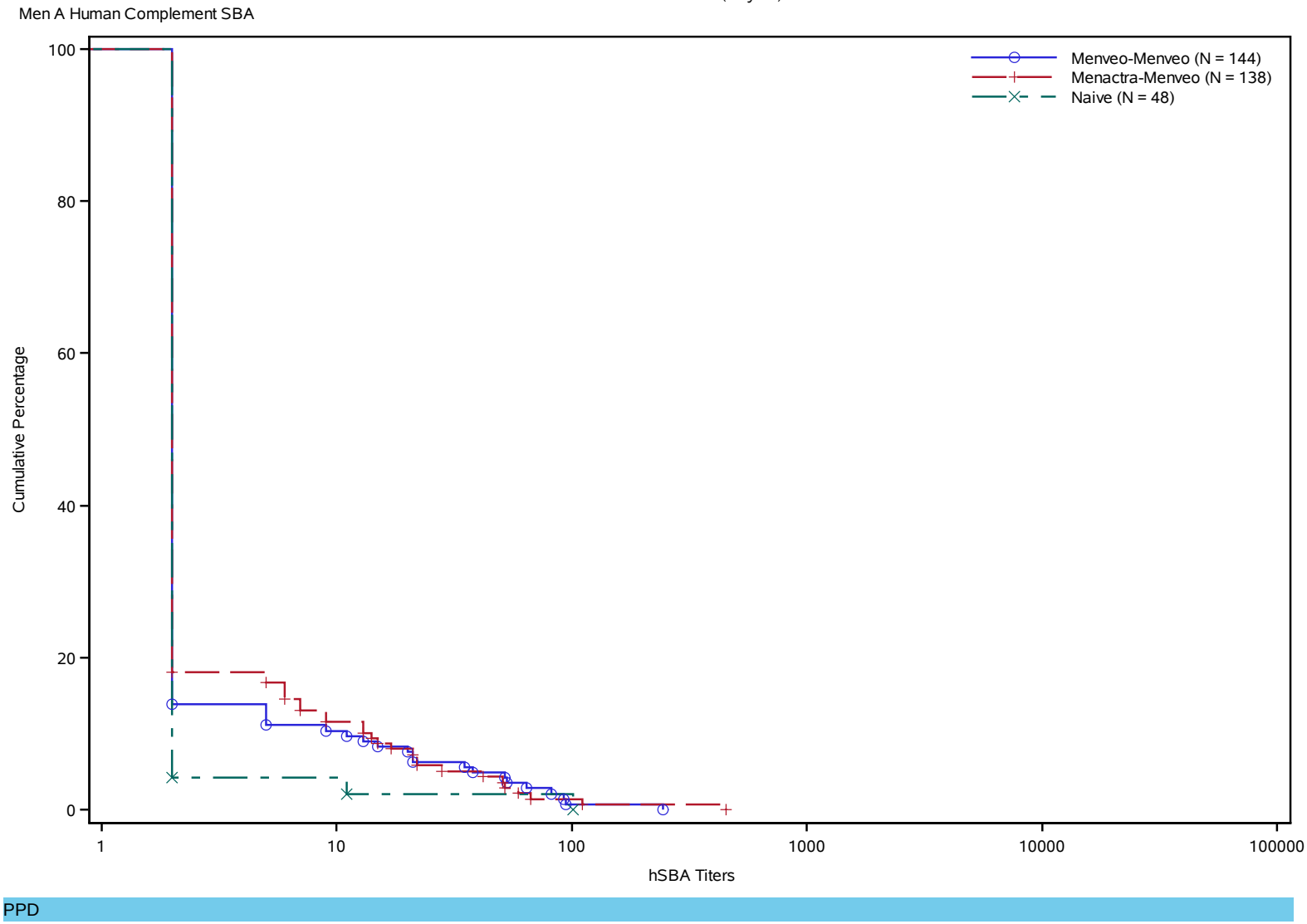
PPD

Figure 14.2.2.1.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 1)



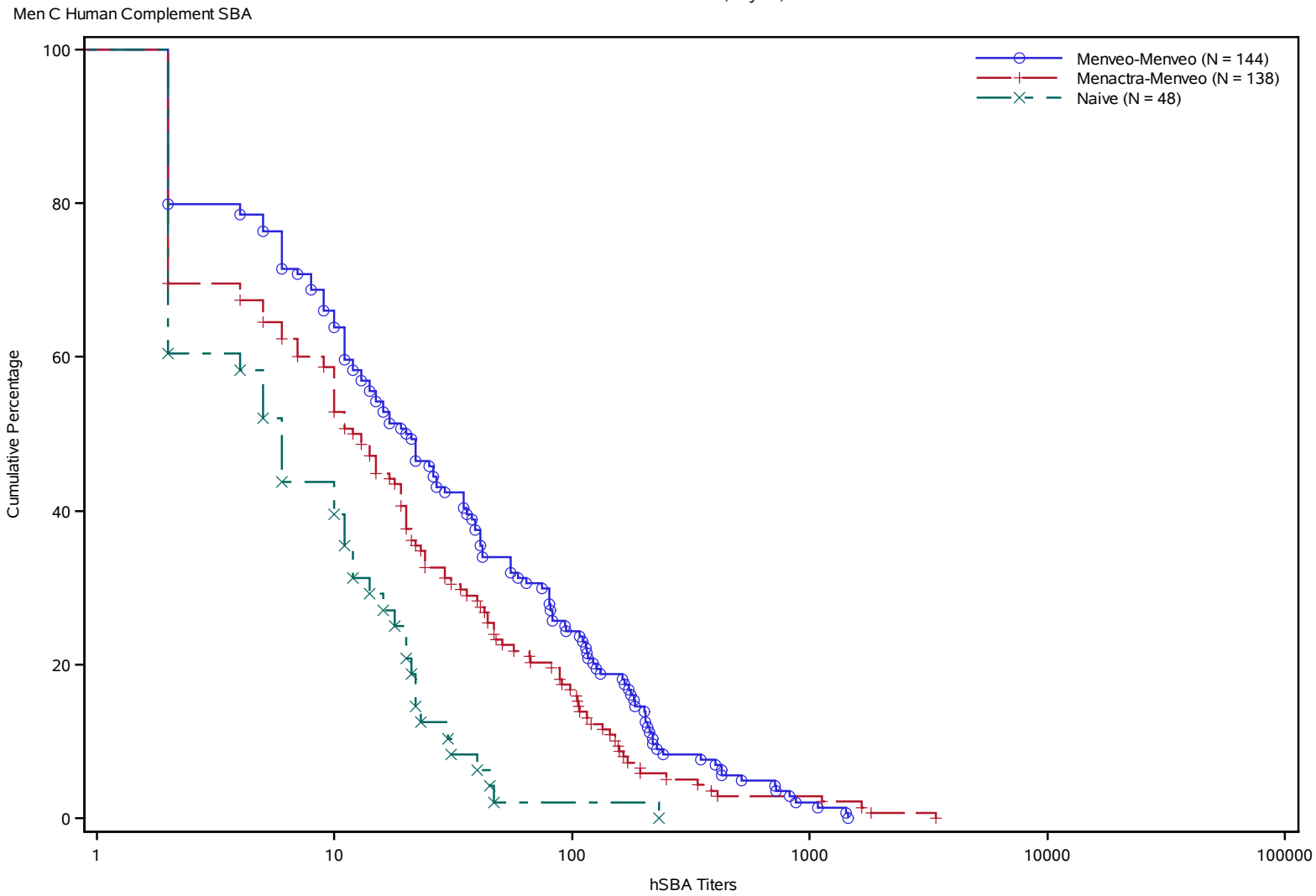
PPD

Figure 14.2.2.1.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



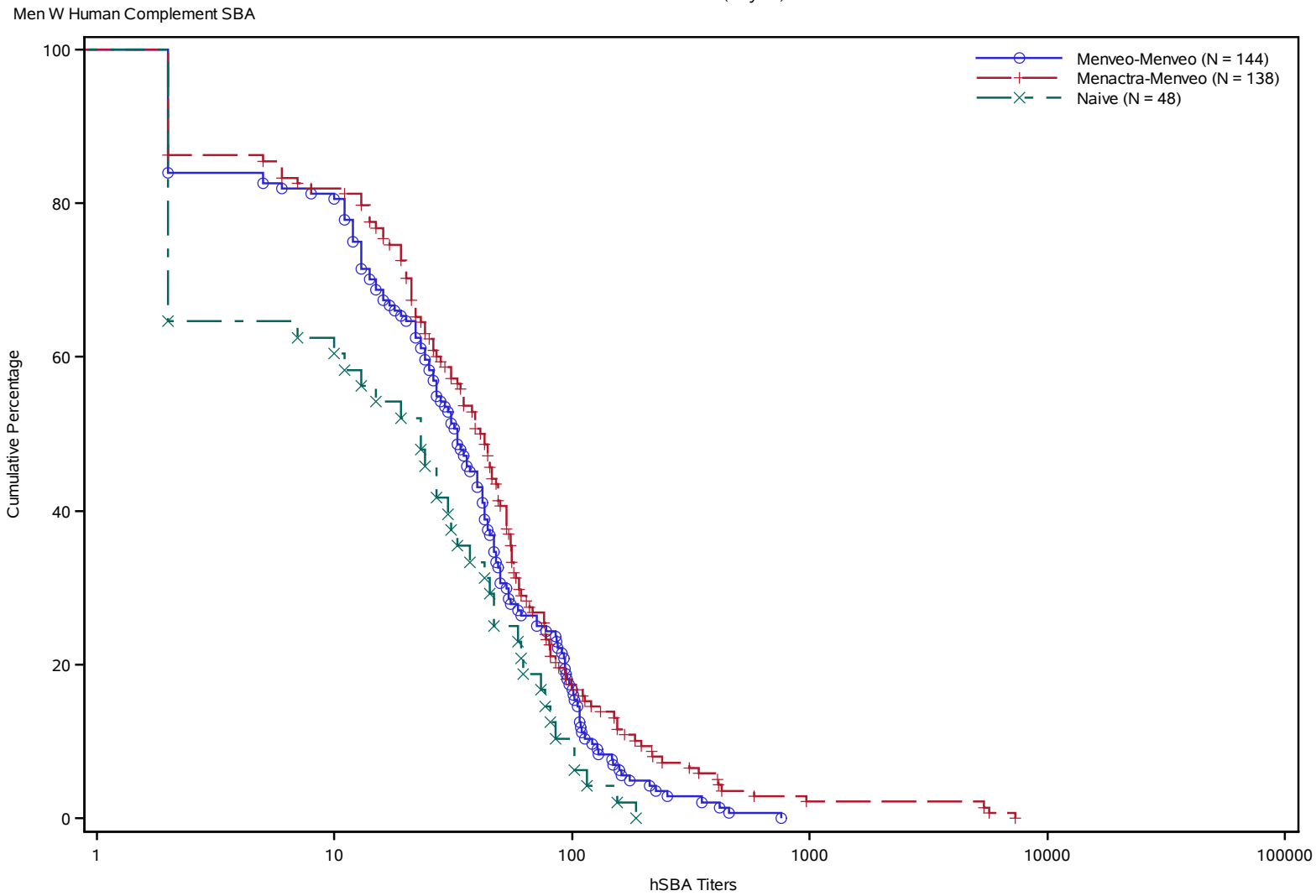
PPD

Figure 14.2.2.1.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



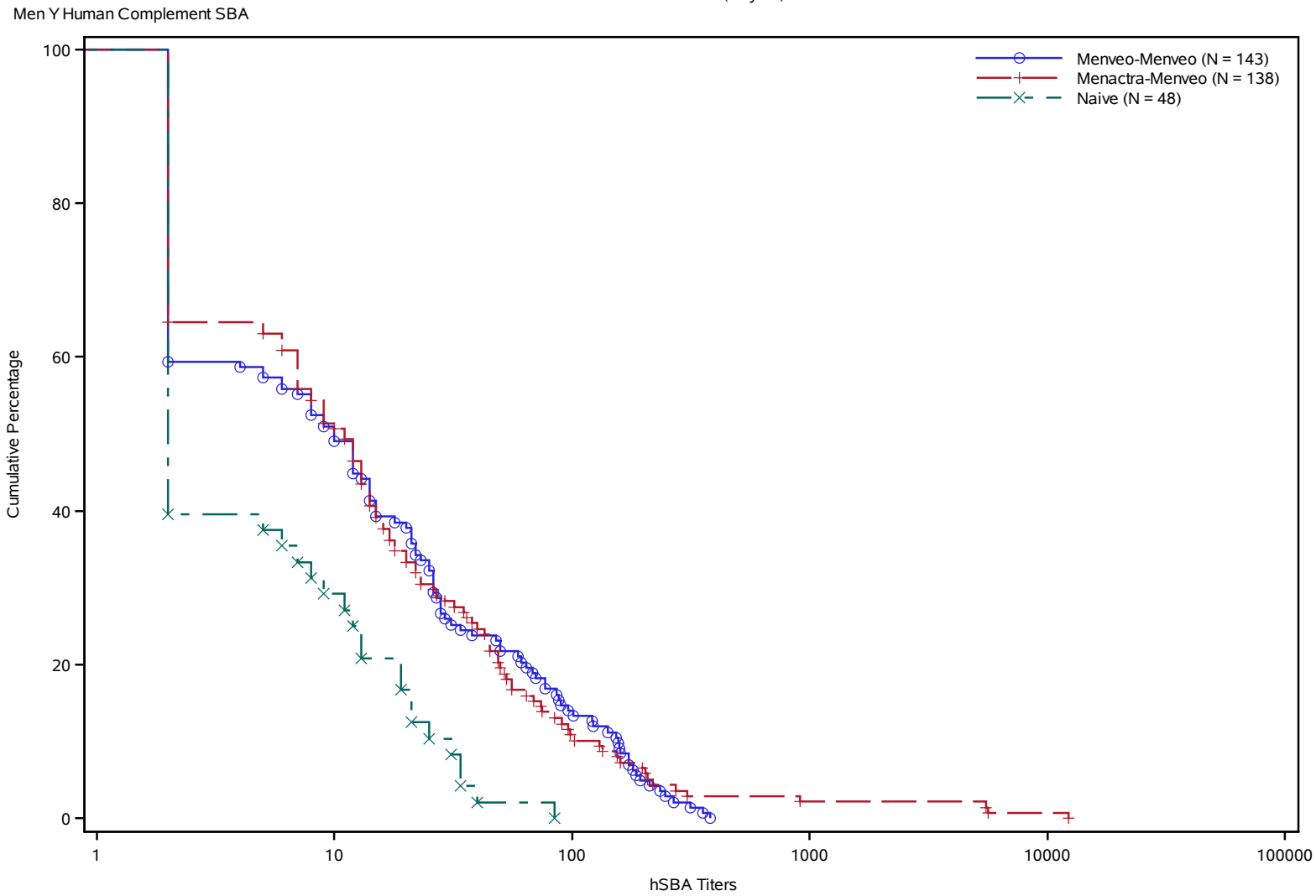
PPD

Figure 14.2.2.1.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



PPD

Figure 14.2.2.1.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



PPD

Figure 14.2.2.1.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)

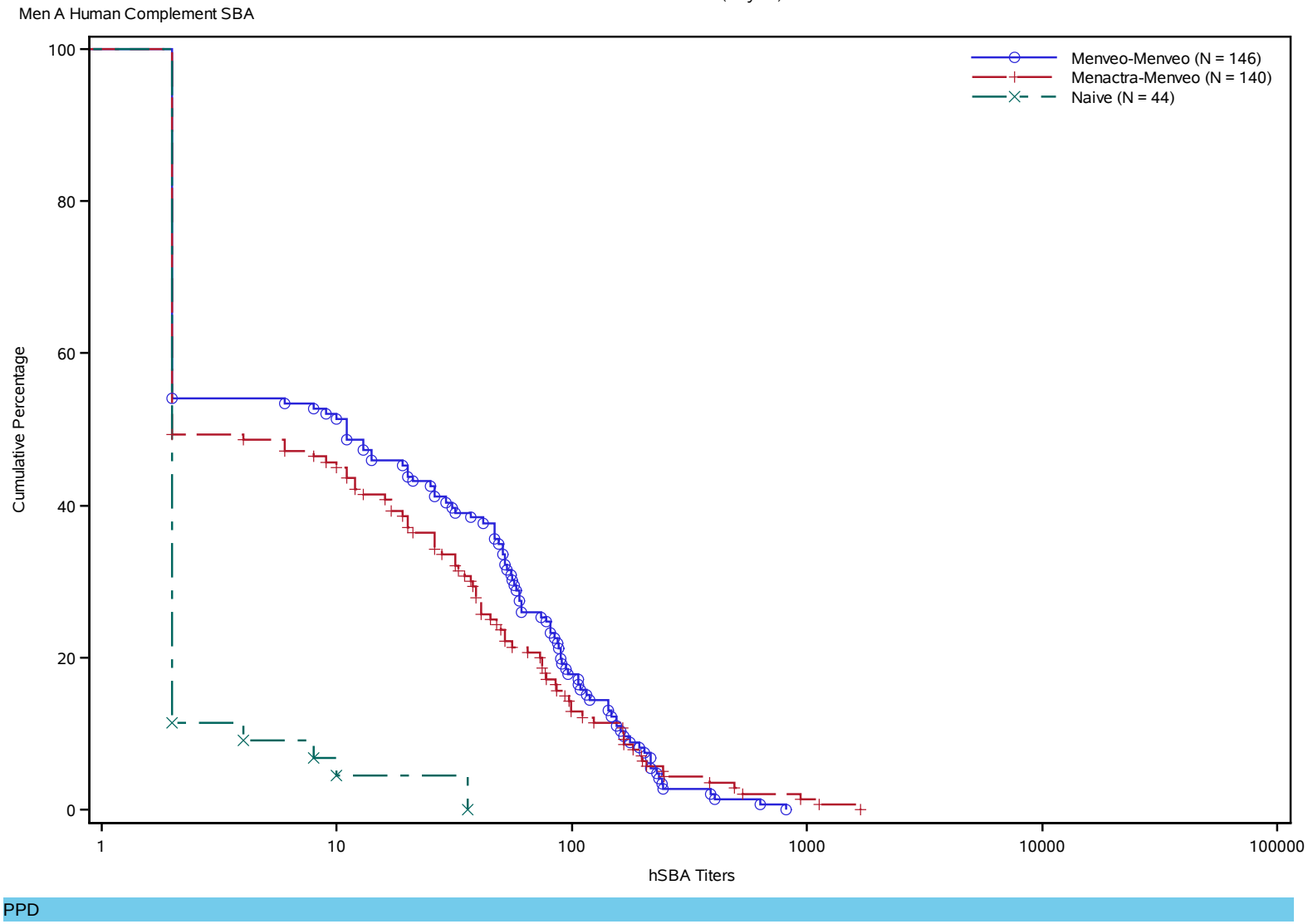
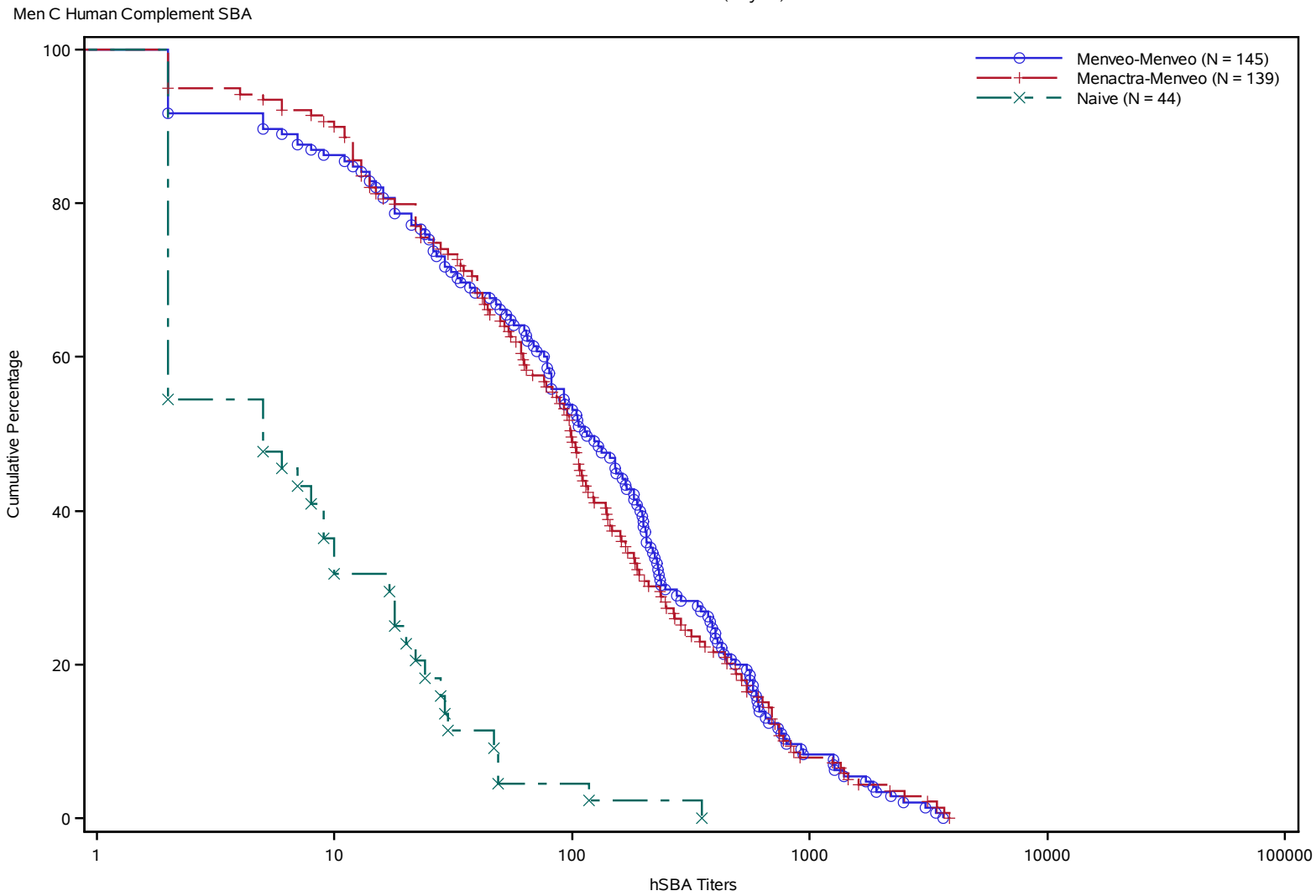
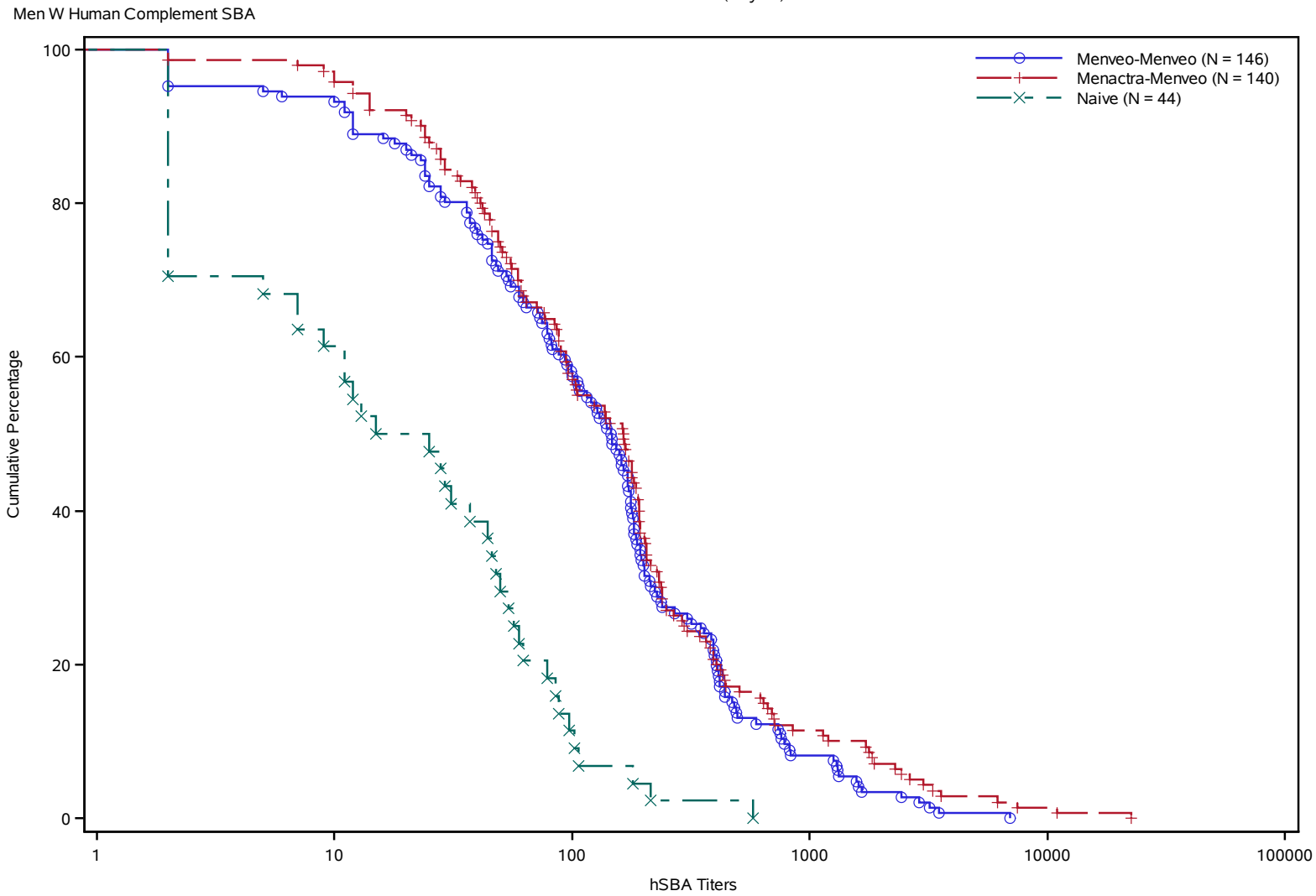


Figure 14.2.2.1.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



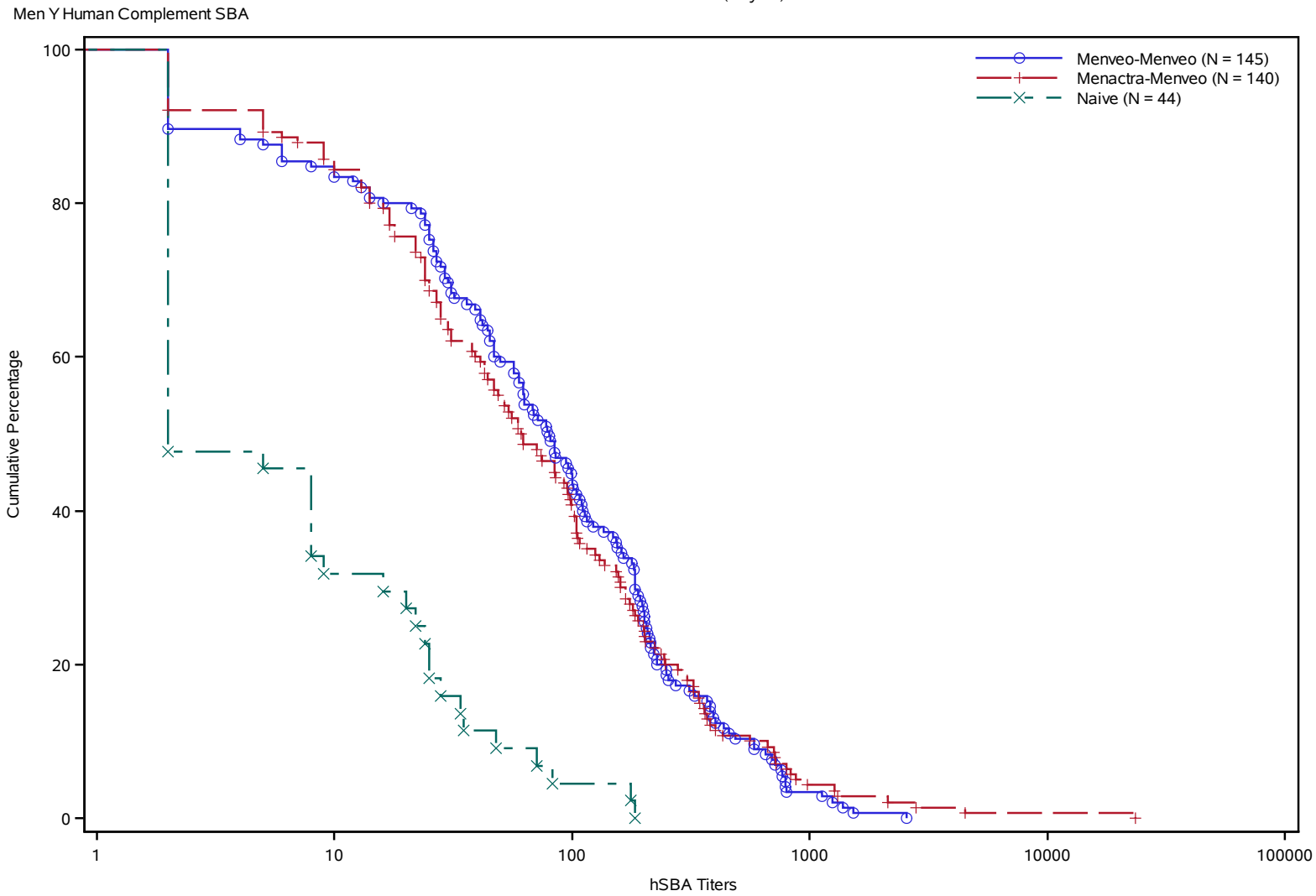
PPD

Figure 14.2.2.1.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



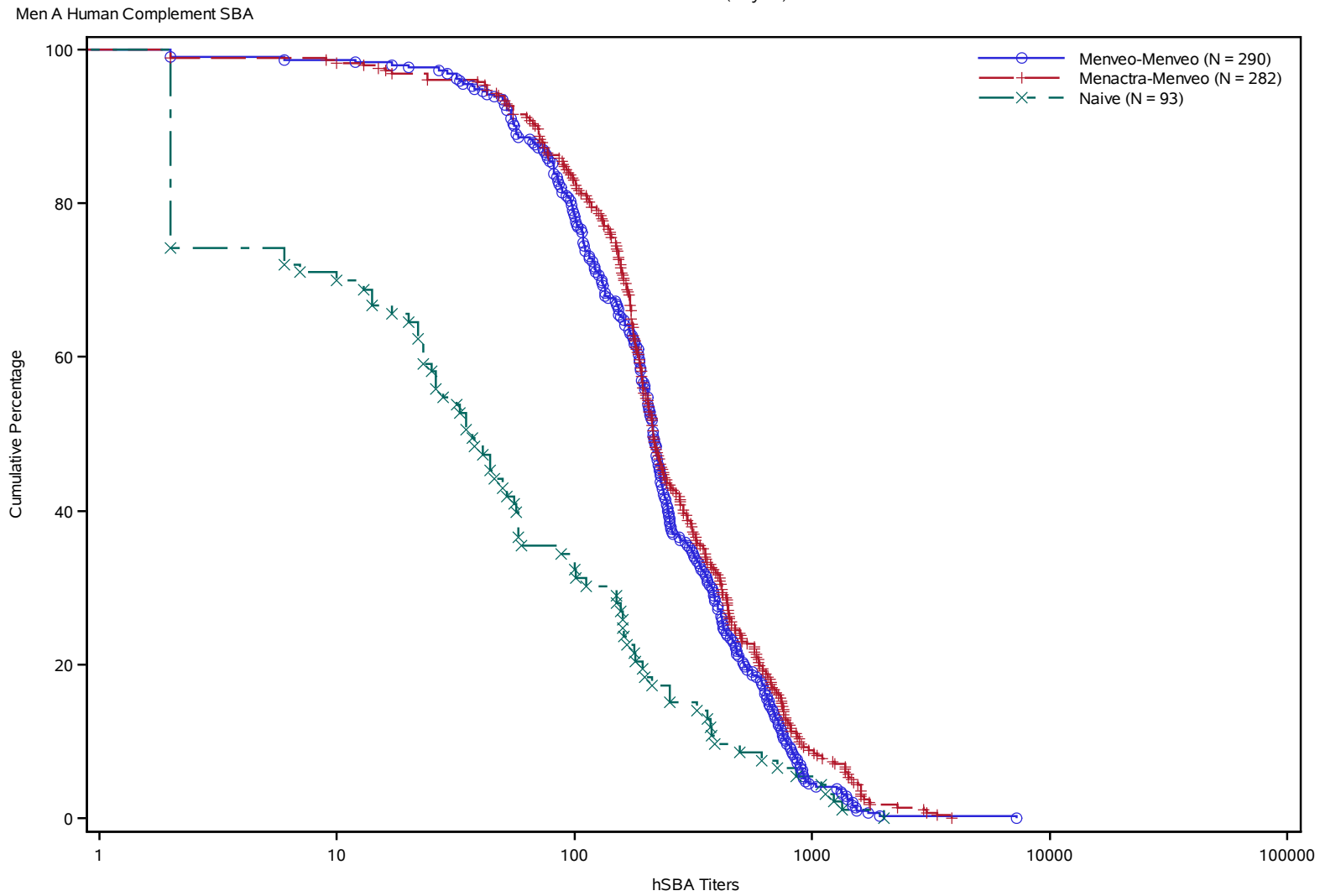
PPD

Figure 14.2.2.1.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



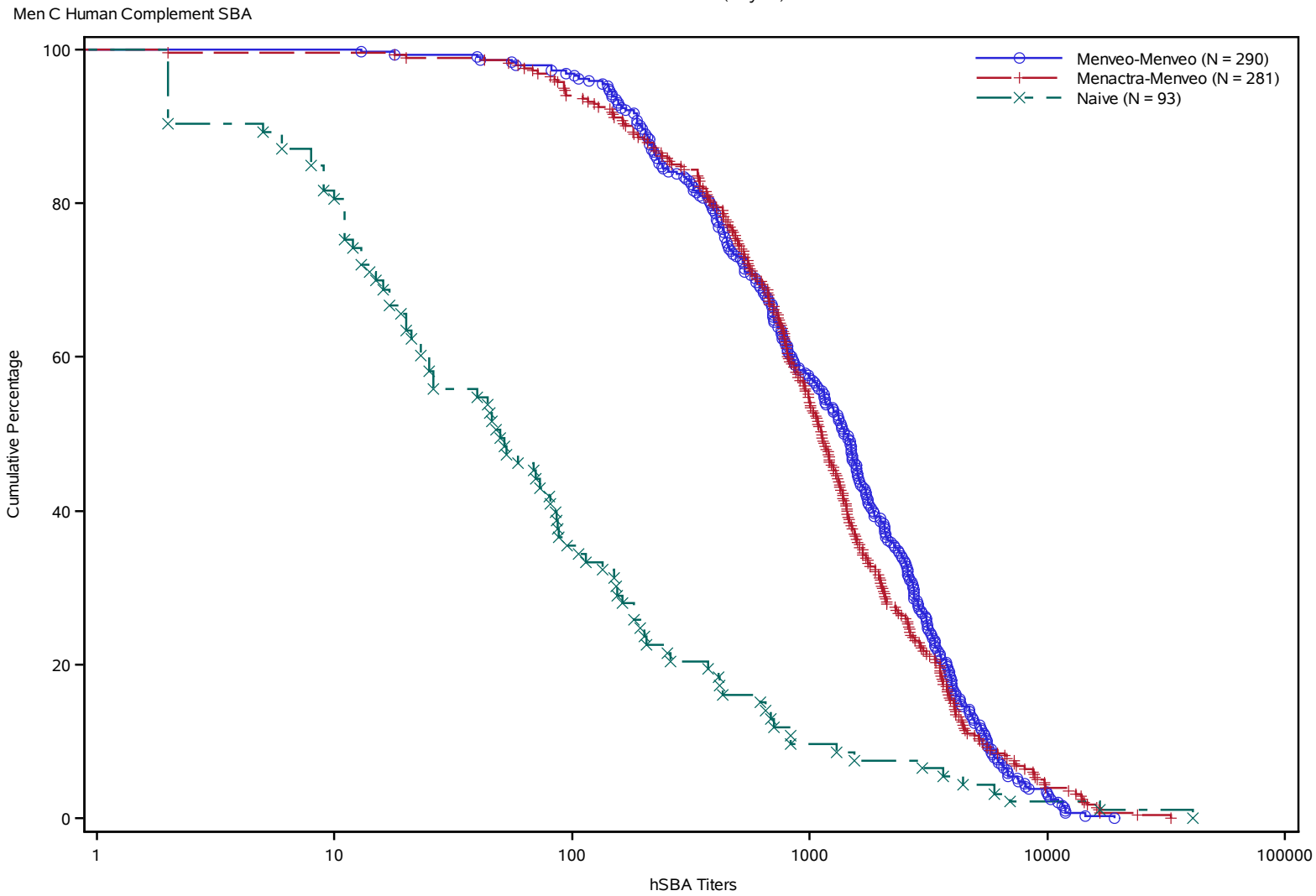
PPD

Figure 14.2.2.1.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



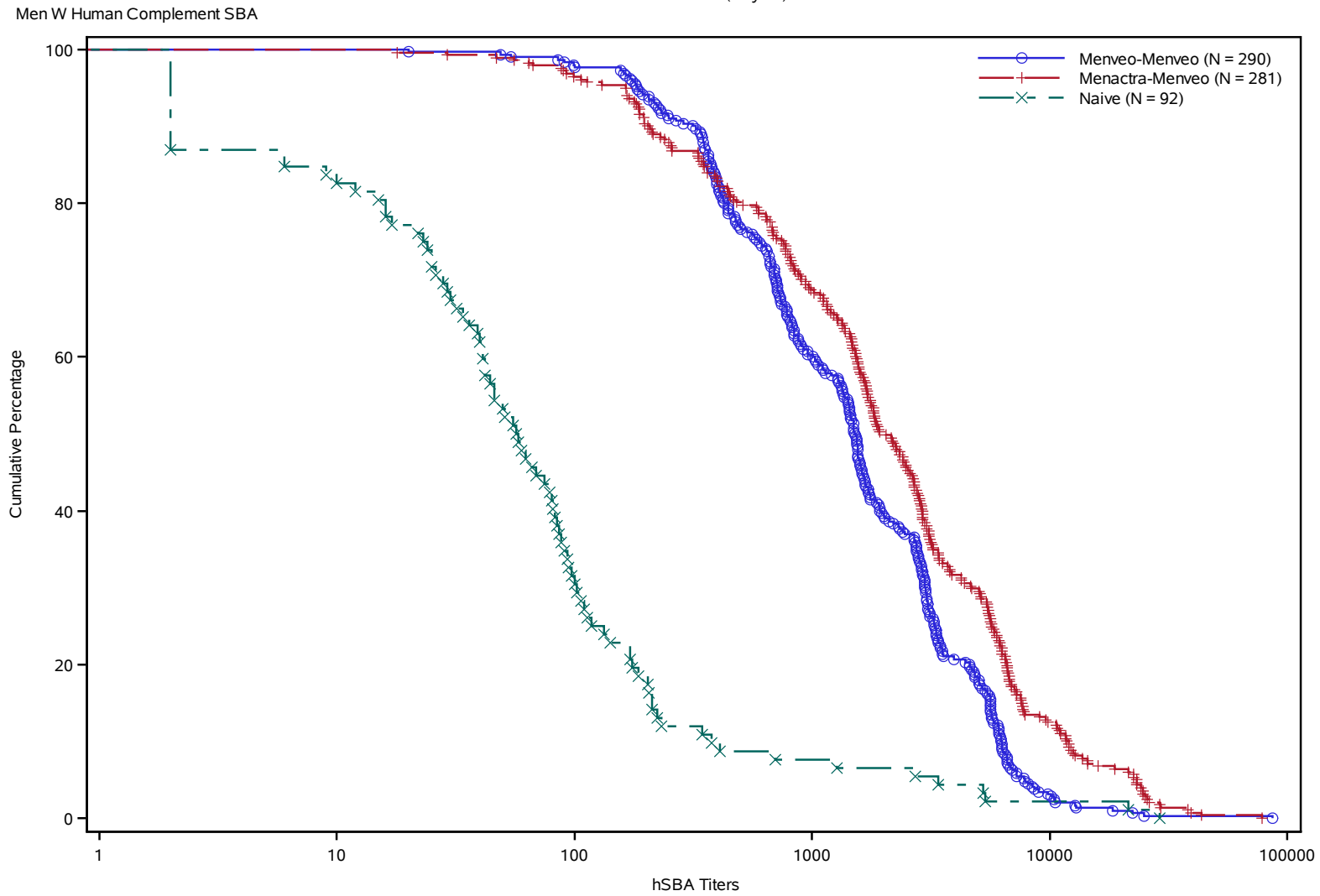
PPD

Figure 14.2.2.1.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



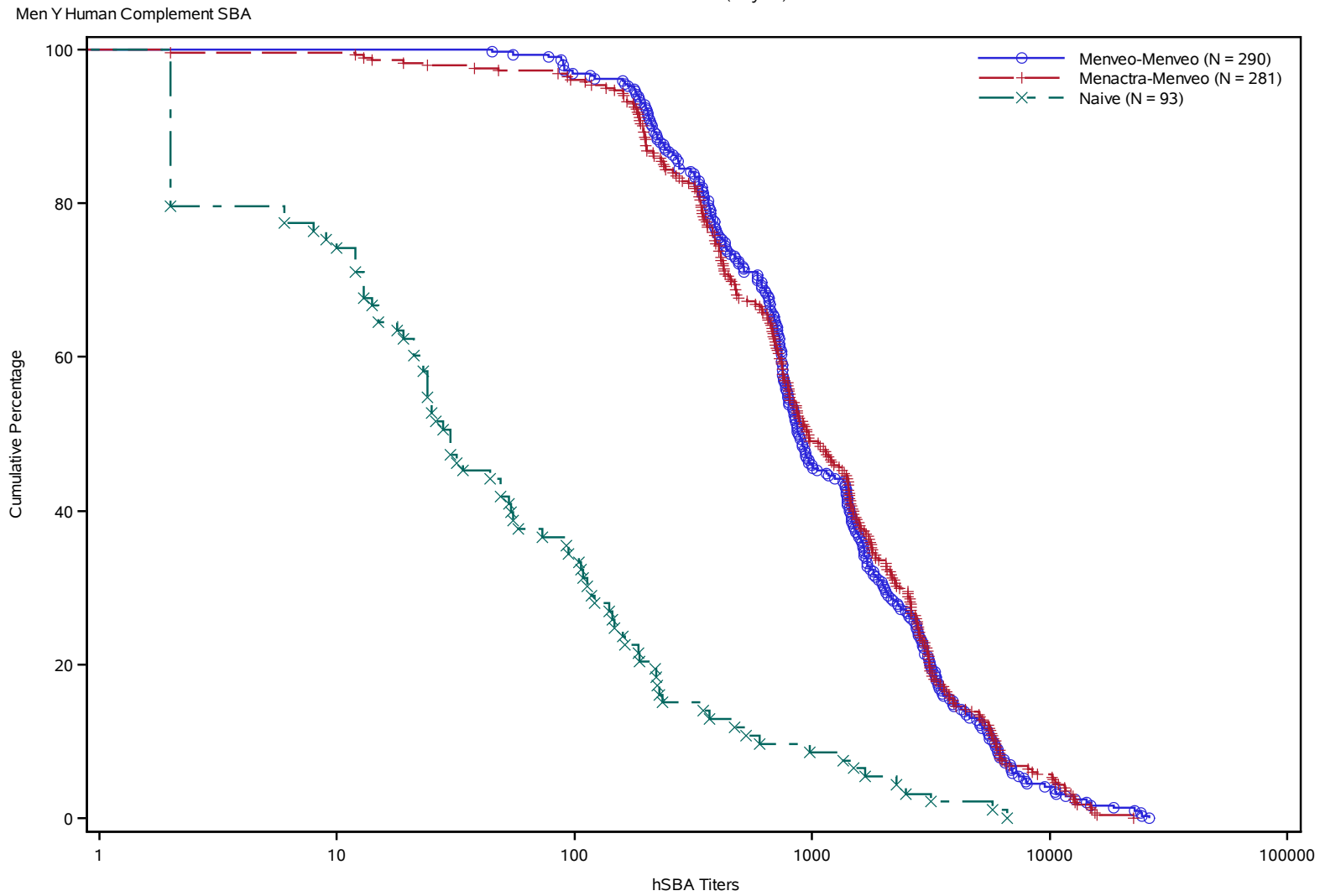
PPD

Figure 14.2.2.1.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



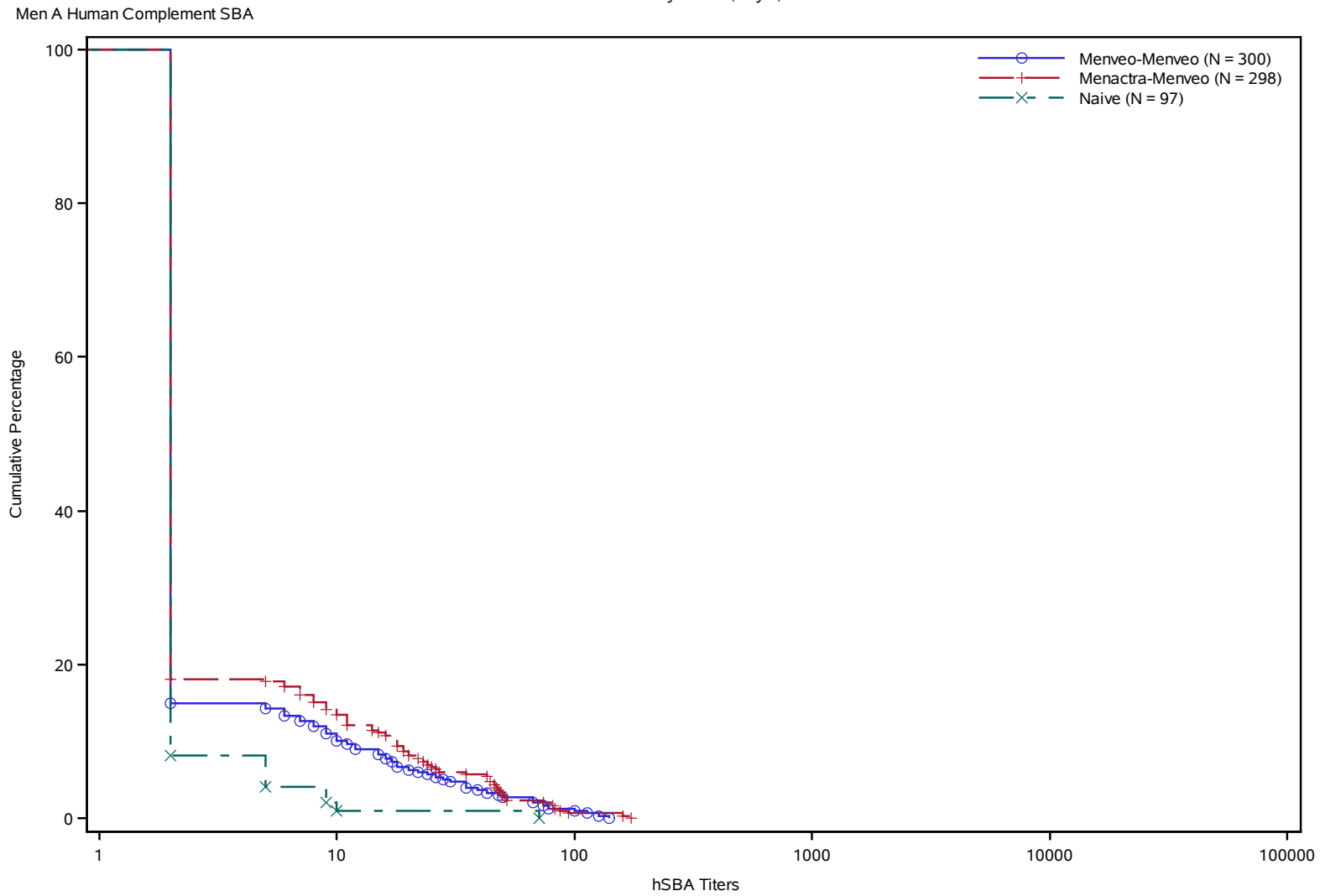
PPD

Figure 14.2.2.1.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Per Protocol Set (Day 29)



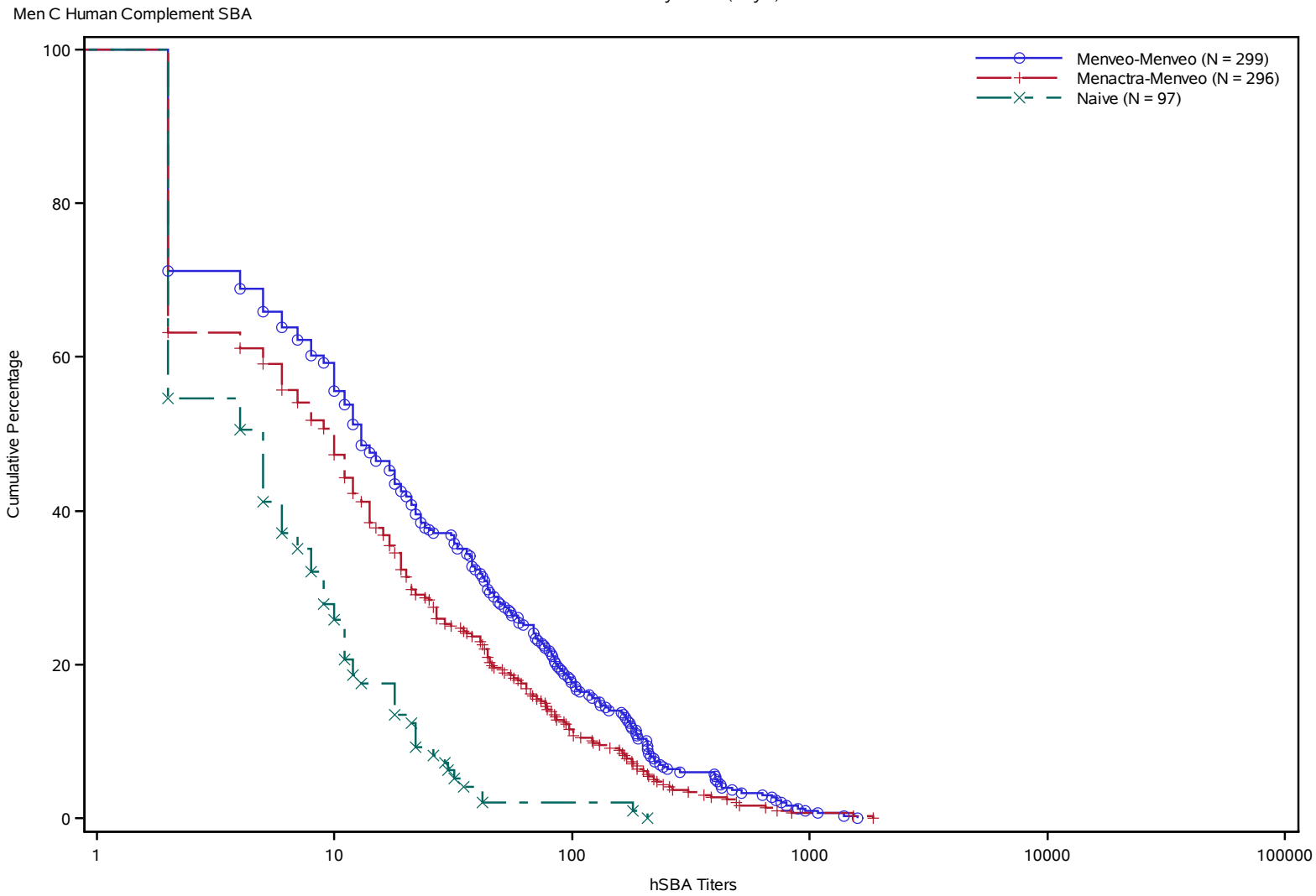
PPD

Figure 14.2.2.2.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 1)



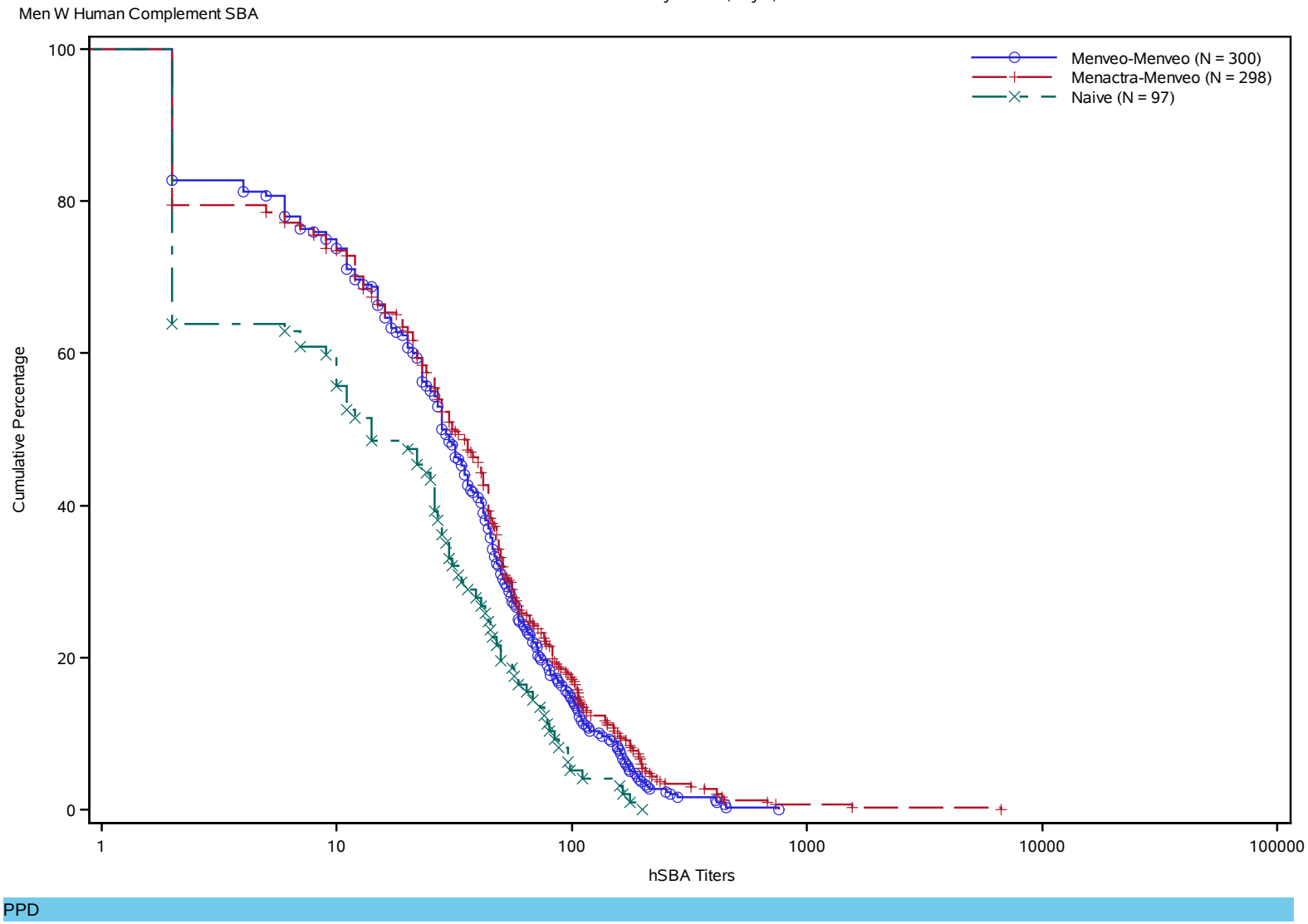
PPD

Figure 14.2.2.2.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 1)



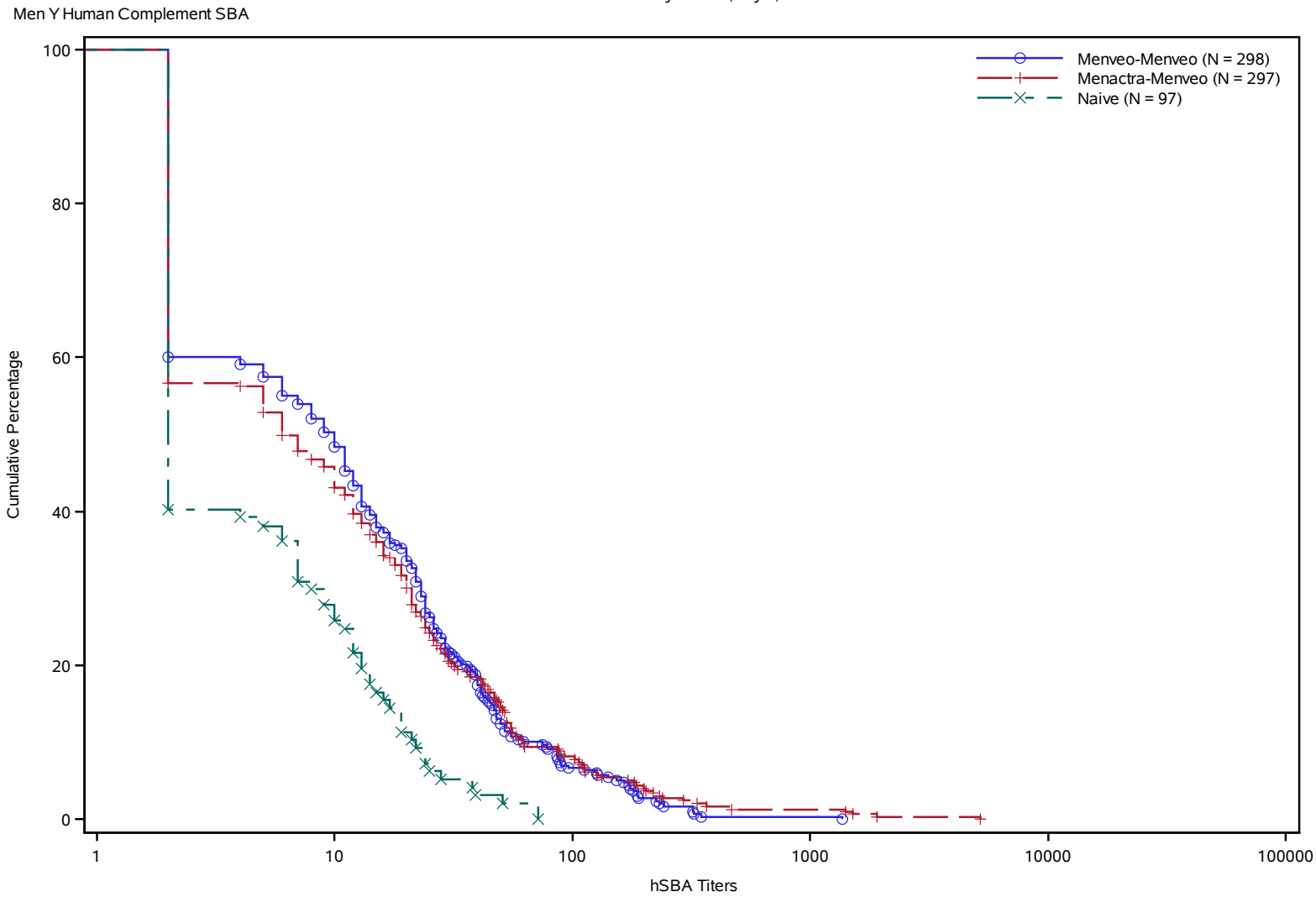
PPD

Figure 14.2.2.2.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 1)



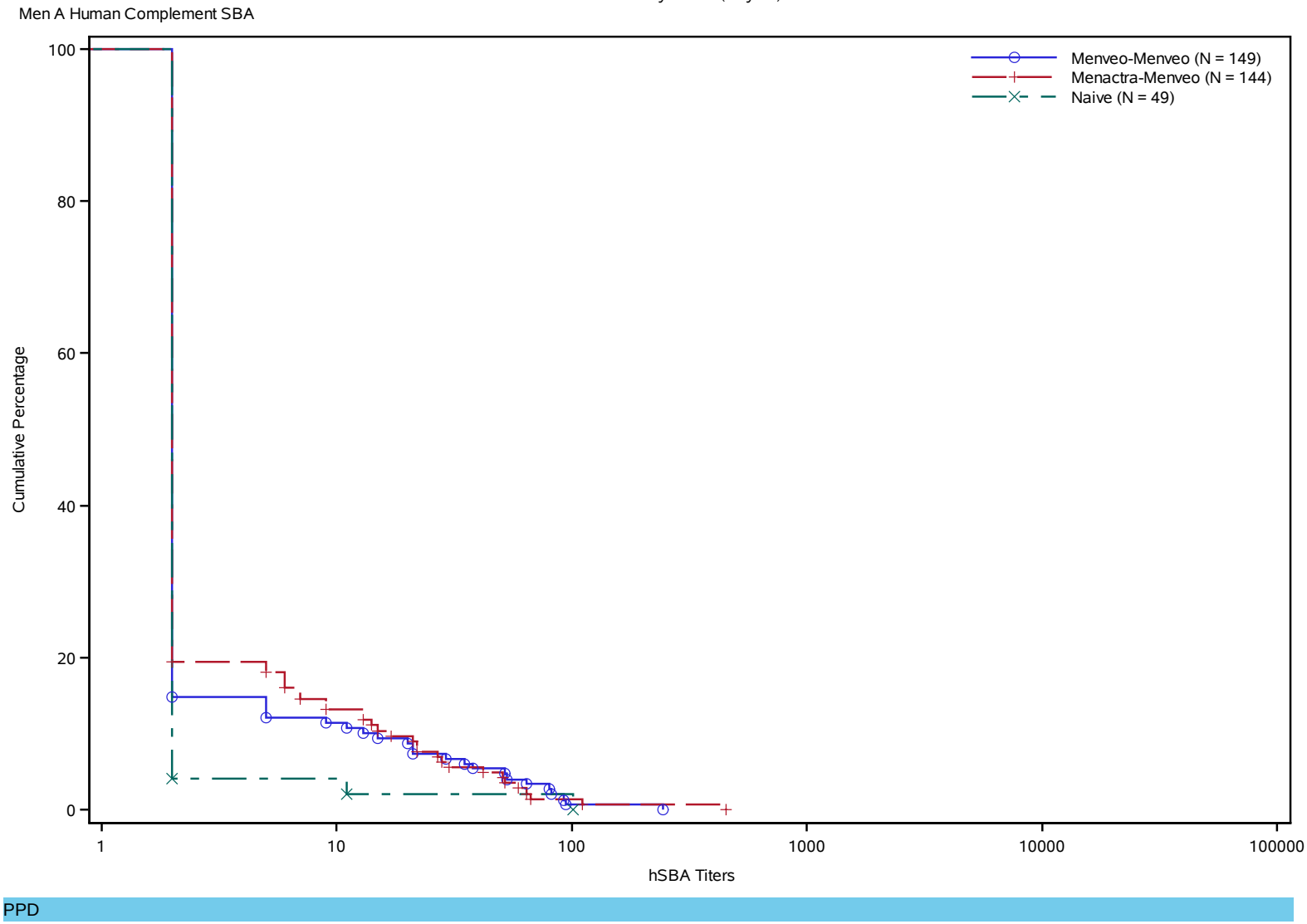
PPD

Figure 14.2.2.2.1
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 1 (pre-vaccination)
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 1)



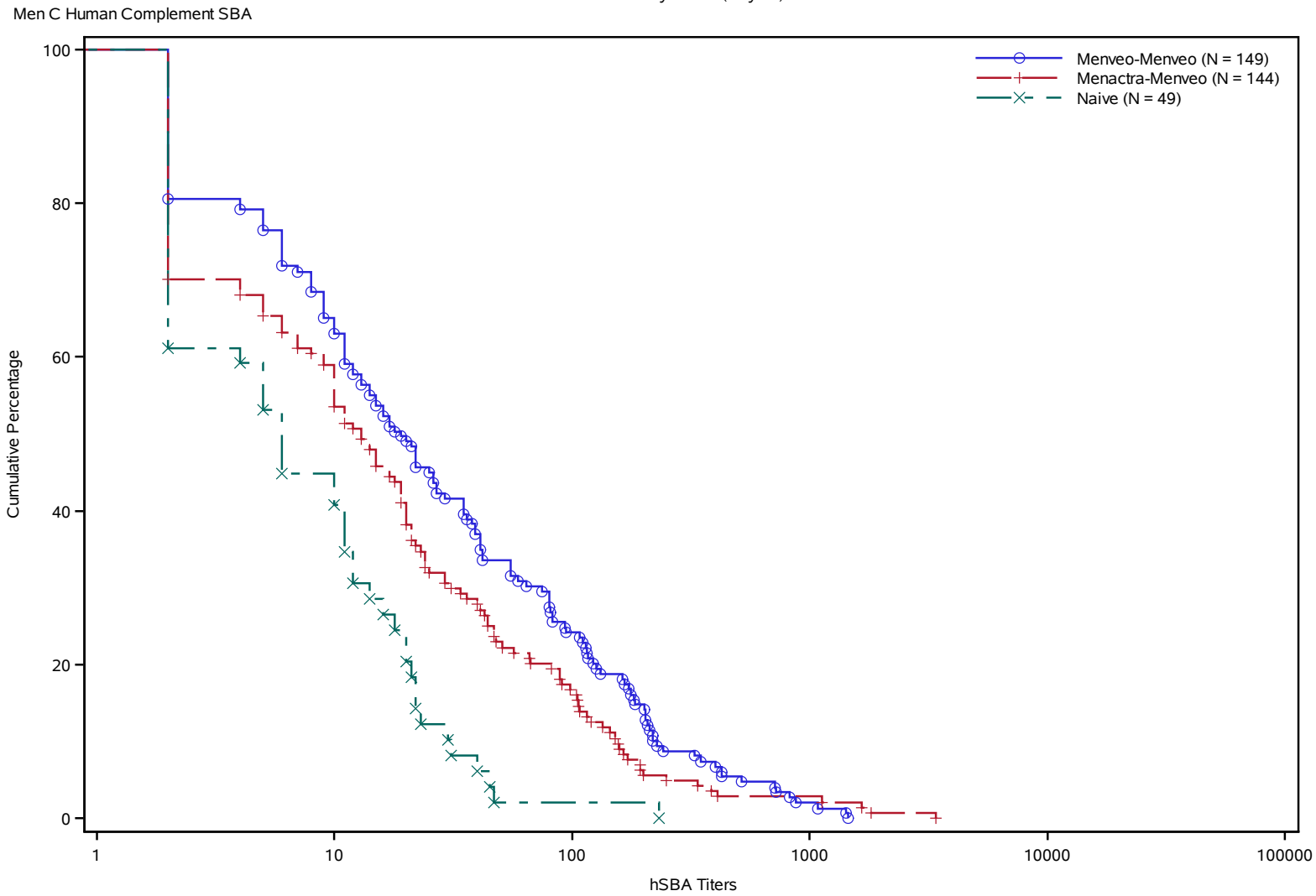
PPD

Figure 14.2.2.2.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



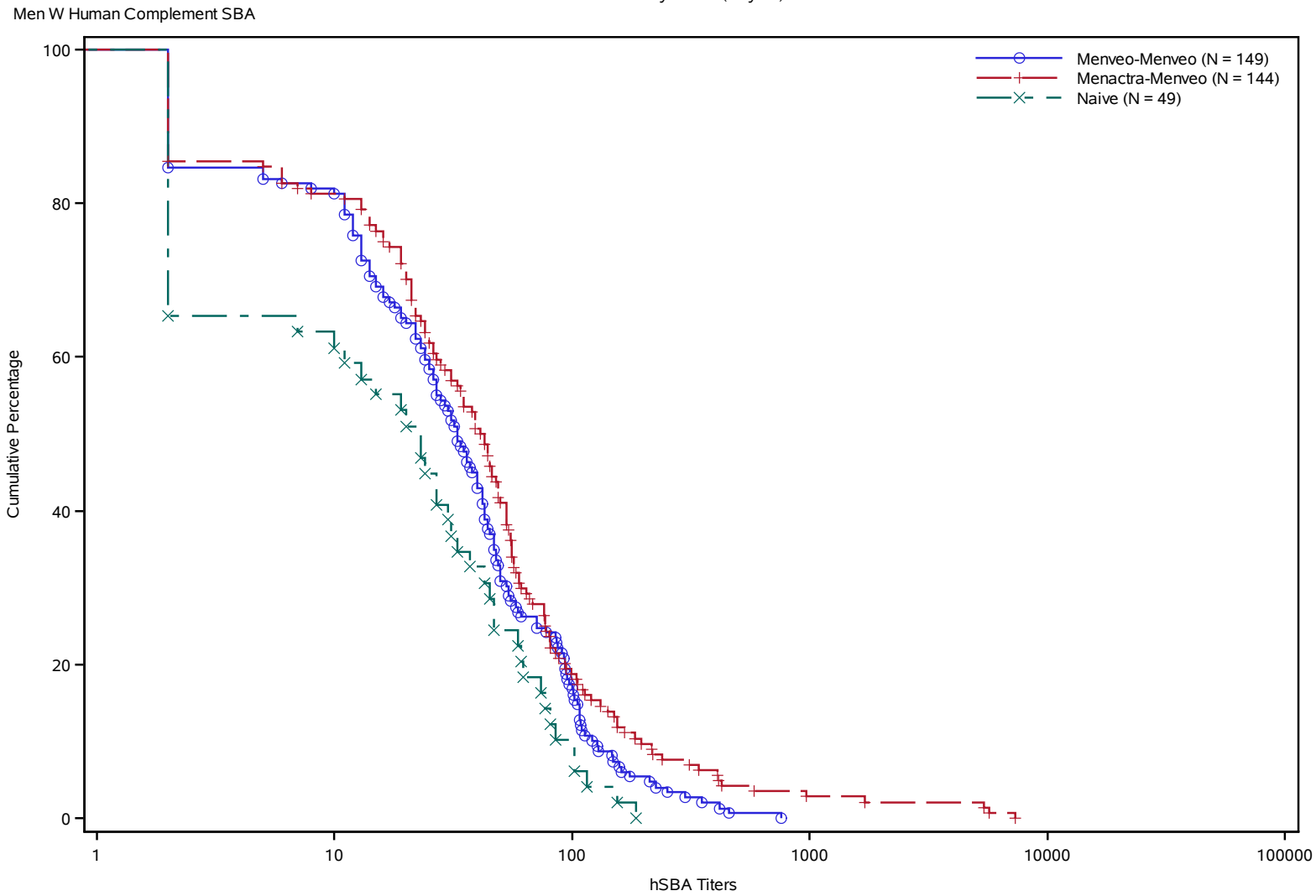
PPD

Figure 14.2.2.2.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



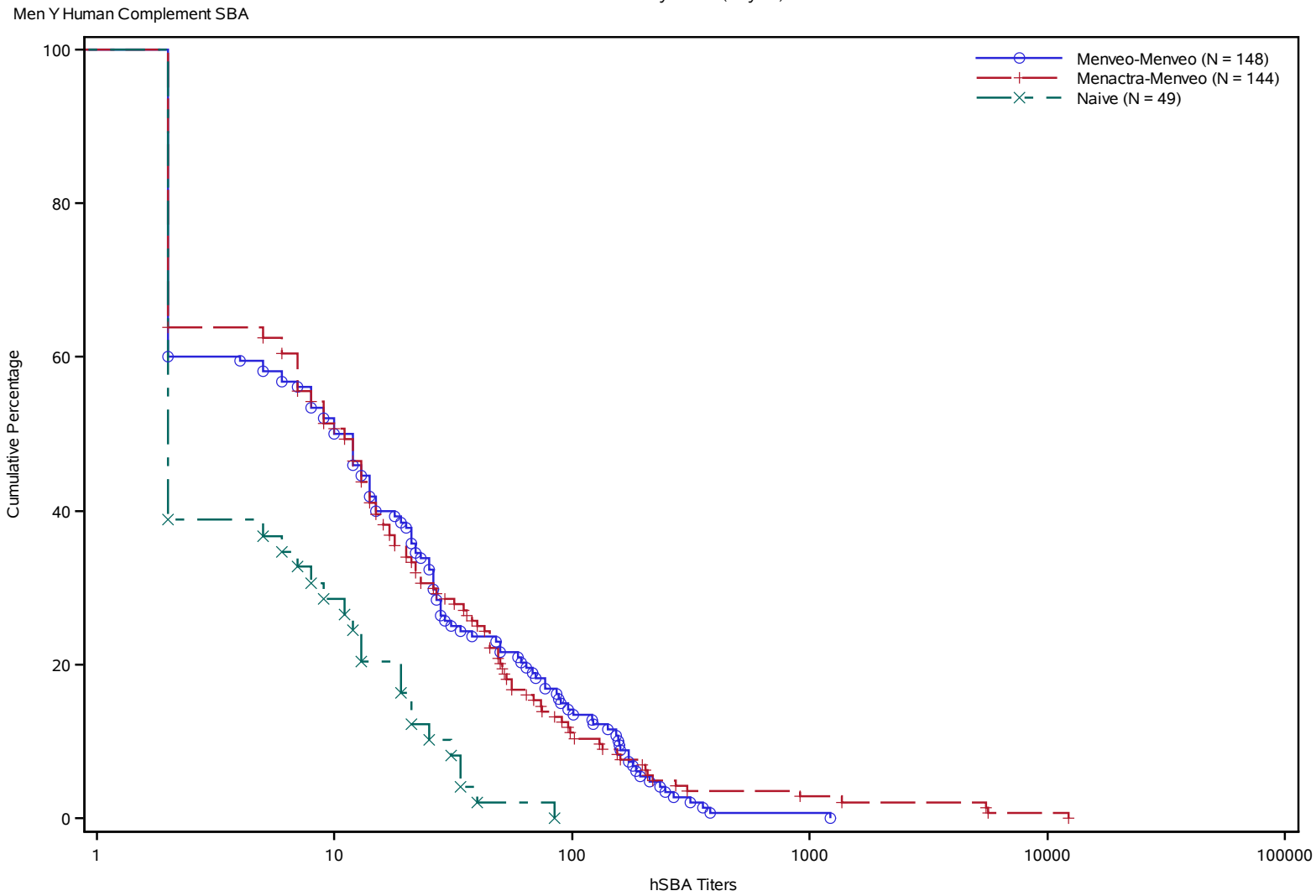
PPD

Figure 14.2.2.2.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



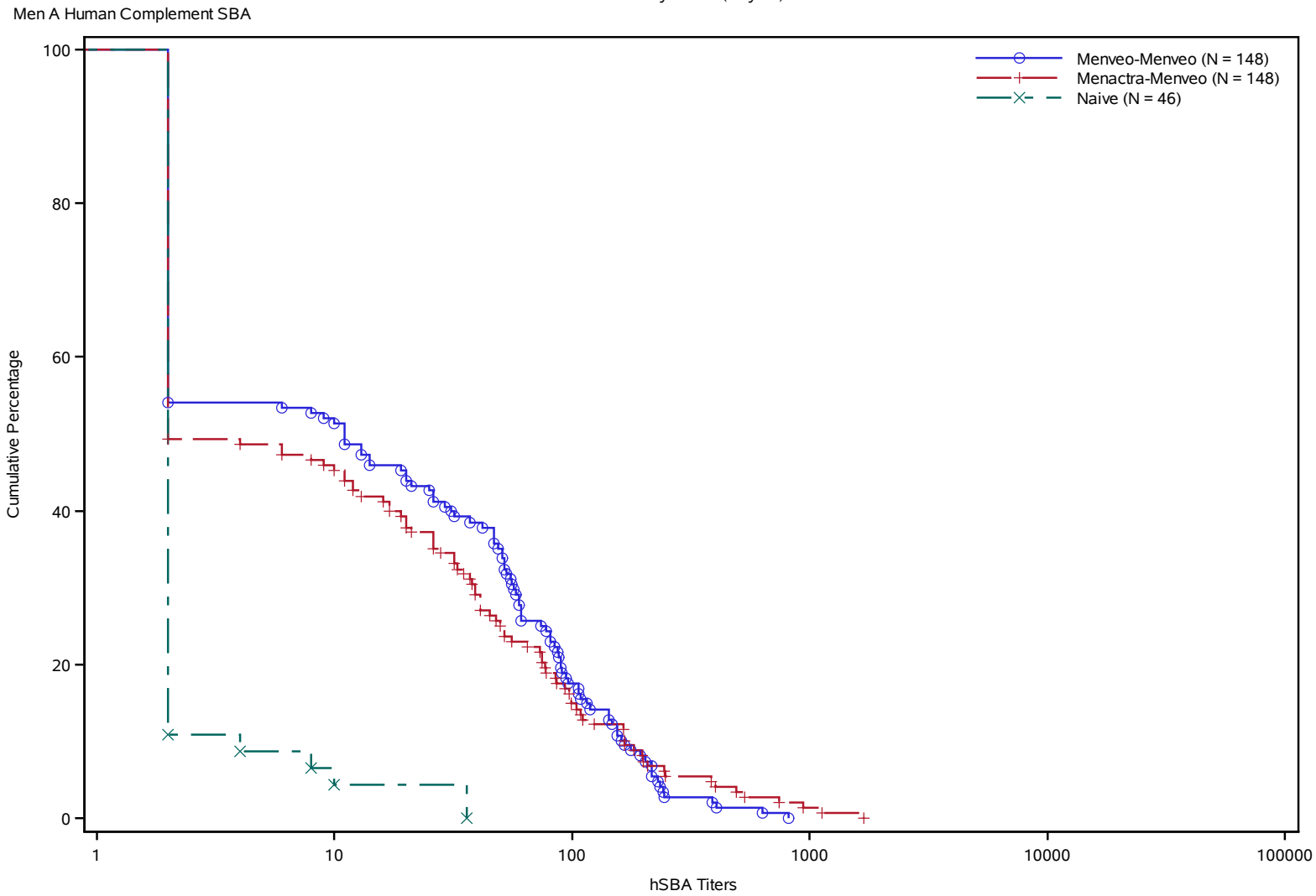
PPD

Figure 14.2.2.2.2
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 4 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



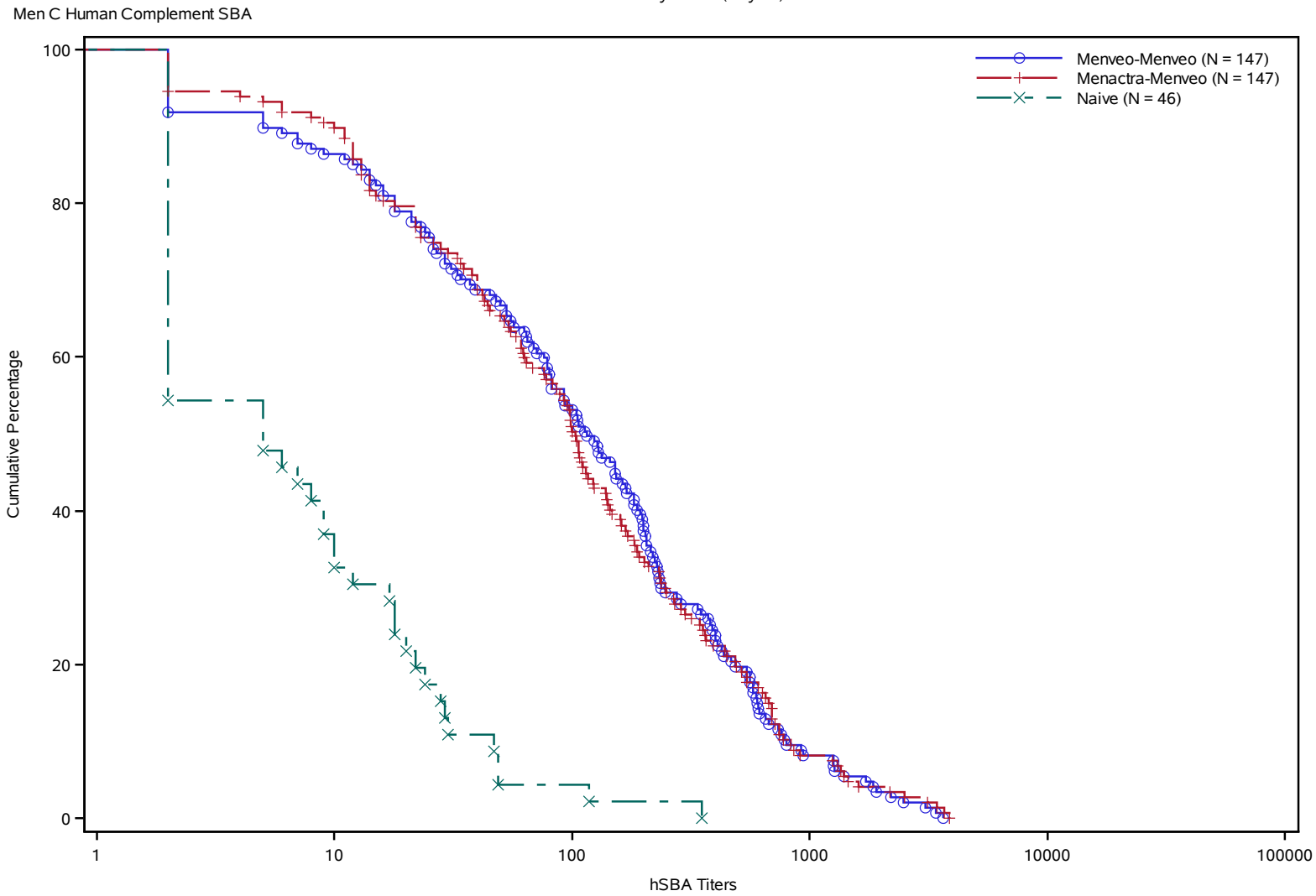
PPD

Figure 14.2.2.2.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



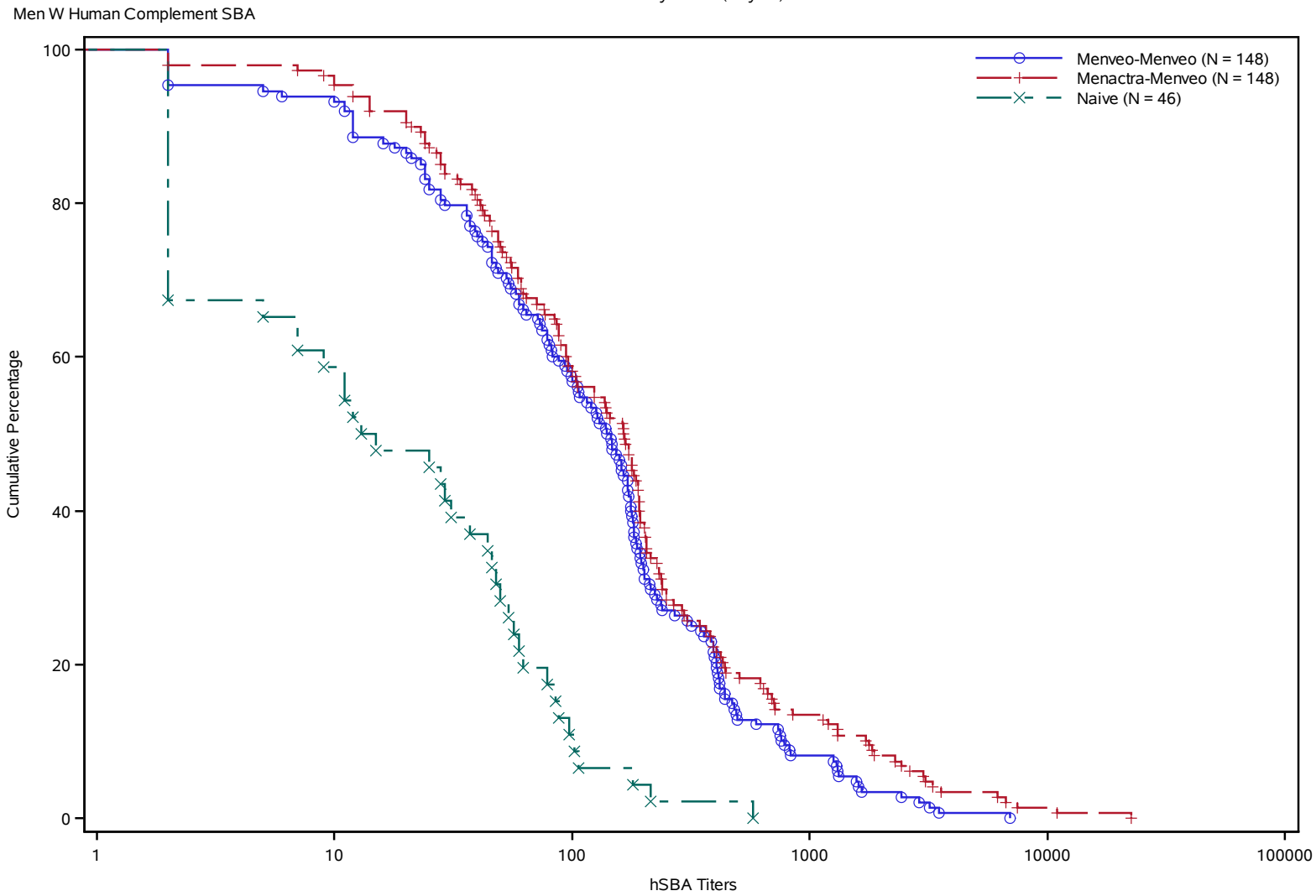
PPD

Figure 14.2.2.2.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



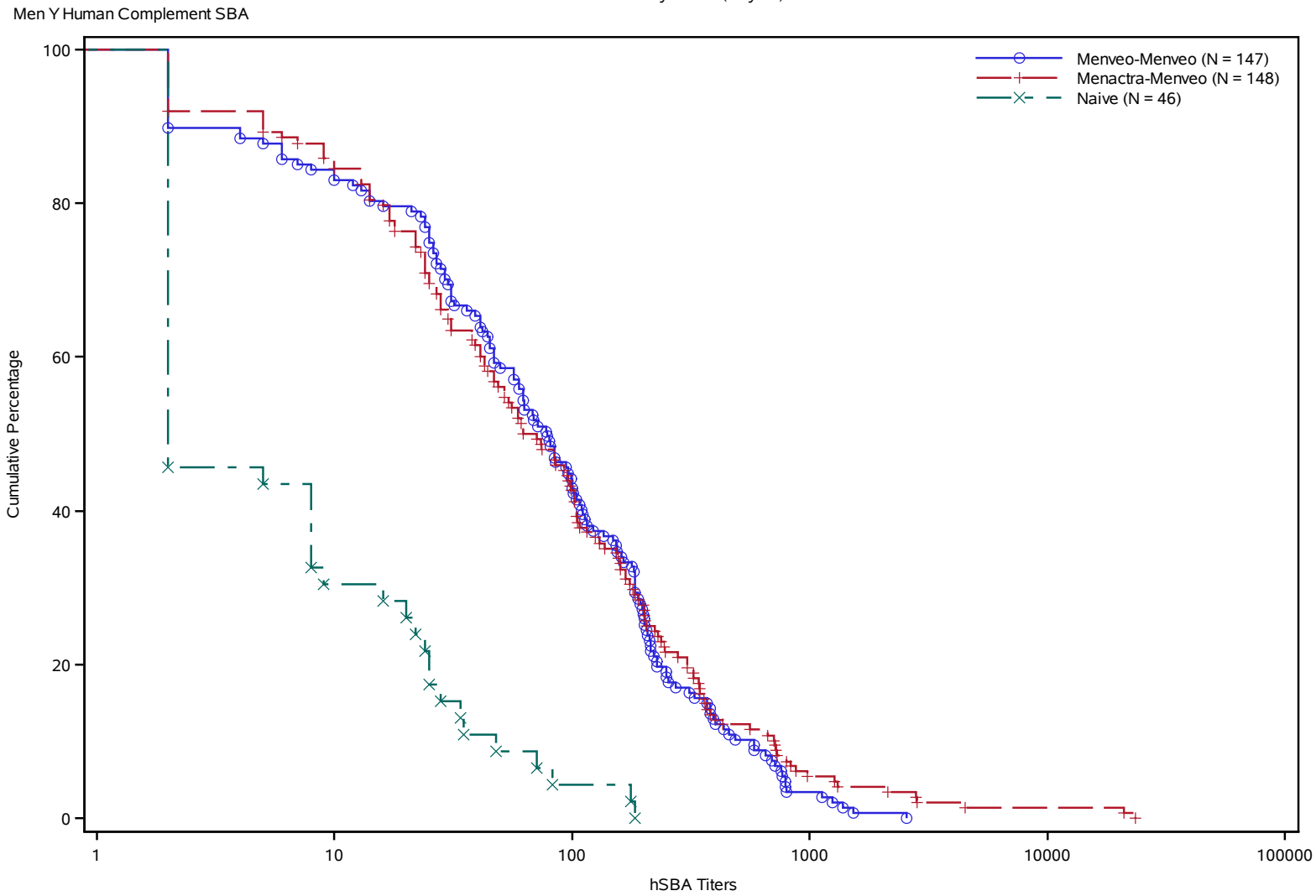
PPD

Figure 14.2.2.2.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



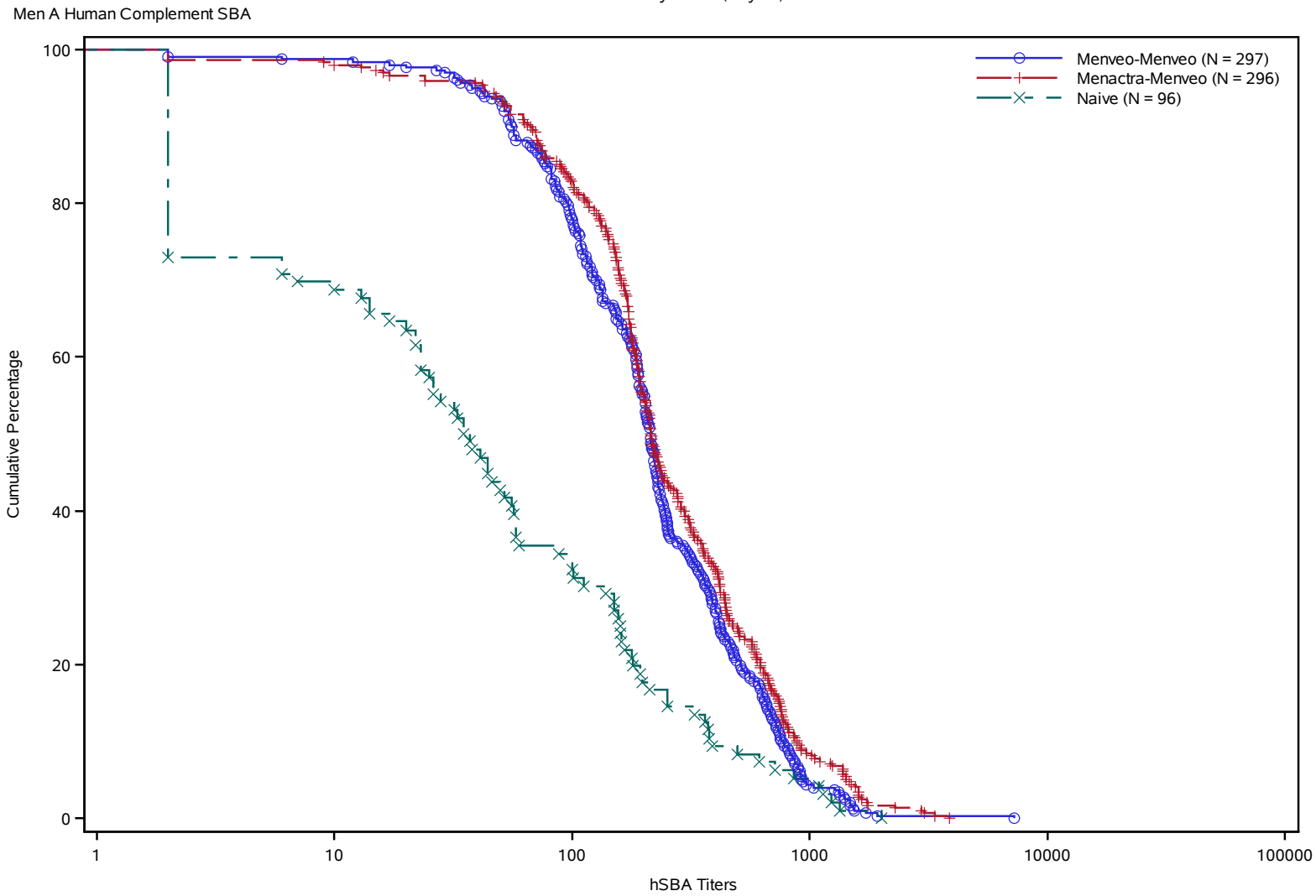
PPD

Figure 14.2.2.2.3
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 6 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



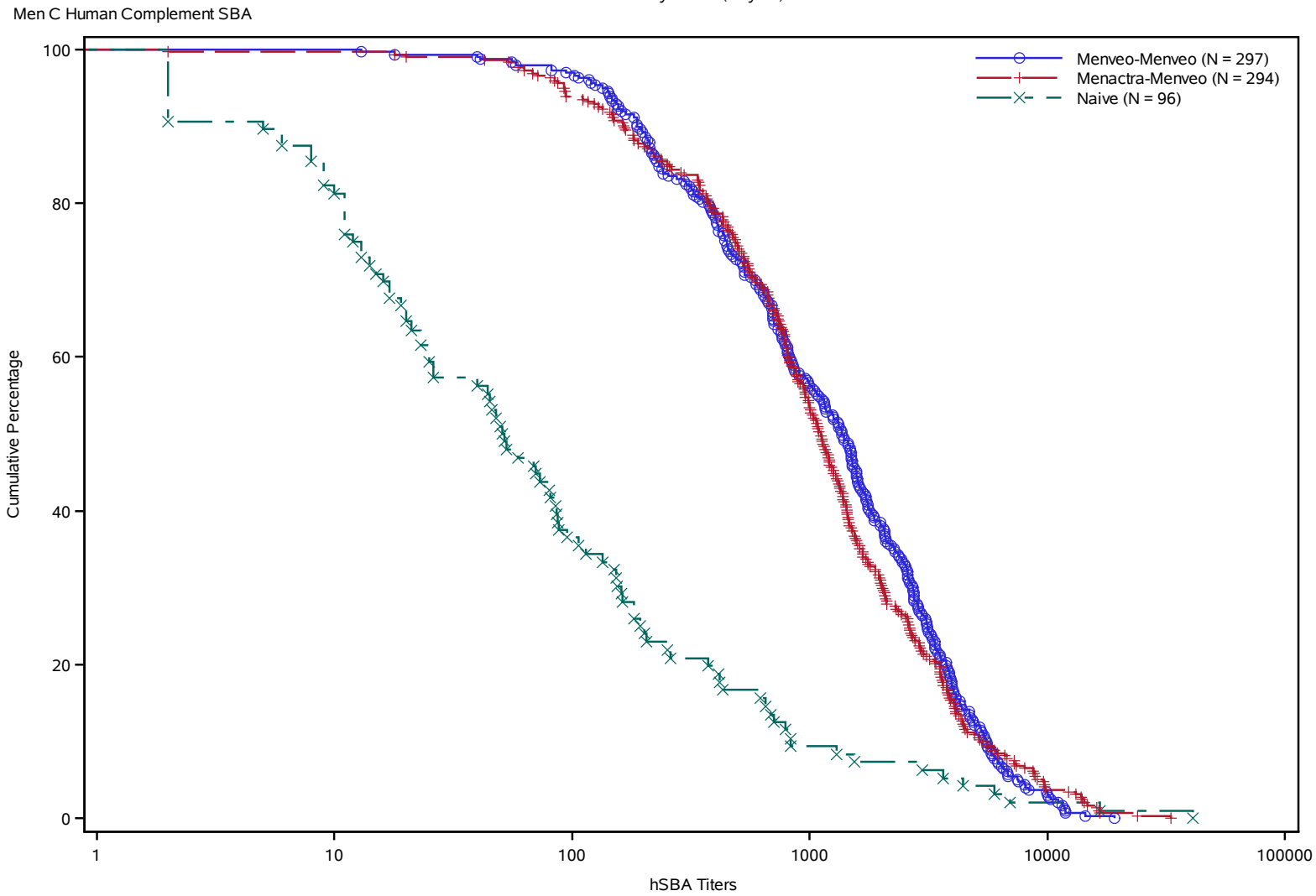
PPD

Figure 14.2.2.2.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



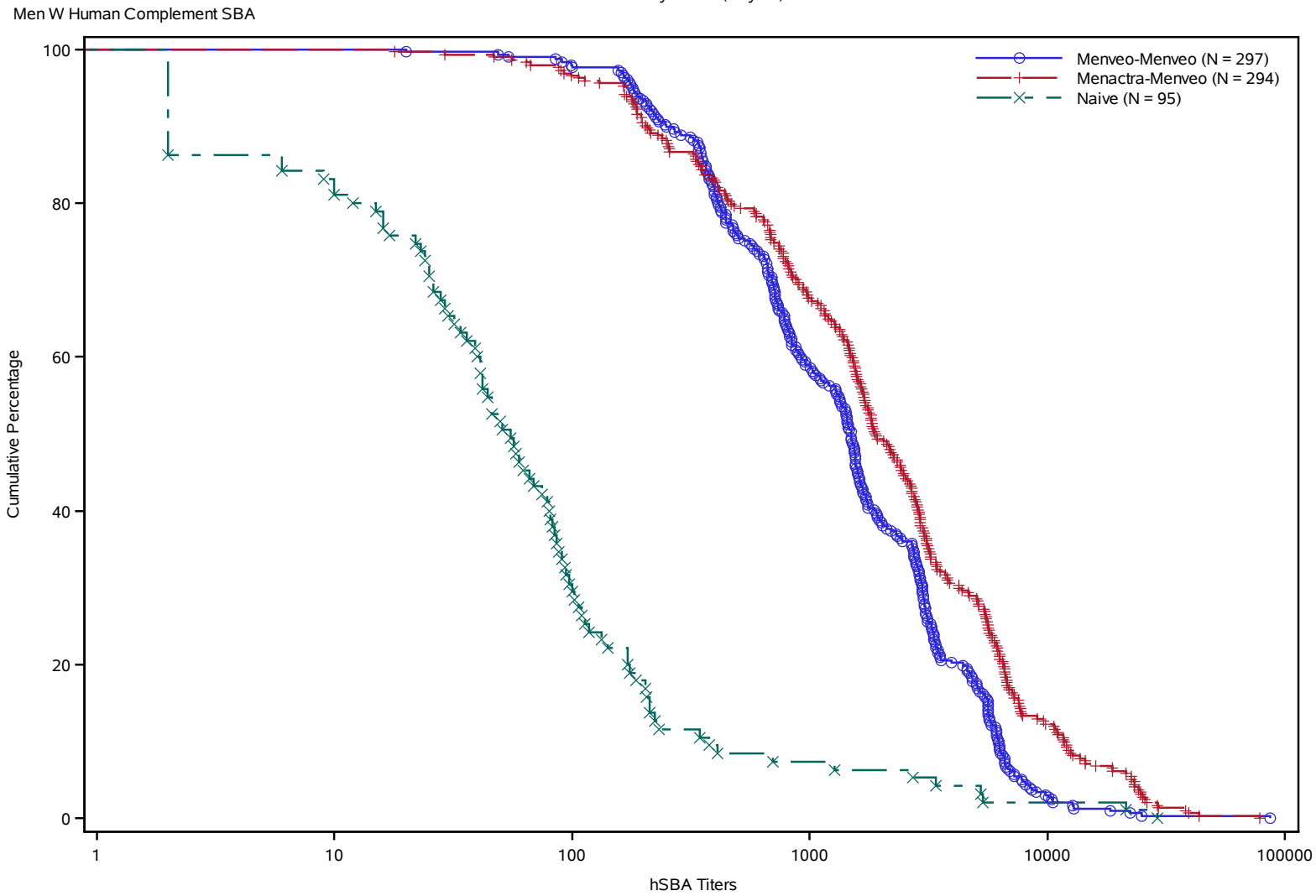
PPD

Figure 14.2.2.2.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



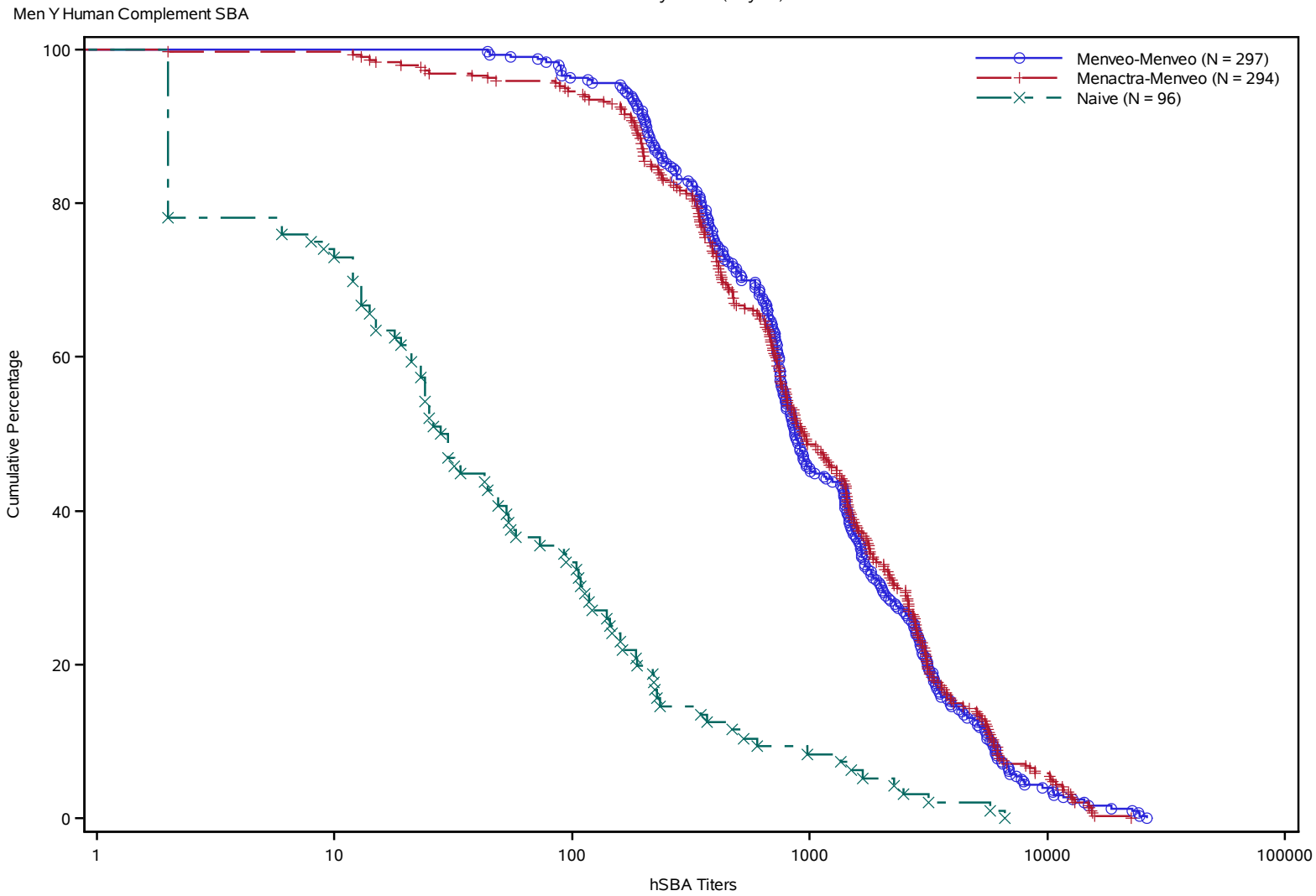
PPD

Figure 14.2.2.2.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



PPD

Figure 14.2.2.2.4
Reverse Cumulative Distributions Curves of hSBA Titers against N. Meningitidis serogroups A, C, W and Y at Day 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo and Naive subjects
Full Analysis Set (Day 29)



PPD

14.3 Safety Data

14.3.1 Displays of Adverse Events

Table 14.3.1.1
Subjects with at Least one Solicited Adverse Event, Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Adverse Event		Menveo-Menveo (N=296)	Menactra-Menveo (N=296)	Pooled Menveo/ Menactra-Menveo (N=592)	Naive (N=97)
Any	Any	202 (68%)	180 (61%)	382 (65%)	53 (55%)
	None	94 (32%)	116 (39%)	210 (35%)	44 (45%)
Local	Any	119 (40%)	97 (33%)	216 (36%)	41 (42%)
	None	173 (58%)	199 (67%)	372 (63%)	56 (58%)
	Missing	4 (1%)	0	4 (1%)	0
Systemic	Any	162 (55%)	148 (50%)	310 (52%)	35 (36%)
	None	134 (45%)	148 (50%)	282 (48%)	62 (64%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	286	286	572	92
	None (0 - 24 mm)	271 (95%)	277 (97%)	548 (96%)	84 (91%)
	Any	15 (5%)	9 (3%)	24 (4%)	8 (9%)
	Mild (25 - 50 mm)	11 (4%)	3 (1%)	14 (2%)	7 (8%)
	Moderate (51 - 100 mm)	4 (1%)	6 (2%)	10 (2%)	1 (1%)
	Severe (> 100 mm)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	286	287	573	92
	None (0 - 24 mm)	274 (96%)	279 (97%)	553 (97%)	82 (89%)
	Any	12 (4%)	8 (3%)	20 (3%)	10 (11%)
	Mild (25 - 50 mm)	9 (3%)	5 (2%)	14 (2%)	5 (5%)
	Moderate (51 - 100 mm)	3 (1%)	3 (1%)	6 (1%)	3 (3%)
	Severe (> 100 mm)	0	0	0	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	292	296	588	97
	Any	114 (39%)	96 (32%)	210 (36%)	40 (41%)
	Mild	92 (32%)	70 (24%)	162 (28%)	31 (32%)
	Moderate	19 (7%)	18 (6%)	37 (6%)	7 (7%)
	Severe	3 (1%)	8 (3%)	11 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	294	588	97
	Any	48 (16%)	44 (15%)	92 (16%)	13 (13%)
	Mild	29 (10%)	26 (9%)	55 (9%)	10 (10%)
	Moderate	17 (6%)	14 (5%)	31 (5%)	1 (1%)
	Severe	2 (1%)	4 (1%)	6 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	295	296	591	97
	Any	113 (38%)	110 (37%)	223 (38%)	19 (20%)
	Mild	74 (25%)	62 (21%)	136 (23%)	12 (12%)
	Moderate	32 (11%)	36 (12%)	68 (12%)	5 (5%)
	Severe	7 (2%)	12 (4%)	19 (3%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	296	590	97
	Any	55 (19%)	54 (18%)	109 (18%)	15 (15%)
	Mild	39 (13%)	32 (11%)	71 (12%)	11 (11%)
	Moderate	10 (3%)	17 (6%)	27 (5%)	2 (2%)
	Severe	6 (2%)	5 (2%)	11 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	96
	Any	44 (15%)	38 (13%)	82 (14%)	13 (14%)
	Mild	28 (10%)	28 (9%)	56 (10%)	10 (10%)
	Moderate	13 (4%)	7 (2%)	20 (3%)	1 (1%)
	Severe	3 (1%)	3 (1%)	6 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	97
	Any	100 (34%)	82 (28%)	182 (31%)	21 (22%)
	Mild	69 (23%)	45 (15%)	114 (19%)	15 (15%)
	Moderate	24 (8%)	23 (8%)	47 (8%)	4 (4%)
	Severe	7 (2%)	14 (5%)	21 (4%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	296	296	592	97
	Yes	2 (1%)	5 (2%)	7 (1%)	0
	No	294 (99%)	291 (98%)	585 (99%)	97 (100%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	97
	Any	34 (12%)	35 (12%)	69 (12%)	10 (10%)
	Mild	25 (9%)	23 (8%)	48 (8%)	9 (9%)
	Moderate	7 (2%)	12 (4%)	19 (3%)	0
	Severe	2 (1%)	0	2 (< 1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss of Appetite

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	296	590	97
	Any	37 (13%)	46 (16%)	83 (14%)	6 (6%)
	Mild	26 (9%)	30 (10%)	56 (9%)	4 (4%)
	Moderate	7 (2%)	14 (5%)	21 (4%)	0
	Severe	4 (1%)	2 (1%)	6 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	96
	Yes	13 (4%)	15 (5%)	28 (5%)	5 (5%)
	No	281 (96%)	280 (95%)	561 (95%)	91 (95%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	293	295	588	96
	Yes	18 (6%)	24 (8%)	42 (7%)	10 (10%)
	No	275 (94%)	271 (92%)	546 (93%)	86 (90%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	299	295	594	94
	None (0 - 24 mm)	299 (100%)	295 (100%)	594 (100%)	94 (100%)
	Any	0	0	0	0
	Mild (25 - 50 mm)	0	0	0	0
	Moderate (51 - 100 mm)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	299	295	594	94
	None (0 - 24 mm)	298 (>99%)	294 (>99%)	592 (>99%)	94 (100%)
	Any	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
	Mild (25 - 50 mm)	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
	Moderate (51 - 100 mm)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	9 (3%)	22 (7%)	31 (5%)	6 (6%)
	Mild	8 (3%)	21 (7%)	29 (5%)	6 (6%)
	Moderate	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	0	0	0	0
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	3 (1%)	2 (1%)	5 (1%)	0
	Mild	3 (1%)	2 (1%)	5 (1%)	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	1 (< 1%)	0	1 (< 1%)	0
	Mild	1 (< 1%)	0	1 (< 1%)	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	0	0	0	0
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	2 (1%)	1 (< 1%)	3 (< 1%)	0
	Mild	2 (1%)	1 (< 1%)	3 (< 1%)	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Yes	0	0	0	0
	No	301 (100%)	300 (100%)	601 (100%)	100 (100%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	1 (< 1%)	3 (1%)	4 (1%)	0
	Mild	1 (< 1%)	3 (1%)	4 (1%)	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss of Appetite

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Any	0	0	0	0
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Yes	0	0	0	0
	No	301 (100%)	300 (100%)	601 (100%)	100 (100%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.1
Subjects with Solicited Adverse Events, Maximum Event Severity Reported Within 30 Minutes After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	301	300	601	100
	Yes	0	0	0	0
	No	301 (100%)	300 (100%)	601 (100%)	100 (100%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	286	285	571	92
	None (0 - 24 mm)	271 (95%)	277 (97%)	548 (96%)	85 (92%)
	Any	15 (5%)	8 (3%)	23 (4%)	7 (8%)
	Mild (25 - 50 mm)	12 (4%)	2 (1%)	14 (2%)	6 (7%)
	Moderate (51 - 100 mm)	3 (1%)	6 (2%)	9 (2%)	1 (1%)
	Severe (> 100 mm)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	286	286	572	92
	None (0 - 24 mm)	274 (96%)	279 (98%)	553 (97%)	84 (91%)
	Any	12 (4%)	7 (2%)	19 (3%)	8 (9%)
	Mild (25 - 50 mm)	9 (3%)	5 (2%)	14 (2%)	6 (7%)
	Moderate (51 - 100 mm)	3 (1%)	2 (1%)	5 (1%)	2 (2%)
	Severe (> 100 mm)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	292	296	588	97
	Any	112 (38%)	95 (32%)	207 (35%)	40 (41%)
	Mild	91 (31%)	70 (24%)	161 (27%)	32 (33%)
	Moderate	19 (7%)	18 (6%)	37 (6%)	6 (6%)
	Severe	2 (1%)	7 (2%)	9 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	294	588	97
	Any	37 (13%)	34 (12%)	71 (12%)	13 (13%)
	Mild	23 (8%)	21 (7%)	44 (7%)	10 (10%)
	Moderate	12 (4%)	11 (4%)	23 (4%)	1 (1%)
	Severe	2 (1%)	2 (1%)	4 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	296	590	97
	Any	105 (36%)	102 (34%)	207 (35%)	18 (19%)
	Mild	72 (24%)	64 (22%)	136 (23%)	11 (11%)
	Moderate	28 (10%)	31 (10%)	59 (10%)	5 (5%)
	Severe	5 (2%)	7 (2%)	12 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	296	590	97
	Any	46 (16%)	43 (15%)	89 (15%)	15 (15%)
	Mild	34 (12%)	26 (9%)	60 (10%)	11 (11%)
	Moderate	10 (3%)	14 (5%)	24 (4%)	2 (2%)
	Severe	2 (1%)	3 (1%)	5 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	96
	Any	34 (12%)	27 (9%)	61 (10%)	13 (14%)
	Mild	23 (8%)	19 (6%)	42 (7%)	10 (10%)
	Moderate	10 (3%)	5 (2%)	15 (3%)	1 (1%)
	Severe	1 (< 1%)	3 (1%)	4 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	97
	Any	84 (29%)	67 (23%)	151 (26%)	20 (21%)
	Mild	61 (21%)	41 (14%)	102 (17%)	14 (14%)
	Moderate	19 (6%)	18 (6%)	37 (6%)	4 (4%)
	Severe	4 (1%)	8 (3%)	12 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	296	296	592	96
	Yes	2 (1%)	1 (< 1%)	3 (1%)	0
	No	294 (99%)	295 (>99%)	589 (99%)	96 (100%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	97
	Any	26 (9%)	29 (10%)	55 (9%)	9 (9%)
	Mild	20 (7%)	21 (7%)	41 (7%)	8 (8%)
	Moderate	6 (2%)	8 (3%)	14 (2%)	0
	Severe	0	0	0	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss of Appetite

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	296	590	97
	Any	29 (10%)	35 (12%)	64 (11%)	4 (4%)
	Mild	21 (7%)	25 (8%)	46 (8%)	2 (2%)
	Moderate	6 (2%)	10 (3%)	16 (3%)	0
	Severe	2 (1%)	0	2 (< 1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	293	295	588	96
	Yes	10 (3%)	10 (3%)	20 (3%)	5 (5%)
	No	283 (97%)	285 (97%)	568 (97%)	91 (95%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.2
Subjects with Solicited Adverse Events, Maximum Event Severity Reported from 6 Hours through Day 3 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	293	295	588	96
	Yes	10 (3%)	14 (5%)	24 (4%)	10 (10%)
	No	283 (97%)	281 (95%)	564 (96%)	86 (90%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3

Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	286	285	571	92
	None (0 - 24 mm)	282 (99%)	283 (99%)	565 (99%)	87 (95%)
	Any	4 (1%)	2 (1%)	6 (1%)	5 (5%)
	Mild (25 - 50 mm)	3 (1%)	2 (1%)	5 (1%)	5 (5%)
	Moderate (51 - 100 mm)	1 (< 1%)	0	1 (< 1%)	0
	Severe (> 100 mm)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3

Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	286	285	571	91
	None (0 - 24 mm)	281 (98%)	282 (99%)	563 (99%)	85 (93%)
	Any	5 (2%)	3 (1%)	8 (1%)	6 (7%)
	Mild (25 - 50 mm)	4 (1%)	2 (1%)	6 (1%)	3 (3%)
	Moderate (51 - 100 mm)	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
	Severe (> 100 mm)	0	0	0	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	292	296	588	97
	Any	22 (8%)	20 (7%)	42 (7%)	15 (15%)
	Mild	18 (6%)	17 (6%)	35 (6%)	12 (12%)
	Moderate	3 (1%)	1 (< 1%)	4 (1%)	1 (1%)
	Severe	1 (< 1%)	2 (1%)	3 (1%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	294	588	97
	Any	22 (7%)	23 (8%)	45 (8%)	3 (3%)
	Mild	15 (5%)	13 (4%)	28 (5%)	1 (1%)
	Moderate	7 (2%)	8 (3%)	15 (3%)	1 (1%)
	Severe	0	2 (1%)	2 (< 1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	295	295	590	97
	Any	48 (16%)	56 (19%)	104 (18%)	6 (6%)
	Mild	35 (12%)	35 (12%)	70 (12%)	4 (4%)
	Moderate	11 (4%)	15 (5%)	26 (4%)	1 (1%)
	Severe	2 (1%)	6 (2%)	8 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	97
	Any	20 (7%)	23 (8%)	43 (7%)	6 (6%)
	Mild	14 (5%)	14 (5%)	28 (5%)	4 (4%)
	Moderate	2 (1%)	7 (2%)	9 (2%)	1 (1%)
	Severe	4 (1%)	2 (1%)	6 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	96
	Any	23 (8%)	19 (6%)	42 (7%)	6 (6%)
	Mild	15 (5%)	16 (5%)	31 (5%)	4 (4%)
	Moderate	6 (2%)	3 (1%)	9 (2%)	1 (1%)
	Severe	2 (1%)	0	2 (< 1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	294	588	97
	Any	54 (18%)	50 (17%)	104 (18%)	7 (7%)
	Mild	37 (13%)	31 (11%)	68 (12%)	4 (4%)
	Moderate	14 (5%)	12 (4%)	26 (4%)	1 (1%)
	Severe	3 (1%)	7 (2%)	10 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	296	296	592	97
	Yes	0	4 (1%)	4 (1%)	0
	No	296 (100%)	292 (99%)	588 (99%)	97 (100%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	294	588	97
	Any	12 (4%)	14 (5%)	26 (4%)	2 (2%)
	Mild	8 (3%)	9 (3%)	17 (3%)	1 (1%)
	Moderate	2 (1%)	5 (2%)	7 (1%)	0
	Severe	2 (1%)	0	2 (< 1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss of Appetite

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	97
	Any	23 (8%)	23 (8%)	46 (8%)	4 (4%)
	Mild	17 (6%)	16 (5%)	33 (6%)	2 (2%)
	Moderate	4 (1%)	5 (2%)	9 (2%)	1 (1%)
	Severe	2 (1%)	2 (1%)	4 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	294	295	589	96
	Yes	5 (2%)	7 (2%)	12 (2%)	1 (1%)
	No	289 (98%)	288 (98%)	577 (98%)	95 (99%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.2.3
Subjects with Solicited Adverse Events, Maximum Event Severity, Reported from Day 4 through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever

Vaccination Number		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
1	n	293	295	588	96
	Yes	11 (4%)	14 (5%)	25 (4%)	2 (2%)
	No	282 (96%)	281 (95%)	563 (96%)	94 (98%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.3
Subjects with Solicited Adverse Events Ongoing After 7 Days After Vaccination
Solicited Safety Set

Vaccination: 1

	Adverse Event		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
Local	Erythema	n	3	3	6	4
		No	2 (67%)	3 (100%)	5 (83%)	1 (25%)
		Yes	1 (33%)	0	1 (17%)	3 (75%)
	Induration	n	1	5	6	2
		No	1 (100%)	4 (80%)	5 (83%)	1 (50%)
		Yes	0	1 (20%)	1 (17%)	1 (50%)
	Pain	n	2	3	5	2
		No	1 (50%)	3 (100%)	4 (80%)	2 (100%)
		Yes	1 (50%)	0	1 (20%)	0
Systemic	Arthralgia	n	5	8	13	3
		No	4 (80%)	5 (63%)	9 (69%)	3 (100%)
		Yes	1 (20%)	3 (38%)	4 (31%)	0
	Chills	n	4	6	10	1
		No	4 (100%)	4 (67%)	8 (80%)	1 (100%)
		Yes	0	2 (33%)	2 (20%)	0
	Fatigue	n	17	18	35	2
		No	12 (71%)	9 (50%)	21 (60%)	2 (100%)
		Yes	5 (29%)	9 (50%)	14 (40%)	0
	Headache	n	15	15	30	4
		No	10 (67%)	9 (60%)	19 (63%)	3 (75%)
		Yes	5 (33%)	6 (40%)	11 (37%)	1 (25%)
	Loss Of Appetite	n	8	11	19	2
		No	7 (88%)	9 (82%)	16 (84%)	2 (100%)
		Yes	1 (13%)	2 (18%)	3 (16%)	0

PPD

Table 14.3.1.3
Subjects with Solicited Adverse Events Ongoing After 7 Days After Vaccination
Solicited Safety Set

Vaccination: 1

Adverse Event		Menveo-Menveo	Menactra-Menveo	Pooled Menveo/ Menactra-Menveo	Naive
Myalgia	n	6	9	15	2
	No	5 (83%)	5 (56%)	10 (67%)	2 (100%)
	Yes	1 (17%)	4 (44%)	5 (33%)	0
Nausea	n	8	7	15	1
	No	6 (75%)	7 (100%)	13 (87%)	1 (100%)
	Yes	2 (25%)	0	2 (13%)	0
Fever	n	0	1	1	0
	No	0	0	0	0
	Yes	0	1 (100%)	1 (100%)	0

PPD

Table 14.3.1.4
Body Temperature Measurements - Maximum Event Severity From 6 Hours Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Any

	Menveo-Menveo (N=296)	Menactra-Menveo (N=296)	Naive (N=97)
Body Temperature (C)			
<36.0 C	2 (1%)	7 (2%)	0
36.0 - 36.4 C	68 (23%)	57 (19%)	16 (16%)
36.5 - 36.9 C	135 (46%)	141 (48%)	45 (46%)
37.0 - 37.4 C	83 (28%)	77 (26%)	33 (34%)
37.5 - 37.9 C	6 (2%)	9 (3%)	3 (3%)
38.0 - 38.4 C	1 (< 1%)	2 (1%)	0
38.5 - 38.9 C	1 (< 1%)	3 (1%)	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	2 (1%)	7 (2%)	0
36.0 - 36.9 C	203 (69%)	198 (67%)	61 (63%)
37.0 - 37.9 C	89 (30%)	86 (29%)	36 (37%)
38.0 - 38.9 C	2 (1%)	5 (2%)	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	294 (99%)	291 (98%)	97 (100%)
Yes	2 (1%)	5 (2%)	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4
Body Temperature Measurements - Maximum Event Severity From 6 Hours Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Axillary

	Menveo-Menveo (N=2)	Menactra-Menveo (N=15)	Naive (N=1)
Body Temperature (C)			
<36.0 C	0	3 (20%)	0
36.0 - 36.4 C	2 (100%)	8 (53%)	0
36.5 - 36.9 C	0	1 (7%)	0
37.0 - 37.4 C	0	3 (20%)	1 (100%)
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	3 (20%)	0
36.0 - 36.9 C	2 (100%)	9 (60%)	0
37.0 - 37.9 C	0	3 (20%)	1 (100%)
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	2 (100%)	15 (100%)	1 (100%)
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4
Body Temperature Measurements - Maximum Event Severity From 6 Hours Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Ear

	Menveo-Menveo (N=0)	Menactra-Menveo (N=3)	Naive (N=0)
Body Temperature (C)			
<36.0 C	0	0	0
36.0 - 36.4 C	0	0	0
36.5 - 36.9 C	0	2 (67%)	0
37.0 - 37.4 C	0	1 (33%)	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	0	0
36.0 - 36.9 C	0	2 (67%)	0
37.0 - 37.9 C	0	1 (33%)	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	0	3 (100%)	0
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4
Body Temperature Measurements - Maximum Event Severity From 6 Hours Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Oral

	Menveo-Menveo (N=294)	Menactra-Menveo (N=278)	Naive (N=96)
Body Temperature (C)			
<36.0 C	2 (1%)	4 (1%)	0
36.0 - 36.4 C	66 (22%)	50 (18%)	16 (17%)
36.5 - 36.9 C	135 (46%)	137 (49%)	45 (47%)
37.0 - 37.4 C	83 (28%)	73 (26%)	32 (33%)
37.5 - 37.9 C	6 (2%)	9 (3%)	3 (3%)
38.0 - 38.4 C	1 (< 1%)	2 (1%)	0
38.5 - 38.9 C	1 (< 1%)	3 (1%)	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	2 (1%)	4 (1%)	0
36.0 - 36.9 C	201 (68%)	187 (67%)	61 (64%)
37.0 - 37.9 C	89 (30%)	82 (29%)	35 (36%)
38.0 - 38.9 C	2 (1%)	5 (2%)	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	292 (99%)	273 (98%)	96 (100%)
Yes	2 (1%)	5 (2%)	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4
Body Temperature Measurements - Maximum Event Severity From 6 Hours Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Unknown

	Menveo-Menveo (N=1)	Menactra-Menveo (N=5)	Naive (N=0)
Body Temperature (C)			
<36.0 C	0	1 (20%)	0
36.0 - 36.4 C	1 (100%)	0	0
36.5 - 36.9 C	0	3 (60%)	0
37.0 - 37.4 C	0	1 (20%)	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	1 (20%)	0
36.0 - 36.9 C	1 (100%)	3 (60%)	0
37.0 - 37.9 C	0	1 (20%)	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	1 (100%)	5 (100%)	0
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.1
Body Temperature Measurements – Maximum Event Severity From 6 Hours Through Day 3 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Any

	Menveo-Menveo (N=296)	Menactra-Menveo (N=296)	Naive (N=96)
Body Temperature (C)			
<36.0 C	18 (6%)	12 (4%)	1 (1%)
36.0 - 36.4 C	101 (34%)	91 (31%)	27 (28%)
36.5 - 36.9 C	117 (40%)	141 (48%)	47 (49%)
37.0 - 37.4 C	56 (19%)	47 (16%)	19 (20%)
37.5 - 37.9 C	2 (1%)	4 (1%)	2 (2%)
38.0 - 38.4 C	1 (< 1%)	0	0
38.5 - 38.9 C	1 (< 1%)	1 (< 1%)	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	18 (6%)	12 (4%)	1 (1%)
36.0 - 36.9 C	218 (74%)	232 (78%)	74 (77%)
37.0 - 37.9 C	58 (20%)	51 (17%)	21 (22%)
38.0 - 38.9 C	2 (1%)	1 (< 1%)	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	294 (99%)	295 (>99%)	96 (100%)
Yes	2 (1%)	1 (< 1%)	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.1
Body Temperature Measurements – Maximum Event Severity From 6 Hours Through Day 3 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Axillary

	Menveo-Menveo (N=2)	Menactra-Menveo (N=15)	Naive (N=1)
Body Temperature (C)			
<36.0 C	0	3 (20%)	0
36.0 - 36.4 C	2 (100%)	8 (53%)	0
36.5 - 36.9 C	0	2 (13%)	1 (100%)
37.0 - 37.4 C	0	2 (13%)	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	3 (20%)	0
36.0 - 36.9 C	2 (100%)	10 (67%)	1 (100%)
37.0 - 37.9 C	0	2 (13%)	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	2 (100%)	15 (100%)	1 (100%)
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.1
Body Temperature Measurements – Maximum Event Severity From 6 Hours Through Day 3 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Ear

	Menveo-Menveo (N=0)	Menactra-Menveo (N=3)	Naive (N=0)
Body Temperature (C)			
<36.0 C	0	0	0
36.0 - 36.4 C	0	0	0
36.5 - 36.9 C	0	2 (67%)	0
37.0 - 37.4 C	0	1 (33%)	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	0	0
36.0 - 36.9 C	0	2 (67%)	0
37.0 - 37.9 C	0	1 (33%)	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	0	3 (100%)	0
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.1
Body Temperature Measurements – Maximum Event Severity From 6 Hours Through Day 3 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Oral

	Menveo-Menveo (N=294)	Menactra-Menveo (N=278)	Naive (N=95)
Body Temperature (C)			
<36.0 C	18 (6%)	10 (4%)	1 (1%)
36.0 - 36.4 C	99 (34%)	83 (30%)	27 (28%)
36.5 - 36.9 C	117 (40%)	136 (49%)	46 (48%)
37.0 - 37.4 C	56 (19%)	44 (16%)	19 (20%)
37.5 - 37.9 C	2 (1%)	4 (1%)	2 (2%)
38.0 - 38.4 C	1 (< 1%)	0	0
38.5 - 38.9 C	1 (< 1%)	1 (< 1%)	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	18 (6%)	10 (4%)	1 (1%)
36.0 - 36.9 C	216 (73%)	219 (79%)	73 (77%)
37.0 - 37.9 C	58 (20%)	48 (17%)	21 (22%)
38.0 - 38.9 C	2 (1%)	1 (< 1%)	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	292 (99%)	277 (>99%)	95 (100%)
Yes	2 (1%)	1 (< 1%)	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.1
Body Temperature Measurements – Maximum Event Severity From 6 Hours Through Day 3 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Unknown

	Menveo-Menveo (N=0)	Menactra-Menveo (N=2)	Naive (N=0)
Body Temperature (C)			
<36.0 C	0	1 (50%)	0
36.0 - 36.4 C	0	0	0
36.5 - 36.9 C	0	1 (50%)	0
37.0 - 37.4 C	0	0	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	1 (50%)	0
36.0 - 36.9 C	0	1 (50%)	0
37.0 - 37.9 C	0	0	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	0	2 (100%)	0
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.2
Body Temperature Measurements – Maximum Event Severity From Day 4 Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Any

	Menveo-Menveo (N=296)	Menactra-Menveo (N=296)	Naive (N=97)
Body Temperature (C)			
<36.0 C	7 (2%)	16 (5%)	4 (4%)
36.0 - 36.4 C	90 (30%)	87 (29%)	23 (24%)
36.5 - 36.9 C	142 (48%)	129 (44%)	39 (40%)
37.0 - 37.4 C	52 (18%)	55 (19%)	30 (31%)
37.5 - 37.9 C	5 (2%)	5 (2%)	1 (1%)
38.0 - 38.4 C	0	2 (1%)	0
38.5 - 38.9 C	0	2 (1%)	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	7 (2%)	16 (5%)	4 (4%)
36.0 - 36.9 C	232 (78%)	216 (73%)	62 (64%)
37.0 - 37.9 C	57 (19%)	60 (20%)	31 (32%)
38.0 - 38.9 C	0	4 (1%)	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	296 (100%)	292 (99%)	97 (100%)
Yes	0	4 (1%)	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.2
Body Temperature Measurements – Maximum Event Severity From Day 4 Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Axillary

	Menveo-Menveo (N=2)	Menactra-Menveo (N=15)	Naive (N=1)
Body Temperature (C)			
<36.0 C	0	4 (27%)	0
36.0 - 36.4 C	2 (100%)	8 (53%)	0
36.5 - 36.9 C	0	1 (7%)	0
37.0 - 37.4 C	0	2 (13%)	1 (100%)
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	4 (27%)	0
36.0 - 36.9 C	2 (100%)	9 (60%)	0
37.0 - 37.9 C	0	2 (13%)	1 (100%)
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	2 (100%)	15 (100%)	1 (100%)
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.2
Body Temperature Measurements – Maximum Event Severity From Day 4 Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Ear

	Menveo-Menveo (N=0)	Menactra-Menveo (N=3)	Naive (N=0)
Body Temperature (C)			
<36.0 C	0	1 (33%)	0
36.0 - 36.4 C	0	1 (33%)	0
36.5 - 36.9 C	0	0	0
37.0 - 37.4 C	0	1 (33%)	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	1 (33%)	0
36.0 - 36.9 C	0	1 (33%)	0
37.0 - 37.9 C	0	1 (33%)	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	0	3 (100%)	0
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.2
Body Temperature Measurements – Maximum Event Severity From Day 4 Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Oral

	Menveo-Menveo (N=294)	Menactra-Menveo (N=278)	Naive (N=96)
Body Temperature (C)			
<36.0 C	8 (3%)	11 (4%)	4 (4%)
36.0 - 36.4 C	87 (30%)	79 (28%)	23 (24%)
36.5 - 36.9 C	142 (48%)	127 (46%)	39 (41%)
37.0 - 37.4 C	52 (18%)	52 (19%)	29 (30%)
37.5 - 37.9 C	5 (2%)	5 (2%)	1 (1%)
38.0 - 38.4 C	0	2 (1%)	0
38.5 - 38.9 C	0	2 (1%)	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	8 (3%)	11 (4%)	4 (4%)
36.0 - 36.9 C	229 (78%)	206 (74%)	62 (65%)
37.0 - 37.9 C	57 (19%)	57 (21%)	30 (31%)
38.0 - 38.9 C	0	4 (1%)	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	294 (100%)	274 (99%)	96 (100%)
Yes	0	4 (1%)	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.4.2
Body Temperature Measurements – Maximum Event Severity From Day 4 Through Day 7 After Vaccination
Overall and by Route of Measurement
Solicited Safety Set

Vaccination: 1
Route: Unknown

	Menveo-Menveo (N=1)	Menactra-Menveo (N=4)	Naive (N=0)
Body Temperature (C)			
<36.0 C	0	0	0
36.0 - 36.4 C	1 (100%)	0	0
36.5 - 36.9 C	0	3 (75%)	0
37.0 - 37.4 C	0	1 (25%)	0
37.5 - 37.9 C	0	0	0
38.0 - 38.4 C	0	0	0
38.5 - 38.9 C	0	0	0
39.0 - 39.4 C	0	0	0
39.5 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature (C)			
<36.0 C	0	0	0
36.0 - 36.9 C	1 (100%)	3 (75%)	0
37.0 - 37.9 C	0	1 (25%)	0
38.0 - 38.9 C	0	0	0
39.0 - 39.9 C	0	0	0
>= 40 C	0	0	0
Body Temperature >= 38.0 C			
No	1 (100%)	4 (100%)	0
Yes	0	0	0

For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.5
Number of Days with Solicited Adverse Events After Vaccination
Solicited Safety Set

Vaccination: 1

	Adverse Event	No. of days	Menveo-Menveo	Menactra-Menveo	Naive
LOCAL	Erythema	n	12	8	10
		1	4 (33%)	5 (63%)	4 (40%)
		2	5 (42%)	2 (25%)	1 (10%)
		3	1 (8%)	0	2 (20%)
		4	1 (8%)	0	1 (10%)
		5	1 (8%)	0	2 (20%)
		6	0	0	0
		7	0	1 (13%)	0
	Induration	n	15	9	8
		1	9 (60%)	2 (22%)	0
		2	4 (27%)	4 (44%)	4 (50%)
		3	0	3 (33%)	2 (25%)
		4	2 (13%)	0	2 (25%)
		5	0	0	0
		6	0	0	0
		7	0	0	0
	Pain	n	114	96	40
		1	53 (46%)	42 (44%)	8 (20%)
		2	30 (26%)	28 (29%)	17 (43%)
		3	18 (16%)	11 (11%)	6 (15%)
		4	6 (5%)	8 (8%)	4 (10%)
		5	5 (4%)	5 (5%)	2 (5%)
		6	0	0	1 (3%)
		7	2 (2%)	2 (2%)	2 (5%)
SYSTEMIC	Arthralgia	n	44	38	13
		1	20 (45%)	25 (66%)	6 (46%)
		2	15 (34%)	4 (11%)	2 (15%)
		3	3 (7%)	3 (8%)	0
		4	1 (2%)	4 (11%)	2 (15%)
		5	3 (7%)	1 (3%)	0
		6	0	1 (3%)	2 (15%)
		7	2 (5%)	0	1 (8%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.5
Number of Days with Solicited Adverse Events After Vaccination
Solicited Safety Set

Vaccination: 1

Adverse Event	No. of days	Menveo-Menveo	Menactra-Menveo	Naive
Chills	n	34	35	10
	1	23 (68%)	19 (54%)	7 (70%)
	2	5 (15%)	12 (34%)	2 (20%)
	3	1 (3%)	2 (6%)	0
	4	3 (9%)	1 (3%)	0
	5	0	0	0
	6	1 (3%)	1 (3%)	0
	7	1 (3%)	0	1 (10%)
Fatigue	n	113	110	19
	1	50 (44%)	39 (35%)	10 (53%)
	2	22 (19%)	27 (25%)	4 (21%)
	3	16 (14%)	13 (12%)	2 (11%)
	4	6 (5%)	13 (12%)	0
	5	10 (9%)	10 (9%)	0
	6	2 (2%)	5 (5%)	2 (11%)
	7	7 (6%)	3 (3%)	1 (5%)
Headache	n	100	82	21
	1	46 (46%)	29 (35%)	11 (52%)
	2	20 (20%)	22 (27%)	5 (24%)
	3	11 (11%)	10 (12%)	0
	4	11 (11%)	12 (15%)	1 (5%)
	5	4 (4%)	3 (4%)	1 (5%)
	6	5 (5%)	4 (5%)	2 (10%)
	7	3 (3%)	2 (2%)	1 (5%)
Loss of Appetite	n	37	46	6
	1	19 (51%)	23 (50%)	4 (67%)
	2	7 (19%)	14 (30%)	0
	3	4 (11%)	3 (7%)	0
	4	1 (3%)	6 (13%)	0
	5	3 (8%)	0	0
	6	2 (5%)	0	1 (17%)
	7	1 (3%)	0	1 (17%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.5
Number of Days with Solicited Adverse Events After Vaccination
Solicited Safety Set

Vaccination: 1

Adverse Event	No. of days	Menveo-Menveo	Menactra-Menveo	Naive
Myalgia	n	55	54	15
	1	27 (49%)	27 (50%)	3 (20%)
	2	15 (27%)	11 (20%)	7 (47%)
	3	5 (9%)	9 (17%)	1 (7%)
	4	2 (4%)	5 (9%)	1 (7%)
	5	1 (2%)	2 (4%)	0
	6	3 (5%)	0	2 (13%)
	7	2 (4%)	0	1 (7%)
Nausea	n	48	44	13
	1	28 (58%)	19 (43%)	6 (46%)
	2	9 (19%)	9 (20%)	4 (31%)
	3	4 (8%)	11 (25%)	0
	4	2 (4%)	2 (5%)	0
	5	3 (6%)	1 (2%)	2 (15%)
	6	1 (2%)	1 (2%)	0
	7	1 (2%)	1 (2%)	1 (8%)
Fever	n	2	5	0
	1	2 (100%)	4 (80%)	0
	2	0	1 (20%)	0
	3	0	0	0
	4	0	0	0
	5	0	0	0
	6	0	0	0
	7	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	299	285	285	285	286	286	286	286
	None (0 - 24 mm)	299 (100%)	278 (98%)	279 (98%)	277 (97%)	282 (99%)	286 (100%)	286 (100%)	286 (100%)
	Any	0	7 (2%)	6 (2%)	8 (3%)	4 (1%)	0	0	0
	Mild (25 - 50 mm)	0	6 (2%)	3 (1%)	7 (2%)	3 (1%)	0	0	0
	Moderate (51 - 100 mm)	0	1 (< 1%)	3 (1%)	1 (< 1%)	1 (< 1%)	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	295	284	284	285	284	284	284	283
	None (0 - 24 mm)	295 (100%)	279 (98%)	278 (98%)	280 (98%)	283 (>99%)	284 (100%)	283 (>99%)	282 (>99%)
	Any	0	5 (2%)	6 (2%)	5 (2%)	1 (< 1%)	0	1 (< 1%)	1 (< 1%)
	Mild (25 - 50 mm)	0	1 (< 1%)	2 (1%)	3 (1%)	1 (< 1%)	0	1 (< 1%)	1 (< 1%)
	Moderate (51 - 100 mm)	0	4 (1%)	4 (1%)	2 (1%)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6
Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	94	90	91	92	92	92	90	91
	None (0 - 24 mm)	94 (100%)	88 (98%)	87 (96%)	85 (92%)	87 (95%)	89 (97%)	89 (99%)	91 (100%)
	Any	0	2 (2%)	4 (4%)	7 (8%)	5 (5%)	3 (3%)	1 (1%)	0
	Mild (25 - 50 mm)	0	2 (2%)	4 (4%)	6 (7%)	5 (5%)	3 (3%)	1 (1%)	0
	Moderate (51 - 100 mm)	0	0	0	1 (1%)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	299	286	286	285	286	286	286	286
	None (0 - 24 mm)	298 (>99%)	284 (99%)	279 (98%)	276 (97%)	281 (98%)	284 (99%)	285 (>99%)	286 (100%)
	Any	1 (< 1%)	2 (1%)	7 (2%)	9 (3%)	5 (2%)	2 (1%)	1 (< 1%)	0
	Mild (25 - 50 mm)	1 (< 1%)	2 (1%)	4 (1%)	6 (2%)	4 (1%)	1 (< 1%)	1 (< 1%)	0
	Moderate (51 - 100 mm)	0	0	3 (1%)	3 (1%)	1 (< 1%)	1 (< 1%)	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	295	284	285	284	284	284	281	281
	None (0 - 24 mm)	294 (>99%)	283 (>99%)	280 (98%)	280 (99%)	281 (99%)	283 (>99%)	280 (>99%)	280 (>99%)
	Any	1 (< 1%)	1 (< 1%)	5 (2%)	4 (1%)	3 (1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)
	Mild (25 - 50 mm)	1 (< 1%)	1 (< 1%)	4 (1%)	3 (1%)	2 (1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)
	Moderate (51 - 100 mm)	0	0	1 (< 1%)	1 (< 1%)	1 (< 1%)	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	94	90	91	92	91	90	90	90
	None (0 - 24 mm)	94 (100%)	88 (98%)	89 (98%)	86 (93%)	85 (93%)	86 (96%)	87 (97%)	87 (97%)
	Any	0	2 (2%)	2 (2%)	6 (7%)	6 (7%)	4 (4%)	3 (3%)	3 (3%)
	Mild (25 - 50 mm)	0	2 (2%)	2 (2%)	4 (4%)	4 (4%)	2 (2%)	0	1 (1%)
	Moderate (51 - 100 mm)	0	0	0	2 (2%)	1 (1%)	1 (1%)	2 (2%)	1 (1%)
	Severe (> 100 mm)	0	0	0	0	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	292	292	292	292	292	292	290
	Any	9 (3%)	86 (29%)	65 (22%)	44 (15%)	19 (7%)	11 (4%)	3 (1%)	2 (1%)
	MILD	8 (3%)	75 (26%)	55 (19%)	38 (13%)	15 (5%)	9 (3%)	2 (1%)	1 (< 1%)
	MODERATE	1 (< 1%)	11 (4%)	8 (3%)	6 (2%)	3 (1%)	2 (1%)	1 (< 1%)	1 (< 1%)
	SEVERE	0	0	2 (1%)	0	1 (< 1%)	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	296	296	296	296	295	293
	Any	22 (7%)	78 (27%)	58 (20%)	31 (10%)	17 (6%)	8 (3%)	7 (2%)	3 (1%)
	MILD	21 (7%)	61 (21%)	46 (16%)	24 (8%)	15 (5%)	6 (2%)	5 (2%)	3 (1%)
	MODERATE	1 (< 1%)	13 (4%)	9 (3%)	6 (2%)	2 (1%)	0	1 (< 1%)	0
	SEVERE	0	4 (1%)	3 (1%)	1 (< 1%)	0	2 (1%)	1 (< 1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	95	97	97	97	97	96	96
	Any	6 (6%)	25 (26%)	32 (33%)	23 (24%)	15 (15%)	6 (6%)	3 (3%)	2 (2%)
	MILD	6 (6%)	22 (23%)	26 (27%)	18 (19%)	12 (12%)	4 (4%)	1 (1%)	0
	MODERATE	0	2 (2%)	5 (5%)	3 (3%)	1 (1%)	0	0	1 (1%)
	SEVERE	0	1 (1%)	1 (1%)	2 (2%)	2 (2%)	2 (2%)	2 (2%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	0	16 (5%)	22 (7%)	18 (6%)	13 (4%)	10 (3%)	7 (2%)	8 (3%)
	MILD	0	10 (3%)	13 (4%)	13 (4%)	11 (4%)	7 (2%)	3 (1%)	5 (2%)
	MODERATE	0	5 (2%)	8 (3%)	4 (1%)	2 (1%)	3 (1%)	4 (1%)	3 (1%)
	SEVERE	0	1 (< 1%)	1 (< 1%)	1 (< 1%)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	292	294	294	294	294	292	293
	Any	0	18 (6%)	20 (7%)	14 (5%)	14 (5%)	13 (4%)	10 (3%)	7 (2%)
	MILD	0	12 (4%)	12 (4%)	12 (4%)	9 (3%)	9 (3%)	7 (2%)	4 (1%)
	MODERATE	0	6 (2%)	6 (2%)	2 (1%)	4 (1%)	3 (1%)	2 (1%)	3 (1%)
	SEVERE	0	0	2 (1%)	0	1 (< 1%)	1 (< 1%)	1 (< 1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	7 (7%)	8 (8%)	7 (7%)	3 (3%)	3 (3%)	2 (2%)	1 (1%)
	MILD	0	6 (6%)	5 (5%)	6 (6%)	2 (2%)	1 (1%)	1 (1%)	0
	MODERATE	0	0	1 (1%)	0	0	1 (1%)	0	0
	SEVERE	0	1 (1%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	295	295	295	292
	Any	3 (1%)	78 (27%)	56 (19%)	46 (16%)	37 (13%)	24 (8%)	19 (6%)	17 (6%)
	MILD	3 (1%)	55 (19%)	41 (14%)	33 (11%)	31 (11%)	16 (5%)	15 (5%)	11 (4%)
	MODERATE	0	19 (6%)	13 (4%)	13 (4%)	6 (2%)	7 (2%)	3 (1%)	5 (2%)
	SEVERE	0	4 (1%)	2 (1%)	0	0	1 (< 1%)	1 (< 1%)	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6
Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	296	296	295	295	293	294
	Any	2 (1%)	67 (23%)	60 (20%)	45 (15%)	42 (14%)	29 (10%)	24 (8%)	18 (6%)
	MILD	2 (1%)	46 (16%)	37 (13%)	33 (11%)	30 (10%)	23 (8%)	19 (6%)	9 (3%)
	MODERATE	0	17 (6%)	19 (6%)	12 (4%)	8 (3%)	3 (1%)	2 (1%)	6 (2%)
	SEVERE	0	4 (1%)	4 (1%)	0	4 (1%)	3 (1%)	3 (1%)	3 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6
Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	12 (12%)	9 (9%)	7 (7%)	5 (5%)	4 (4%)	3 (3%)	3 (3%)
	MILD	0	7 (7%)	5 (5%)	5 (5%)	4 (4%)	2 (2%)	2 (2%)	2 (2%)
	MODERATE	0	4 (4%)	2 (2%)	0	0	1 (1%)	0	0
	SEVERE	0	1 (1%)	2 (2%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	1 (< 1%)	24 (8%)	35 (12%)	19 (6%)	16 (5%)	11 (4%)	6 (2%)	6 (2%)
	MILD	1 (< 1%)	21 (7%)	25 (9%)	14 (5%)	13 (4%)	7 (2%)	3 (1%)	3 (1%)
	MODERATE	0	2 (1%)	9 (3%)	5 (2%)	1 (< 1%)	3 (1%)	3 (1%)	2 (1%)
	SEVERE	0	1 (< 1%)	1 (< 1%)	0	2 (1%)	1 (< 1%)	0	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	295	295	296	295	295	293	294
	Any	0	25 (8%)	23 (8%)	16 (5%)	14 (5%)	9 (3%)	9 (3%)	10 (3%)
	MILD	0	19 (6%)	14 (5%)	10 (3%)	11 (4%)	5 (2%)	4 (1%)	4 (1%)
	MODERATE	0	4 (1%)	8 (3%)	6 (2%)	3 (1%)	3 (1%)	3 (1%)	5 (2%)
	SEVERE	0	2 (1%)	1 (< 1%)	0	0	1 (< 1%)	2 (1%)	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6
Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	8 (8%)	11 (11%)	8 (8%)	6 (6%)	4 (4%)	3 (3%)	3 (3%)
	MILD	0	6 (6%)	8 (8%)	6 (6%)	5 (5%)	2 (2%)	2 (2%)	2 (2%)
	MODERATE	0	1 (1%)	1 (1%)	1 (1%)	0	1 (1%)	0	0
	SEVERE	0	1 (1%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	0	15 (5%)	21 (7%)	18 (6%)	14 (5%)	10 (3%)	9 (3%)	5 (2%)
	MILD	0	13 (4%)	11 (4%)	15 (5%)	10 (3%)	5 (2%)	5 (2%)	2 (1%)
	MODERATE	0	2 (1%)	9 (3%)	3 (1%)	3 (1%)	4 (1%)	4 (1%)	3 (1%)
	SEVERE	0	0	1 (< 1%)	0	1 (< 1%)	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	295	295	295	295	293	294
	Any	0	15 (5%)	18 (6%)	7 (2%)	9 (3%)	6 (2%)	6 (2%)	8 (3%)
	MILD	0	11 (4%)	14 (5%)	5 (2%)	8 (3%)	5 (2%)	5 (2%)	5 (2%)
	MODERATE	0	2 (1%)	3 (1%)	2 (1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)	3 (1%)
	SEVERE	0	2 (1%)	1 (< 1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	96	96	96	96	96	96	96
	Any	0	6 (6%)	7 (7%)	8 (8%)	6 (6%)	4 (4%)	3 (3%)	3 (3%)
	MILD	0	5 (5%)	5 (5%)	6 (6%)	5 (5%)	2 (2%)	2 (2%)	2 (2%)
	MODERATE	0	0	0	1 (1%)	0	1 (1%)	0	0
	SEVERE	0	1 (1%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	292
	Any	2 (1%)	54 (18%)	51 (17%)	36 (12%)	34 (12%)	25 (9%)	19 (6%)	15 (5%)
	MILD	2 (1%)	45 (15%)	39 (13%)	27 (9%)	28 (10%)	17 (6%)	13 (4%)	12 (4%)
	MODERATE	0	6 (2%)	12 (4%)	8 (3%)	5 (2%)	7 (2%)	5 (2%)	2 (1%)
	SEVERE	0	3 (1%)	0	1 (< 1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6
Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	295	295	294	294	292	293
	Any	1 (< 1%)	36 (12%)	37 (13%)	38 (13%)	28 (10%)	26 (9%)	24 (8%)	15 (5%)
	MILD	1 (< 1%)	23 (8%)	23 (8%)	30 (10%)	21 (7%)	20 (7%)	19 (7%)	9 (3%)
	MODERATE	0	11 (4%)	8 (3%)	7 (2%)	7 (2%)	2 (1%)	2 (1%)	3 (1%)
	SEVERE	0	2 (1%)	6 (2%)	1 (< 1%)	0	4 (1%)	3 (1%)	3 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6
Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	11 (11%)	12 (12%)	8 (8%)	5 (5%)	4 (4%)	5 (5%)	4 (4%)
	MILD	0	10 (10%)	6 (6%)	5 (5%)	3 (3%)	1 (1%)	2 (2%)	1 (1%)
	MODERATE	0	0	4 (4%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)
	SEVERE	0	1 (1%)	2 (2%)	2 (2%)	1 (1%)	2 (2%)	2 (2%)	2 (2%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	293
	Any	1 (< 1%)	18 (6%)	13 (4%)	9 (3%)	6 (2%)	8 (3%)	3 (1%)	4 (1%)
	MILD	1 (< 1%)	13 (4%)	9 (3%)	6 (2%)	5 (2%)	4 (1%)	1 (< 1%)	3 (1%)
	MODERATE	0	5 (2%)	4 (1%)	3 (1%)	1 (< 1%)	2 (1%)	1 (< 1%)	1 (< 1%)
	SEVERE	0	0	0	0	0	2 (1%)	1 (< 1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	295	295	293	294	292	293
	Any	3 (1%)	13 (4%)	17 (6%)	7 (2%)	6 (2%)	6 (2%)	4 (1%)	6 (2%)
	MILD	3 (1%)	10 (3%)	14 (5%)	5 (2%)	5 (2%)	5 (2%)	3 (1%)	2 (1%)
	MODERATE	0	3 (1%)	3 (1%)	2 (1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)	4 (1%)
	SEVERE	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	5 (5%)	6 (6%)	2 (2%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)
	MILD	0	4 (4%)	5 (5%)	1 (1%)	1 (1%)	0	0	0
	MODERATE	0	0	0	0	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss Of Appetite
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	0	13 (4%)	16 (5%)	17 (6%)	14 (5%)	10 (3%)	5 (2%)	8 (3%)
	MILD	0	8 (3%)	11 (4%)	14 (5%)	11 (4%)	8 (3%)	2 (1%)	6 (2%)
	MODERATE	0	4 (1%)	4 (1%)	3 (1%)	3 (1%)	1 (< 1%)	2 (1%)	2 (1%)
	SEVERE	0	1 (< 1%)	1 (< 1%)	0	0	1 (< 1%)	1 (< 1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss Of Appetite
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	295	296	294	295	293	294
	Any	0	15 (5%)	23 (8%)	8 (3%)	11 (4%)	9 (3%)	7 (2%)	11 (4%)
	MILD	0	10 (3%)	18 (6%)	7 (2%)	8 (3%)	8 (3%)	3 (1%)	8 (3%)
	MODERATE	0	5 (2%)	5 (2%)	1 (< 1%)	2 (1%)	1 (< 1%)	3 (1%)	3 (1%)
	SEVERE	0	0	0	0	1 (< 1%)	0	1 (< 1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss Of Appetite
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	1 (1%)	4 (4%)	2 (2%)	3 (3%)	3 (3%)	2 (2%)	2 (2%)
	MILD	0	0	2 (2%)	0	2 (2%)	1 (1%)	1 (1%)	1 (1%)
	MODERATE	0	0	0	0	0	1 (1%)	0	0
	SEVERE	0	1 (1%)	2 (2%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	296	296	296	296	295	295	292
	NO	301 (100%)	296 (100%)	294 (99%)	296 (100%)	296 (100%)	295 (100%)	295 (100%)	292 (100%)
	YES	0	0	2 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	296	296	295	296	294	294
	NO	300 (100%)	293 (>99%)	296 (100%)	296 (100%)	295 (100%)	295 (>99%)	291 (99%)	293 (>99%)
	YES	0	1 (< 1%)	0	0	0	1 (< 1%)	3 (1%)	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	95	96	96	96	97	97	97
	NO	100 (100%)	95 (100%)	96 (100%)	96 (100%)	96 (100%)	97 (100%)	97 (100%)	97 (100%)
	YES	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	293	293	293	293	294	294	293
	NO	301 (100%)	288 (98%)	287 (98%)	289 (99%)	290 (99%)	290 (99%)	292 (99%)	292 (>99%)
	YES	0	5 (2%)	6 (2%)	4 (1%)	3 (1%)	4 (1%)	2 (1%)	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	295	295	295	295	295	294	295
	NO	300 (100%)	288 (98%)	290 (98%)	290 (98%)	293 (99%)	291 (99%)	289 (98%)	292 (99%)
	YES	0	7 (2%)	5 (2%)	5 (2%)	2 (1%)	4 (1%)	5 (2%)	3 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention of Pain and/or Fever
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	96	96	95	96	96	96	96
	NO	100 (100%)	94 (98%)	92 (96%)	94 (99%)	95 (99%)	95 (99%)	95 (99%)	95 (99%)
	YES	0	2 (2%)	4 (4%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	293	293	293	293	293	293	293
	NO	301 (100%)	292 (>99%)	287 (98%)	289 (99%)	287 (98%)	287 (98%)	289 (99%)	290 (99%)
	YES	0	1 (< 1%)	6 (2%)	4 (1%)	6 (2%)	6 (2%)	4 (1%)	3 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	295	295	295	295	294	294
	NO	300 (100%)	292 (99%)	286 (97%)	290 (98%)	291 (99%)	293 (99%)	287 (98%)	286 (97%)
	YES	0	2 (1%)	9 (3%)	5 (2%)	4 (1%)	2 (1%)	7 (2%)	8 (3%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.6

Daily Reports of Subjects with Solicited Adverse Events, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment of Pain and/or Fever
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	96	96	95	96	96	96	96
	NO	100 (100%)	93 (97%)	87 (91%)	92 (97%)	94 (98%)	95 (99%)	95 (99%)	95 (99%)
	YES	0	3 (3%)	9 (9%)	3 (3%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	299	286	286	285	286	286	286	286
	None (0 - 24 mm)	0	0	0	0	0	0	0	0
	Any	1 (< 1%)	2 (1%)	7 (2%)	3 (1%)	0	0	0	0
	Mild (25 - 50 mm)	1 (< 1%)	2 (1%)	4 (1%)	3 (1%)	0	0	0	0
	Moderate (51 - 100 mm)	0	0	3 (1%)	0	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	295	284	285	284	284	284	281	281
	None (0 - 24 mm)	0	0	0	0	0	0	0	0
	Any	1 (< 1%)	1 (< 1%)	4 (1%)	2 (1%)	1 (< 1%)	0	0	0
	Mild (25 - 50 mm)	1 (< 1%)	1 (< 1%)	3 (1%)	1 (< 1%)	0	0	0	0
	Moderate (51 - 100 mm)	0	0	1 (< 1%)	1 (< 1%)	1 (< 1%)	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Erythema
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	94	90	91	92	91	90	90	90
	None (0 - 24 mm)	0	0	0	0	0	0	0	0
	Any	0	2 (2%)	2 (2%)	4 (4%)	2 (2%)	0	0	0
	Mild (25 - 50 mm)	0	2 (2%)	2 (2%)	3 (3%)	1 (1%)	0	0	0
	Moderate (51 - 100 mm)	0	0	0	1 (1%)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	1 (1%)	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	299	285	285	285	286	286	286	286
	None (0 - 24 mm)	0	0	0	0	0	0	0	0
	Any	0	7 (2%)	4 (1%)	4 (1%)	0	0	0	0
	Mild (25 - 50 mm)	0	6 (2%)	3 (1%)	4 (1%)	0	0	0	0
	Moderate (51 - 100 mm)	0	1 (< 1%)	1 (< 1%)	0	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	295	284	284	285	284	284	284	283
	None (0 - 24 mm)	0	0	0	0	0	0	0	0
	Any	0	5 (2%)	2 (1%)	1 (< 1%)	0	0	1 (< 1%)	0
	Mild (25 - 50 mm)	0	1 (< 1%)	1 (< 1%)	0	0	0	1 (< 1%)	0
	Moderate (51 - 100 mm)	0	4 (1%)	1 (< 1%)	1 (< 1%)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Induration
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	94	90	91	92	92	92	90	91
	None (0 - 24 mm)	0	0	0	0	0	0	0	0
	Any	0	2 (2%)	2 (2%)	3 (3%)	1 (1%)	0	0	0
	Mild (25 - 50 mm)	0	2 (2%)	2 (2%)	2 (2%)	1 (1%)	0	0	0
	Moderate (51 - 100 mm)	0	0	0	1 (1%)	0	0	0	0
	Severe (> 100 mm)	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	292	292	292	292	292	292	290
	Any	9 (3%)	86 (29%)	21 (7%)	5 (2%)	1 (< 1%)	0	1 (< 1%)	0
	MILD	8 (3%)	75 (26%)	17 (6%)	5 (2%)	1 (< 1%)	0	1 (< 1%)	0
	MODERATE	1 (< 1%)	11 (4%)	3 (1%)	0	0	0	0	0
	SEVERE	0	0	1 (< 1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	296	296	296	296	295	293
	Any	22 (7%)	78 (27%)	15 (5%)	2 (1%)	0	1 (< 1%)	0	0
	MILD	21 (7%)	61 (21%)	13 (4%)	2 (1%)	0	0	0	0
	MODERATE	1 (< 1%)	13 (4%)	2 (1%)	0	0	0	0	0
	SEVERE	0	4 (1%)	0	0	0	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Local Solicited Adverse Event: Pain
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	95	97	97	97	97	96	96
	Any	6 (6%)	25 (26%)	12 (12%)	3 (3%)	0	0	0	0
	MILD	6 (6%)	22 (23%)	12 (12%)	3 (3%)	0	0	0	0
	MODERATE	0	2 (2%)	0	0	0	0	0	0
	SEVERE	0	1 (1%)	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	0	15 (5%)	15 (5%)	4 (1%)	3 (1%)	4 (1%)	2 (1%)	1 (< 1%)
	MILD	0	13 (4%)	8 (3%)	3 (1%)	2 (1%)	1 (< 1%)	1 (< 1%)	1 (< 1%)
	MODERATE	0	2 (1%)	6 (2%)	1 (< 1%)	0	2 (1%)	1 (< 1%)	0
	SEVERE	0	0	1 (< 1%)	0	1 (< 1%)	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	295	295	295	295	293	294
	Any	0	15 (5%)	11 (4%)	1 (< 1%)	2 (1%)	4 (1%)	2 (1%)	3 (1%)
	MILD	0	11 (4%)	9 (3%)	1 (< 1%)	2 (1%)	3 (1%)	2 (1%)	3 (1%)
	MODERATE	0	2 (1%)	2 (1%)	0	0	1 (< 1%)	0	0
	SEVERE	0	2 (1%)	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Arthralgia
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	96	96	96	96	96	96	96
	Any	0	6 (6%)	4 (4%)	3 (3%)	0	0	0	0
	MILD	0	5 (5%)	3 (3%)	2 (2%)	0	0	0	0
	MODERATE	0	0	0	1 (1%)	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	293
	Any	1 (< 1%)	18 (6%)	6 (2%)	2 (1%)	3 (1%)	4 (1%)	1 (< 1%)	0
	MILD	1 (< 1%)	13 (4%)	5 (2%)	2 (1%)	3 (1%)	2 (1%)	1 (< 1%)	0
	MODERATE	0	5 (2%)	1 (< 1%)	0	0	1 (< 1%)	0	0
	SEVERE	0	0	0	0	0	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	295	295	293	294	292	293
	Any	3 (1%)	13 (4%)	12 (4%)	4 (1%)	2 (1%)	3 (1%)	0	1 (< 1%)
	MILD	3 (1%)	10 (3%)	9 (3%)	4 (1%)	2 (1%)	2 (1%)	0	0
	MODERATE	0	3 (1%)	3 (1%)	0	0	1 (< 1%)	0	1 (< 1%)
	SEVERE	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Chills
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	5 (5%)	4 (4%)	0	1 (1%)	0	0	0
	MILD	0	4 (4%)	4 (4%)	0	1 (1%)	0	0	0
	MODERATE	0	0	0	0	0	0	0	0
	SEVERE	0	1 (1%)	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	295	295	295	292
	Any	3 (1%)	78 (27%)	18 (6%)	9 (3%)	3 (1%)	2 (1%)	3 (1%)	0
	MILD	3 (1%)	55 (19%)	16 (5%)	7 (2%)	3 (1%)	1 (< 1%)	3 (1%)	0
	MODERATE	0	19 (6%)	2 (1%)	2 (1%)	0	1 (< 1%)	0	0
	SEVERE	0	4 (1%)	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	296	296	295	295	293	294
	Any	2 (1%)	67 (23%)	28 (9%)	7 (2%)	6 (2%)	1 (< 1%)	0	1 (< 1%)
	MILD	2 (1%)	46 (16%)	22 (7%)	6 (2%)	4 (1%)	1 (< 1%)	0	1 (< 1%)
	MODERATE	0	17 (6%)	4 (1%)	1 (< 1%)	0	0	0	0
	SEVERE	0	4 (1%)	2 (1%)	0	2 (1%)	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fatigue
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	12 (12%)	5 (5%)	1 (1%)	0	1 (1%)	0	0
	MILD	0	7 (7%)	3 (3%)	1 (1%)	0	1 (1%)	0	0
	MODERATE	0	4 (4%)	1 (1%)	0	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	292
	Any	2 (1%)	54 (18%)	25 (9%)	5 (2%)	7 (2%)	5 (2%)	1 (< 1%)	3 (1%)
	MILD	2 (1%)	45 (15%)	21 (7%)	5 (2%)	5 (2%)	4 (1%)	1 (< 1%)	2 (1%)
	MODERATE	0	6 (2%)	4 (1%)	0	2 (1%)	0	0	1 (< 1%)
	SEVERE	0	3 (1%)	0	0	0	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	293	295	295	294	294	292	293
	Any	1 (< 1%)	36 (12%)	19 (6%)	12 (4%)	9 (3%)	4 (1%)	1 (< 1%)	1 (< 1%)
	MILD	1 (< 1%)	23 (8%)	14 (5%)	10 (3%)	6 (2%)	3 (1%)	1 (< 1%)	1 (< 1%)
	MODERATE	0	11 (4%)	2 (1%)	2 (1%)	3 (1%)	0	0	0
	SEVERE	0	2 (1%)	3 (1%)	0	0	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Headache
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	11 (11%)	8 (8%)	1 (1%)	0	1 (1%)	0	0
	MILD	0	10 (10%)	4 (4%)	1 (1%)	0	1 (1%)	0	0
	MODERATE	0	0	3 (3%)	0	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss Of Appetite
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	0	13 (4%)	10 (3%)	6 (2%)	2 (1%)	3 (1%)	2 (1%)	1 (< 1%)
	MILD	0	8 (3%)	8 (3%)	5 (2%)	2 (1%)	2 (1%)	1 (< 1%)	1 (< 1%)
	MODERATE	0	4 (1%)	1 (< 1%)	1 (< 1%)	0	0	0	0
	SEVERE	0	1 (< 1%)	1 (< 1%)	0	0	1 (< 1%)	1 (< 1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss Of Appetite
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	295	296	294	295	293	294
	Any	0	15 (5%)	16 (5%)	4 (1%)	4 (1%)	3 (1%)	2 (1%)	2 (1%)
	MILD	0	10 (3%)	11 (4%)	4 (1%)	2 (1%)	2 (1%)	2 (1%)	1 (< 1%)
	MODERATE	0	5 (2%)	5 (2%)	0	1 (< 1%)	1 (< 1%)	0	1 (< 1%)
	SEVERE	0	0	0	0	1 (< 1%)	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Loss Of Appetite
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	1 (1%)	3 (3%)	0	1 (1%)	1 (1%)	0	0
	MILD	0	0	2 (2%)	0	1 (1%)	1 (1%)	0	0
	MODERATE	0	0	0	0	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	1 (< 1%)	24 (8%)	20 (7%)	2 (1%)	6 (2%)	2 (1%)	0	1 (< 1%)
	MILD	1 (< 1%)	21 (7%)	14 (5%)	2 (1%)	5 (2%)	1 (< 1%)	0	1 (< 1%)
	MODERATE	0	2 (1%)	5 (2%)	0	0	0	0	0
	SEVERE	0	1 (< 1%)	1 (< 1%)	0	1 (< 1%)	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	295	295	296	295	295	293	294
	Any	0	25 (8%)	11 (4%)	7 (2%)	6 (2%)	3 (1%)	0	2 (1%)
	MILD	0	19 (6%)	6 (2%)	4 (1%)	4 (1%)	2 (1%)	0	1 (< 1%)
	MODERATE	0	4 (1%)	4 (1%)	3 (1%)	2 (1%)	1 (< 1%)	0	1 (< 1%)
	SEVERE	0	2 (1%)	1 (< 1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Myalgia
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	8 (8%)	6 (6%)	1 (1%)	0	0	0	0
	MILD	0	6 (6%)	5 (5%)	1 (1%)	0	0	0	0
	MODERATE	0	1 (1%)	0	0	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	294	294	294	294	294	294	294
	Any	0	16 (5%)	15 (5%)	6 (2%)	4 (1%)	5 (2%)	1 (< 1%)	1 (< 1%)
	MILD	0	10 (3%)	11 (4%)	4 (1%)	3 (1%)	3 (1%)	1 (< 1%)	1 (< 1%)
	MODERATE	0	5 (2%)	4 (1%)	1 (< 1%)	1 (< 1%)	2 (1%)	0	0
	SEVERE	0	1 (< 1%)	0	1 (< 1%)	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	292	294	294	294	294	292	293
	Any	0	18 (6%)	13 (4%)	3 (1%)	6 (2%)	3 (1%)	0	1 (< 1%)
	MILD	0	12 (4%)	8 (3%)	3 (1%)	4 (1%)	2 (1%)	0	1 (< 1%)
	MODERATE	0	6 (2%)	3 (1%)	0	1 (< 1%)	0	0	0
	SEVERE	0	0	2 (1%)	0	1 (< 1%)	1 (< 1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Nausea
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	97	97	97	97	97	97	97
	Any	0	7 (7%)	4 (4%)	2 (2%)	0	0	0	0
	MILD	0	6 (6%)	2 (2%)	2 (2%)	0	0	0	0
	MODERATE	0	0	1 (1%)	0	0	0	0	0
	SEVERE	0	1 (1%)	1 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention Of Pain And/Or Fever
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	293	293	293	293	294	294	293
	NO	301 (100%)	288 (98%)	288 (98%)	293 (100%)	292 (>99%)	292 (99%)	294 (100%)	293 (100%)
	YES	0	5 (2%)	5 (2%)	0	1 (< 1%)	2 (1%)	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention Of Pain And/Or Fever
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	295	295	295	295	295	294	295
	NO	300 (100%)	288 (98%)	294 (>99%)	293 (99%)	294 (>99%)	294 (>99%)	291 (99%)	295 (100%)
	YES	0	7 (2%)	1 (< 1%)	2 (1%)	1 (< 1%)	1 (< 1%)	3 (1%)	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Prevention Of Pain And/Or Fever
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	96	96	95	96	96	96	96
	NO	100 (100%)	94 (98%)	93 (97%)	95 (100%)	96 (100%)	96 (100%)	96 (100%)	96 (100%)
	YES	0	2 (2%)	3 (3%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment Of Pain And/Or Fever
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	293	293	293	293	293	293	293
	NO	301 (100%)	292 (>99%)	287 (98%)	290 (99%)	289 (99%)	290 (99%)	293 (100%)	292 (>99%)
	YES	0	1 (< 1%)	6 (2%)	3 (1%)	4 (1%)	3 (1%)	0	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment Of Pain And/Or Fever
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	295	295	295	295	294	294
	NO	300 (100%)	292 (99%)	287 (97%)	291 (99%)	291 (99%)	294 (>99%)	291 (99%)	292 (99%)
	YES	0	2 (1%)	8 (3%)	4 (1%)	4 (1%)	1 (< 1%)	3 (1%)	2 (1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Indicator of Solicited Adverse Event: Treatment Of Pain And/Or Fever
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	96	96	95	96	96	96	96
	NO	100 (100%)	93 (97%)	89 (93%)	95 (100%)	96 (100%)	96 (100%)	96 (100%)	96 (100%)
	YES	0	3 (3%)	7 (7%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7

Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever
Group: Menveo-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	301	296	296	296	296	295	295	292
	NO	301 (100%)	296 (100%)	294 (99%)	296 (100%)	296 (100%)	295 (100%)	295 (100%)	292 (100%)
	YES	0	0	2 (1%)	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever
Group: Menactra-Menveo

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	300	294	296	296	295	296	294	294
	NO	300 (100%)	293 (>99%)	296 (100%)	296 (100%)	295 (100%)	295 (>99%)	292 (99%)	293 (>99%)
	YES	0	1 (< 1%)	0	0	0	1 (< 1%)	2 (1%)	1 (< 1%)

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.7
Solicited Adverse Events, Time of First Onset, From Day 1 (30 minutes and 6 hours) Through Day 7 After Vaccination
Threshold for Erythema, Swelling and Induration: Grade 0 (<25 mm), Any (>= 25 mm)
Solicited Safety Set

Category: Systemic Solicited Adverse Event: Fever
Group: Naïve

Vaccination Number		30 MIN	6 HRS	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	n	100	95	96	96	96	97	97	97
	NO	100 (100%)	95 (100%)	96 (100%)	96 (100%)	96 (100%)	97 (100%)	97 (100%)	97 (100%)
	YES	0	0	0	0	0	0	0	0

For Induration, values recorded below 0 or equal to or above 500 mm and for Erythema, values recorded below 0 or equal to or above 900 mm have been considered implausible and not taken into account in the summaries. For body temperature, values recorded equal to or below 33.0 or equal to or above 42.0 C have been considered implausible and not taken into account for the summaries.

PPD

Table 14.3.1.8
Diary Card Collection Method and Safety Assessment
Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
Was the Day 3 Reminder Phone Call Made after vaccination?			
No	9 (3%)	26 (9%)	6 (6%)
Yes	292 (97%)	274 (91%)	94 (94%)
Was the Subject/Legal Guardian Reached on Day 3 after vaccination?			
No	6 (2%)	3 (1%)	2 (2%)
Yes	286 (95%)	271 (90%)	92 (92%)
Not Done	9 (3%)	26 (9%)	6 (6%)
Was the Day 5 Reminder Phone Call Made after vaccination?			
No	3 (1%)	30 (10%)	9 (9%)
Yes	297 (99%)	270 (90%)	91 (91%)
Not Done	1 (< 1%)	0	0
Was the Subject/Legal Guardian Reached on Day 5 after vaccination?			
No	13 (4%)	2 (1%)	0
Yes	284 (94%)	268 (89%)	91 (91%)
Not Done	4 (1%)	30 (10%)	9 (9%)
Was the Safety Assessed at the Scheduled Visit 2?			
Yes	300 (>99%)	299 (>99%)	99 (99%)
Missing	1 (< 1%)	1 (< 1%)	1 (1%)
Was the Subject/Legal Guardian Reached for Day 15 Safety Phone Call?			
No	1 (< 1%)	3 (1%)	0
Yes	295 (98%)	295 (98%)	97 (97%)
Missing	5 (2%)	2 (1%)	3 (3%)
Was Safety Assessed for Day 15 Safety Phone Call?			
Yes	295 (98%)	295 (98%)	97 (97%)
Not Done	1 (< 1%)	3 (1%)	0
Missing	5 (2%)	2 (1%)	3 (3%)
Was the Safety Assessed at the Scheduled Visit 4?			
Yes	300 (>99%)	298 (99%)	98 (98%)
Missing	1 (< 1%)	2 (1%)	2 (2%)
Diary Card Returned on Day 29?			
No	4 (1%)	4 (1%)	3 (3%)

PPD

Table 14.3.1.8
Diary Card Collection Method and Safety Assessment
Exposed Set

	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
Yes at the scheduled visit	270 (90%)	271 (90%)	85 (85%)
Yes not at the scheduled visit	26 (9%)	25 (8%)	12 (12%)
Missing	1 (< 1%)	0	0
Study Day of Diary Card Returned:			
Mean, Std.Dev	31.1, 13	28.8, 5.9	27.3, 5.21
Median	29	29	28
Min	14	12	6
Max	176	69	42
N	296	296	97
How Was the Diary Card Returned, if not at the Scheduled Visit?			
Brought to the site	21 (7%)	17 (6%)	11 (11%)
Mail	5 (2%)	8 (3%)	1 (1%)
Was the Subject/Legal Guardian Reached for Day 91 Safety Phone Call?			
No	0	2 (1%)	0
Yes	298 (99%)	295 (98%)	98 (98%)
Missing	3 (1%)	3 (1%)	2 (2%)
Was Safety Assessed for Day 91 Safety Phone Call?			
Yes	298 (99%)	295 (98%)	98 (98%)
Not Done	0	2 (1%)	0
Missing	3 (1%)	3 (1%)	2 (2%)
Was the Subject/Legal Guardian Reached for Day 181 Safety Phone Call?			
No	0	1 (< 1%)	0
Yes	298 (99%)	288 (96%)	97 (97%)
Missing	3 (1%)	11 (4%)	3 (3%)
Was Safety Assessed for Day 181 Safety Phone Call?			
Yes	298 (99%)	288 (96%)	97 (97%)
Not Done	0	1 (< 1%)	0
Missing	3 (1%)	11 (4%)	3 (3%)

PPD

Table 14.3.1.9
Solicited Adverse Events, Completeness Analysis, for Each Solicited Event and Time Point
Exposed Set

Vaccination: 1
Group: Menveo-Menveo

Adverse Event	30 MIN (N=301)	6 HRS (N=301)	DAY 2 (N=301)	DAY 3 (N=301)	DAY 4 (N=301)	DAY 5 (N=301)	DAY 6 (N=301)	DAY 7 (N=301)
Local								
Erythema	299 (99%)	286 (95%)	286 (95%)	285 (95%)	286 (95%)	286 (95%)	286 (95%)	286 (95%)
Induration	299 (99%)	285 (95%)	285 (95%)	285 (95%)	286 (95%)	286 (95%)	286 (95%)	286 (95%)
Pain	301 (100%)	292 (97%)	292 (97%)	292 (97%)	292 (97%)	292 (97%)	292 (97%)	290 (96%)
Systemic								
Arthralgia	301 (100%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)
Chills	301 (100%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	293 (97%)
Fatigue	301 (100%)	294 (98%)	294 (98%)	294 (98%)	295 (98%)	295 (98%)	295 (98%)	292 (97%)
Fever	301 (100%)	296 (98%)	296 (98%)	296 (98%)	296 (98%)	295 (98%)	295 (98%)	292 (97%)
Headache	301 (100%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	292 (97%)
Loss Of Appetite	301 (100%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)
Myalgia	301 (100%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)
Nausea	301 (100%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)
Other								
Prevention of Pain and/or Fever	301 (100%)	293 (97%)	293 (97%)	293 (97%)	293 (97%)	294 (98%)	294 (98%)	293 (97%)
Treatment of Pain and/or Fever	301 (100%)	293 (97%)	293 (97%)	293 (97%)	293 (97%)	293 (97%)	293 (97%)	293 (97%)

PPD

Table 14.3.1.9
Solicited Adverse Events, Completeness Analysis, for Each Solicited Event and Time Point
Exposed Set

Vaccination: 1
Group: Menactra-Menveo

Adverse Event	30 MIN (N=300)	6 HRS (N=300)	DAY 2 (N=300)	DAY 3 (N=300)	DAY 4 (N=300)	DAY 5 (N=300)	DAY 6 (N=300)	DAY 7 (N=300)
Local								
Erythema	295 (98%)	284 (95%)	285 (95%)	284 (95%)	284 (95%)	284 (95%)	281 (94%)	281 (94%)
Induration	295 (98%)	284 (95%)	284 (95%)	285 (95%)	284 (95%)	284 (95%)	284 (95%)	283 (94%)
Pain	300 (100%)	293 (98%)	296 (99%)	296 (99%)	296 (99%)	296 (99%)	295 (98%)	293 (98%)
Systemic								
Arthralgia	300 (100%)	294 (98%)	295 (98%)	295 (98%)	295 (98%)	295 (98%)	293 (98%)	294 (98%)
Chills	300 (100%)	293 (98%)	295 (98%)	295 (98%)	293 (98%)	294 (98%)	292 (97%)	293 (98%)
Fatigue	300 (100%)	293 (98%)	296 (99%)	296 (99%)	295 (98%)	295 (98%)	293 (98%)	294 (98%)
Fever	300 (100%)	294 (98%)	296 (99%)	296 (99%)	295 (98%)	296 (99%)	294 (98%)	294 (98%)
Headache	300 (100%)	293 (98%)	295 (98%)	295 (98%)	294 (98%)	294 (98%)	292 (97%)	293 (98%)
Loss Of Appetite	300 (100%)	294 (98%)	295 (98%)	296 (99%)	294 (98%)	295 (98%)	293 (98%)	294 (98%)
Myalgia	300 (100%)	295 (98%)	295 (98%)	296 (99%)	295 (98%)	295 (98%)	293 (98%)	294 (98%)
Nausea	300 (100%)	292 (97%)	294 (98%)	294 (98%)	294 (98%)	294 (98%)	292 (97%)	293 (98%)
Other								
Prevention of Pain and/or Fever	300 (100%)	295 (98%)	295 (98%)	295 (98%)	295 (98%)	295 (98%)	294 (98%)	295 (98%)
Treatment of Pain and/or Fever	300 (100%)	294 (98%)	295 (98%)	295 (98%)	295 (98%)	295 (98%)	294 (98%)	294 (98%)

PPD

Table 14.3.1.9
Solicited Adverse Events, Completeness Analysis, for Each Solicited Event and Time Point
Exposed Set

Vaccination: 1
Group: Naïve

Adverse Event	30 MIN (N=100)	6 HRS (N=100)	DAY 2 (N=100)	DAY 3 (N=100)	DAY 4 (N=100)	DAY 5 (N=100)	DAY 6 (N=100)	DAY 7 (N=100)
Local								
Erythema	94 (94%)	90 (90%)	91 (91%)	92 (92%)	91 (91%)	90 (90%)	90 (90%)	90 (90%)
Induration	94 (94%)	90 (90%)	91 (91%)	92 (92%)	92 (92%)	92 (92%)	90 (90%)	91 (91%)
Pain	100 (100%)	95 (95%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	96 (96%)	96 (96%)
Systemic								
Arthralgia	100 (100%)	96 (96%)	96 (96%)	96 (96%)	96 (96%)	96 (96%)	96 (96%)	96 (96%)
Chills	100 (100%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)
Fatigue	100 (100%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)
Fever	100 (100%)	95 (95%)	96 (96%)	96 (96%)	96 (96%)	97 (97%)	97 (97%)	97 (97%)
Headache	100 (100%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)
Loss Of Appetite	100 (100%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)
Myalgia	100 (100%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)
Nausea	100 (100%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)	97 (97%)
Other								
Prevention of Pain and/or Fever	100 (100%)	96 (96%)	96 (96%)	95 (95%)	96 (96%)	96 (96%)	96 (96%)	96 (96%)
Treatment of Pain and/or Fever	100 (100%)	96 (96%)	96 (96%)	95 (95%)	96 (96%)	96 (96%)	96 (96%)	96 (96%)

PPD

Table 14.3.1.10
Solicited Adverse Events, Completeness Analysis, for Each Solicited Event, Overall Between 6 Hours and Day 7
Exposed Set

Vaccination: 1

Adverse Event	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)
Local				
Erythema	286 (95%)	287 (96%)	573 (95%)	92 (92%)
Induration	286 (95%)	286 (95%)	572 (95%)	92 (92%)
Pain	292 (97%)	296 (99%)	588 (98%)	97 (97%)
Systemic				
Arthralgia	294 (98%)	295 (98%)	589 (98%)	96 (96%)
Chills	294 (98%)	295 (98%)	589 (98%)	97 (97%)
Fatigue	295 (98%)	296 (99%)	591 (98%)	97 (97%)
Fever	296 (98%)	296 (99%)	592 (99%)	97 (97%)
Headache	294 (98%)	295 (98%)	589 (98%)	97 (97%)
Loss Of Appetite	294 (98%)	296 (99%)	590 (98%)	97 (97%)
Myalgia	294 (98%)	296 (99%)	590 (98%)	97 (97%)
Nausea	294 (98%)	294 (98%)	588 (98%)	97 (97%)
Other				
Prevention of Pain and/or Fever	294 (98%)	295 (98%)	589 (98%)	96 (96%)
Treatment of Pain and/or Fever	293 (97%)	295 (98%)	588 (98%)	96 (96%)

PPD

Table 14.3.1.11
Solicited Adverse Events, Completeness Analysis, by Local and Systemic Category, Overall Between 6 Hours and Day 7
Exposed Set

Vaccination: 1

Adverse Event	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/ Menactra-Menveo (N=601)	Naive (N=100)
Local	292 (97%)	296 (99%)	588 (98%)	97 (97%)
Systemic	296 (98%)	296 (99%)	592 (99%)	97 (97%)
Other	295 (98%)	295 (98%)	590 (98%)	96 (96%)

PPD

Table 14.3.1.12

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Upper respiratory tract infection	12 (4%)	9 (3%)	21 (3%)	3 (3%)
Fatigue	9 (3%)	12 (4%)	21 (3%)	0
Headache	9 (3%)	8 (3%)	17 (3%)	4 (4%)
Nasopharyngitis	13 (4%)	5 (2%)	18 (3%)	2 (2%)
Arthralgia	7 (2%)	7 (2%)	14 (2%)	0
Influenza	3 (1%)	7 (2%)	10 (2%)	3 (3%)
Oropharyngeal pain	7 (2%)	5 (2%)	12 (2%)	1 (1%)
Acute sinusitis	11 (4%)	0	11 (2%)	1 (1%)
Myalgia	5 (2%)	7 (2%)	12 (2%)	0
Nausea	8 (3%)	0	8 (1%)	3 (3%)
Nasal congestion	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Pharyngitis	3 (1%)	5 (2%)	8 (1%)	1 (1%)
Sinusitis	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Abdominal pain	6 (2%)	1 (< 1%)	7 (1%)	1 (1%)
Acne	3 (1%)	5 (2%)	8 (1%)	0
Anxiety	5 (2%)	3 (1%)	8 (1%)	0
Asthma	7 (2%)	1 (< 1%)	8 (1%)	0
Bronchitis	4 (1%)	3 (1%)	7 (1%)	1 (1%)
Cough	2 (1%)	6 (2%)	8 (1%)	0
Otitis media	4 (1%)	4 (1%)	8 (1%)	0
Decreased appetite	2 (1%)	5 (2%)	7 (1%)	0
Diarrhoea	2 (1%)	2 (1%)	4 (1%)	3 (3%)
Gastroenteritis viral	1 (< 1%)	6 (2%)	7 (1%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Urinary tract infection	2 (1%)	3 (1%)	5 (1%)	2 (2%)
Injection site pruritus	1 (< 1%)	2 (1%)	3 (< 1%)	3 (3%)
Ligament sprain	3 (1%)	3 (1%)	6 (1%)	0
Pain in extremity	4 (1%)	1 (< 1%)	5 (1%)	1 (1%)
Pharyngitis streptococcal	3 (1%)	3 (1%)	6 (1%)	0
Contusion	4 (1%)	1 (< 1%)	5 (1%)	0
Depression	4 (1%)	1 (< 1%)	5 (1%)	0
Dermatitis contact	4 (1%)	1 (< 1%)	5 (1%)	0
Gastrooesophageal reflux disease	2 (1%)	3 (1%)	5 (1%)	0
Laceration	4 (1%)	1 (< 1%)	5 (1%)	0
Pneumonia mycoplasmal	4 (1%)	1 (< 1%)	5 (1%)	0
Pyrexia	1 (< 1%)	3 (1%)	4 (1%)	1 (1%)
Syncope	2 (1%)	3 (1%)	5 (1%)	0
Viral pharyngitis	3 (1%)	2 (1%)	5 (1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Attention deficit/hyperactivity disorder	2 (1%)	2 (1%)	4 (1%)	0
Cellulitis	4 (1%)	0	4 (1%)	0
Concussion	2 (1%)	2 (1%)	4 (1%)	0
Dizziness	0	4 (1%)	4 (1%)	0
Epistaxis	2 (1%)	2 (1%)	4 (1%)	0
Injection site induration	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Otitis media acute	3 (1%)	1 (< 1%)	4 (1%)	0
Procedural pain	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Sinus congestion	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Arthropod bite	3 (1%)	0	3 (< 1%)	0
Chills	0	3 (1%)	3 (< 1%)	0
Conjunctivitis	2 (1%)	1 (< 1%)	3 (< 1%)	0
Haematuria	2 (1%)	1 (< 1%)	3 (< 1%)	0
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Meniscus injury	1 (< 1%)	2 (1%)	3 (< 1%)	0
Otitis externa	2 (1%)	1 (< 1%)	3 (< 1%)	0
Pneumonia	1 (< 1%)	2 (1%)	3 (< 1%)	0
Rhinitis allergic	1 (< 1%)	2 (1%)	3 (< 1%)	0
Seasonal allergy	2 (1%)	1 (< 1%)	3 (< 1%)	0
Suicide attempt	2 (1%)	1 (< 1%)	3 (< 1%)	0
Tooth abscess	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Vomiting	2 (1%)	1 (< 1%)	3 (< 1%)	0
Anaemia	0	2 (1%)	2 (< 1%)	0
Back pain	2 (1%)	0	2 (< 1%)	0
Bacterial vaginosis	0	1 (< 1%)	1 (< 1%)	1 (1%)
Dysmenorrhoea	0	2 (1%)	2 (< 1%)	0
Folliculitis	1 (< 1%)	0	1 (< 1%)	1 (1%)
Food poisoning	0	2 (1%)	2 (< 1%)	0
Haemorrhoids	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Hand fracture	0	2 (1%)	2 (< 1%)	0
Hypersensitivity	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Influenza like illness	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Insomnia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Joint injury	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Limb injury	2 (1%)	0	2 (< 1%)	0
Major depression	2 (1%)	0	2 (< 1%)	0
Migraine	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Rash	1 (< 1%)	1 (< 1%)	2 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Sleep disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Tooth impacted	2 (1%)	0	2 (< 1%)	0
Urticaria	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Viral upper respiratory tract infection	0	2 (1%)	2 (< 1%)	0
Wheezing	2 (1%)	0	2 (< 1%)	0
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Abdominal tenderness	1 (< 1%)	0	1 (< 1%)	0
Abortion spontaneous	0	0	0	1 (1%)
Alcohol poisoning	0	1 (< 1%)	1 (< 1%)	0
Allergy to animal	0	1 (< 1%)	1 (< 1%)	0
Alopecia	1 (< 1%)	0	1 (< 1%)	0
Anal skin tags	0	1 (< 1%)	1 (< 1%)	0
Anaphylactic reaction	1 (< 1%)	0	1 (< 1%)	0
Angina pectoris	0	0	0	1 (1%)
Arthropod sting	1 (< 1%)	0	1 (< 1%)	0
Axillary pain	0	0	0	1 (1%)
Bartholin's abscess	0	1 (< 1%)	1 (< 1%)	0
Benign bone neoplasm	0	1 (< 1%)	1 (< 1%)	0
Biliary dyskinesia	0	0	0	1 (1%)
Bronchitis viral	1 (< 1%)	0	1 (< 1%)	0
Cardiac murmur	0	1 (< 1%)	1 (< 1%)	0
Cerumen impaction	0	1 (< 1%)	1 (< 1%)	0
Chest pain	1 (< 1%)	0	1 (< 1%)	0
Chlamydial infection	0	1 (< 1%)	1 (< 1%)	0
Conjunctival abrasion	0	1 (< 1%)	1 (< 1%)	0
Conjunctivitis allergic	0	1 (< 1%)	1 (< 1%)	0
Constipation	0	1 (< 1%)	1 (< 1%)	0
Croup infectious	1 (< 1%)	0	1 (< 1%)	0
Cystitis	1 (< 1%)	0	1 (< 1%)	0
Dehydration	0	1 (< 1%)	1 (< 1%)	0
Diabetic ketoacidotic hyperglycaemic coma	0	0	0	1 (1%)
Disruptive mood dysregulation disorder	1 (< 1%)	0	1 (< 1%)	0
Diverticulitis	0	0	0	1 (1%)
Dyspepsia	1 (< 1%)	0	1 (< 1%)	0
Dysphonia	0	1 (< 1%)	1 (< 1%)	0
Dyspnoea	0	1 (< 1%)	1 (< 1%)	0
Dysuria	1 (< 1%)	0	1 (< 1%)	0
Ear pain	1 (< 1%)	0	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Eosinophilic oesophagitis	0	1 (< 1%)	1 (< 1%)	0
Erythema of eyelid	0	0	0	1 (1%)
Essential hypertension	0	0	0	1 (1%)
Eye disorder	0	1 (< 1%)	1 (< 1%)	0
Facial bones fracture	0	1 (< 1%)	1 (< 1%)	0
Foot fracture	0	0	0	1 (1%)
Fungal infection	0	1 (< 1%)	1 (< 1%)	0
Gastritis	0	1 (< 1%)	1 (< 1%)	0
Groin pain	0	0	0	1 (1%)
Hordeolum	1 (< 1%)	0	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0
Hypoglycaemia	1 (< 1%)	0	1 (< 1%)	0
Infectious mononucleosis	0	1 (< 1%)	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Intentional overdose	1 (< 1%)	0	1 (< 1%)	0
Joint dislocation	0	1 (< 1%)	1 (< 1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Kidney infection	0	0	0	1 (1%)
Laryngitis	1 (< 1%)	0	1 (< 1%)	0
Ligament rupture	1 (< 1%)	0	1 (< 1%)	0
Loss of consciousness	1 (< 1%)	0	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Lymphangiopathy	1 (< 1%)	0	1 (< 1%)	0
Medical device site erythema	1 (< 1%)	0	1 (< 1%)	0
Medical device site swelling	1 (< 1%)	0	1 (< 1%)	0
Menstruation irregular	1 (< 1%)	0	1 (< 1%)	0
Metatarsalgia	1 (< 1%)	0	1 (< 1%)	0
Metrorrhagia	0	1 (< 1%)	1 (< 1%)	0
Middle ear effusion	0	1 (< 1%)	1 (< 1%)	0
Migraine with aura	1 (< 1%)	0	1 (< 1%)	0
Muscle strain	0	1 (< 1%)	1 (< 1%)	0
Muscle tightness	0	0	0	1 (1%)
Musculoskeletal pain	0	1 (< 1%)	1 (< 1%)	0
Myalgia intercostal	1 (< 1%)	0	1 (< 1%)	0
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Oral herpes	0	1 (< 1%)	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Pain	1 (< 1%)	0	1 (< 1%)	0
Pain in jaw	0	1 (< 1%)	1 (< 1%)	0
Pelvic congestion	0	0	0	1 (1%)
Peripheral swelling	0	1 (< 1%)	1 (< 1%)	0
Pneumonia bacterial	1 (< 1%)	0	1 (< 1%)	0
Pollakiuria	1 (< 1%)	0	1 (< 1%)	0
Polyuria	1 (< 1%)	0	1 (< 1%)	0
Post procedural complication	1 (< 1%)	0	1 (< 1%)	0
Post-traumatic stress disorder	1 (< 1%)	0	1 (< 1%)	0
Presyncope	0	1 (< 1%)	1 (< 1%)	0
Proteinuria	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Pulmonary congestion	0	1 (< 1%)	1 (< 1%)	0
Pulmonary contusion	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection viral	1 (< 1%)	0	1 (< 1%)	0
Retinal tear	1 (< 1%)	0	1 (< 1%)	0
Rheumatoid arthritis	1 (< 1%)	0	1 (< 1%)	0
Rhinitis	0	1 (< 1%)	1 (< 1%)	0
Rhinorrhoea	0	1 (< 1%)	1 (< 1%)	0
Rhonchi	0	1 (< 1%)	1 (< 1%)	0
Road traffic accident	1 (< 1%)	0	1 (< 1%)	0
Salivary gland mucocoele	0	1 (< 1%)	1 (< 1%)	0
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Skin papilloma	0	1 (< 1%)	1 (< 1%)	0
Snoring	1 (< 1%)	0	1 (< 1%)	0
Subcutaneous abscess	0	1 (< 1%)	1 (< 1%)	0
Suicidal ideation	0	1 (< 1%)	1 (< 1%)	0
Synovial cyst	1 (< 1%)	0	1 (< 1%)	0
Tension headache	1 (< 1%)	0	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Tympanic membrane perforation	1 (< 1%)	0	1 (< 1%)	0
Umbilical hernia	0	1 (< 1%)	1 (< 1%)	0
Upper-airway cough syndrome	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Vaginal infection	0	0	0	1 (1%)

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Vertigo	0	1 (< 1%)	1 (< 1%)	0
Viral rash	1 (< 1%)	0	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Vitamin D deficiency	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal candidiasis	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal mycotic infection	0	0	0	1 (1%)

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.1

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Headache	8 (3%)	8 (3%)	16 (3%)	3 (3%)
Fatigue	6 (2%)	12 (4%)	18 (3%)	0
Nasopharyngitis	11 (4%)	4 (1%)	15 (2%)	2 (2%)
Arthralgia	5 (2%)	7 (2%)	12 (2%)	0
Myalgia	4 (1%)	7 (2%)	11 (2%)	0
Upper respiratory tract infection	4 (1%)	4 (1%)	8 (1%)	2 (2%)
Nasal congestion	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Nausea	6 (2%)	0	6 (1%)	2 (2%)
Oropharyngeal pain	3 (1%)	4 (1%)	7 (1%)	1 (1%)
Decreased appetite	2 (1%)	5 (2%)	7 (1%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Diarrhoea	2 (1%)	2 (1%)	4 (1%)	2 (2%)
Injection site pruritus	1 (< 1%)	2 (1%)	3 (< 1%)	3 (3%)
Abdominal pain	4 (1%)	1 (< 1%)	5 (1%)	0
Acute sinusitis	3 (1%)	0	3 (< 1%)	1 (1%)
Cough	1 (< 1%)	3 (1%)	4 (1%)	0
Dizziness	0	4 (1%)	4 (1%)	0
Gastroenteritis viral	0	4 (1%)	4 (1%)	0
Injection site induration	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Pyrexia	0	3 (1%)	3 (< 1%)	1 (1%)
Sinus congestion	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Syncope	1 (< 1%)	3 (1%)	4 (1%)	0
Urinary tract infection	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Asthma	3 (1%)	0	3 (< 1%)	0
Chills	0	3 (1%)	3 (< 1%)	0
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Pain in extremity	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Pharyngitis	1 (< 1%)	2 (1%)	3 (< 1%)	0
Sinusitis	1 (< 1%)	2 (1%)	3 (< 1%)	0
Vomiting	2 (1%)	1 (< 1%)	3 (< 1%)	0
Acne	0	2 (1%)	2 (< 1%)	0
Attention deficit/hyperactivity disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Dermatitis contact	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Epistaxis	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Food poisoning	0	2 (1%)	2 (< 1%)	0
Influenza	0	1 (< 1%)	1 (< 1%)	1 (1%)
Otitis media	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Pneumonia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.1

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Procedural pain	1 (< 1%)	0	1 (< 1%)	1 (1%)
Rash	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Urticaria	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Alcohol poisoning	0	1 (< 1%)	1 (< 1%)	0
Allergy to animal	0	1 (< 1%)	1 (< 1%)	0
Angina pectoris	0	0	0	1 (1%)
Anxiety	0	1 (< 1%)	1 (< 1%)	0
Arthropod bite	1 (< 1%)	0	1 (< 1%)	0
Axillary pain	0	0	0	1 (1%)
Back pain	1 (< 1%)	0	1 (< 1%)	0
Benign bone neoplasm	0	1 (< 1%)	1 (< 1%)	0
Bronchitis viral	1 (< 1%)	0	1 (< 1%)	0
Cellulitis	1 (< 1%)	0	1 (< 1%)	0
Chest pain	1 (< 1%)	0	1 (< 1%)	0
Concussion	1 (< 1%)	0	1 (< 1%)	0
Conjunctivitis	1 (< 1%)	0	1 (< 1%)	0
Cystitis	1 (< 1%)	0	1 (< 1%)	0
Depression	0	1 (< 1%)	1 (< 1%)	0
Dysmenorrhoea	0	1 (< 1%)	1 (< 1%)	0
Dyspepsia	1 (< 1%)	0	1 (< 1%)	0
Dysphonia	0	1 (< 1%)	1 (< 1%)	0
Dysuria	1 (< 1%)	0	1 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Erythema of eyelid	0	0	0	1 (1%)
Fungal infection	0	1 (< 1%)	1 (< 1%)	0
Gastritis	0	1 (< 1%)	1 (< 1%)	0
Gastrooesophageal reflux disease	1 (< 1%)	0	1 (< 1%)	0
Haematuria	1 (< 1%)	0	1 (< 1%)	0
Haemorrhoids	1 (< 1%)	0	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0
Hypersensitivity	1 (< 1%)	0	1 (< 1%)	0
Influenza like illness	1 (< 1%)	0	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Joint injury	0	1 (< 1%)	1 (< 1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Laceration	1 (< 1%)	0	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.1

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Laryngitis	1 (< 1%)	0	1 (< 1%)	0
Ligament rupture	1 (< 1%)	0	1 (< 1%)	0
Ligament sprain	0	1 (< 1%)	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Meniscus injury	1 (< 1%)	0	1 (< 1%)	0
Metrorrhagia	0	1 (< 1%)	1 (< 1%)	0
Migraine	1 (< 1%)	0	1 (< 1%)	0
Muscle tightness	0	0	0	1 (1%)
Myalgia intercostal	1 (< 1%)	0	1 (< 1%)	0
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Oral herpes	0	1 (< 1%)	1 (< 1%)	0
Peripheral swelling	0	1 (< 1%)	1 (< 1%)	0
Pneumonia bacterial	1 (< 1%)	0	1 (< 1%)	0
Post procedural complication	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Pulmonary congestion	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection viral	1 (< 1%)	0	1 (< 1%)	0
Rheumatoid arthritis	1 (< 1%)	0	1 (< 1%)	0
Rhinorrhoea	0	1 (< 1%)	1 (< 1%)	0
Rhonchi	0	1 (< 1%)	1 (< 1%)	0
Road traffic accident	1 (< 1%)	0	1 (< 1%)	0
Salivary gland mucocoele	0	1 (< 1%)	1 (< 1%)	0
Seasonal allergy	1 (< 1%)	0	1 (< 1%)	0
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Synovial cyst	1 (< 1%)	0	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Tooth abscess	1 (< 1%)	0	1 (< 1%)	0
Tooth impacted	1 (< 1%)	0	1 (< 1%)	0
Upper-airway cough syndrome	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Viral pharyngitis	1 (< 1%)	0	1 (< 1%)	0
Viral rash	1 (< 1%)	0	1 (< 1%)	0
Viral upper respiratory tract infection	0	1 (< 1%)	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.2

Subjects With Unsolicited Adverse Events With Onset Within 30 Minutes After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Injection site pain	0	2 (1%)	2 (< 1%)	0
Chills	0	1 (< 1%)	1 (< 1%)	0
Dizziness	0	1 (< 1%)	1 (< 1%)	0
Fatigue	0	1 (< 1%)	1 (< 1%)	0
Injection site erythema	0	0	0	1 (1%)
Myalgia	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0
Syncope	0	1 (< 1%)	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.3

Subjects With Unsolicited Adverse Events With Onset After Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Upper respiratory tract infection	8 (3%)	5 (2%)	13 (2%)	1 (1%)
Influenza	3 (1%)	6 (2%)	9 (1%)	2 (2%)
Acute sinusitis	9 (3%)	0	9 (1%)	0
Bronchitis	4 (1%)	3 (1%)	7 (1%)	1 (1%)
Anxiety	5 (2%)	2 (1%)	7 (1%)	0
Acne	3 (1%)	3 (1%)	6 (1%)	0
Otitis media	3 (1%)	3 (1%)	6 (1%)	0
Pharyngitis streptococcal	3 (1%)	3 (1%)	6 (1%)	0
Pharyngitis	2 (1%)	3 (1%)	5 (1%)	1 (1%)
Sinusitis	1 (< 1%)	4 (1%)	5 (1%)	1 (1%)
Asthma	4 (1%)	1 (< 1%)	5 (1%)	0
Contusion	4 (1%)	1 (< 1%)	5 (1%)	0
Ligament sprain	3 (1%)	2 (1%)	5 (1%)	0
Nasopharyngitis	4 (1%)	1 (< 1%)	5 (1%)	0
Oropharyngeal pain	4 (1%)	1 (< 1%)	5 (1%)	0
Pneumonia mycoplasmal	4 (1%)	1 (< 1%)	5 (1%)	0
Cough	1 (< 1%)	3 (1%)	4 (1%)	0
Depression	4 (1%)	0	4 (1%)	0
Gastrooesophageal reflux disease	1 (< 1%)	3 (1%)	4 (1%)	0
Laceration	3 (1%)	1 (< 1%)	4 (1%)	0
Otitis media acute	3 (1%)	1 (< 1%)	4 (1%)	0
Viral pharyngitis	2 (1%)	2 (1%)	4 (1%)	0
Pain in extremity	3 (1%)	0	3 (< 1%)	1 (1%)
Cellulitis	3 (1%)	0	3 (< 1%)	0
Concussion	1 (< 1%)	2 (1%)	3 (< 1%)	0
Dermatitis contact	3 (1%)	0	3 (< 1%)	0
Fatigue	3 (1%)	0	3 (< 1%)	0
Gastroenteritis viral	1 (< 1%)	2 (1%)	3 (< 1%)	0
Nausea	2 (1%)	0	2 (< 1%)	2 (2%)
Otitis externa	2 (1%)	1 (< 1%)	3 (< 1%)	0
Rhinitis allergic	1 (< 1%)	2 (1%)	3 (< 1%)	0
Suicide attempt	2 (1%)	1 (< 1%)	3 (< 1%)	0
Urinary tract infection	1 (< 1%)	1 (< 1%)	2 (< 1%)	2 (2%)
Abdominal pain	2 (1%)	0	2 (< 1%)	1 (1%)
Anaemia	0	2 (1%)	2 (< 1%)	0
Arthralgia	2 (1%)	0	2 (< 1%)	0
Arthropod bite	2 (1%)	0	2 (< 1%)	0
Attention deficit/hyperactivity disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.3

Subjects With Unsolicited Adverse Events With Onset After Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Conjunctivitis	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Epistaxis	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Haematuria	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Hand fracture	0	2 (1%)	2 (< 1%)	0
Insomnia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Limb injury	2 (1%)	0	2 (< 1%)	0
Major depression	2 (1%)	0	2 (< 1%)	0
Meniscus injury	0	2 (1%)	2 (< 1%)	0
Procedural pain	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Seasonal allergy	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Sleep disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Wheezing	2 (1%)	0	2 (< 1%)	0
Bacterial vaginosis	0	1 (< 1%)	1 (< 1%)	1 (1%)
Folliculitis	1 (< 1%)	0	1 (< 1%)	1 (1%)
Headache	1 (< 1%)	0	1 (< 1%)	1 (1%)
Tooth abscess	0	1 (< 1%)	1 (< 1%)	1 (1%)
Abdominal tenderness	1 (< 1%)	0	1 (< 1%)	0
Alopecia	1 (< 1%)	0	1 (< 1%)	0
Anal skin tags	0	1 (< 1%)	1 (< 1%)	0
Anaphylactic reaction	1 (< 1%)	0	1 (< 1%)	0
Arthropod sting	1 (< 1%)	0	1 (< 1%)	0
Back pain	1 (< 1%)	0	1 (< 1%)	0
Bartholin's abscess	0	1 (< 1%)	1 (< 1%)	0
Cardiac murmur	0	1 (< 1%)	1 (< 1%)	0
Cerumen impaction	0	1 (< 1%)	1 (< 1%)	0
Chlamydial infection	0	1 (< 1%)	1 (< 1%)	0
Conjunctival abrasion	0	1 (< 1%)	1 (< 1%)	0
Conjunctivitis allergic	0	1 (< 1%)	1 (< 1%)	0
Constipation	0	1 (< 1%)	1 (< 1%)	0
Croup infectious	1 (< 1%)	0	1 (< 1%)	0
Dehydration	0	1 (< 1%)	1 (< 1%)	0
Disruptive mood dysregulation disorder	1 (< 1%)	0	1 (< 1%)	0
Dysmenorrhoea	0	1 (< 1%)	1 (< 1%)	0
Dyspnoea	0	1 (< 1%)	1 (< 1%)	0
Ear pain	1 (< 1%)	0	1 (< 1%)	0
Eosinophilic oesophagitis	0	1 (< 1%)	1 (< 1%)	0
Eye disorder	0	1 (< 1%)	1 (< 1%)	0
Facial bones fracture	0	1 (< 1%)	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.3
Subjects With Unsolicited Adverse Events With Onset After Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Haemorrhoids	0	1 (< 1%)	1 (< 1%)	0
Hordeolum	1 (< 1%)	0	1 (< 1%)	0
Hypersensitivity	0	1 (< 1%)	1 (< 1%)	0
Hypoglycaemia	1 (< 1%)	0	1 (< 1%)	0
Infectious mononucleosis	0	1 (< 1%)	1 (< 1%)	0
Influenza like illness	0	1 (< 1%)	1 (< 1%)	0
Intentional overdose	1 (< 1%)	0	1 (< 1%)	0
Joint dislocation	0	1 (< 1%)	1 (< 1%)	0
Joint injury	1 (< 1%)	0	1 (< 1%)	0
Loss of consciousness	1 (< 1%)	0	1 (< 1%)	0
Lymphangiopathy	1 (< 1%)	0	1 (< 1%)	0
Medical device site erythema	1 (< 1%)	0	1 (< 1%)	0
Medical device site swelling	1 (< 1%)	0	1 (< 1%)	0
Menstruation irregular	1 (< 1%)	0	1 (< 1%)	0
Metatarsalgia	1 (< 1%)	0	1 (< 1%)	0
Middle ear effusion	0	1 (< 1%)	1 (< 1%)	0
Migraine	0	1 (< 1%)	1 (< 1%)	0
Migraine with aura	1 (< 1%)	0	1 (< 1%)	0
Muscle strain	0	1 (< 1%)	1 (< 1%)	0
Musculoskeletal pain	0	1 (< 1%)	1 (< 1%)	0
Myalgia	1 (< 1%)	0	1 (< 1%)	0
Pain	1 (< 1%)	0	1 (< 1%)	0
Pain in jaw	0	1 (< 1%)	1 (< 1%)	0
Pneumonia	0	1 (< 1%)	1 (< 1%)	0
Pollakiuria	1 (< 1%)	0	1 (< 1%)	0
Polyuria	1 (< 1%)	0	1 (< 1%)	0
Post-traumatic stress disorder	1 (< 1%)	0	1 (< 1%)	0
Presyncope	0	1 (< 1%)	1 (< 1%)	0
Proteinuria	1 (< 1%)	0	1 (< 1%)	0
Pulmonary contusion	0	1 (< 1%)	1 (< 1%)	0
Pyrexia	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection	1 (< 1%)	0	1 (< 1%)	0
Retinal tear	1 (< 1%)	0	1 (< 1%)	0
Rhinitis	0	1 (< 1%)	1 (< 1%)	0
Skin papilloma	0	1 (< 1%)	1 (< 1%)	0
Snoring	1 (< 1%)	0	1 (< 1%)	0
Subcutaneous abscess	0	1 (< 1%)	1 (< 1%)	0
Suicidal ideation	0	1 (< 1%)	1 (< 1%)	0

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.12.3

Subjects With Unsolicited Adverse Events With Onset After Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Syncope	1 (< 1%)	0	1 (< 1%)	0
Tension headache	1 (< 1%)	0	1 (< 1%)	0
Tooth impacted	1 (< 1%)	0	1 (< 1%)	0
Tympanic membrane perforation	1 (< 1%)	0	1 (< 1%)	0
Umbilical hernia	0	1 (< 1%)	1 (< 1%)	0
Urticaria	0	1 (< 1%)	1 (< 1%)	0
Vertigo	0	1 (< 1%)	1 (< 1%)	0
Viral upper respiratory tract infection	0	1 (< 1%)	1 (< 1%)	0
Vitamin D deficiency	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal candidiasis	1 (< 1%)	0	1 (< 1%)	0
Abortion spontaneous	0	0	0	1 (1%)
Biliary dyskinesia	0	0	0	1 (1%)
Diabetic ketoacidotic hyperglycaemic coma	0	0	0	1 (1%)
Diarrhoea	0	0	0	1 (1%)
Diverticulitis	0	0	0	1 (1%)
Essential hypertension	0	0	0	1 (1%)
Foot fracture	0	0	0	1 (1%)
Groin pain	0	0	0	1 (1%)
Kidney infection	0	0	0	1 (1%)
Pelvic congestion	0	0	0	1 (1%)
Vaginal infection	0	0	0	1 (1%)
Vulvovaginal mycotic infection	0	0	0	1 (1%)

Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	137 (46%)	120 (40%)	257 (43%)	32 (32%)
Blood and lymphatic system disorders	1 (< 1%)	2 (1%)	3 (< 1%)	0
Anaemia	0	2 (1%)	2 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Cardiac disorders	0	0	0	1 (1%)
Angina pectoris	0	0	0	1 (1%)
Ear and labyrinth disorders	2 (1%)	2 (1%)	4 (1%)	0
Cerumen impaction	0	1 (< 1%)	1 (< 1%)	0
Ear pain	1 (< 1%)	0	1 (< 1%)	0
Middle ear effusion	0	1 (< 1%)	1 (< 1%)	0
Tympanic membrane perforation	1 (< 1%)	0	1 (< 1%)	0
Vertigo	0	1 (< 1%)	1 (< 1%)	0
Eye disorders	2 (1%)	3 (1%)	5 (1%)	1 (1%)
Conjunctivitis allergic	0	1 (< 1%)	1 (< 1%)	0
Erythema of eyelid	0	0	0	1 (1%)
Eye disorder	0	1 (< 1%)	1 (< 1%)	0
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Retinal tear	1 (< 1%)	0	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Gastrointestinal disorders	22 (7%)	14 (5%)	36 (6%)	6 (6%)
Nausea	8 (3%)	0	8 (1%)	3 (3%)
Abdominal pain	6 (2%)	1 (< 1%)	7 (1%)	1 (1%)
Diarrhoea	2 (1%)	2 (1%)	4 (1%)	3 (3%)
Gastrooesophageal reflux disease	2 (1%)	3 (1%)	5 (1%)	0
Vomiting	2 (1%)	1 (< 1%)	3 (< 1%)	0
Food poisoning	0	2 (1%)	2 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Haemorrhoids	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Tooth impacted	2 (1%)	0	2 (< 1%)	0
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Abdominal tenderness	1 (< 1%)	0	1 (< 1%)	0
Anal skin tags	0	1 (< 1%)	1 (< 1%)	0
Constipation	0	1 (< 1%)	1 (< 1%)	0
Dyspepsia	1 (< 1%)	0	1 (< 1%)	0
Eosinophilic oesophagitis	0	1 (< 1%)	1 (< 1%)	0
Gastritis	0	1 (< 1%)	1 (< 1%)	0
Salivary gland mucocoele	0	1 (< 1%)	1 (< 1%)	0
Umbilical hernia	0	1 (< 1%)	1 (< 1%)	0
General disorders and administration site conditions	18 (6%)	25 (8%)	43 (7%)	9 (9%)
Fatigue	9 (3%)	12 (4%)	21 (3%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Injection site pruritus	1 (< 1%)	2 (1%)	3 (< 1%)	3 (3%)
Pyrexia	1 (< 1%)	3 (1%)	4 (1%)	1 (1%)
Injection site induration	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Chills	0	3 (1%)	3 (< 1%)	0
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Influenza like illness	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Axillary pain	0	0	0	1 (1%)
Chest pain	1 (< 1%)	0	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Medical device site erythema	1 (< 1%)	0	1 (< 1%)	0
Medical device site swelling	1 (< 1%)	0	1 (< 1%)	0
Pain	1 (< 1%)	0	1 (< 1%)	0
Peripheral swelling	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Hepatobiliary disorders	0	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Biliary dyskinesia	0	0	0	1 (1%)
Immune system disorders	4 (1%)	3 (1%)	7 (1%)	0
Seasonal allergy	2 (1%)	1 (< 1%)	3 (< 1%)	0
Hypersensitivity	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Allergy to animal	0	1 (< 1%)	1 (< 1%)	0
Anaphylactic reaction	1 (< 1%)	0	1 (< 1%)	0
Infections and infestations	64 (21%)	57 (19%)	121 (20%)	13 (13%)
Upper respiratory tract infection	12 (4%)	9 (3%)	21 (3%)	3 (3%)
Nasopharyngitis	13 (4%)	5 (2%)	18 (3%)	2 (2%)
Influenza	3 (1%)	7 (2%)	10 (2%)	3 (3%)
Acute sinusitis	11 (4%)	0	11 (2%)	1 (1%)
Pharyngitis	3 (1%)	5 (2%)	8 (1%)	1 (1%)
Sinusitis	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Bronchitis	4 (1%)	3 (1%)	7 (1%)	1 (1%)
Otitis media	4 (1%)	4 (1%)	8 (1%)	0
Gastroenteritis viral	1 (< 1%)	6 (2%)	7 (1%)	0
Urinary tract infection	2 (1%)	3 (1%)	5 (1%)	2 (2%)
Pharyngitis streptococcal	3 (1%)	3 (1%)	6 (1%)	0
Pneumonia mycoplasmal	4 (1%)	1 (< 1%)	5 (1%)	0
Viral pharyngitis	3 (1%)	2 (1%)	5 (1%)	0
Cellulitis	4 (1%)	0	4 (1%)	0
Otitis media acute	3 (1%)	1 (< 1%)	4 (1%)	0
Conjunctivitis	2 (1%)	1 (< 1%)	3 (< 1%)	0
Otitis externa	2 (1%)	1 (< 1%)	3 (< 1%)	0
Pneumonia	1 (< 1%)	2 (1%)	3 (< 1%)	0
Tooth abscess	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Bacterial vaginosis	0	1 (< 1%)	1 (< 1%)	1 (1%)
Folliculitis	1 (< 1%)	0	1 (< 1%)	1 (1%)
Viral upper respiratory tract infection	0	2 (1%)	2 (< 1%)	0
Bartholin's abscess	0	1 (< 1%)	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Bronchitis viral	1 (< 1%)	0	1 (< 1%)	0
Chlamydial infection	0	1 (< 1%)	1 (< 1%)	0
Croup infectious	1 (< 1%)	0	1 (< 1%)	0
Cystitis	1 (< 1%)	0	1 (< 1%)	0
Diverticulitis	0	0	0	1 (1%)
Fungal infection	0	1 (< 1%)	1 (< 1%)	0
Hordeolum	1 (< 1%)	0	1 (< 1%)	0
Infectious mononucleosis	0	1 (< 1%)	1 (< 1%)	0
Kidney infection	0	0	0	1 (1%)
Laryngitis	1 (< 1%)	0	1 (< 1%)	0
Oral herpes	0	1 (< 1%)	1 (< 1%)	0
Pneumonia bacterial	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection viral	1 (< 1%)	0	1 (< 1%)	0
Rhinitis	0	1 (< 1%)	1 (< 1%)	0
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Subcutaneous abscess	0	1 (< 1%)	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Vaginal infection	0	0	0	1 (1%)
Viral rash	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal candidiasis	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal mycotic infection	0	0	0	1 (1%)
Injury, poisoning and procedural complications	24 (8%)	15 (5%)	39 (6%)	2 (2%)
Ligament sprain	3 (1%)	3 (1%)	6 (1%)	0
Contusion	4 (1%)	1 (< 1%)	5 (1%)	0
Laceration	4 (1%)	1 (< 1%)	5 (1%)	0
Concussion	2 (1%)	2 (1%)	4 (1%)	0
Procedural pain	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Arthropod bite	3 (1%)	0	3 (< 1%)	0
Meniscus injury	1 (< 1%)	2 (1%)	3 (< 1%)	0
Hand fracture	0	2 (1%)	2 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Joint injury	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Limb injury	2 (1%)	0	2 (< 1%)	0
Alcohol poisoning	0	1 (< 1%)	1 (< 1%)	0
Arthropod sting	1 (< 1%)	0	1 (< 1%)	0
Conjunctival abrasion	0	1 (< 1%)	1 (< 1%)	0
Facial bones fracture	0	1 (< 1%)	1 (< 1%)	0
Foot fracture	0	0	0	1 (1%)
Intentional overdose	1 (< 1%)	0	1 (< 1%)	0
Joint dislocation	0	1 (< 1%)	1 (< 1%)	0
Ligament rupture	1 (< 1%)	0	1 (< 1%)	0
Muscle strain	0	1 (< 1%)	1 (< 1%)	0
Post procedural complication	1 (< 1%)	0	1 (< 1%)	0
Pulmonary contusion	0	1 (< 1%)	1 (< 1%)	0
Road traffic accident	1 (< 1%)	0	1 (< 1%)	0
Investigations	0	1 (< 1%)	1 (< 1%)	0
Cardiac murmur	0	1 (< 1%)	1 (< 1%)	0
Metabolism and nutrition disorders	4 (1%)	6 (2%)	10 (2%)	0
Decreased appetite	2 (1%)	5 (2%)	7 (1%)	0
Dehydration	0	1 (< 1%)	1 (< 1%)	0
Hypoglycaemia	1 (< 1%)	0	1 (< 1%)	0
Vitamin D deficiency	1 (< 1%)	0	1 (< 1%)	0
Musculoskeletal and connective tissue disorders	17 (6%)	17 (6%)	34 (6%)	2 (2%)
Arthralgia	7 (2%)	7 (2%)	14 (2%)	0
Myalgia	5 (2%)	7 (2%)	12 (2%)	0
Pain in extremity	4 (1%)	1 (< 1%)	5 (1%)	1 (1%)
Back pain	2 (1%)	0	2 (< 1%)	0
Groin pain	0	0	0	1 (1%)
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Metatarsalgia	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Muscle tightness	0	0	0	1 (1%)
Musculoskeletal pain	0	1 (< 1%)	1 (< 1%)	0
Myalgia intercostal	1 (< 1%)	0	1 (< 1%)	0
Pain in jaw	0	1 (< 1%)	1 (< 1%)	0
Rheumatoid arthritis	1 (< 1%)	0	1 (< 1%)	0
Synovial cyst	1 (< 1%)	0	1 (< 1%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (1%)	2 (< 1%)	0
Benign bone neoplasm	0	1 (< 1%)	1 (< 1%)	0
Skin papilloma	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders	14 (5%)	15 (5%)	29 (5%)	5 (5%)
Headache	9 (3%)	8 (3%)	17 (3%)	4 (4%)
Syncope	2 (1%)	3 (1%)	5 (1%)	0
Dizziness	0	4 (1%)	4 (1%)	0
Migraine	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Diabetic ketoacidotic hyperglycaemic coma	0	0	0	1 (1%)
Loss of consciousness	1 (< 1%)	0	1 (< 1%)	0
Migraine with aura	1 (< 1%)	0	1 (< 1%)	0
Presyncope	0	1 (< 1%)	1 (< 1%)	0
Tension headache	1 (< 1%)	0	1 (< 1%)	0
Pregnancy, puerperium and perinatal conditions	0	0	0	1 (1%)
Abortion spontaneous	0	0	0	1 (1%)
Psychiatric disorders	15 (5%)	9 (3%)	24 (4%)	0
Anxiety	5 (2%)	3 (1%)	8 (1%)	0
Depression	4 (1%)	1 (< 1%)	5 (1%)	0
Attention deficit/hyperactivity disorder	2 (1%)	2 (1%)	4 (1%)	0
Suicide attempt	2 (1%)	1 (< 1%)	3 (< 1%)	0
Insomnia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Major depression	2 (1%)	0	2 (< 1%)	0
Sleep disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Disruptive mood dysregulation disorder	1 (< 1%)	0	1 (< 1%)	0
Post-traumatic stress disorder	1 (< 1%)	0	1 (< 1%)	0
Suicidal ideation	0	1 (< 1%)	1 (< 1%)	0
Renal and urinary disorders	4 (1%)	1 (< 1%)	5 (1%)	0
Haematuria	2 (1%)	1 (< 1%)	3 (< 1%)	0
Dysuria	1 (< 1%)	0	1 (< 1%)	0
Pollakiuria	1 (< 1%)	0	1 (< 1%)	0
Polyuria	1 (< 1%)	0	1 (< 1%)	0
Proteinuria	1 (< 1%)	0	1 (< 1%)	0
Reproductive system and breast disorders	1 (< 1%)	3 (1%)	4 (1%)	1 (1%)
Dysmenorrhoea	0	2 (1%)	2 (< 1%)	0
Menstruation irregular	1 (< 1%)	0	1 (< 1%)	0
Metrorrhagia	0	1 (< 1%)	1 (< 1%)	0
Pelvic congestion	0	0	0	1 (1%)
Respiratory, thoracic and mediastinal disorders	23 (8%)	24 (8%)	47 (8%)	3 (3%)
Oropharyngeal pain	7 (2%)	5 (2%)	12 (2%)	1 (1%)
Nasal congestion	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Asthma	7 (2%)	1 (< 1%)	8 (1%)	0
Cough	2 (1%)	6 (2%)	8 (1%)	0
Epistaxis	2 (1%)	2 (1%)	4 (1%)	0
Sinus congestion	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Rhinitis allergic	1 (< 1%)	2 (1%)	3 (< 1%)	0
Wheezing	2 (1%)	0	2 (< 1%)	0
Dysphonia	0	1 (< 1%)	1 (< 1%)	0
Dyspnoea	0	1 (< 1%)	1 (< 1%)	0
Pulmonary congestion	0	1 (< 1%)	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Rhinorrhoea	0	1 (< 1%)	1 (< 1%)	0
Rhonchi	0	1 (< 1%)	1 (< 1%)	0
Snoring	1 (< 1%)	0	1 (< 1%)	0
Upper-airway cough syndrome	0	1 (< 1%)	1 (< 1%)	0
Skin and subcutaneous tissue disorders	10 (3%)	10 (3%)	20 (3%)	0
Acne	3 (1%)	5 (2%)	8 (1%)	0
Dermatitis contact	4 (1%)	1 (< 1%)	5 (1%)	0
Rash	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Urticaria	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Alopecia	1 (< 1%)	0	1 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0
Vascular disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Essential hypertension	0	0	0	1 (1%)
Hot flush	0	1 (< 1%)	1 (< 1%)	0
Lymphangiopathy	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13.1

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	74 (25%)	78 (26%)	152 (25%)	22 (22%)
Blood and lymphatic system disorders	1 (< 1%)	0	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Cardiac disorders	0	0	0	1 (1%)
Angina pectoris	0	0	0	1 (1%)
Eye disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Erythema of eyelid	0	0	0	1 (1%)
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Gastrointestinal disorders	16 (5%)	8 (3%)	24 (4%)	4 (4%)
Nausea	6 (2%)	0	6 (1%)	2 (2%)
Diarrhoea	2 (1%)	2 (1%)	4 (1%)	2 (2%)
Abdominal pain	4 (1%)	1 (< 1%)	5 (1%)	0
Vomiting	2 (1%)	1 (< 1%)	3 (< 1%)	0
Food poisoning	0	2 (1%)	2 (< 1%)	0
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Dyspepsia	1 (< 1%)	0	1 (< 1%)	0
Gastritis	0	1 (< 1%)	1 (< 1%)	0
Gastrooesophageal reflux disease	1 (< 1%)	0	1 (< 1%)	0
Haemorrhoids	1 (< 1%)	0	1 (< 1%)	0
Salivary gland mucocoele	0	1 (< 1%)	1 (< 1%)	0
Tooth impacted	1 (< 1%)	0	1 (< 1%)	0
General disorders and administration site conditions	12 (4%)	24 (8%)	36 (6%)	9 (9%)
Fatigue	6 (2%)	12 (4%)	18 (3%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Injection site pruritus	1 (< 1%)	2 (1%)	3 (< 1%)	3 (3%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Injection site induration	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Pyrexia	0	3 (1%)	3 (< 1%)	1 (1%)
Chills	0	3 (1%)	3 (< 1%)	0
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Axillary pain	0	0	0	1 (1%)
Chest pain	1 (< 1%)	0	1 (< 1%)	0
Influenza like illness	1 (< 1%)	0	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Peripheral swelling	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Immune system disorders	2 (1%)	1 (< 1%)	3 (< 1%)	0
Allergy to animal	0	1 (< 1%)	1 (< 1%)	0
Hypersensitivity	1 (< 1%)	0	1 (< 1%)	0
Seasonal allergy	1 (< 1%)	0	1 (< 1%)	0
Infections and infestations	33 (11%)	22 (7%)	55 (9%)	6 (6%)
Nasopharyngitis	11 (4%)	4 (1%)	15 (2%)	2 (2%)
Upper respiratory tract infection	4 (1%)	4 (1%)	8 (1%)	2 (2%)
Acute sinusitis	3 (1%)	0	3 (< 1%)	1 (1%)
Gastroenteritis viral	0	4 (1%)	4 (1%)	0
Urinary tract infection	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Pharyngitis	1 (< 1%)	2 (1%)	3 (< 1%)	0
Sinusitis	1 (< 1%)	2 (1%)	3 (< 1%)	0
Influenza	0	1 (< 1%)	1 (< 1%)	1 (1%)
Otitis media	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Pneumonia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Bronchitis viral	1 (< 1%)	0	1 (< 1%)	0
Cellulitis	1 (< 1%)	0	1 (< 1%)	0
Conjunctivitis	1 (< 1%)	0	1 (< 1%)	0
Cystitis	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Fungal infection	0	1 (< 1%)	1 (< 1%)	0
Laryngitis	1 (< 1%)	0	1 (< 1%)	0
Oral herpes	0	1 (< 1%)	1 (< 1%)	0
Pneumonia bacterial	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection viral	1 (< 1%)	0	1 (< 1%)	0
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Tooth abscess	1 (< 1%)	0	1 (< 1%)	0
Viral pharyngitis	1 (< 1%)	0	1 (< 1%)	0
Viral rash	1 (< 1%)	0	1 (< 1%)	0
Viral upper respiratory tract infection	0	1 (< 1%)	1 (< 1%)	0
Injury, poisoning and procedural complications	6 (2%)	3 (1%)	9 (1%)	1 (1%)
Procedural pain	1 (< 1%)	0	1 (< 1%)	1 (1%)
Alcohol poisoning	0	1 (< 1%)	1 (< 1%)	0
Arthropod bite	1 (< 1%)	0	1 (< 1%)	0
Concussion	1 (< 1%)	0	1 (< 1%)	0
Joint injury	0	1 (< 1%)	1 (< 1%)	0
Laceration	1 (< 1%)	0	1 (< 1%)	0
Ligament rupture	1 (< 1%)	0	1 (< 1%)	0
Ligament sprain	0	1 (< 1%)	1 (< 1%)	0
Meniscus injury	1 (< 1%)	0	1 (< 1%)	0
Post procedural complication	1 (< 1%)	0	1 (< 1%)	0
Road traffic accident	1 (< 1%)	0	1 (< 1%)	0
Metabolism and nutrition disorders	2 (1%)	5 (2%)	7 (1%)	0
Decreased appetite	2 (1%)	5 (2%)	7 (1%)	0
Musculoskeletal and connective tissue disorders	9 (3%)	15 (5%)	24 (4%)	2 (2%)
Arthralgia	5 (2%)	7 (2%)	12 (2%)	0
Myalgia	4 (1%)	7 (2%)	11 (2%)	0
Pain in extremity	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Back pain	1 (< 1%)	0	1 (< 1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Muscle tightness	0	0	0	1 (1%)
Myalgia intercostal	1 (< 1%)	0	1 (< 1%)	0
Rheumatoid arthritis	1 (< 1%)	0	1 (< 1%)	0
Synovial cyst	1 (< 1%)	0	1 (< 1%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (< 1%)	1 (< 1%)	0
Benign bone neoplasm	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders	9 (3%)	14 (5%)	23 (4%)	3 (3%)
Headache	8 (3%)	8 (3%)	16 (3%)	3 (3%)
Dizziness	0	4 (1%)	4 (1%)	0
Syncope	1 (< 1%)	3 (1%)	4 (1%)	0
Migraine	1 (< 1%)	0	1 (< 1%)	0
Psychiatric disorders	1 (< 1%)	3 (1%)	4 (1%)	0
Attention deficit/hyperactivity disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Anxiety	0	1 (< 1%)	1 (< 1%)	0
Depression	0	1 (< 1%)	1 (< 1%)	0
Renal and urinary disorders	1 (< 1%)	0	1 (< 1%)	0
Dysuria	1 (< 1%)	0	1 (< 1%)	0
Haematuria	1 (< 1%)	0	1 (< 1%)	0
Reproductive system and breast disorders	0	2 (1%)	2 (< 1%)	0
Dysmenorrhoea	0	1 (< 1%)	1 (< 1%)	0
Metrorrhagia	0	1 (< 1%)	1 (< 1%)	0
Respiratory, thoracic and mediastinal disorders	11 (4%)	17 (6%)	28 (5%)	3 (3%)
Nasal congestion	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Oropharyngeal pain	3 (1%)	4 (1%)	7 (1%)	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Cough	1 (< 1%)	3 (1%)	4 (1%)	0
Sinus congestion	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Asthma	3 (1%)	0	3 (< 1%)	0
Epistaxis	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Dysphonia	0	1 (< 1%)	1 (< 1%)	0
Pulmonary congestion	0	1 (< 1%)	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0
Rhinorrhoea	0	1 (< 1%)	1 (< 1%)	0
Rhonchi	0	1 (< 1%)	1 (< 1%)	0
Upper-airway cough syndrome	0	1 (< 1%)	1 (< 1%)	0
Skin and subcutaneous tissue disorders	4 (1%)	7 (2%)	11 (2%)	0
Acne	0	2 (1%)	2 (< 1%)	0
Dermatitis contact	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Rash	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Urticaria	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0
Vascular disorders	0	1 (< 1%)	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.13.2
Subjects With Unsolicited Adverse Events With Onset Within 30 Minutes After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	0	8 (3%)	8 (1%)	1 (1%)
General disorders and administration site conditions	0	4 (1%)	4 (1%)	1 (1%)
Injection site pain	0	2 (1%)	2 (< 1%)	0
Chills	0	1 (< 1%)	1 (< 1%)	0
Fatigue	0	1 (< 1%)	1 (< 1%)	0
Injection site erythema	0	0	0	1 (1%)
Musculoskeletal and connective tissue disorders	0	1 (< 1%)	1 (< 1%)	0
Myalgia	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders	0	2 (1%)	2 (< 1%)	0
Dizziness	0	1 (< 1%)	1 (< 1%)	0
Syncope	0	1 (< 1%)	1 (< 1%)	0
Skin and subcutaneous tissue disorders	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	98 (33%)	60 (20%)	10 (3%)	137 (46%)
Blood and lymphatic system disorders	1 (< 1%)	0	0	1 (< 1%)
Lymphadenopathy	1 (< 1%)	0	0	1 (< 1%)
Ear and labyrinth disorders	2 (1%)	0	0	2 (1%)
Ear pain	1 (< 1%)	0	0	1 (< 1%)
Tympanic membrane perforation	1 (< 1%)	0	0	1 (< 1%)
Eye disorders	2 (1%)	0	0	2 (1%)
Oculogyric crisis	1 (< 1%)	0	0	1 (< 1%)
Retinal tear	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	13 (4%)	8 (3%)	1 (< 1%)	22 (7%)
Abdominal pain	2 (1%)	4 (1%)	0	6 (2%)
Abdominal tenderness	0	1 (< 1%)	0	1 (< 1%)
Diarrhoea	1 (< 1%)	1 (< 1%)	0	2 (1%)
Dyspepsia	1 (< 1%)	0	0	1 (< 1%)
Gastrooesophageal reflux disease	2 (1%)	0	0	2 (1%)
Haemorrhoids	1 (< 1%)	0	0	1 (< 1%)
Nausea	5 (2%)	2 (1%)	1 (< 1%)	8 (3%)
Tooth impacted	1 (< 1%)	1 (< 1%)	0	2 (1%)
Vomiting	2 (1%)	0	0	2 (1%)
General disorders and administration site conditions	16 (5%)	3 (1%)	0	18 (6%)
Chest pain	1 (< 1%)	0	0	1 (< 1%)
Fatigue	7 (2%)	2 (1%)	0	9 (3%)
Influenza like illness	1 (< 1%)	0	0	1 (< 1%)
Injection site erythema	2 (1%)	0	0	2 (1%)
Injection site induration	2 (1%)	0	0	2 (1%)
Injection site pain	1 (< 1%)	0	0	1 (< 1%)
Injection site pruritus	1 (< 1%)	0	0	1 (< 1%)
Medical device site erythema	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Medical device site swelling	1 (< 1%)	0	0	1 (< 1%)
Pain	1 (< 1%)	0	0	1 (< 1%)
Pyrexia	1 (< 1%)	1 (< 1%)	0	1 (< 1%)
Immune system disorders	1 (< 1%)	3 (1%)	0	4 (1%)
Anaphylactic reaction	0	1 (< 1%)	0	1 (< 1%)
Hypersensitivity	0	1 (< 1%)	0	1 (< 1%)
Seasonal allergy	1 (< 1%)	1 (< 1%)	0	2 (1%)
Infections and infestations	43 (14%)	27 (9%)	3 (1%)	64 (21%)
Acute sinusitis	6 (2%)	5 (2%)	1 (< 1%)	11 (4%)
Bronchitis	4 (1%)	0	0	4 (1%)
Bronchitis viral	1 (< 1%)	0	0	1 (< 1%)
Cellulitis	3 (1%)	1 (< 1%)	0	4 (1%)
Conjunctivitis	2 (1%)	0	0	2 (1%)
Croup infectious	1 (< 1%)	0	0	1 (< 1%)
Cystitis	1 (< 1%)	0	0	1 (< 1%)
Folliculitis	1 (< 1%)	0	0	1 (< 1%)
Gastroenteritis viral	1 (< 1%)	0	0	1 (< 1%)
Hordeolum	1 (< 1%)	0	0	1 (< 1%)
Influenza	2 (1%)	1 (< 1%)	0	3 (1%)
Laryngitis	0	1 (< 1%)	0	1 (< 1%)
Nasopharyngitis	8 (3%)	4 (1%)	1 (< 1%)	13 (4%)
Otitis externa	1 (< 1%)	1 (< 1%)	0	2 (1%)
Otitis media	2 (1%)	2 (1%)	0	4 (1%)
Otitis media acute	2 (1%)	1 (< 1%)	0	3 (1%)
Pharyngitis	3 (1%)	0	0	3 (1%)
Pharyngitis streptococcal	3 (1%)	0	0	3 (1%)
Pneumonia	1 (< 1%)	0	0	1 (< 1%)
Pneumonia bacterial	0	1 (< 1%)	0	1 (< 1%)
Pneumonia mycoplasmal	1 (< 1%)	3 (1%)	0	4 (1%)
Respiratory tract infection	1 (< 1%)	0	0	1 (< 1%)
Respiratory tract infection viral	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Septic shock	0	0	1 (< 1%)	1 (< 1%)
Sinusitis	0	2 (1%)	0	2 (1%)
Tonsillitis	0	0	1 (< 1%)	1 (< 1%)
Tooth abscess	0	1 (< 1%)	0	1 (< 1%)
Upper respiratory tract infection	6 (2%)	6 (2%)	0	12 (4%)
Urinary tract infection	1 (< 1%)	1 (< 1%)	0	2 (1%)
Viral pharyngitis	3 (1%)	1 (< 1%)	0	3 (1%)
Viral rash	0	1 (< 1%)	0	1 (< 1%)
Vulvovaginal candidiasis	1 (< 1%)	0	0	1 (< 1%)
Injury, poisoning and procedural complications	14 (5%)	8 (3%)	2 (1%)	24 (8%)
Arthropod bite	3 (1%)	0	0	3 (1%)
Arthropod sting	1 (< 1%)	0	0	1 (< 1%)
Concussion	2 (1%)	0	0	2 (1%)
Contusion	3 (1%)	1 (< 1%)	0	4 (1%)
Intentional overdose	0	0	1 (< 1%)	1 (< 1%)
Joint injury	0	1 (< 1%)	0	1 (< 1%)
Laceration	3 (1%)	1 (< 1%)	0	4 (1%)
Ligament rupture	0	0	1 (< 1%)	1 (< 1%)
Ligament sprain	2 (1%)	1 (< 1%)	0	3 (1%)
Limb injury	0	2 (1%)	0	2 (1%)
Meniscus injury	0	0	1 (< 1%)	1 (< 1%)
Post procedural complication	0	1 (< 1%)	0	1 (< 1%)
Procedural pain	1 (< 1%)	1 (< 1%)	0	2 (1%)
Road traffic accident	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	3 (1%)	1 (< 1%)	0	4 (1%)
Decreased appetite	1 (< 1%)	1 (< 1%)	0	2 (1%)
Hypoglycaemia	1 (< 1%)	0	0	1 (< 1%)
Vitamin D deficiency	1 (< 1%)	0	0	1 (< 1%)
Musculoskeletal and connective tissue disorders	11 (4%)	7 (2%)	1 (< 1%)	17 (6%)
Arthralgia	5 (2%)	1 (< 1%)	1 (< 1%)	7 (2%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Back pain	1 (< 1%)	1 (< 1%)	0	2 (1%)
Metatarsalgia	0	1 (< 1%)	0	1 (< 1%)
Myalgia	3 (1%)	2 (1%)	0	5 (2%)
Myalgia intercostal	1 (< 1%)	0	0	1 (< 1%)
Pain in extremity	2 (1%)	2 (1%)	0	4 (1%)
Rheumatoid arthritis	0	1 (< 1%)	0	1 (< 1%)
Synovial cyst	1 (< 1%)	0	0	1 (< 1%)
Nervous system disorders	6 (2%)	7 (2%)	2 (1%)	14 (5%)
Headache	5 (2%)	3 (1%)	1 (< 1%)	9 (3%)
Loss of consciousness	0	1 (< 1%)	0	1 (< 1%)
Migraine	1 (< 1%)	0	0	1 (< 1%)
Migraine with aura	0	1 (< 1%)	0	1 (< 1%)
Syncope	0	1 (< 1%)	1 (< 1%)	2 (1%)
Tension headache	0	1 (< 1%)	0	1 (< 1%)
Psychiatric disorders	10 (3%)	5 (2%)	2 (1%)	15 (5%)
Anxiety	2 (1%)	3 (1%)	0	5 (2%)
Attention deficit/hyperactivity disorder	2 (1%)	0	0	2 (1%)
Depression	3 (1%)	1 (< 1%)	0	4 (1%)
Disruptive mood dysregulation disorder	1 (< 1%)	0	0	1 (< 1%)
Insomnia	1 (< 1%)	0	0	1 (< 1%)
Major depression	0	2 (1%)	1 (< 1%)	2 (1%)
Post-traumatic stress disorder	1 (< 1%)	0	0	1 (< 1%)
Sleep disorder	1 (< 1%)	0	0	1 (< 1%)
Suicide attempt	0	0	2 (1%)	2 (1%)
Renal and urinary disorders	4 (1%)	0	0	4 (1%)
Dysuria	1 (< 1%)	0	0	1 (< 1%)
Haematuria	2 (1%)	0	0	2 (1%)
Pollakiuria	1 (< 1%)	0	0	1 (< 1%)
Polyuria	1 (< 1%)	0	0	1 (< 1%)
Proteinuria	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Reproductive system and breast disorders	1 (< 1%)	0	0	1 (< 1%)
Menstruation irregular	1 (< 1%)	0	0	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	14 (5%)	8 (3%)	3 (1%)	23 (8%)
Asthma	2 (1%)	4 (1%)	1 (< 1%)	7 (2%)
Cough	2 (1%)	0	0	2 (1%)
Epistaxis	2 (1%)	0	0	2 (1%)
Nasal congestion	2 (1%)	0	0	2 (1%)
Oropharyngeal pain	4 (1%)	2 (1%)	1 (< 1%)	7 (2%)
Respiratory disorder	0	0	1 (< 1%)	1 (< 1%)
Rhinitis allergic	0	1 (< 1%)	0	1 (< 1%)
Sinus congestion	1 (< 1%)	0	0	1 (< 1%)
Snoring	1 (< 1%)	0	0	1 (< 1%)
Wheezing	1 (< 1%)	1 (< 1%)	0	2 (1%)
Skin and subcutaneous tissue disorders	5 (2%)	5 (2%)	0	10 (3%)
Acne	2 (1%)	1 (< 1%)	0	3 (1%)
Alopecia	1 (< 1%)	0	0	1 (< 1%)
Dermatitis contact	2 (1%)	2 (1%)	0	4 (1%)
Ecchymosis	1 (< 1%)	0	0	1 (< 1%)
Rash	0	1 (< 1%)	0	1 (< 1%)
Urticaria	0	1 (< 1%)	0	1 (< 1%)
Vascular disorders	1 (< 1%)	0	0	1 (< 1%)
Lymphangiopathy	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	80 (27%)	67 (22%)	6 (2%)	120 (40%)
Blood and lymphatic system disorders	2 (1%)	0	0	2 (1%)
Anaemia	2 (1%)	0	0	2 (1%)
Ear and labyrinth disorders	1 (< 1%)	2 (1%)	0	2 (1%)
Cerumen impaction	0	1 (< 1%)	0	1 (< 1%)
Middle ear effusion	1 (< 1%)	0	0	1 (< 1%)
Vertigo	0	1 (< 1%)	0	1 (< 1%)
Eye disorders	3 (1%)	0	0	3 (1%)
Conjunctivitis allergic	1 (< 1%)	0	0	1 (< 1%)
Eye disorder	1 (< 1%)	0	0	1 (< 1%)
Vision blurred	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	6 (2%)	8 (3%)	1 (< 1%)	14 (5%)
Abdominal pain	0	1 (< 1%)	0	1 (< 1%)
Abdominal pain upper	1 (< 1%)	0	0	1 (< 1%)
Anal skin tags	0	1 (< 1%)	0	1 (< 1%)
Constipation	0	1 (< 1%)	0	1 (< 1%)
Diarrhoea	1 (< 1%)	0	1 (< 1%)	2 (1%)
Eosinophilic oesophagitis	0	1 (< 1%)	0	1 (< 1%)
Food poisoning	2 (1%)	0	0	2 (1%)
Gastritis	0	1 (< 1%)	0	1 (< 1%)
Gastrooesophageal reflux disease	1 (< 1%)	2 (1%)	0	3 (1%)
Haemorrhoids	0	1 (< 1%)	0	1 (< 1%)
Salivary gland mucocoele	1 (< 1%)	0	0	1 (< 1%)
Umbilical hernia	0	1 (< 1%)	0	1 (< 1%)
Vomiting	1 (< 1%)	0	0	1 (< 1%)
General disorders and administration site conditions	16 (5%)	9 (3%)	1 (< 1%)	25 (8%)
Chills	2 (1%)	1 (< 1%)	0	3 (1%)
Fatigue	6 (2%)	5 (2%)	1 (< 1%)	12 (4%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Influenza like illness	0	1 (< 1%)	0	1 (< 1%)
Injection site erythema	1 (< 1%)	0	0	1 (< 1%)
Injection site induration	1 (< 1%)	0	0	1 (< 1%)
Injection site pain	2 (1%)	0	0	2 (1%)
Injection site pruritus	1 (< 1%)	1 (< 1%)	0	2 (1%)
Injection site swelling	1 (< 1%)	0	0	1 (< 1%)
Peripheral swelling	0	1 (< 1%)	0	1 (< 1%)
Pyrexia	2 (1%)	1 (< 1%)	0	3 (1%)
Vaccination site pruritus	1 (< 1%)	0	0	1 (< 1%)
Immune system disorders	2 (1%)	1 (< 1%)	0	3 (1%)
Allergy to animal	1 (< 1%)	0	0	1 (< 1%)
Hypersensitivity	0	1 (< 1%)	0	1 (< 1%)
Seasonal allergy	1 (< 1%)	0	0	1 (< 1%)
Infections and infestations	27 (9%)	34 (11%)	0	57 (19%)
Bacterial vaginosis	0	1 (< 1%)	0	1 (< 1%)
Bartholin's abscess	1 (< 1%)	0	0	1 (< 1%)
Bronchitis	1 (< 1%)	2 (1%)	0	3 (1%)
Chlamydial infection	0	1 (< 1%)	0	1 (< 1%)
Conjunctivitis	1 (< 1%)	0	0	1 (< 1%)
Fungal infection	1 (< 1%)	0	0	1 (< 1%)
Gastroenteritis viral	5 (2%)	1 (< 1%)	0	6 (2%)
Infectious mononucleosis	0	1 (< 1%)	0	1 (< 1%)
Influenza	1 (< 1%)	6 (2%)	0	7 (2%)
Nasopharyngitis	4 (1%)	1 (< 1%)	0	5 (2%)
Oral herpes	1 (< 1%)	0	0	1 (< 1%)
Otitis externa	0	1 (< 1%)	0	1 (< 1%)
Otitis media	3 (1%)	1 (< 1%)	0	4 (1%)
Otitis media acute	0	1 (< 1%)	0	1 (< 1%)
Pharyngitis	2 (1%)	3 (1%)	0	5 (2%)
Pharyngitis streptococcal	0	3 (1%)	0	3 (1%)
Pneumonia	1 (< 1%)	1 (< 1%)	0	2 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Pneumonia mycoplasmal	0	1 (< 1%)	0	1 (< 1%)
Rhinitis	1 (< 1%)	0	0	1 (< 1%)
Sinusitis	3 (1%)	4 (1%)	0	6 (2%)
Subcutaneous abscess	1 (< 1%)	0	0	1 (< 1%)
Tooth abscess	0	1 (< 1%)	0	1 (< 1%)
Upper respiratory tract infection	3 (1%)	6 (2%)	0	9 (3%)
Urinary tract infection	1 (< 1%)	2 (1%)	0	3 (1%)
Viral pharyngitis	0	2 (1%)	0	2 (1%)
Viral upper respiratory tract infection	1 (< 1%)	1 (< 1%)	0	2 (1%)
Injury, poisoning and procedural complications	5 (2%)	11 (4%)	1 (< 1%)	15 (5%)
Alcohol poisoning	0	0	1 (< 1%)	1 (< 1%)
Concussion	0	2 (1%)	0	2 (1%)
Conjunctival abrasion	1 (< 1%)	0	0	1 (< 1%)
Contusion	1 (< 1%)	0	0	1 (< 1%)
Facial bones fracture	1 (< 1%)	0	0	1 (< 1%)
Hand fracture	0	2 (1%)	0	2 (1%)
Joint dislocation	0	1 (< 1%)	0	1 (< 1%)
Joint injury	0	1 (< 1%)	0	1 (< 1%)
Laceration	1 (< 1%)	0	0	1 (< 1%)
Ligament sprain	1 (< 1%)	2 (1%)	0	3 (1%)
Meniscus injury	0	2 (1%)	0	2 (1%)
Muscle strain	1 (< 1%)	0	0	1 (< 1%)
Procedural pain	0	1 (< 1%)	0	1 (< 1%)
Pulmonary contusion	0	1 (< 1%)	0	1 (< 1%)
Investigations	1 (< 1%)	0	0	1 (< 1%)
Cardiac murmur	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	4 (1%)	2 (1%)	0	6 (2%)
Decreased appetite	3 (1%)	2 (1%)	0	5 (2%)
Dehydration	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Musculoskeletal and connective tissue disorders	11 (4%)	5 (2%)	1 (< 1%)	17 (6%)
Arthralgia	6 (2%)	1 (< 1%)	0	7 (2%)
Joint stiffness	1 (< 1%)	0	0	1 (< 1%)
Musculoskeletal pain	0	1 (< 1%)	0	1 (< 1%)
Myalgia	4 (1%)	2 (1%)	1 (< 1%)	7 (2%)
Pain in extremity	0	1 (< 1%)	0	1 (< 1%)
Pain in jaw	1 (< 1%)	0	0	1 (< 1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (< 1%)	1 (< 1%)	0	2 (1%)
Benign bone neoplasm	1 (< 1%)	0	0	1 (< 1%)
Skin papilloma	0	1 (< 1%)	0	1 (< 1%)
Nervous system disorders	10 (3%)	4 (1%)	2 (1%)	15 (5%)
Dizziness	3 (1%)	1 (< 1%)	0	4 (1%)
Headache	6 (2%)	1 (< 1%)	1 (< 1%)	8 (3%)
Migraine	0	1 (< 1%)	0	1 (< 1%)
Presyncope	0	1 (< 1%)	0	1 (< 1%)
Syncope	1 (< 1%)	1 (< 1%)	1 (< 1%)	3 (1%)
Psychiatric disorders	4 (1%)	3 (1%)	2 (1%)	9 (3%)
Anxiety	2 (1%)	1 (< 1%)	0	3 (1%)
Attention deficit/hyperactivity disorder	2 (1%)	0	0	2 (1%)
Depression	0	1 (< 1%)	0	1 (< 1%)
Insomnia	1 (< 1%)	0	0	1 (< 1%)
Sleep disorder	0	1 (< 1%)	0	1 (< 1%)
Suicidal ideation	0	0	1 (< 1%)	1 (< 1%)
Suicide attempt	0	0	1 (< 1%)	1 (< 1%)
Renal and urinary disorders	1 (< 1%)	0	0	1 (< 1%)
Haematuria	1 (< 1%)	0	0	1 (< 1%)
Reproductive system and breast disorders	2 (1%)	1 (< 1%)	0	3 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Dysmenorrhoea	1 (< 1%)	1 (< 1%)	0	2 (1%)
Metrorrhagia	1 (< 1%)	0	0	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	19 (6%)	8 (3%)	0	24 (8%)
Asthma	0	1 (< 1%)	0	1 (< 1%)
Cough	3 (1%)	3 (1%)	0	6 (2%)
Dysphonia	1 (< 1%)	0	0	1 (< 1%)
Dyspnoea	0	1 (< 1%)	0	1 (< 1%)
Epistaxis	2 (1%)	0	0	2 (1%)
Nasal congestion	6 (2%)	0	0	6 (2%)
Oropharyngeal pain	4 (1%)	1 (< 1%)	0	5 (2%)
Pulmonary congestion	0	1 (< 1%)	0	1 (< 1%)
Rhinitis allergic	1 (< 1%)	1 (< 1%)	0	2 (1%)
Rhinorrhoea	0	1 (< 1%)	0	1 (< 1%)
Rhonchi	1 (< 1%)	0	0	1 (< 1%)
Sinus congestion	2 (1%)	0	0	2 (1%)
Upper-airway cough syndrome	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	6 (2%)	4 (1%)	0	10 (3%)
Acne	2 (1%)	3 (1%)	0	5 (2%)
Dermatitis contact	1 (< 1%)	0	0	1 (< 1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Rash	1 (< 1%)	0	0	1 (< 1%)
Rash macular	1 (< 1%)	0	0	1 (< 1%)
Urticaria	0	1 (< 1%)	0	1 (< 1%)
Vascular disorders	1 (< 1%)	0	0	1 (< 1%)
Hot flush	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	24 (24%)	12 (12%)	5 (5%)	32 (32%)
Cardiac disorders	0	1 (1%)	0	1 (1%)
Angina pectoris	0	1 (1%)	0	1 (1%)
Eye disorders	1 (1%)	0	0	1 (1%)
Erythema of eyelid	1 (1%)	0	0	1 (1%)
Gastrointestinal disorders	5 (5%)	1 (1%)	1 (1%)	6 (6%)
Abdominal pain	1 (1%)	0	0	1 (1%)
Diarrhoea	1 (1%)	1 (1%)	1 (1%)	3 (3%)
Nausea	3 (3%)	1 (1%)	0	3 (3%)
General disorders and administration site conditions	6 (6%)	3 (3%)	0	9 (9%)
Axillary pain	1 (1%)	0	0	1 (1%)
Injection site bruising	1 (1%)	0	0	1 (1%)
Injection site erythema	1 (1%)	3 (3%)	0	4 (4%)
Injection site induration	0	1 (1%)	0	1 (1%)
Injection site pruritus	3 (3%)	0	0	3 (3%)
Pyrexia	1 (1%)	0	0	1 (1%)
Hepatobiliary disorders	0	1 (1%)	0	1 (1%)
Biliary dyskinesia	0	1 (1%)	0	1 (1%)
Infections and infestations	10 (10%)	4 (4%)	1 (1%)	13 (13%)
Acute sinusitis	0	1 (1%)	0	1 (1%)
Bacterial vaginosis	1 (1%)	0	0	1 (1%)
Bronchitis	0	1 (1%)	0	1 (1%)
Diverticulitis	0	1 (1%)	1 (1%)	1 (1%)
Folliculitis	1 (1%)	0	0	1 (1%)
Influenza	2 (2%)	1 (1%)	0	3 (3%)
Kidney infection	0	1 (1%)	0	1 (1%)
Nasopharyngitis	2 (2%)	0	0	2 (2%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14
Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Pharyngitis	1 (1%)	0	0	1 (1%)
Sinusitis	0	1 (1%)	0	1 (1%)
Tooth abscess	0	1 (1%)	0	1 (1%)
Upper respiratory tract infection	3 (3%)	0	0	3 (3%)
Urinary tract infection	1 (1%)	1 (1%)	0	2 (2%)
Vaginal infection	1 (1%)	0	0	1 (1%)
Vulvovaginal mycotic infection	0	1 (1%)	0	1 (1%)
Injury, poisoning and procedural complications	0	1 (1%)	1 (1%)	2 (2%)
Foot fracture	0	1 (1%)	0	1 (1%)
Procedural pain	0	0	1 (1%)	1 (1%)
Musculoskeletal and connective tissue disorders	2 (2%)	1 (1%)	0	2 (2%)
Groin pain	1 (1%)	0	0	1 (1%)
Muscle tightness	1 (1%)	0	0	1 (1%)
Pain in extremity	1 (1%)	1 (1%)	0	1 (1%)
Nervous system disorders	3 (3%)	1 (1%)	1 (1%)	5 (5%)
Diabetic ketoacidotic hyperglycaemic coma	0	0	1 (1%)	1 (1%)
Headache	3 (3%)	1 (1%)	0	4 (4%)
Pregnancy, puerperium and perinatal conditions	0	0	1 (1%)	1 (1%)
Abortion spontaneous	0	0	1 (1%)	1 (1%)
Reproductive system and breast disorders	0	1 (1%)	0	1 (1%)
Pelvic congestion	0	1 (1%)	0	1 (1%)
Respiratory, thoracic and mediastinal disorders	3 (3%)	0	0	3 (3%)
Nasal congestion	1 (1%)	0	0	1 (1%)
Oropharyngeal pain	1 (1%)	0	0	1 (1%)
Sinus congestion	1 (1%)	0	0	1 (1%)
Vascular disorders	1 (1%)	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Essential hypertension	1 (1%)	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14.1

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	52 (17%)	25 (8%)	6 (2%)	74 (25%)
Blood and lymphatic system disorders	1 (< 1%)	0	0	1 (< 1%)
Lymphadenopathy	1 (< 1%)	0	0	1 (< 1%)
Eye disorders	1 (< 1%)	0	0	1 (< 1%)
Oculogyric crisis	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	12 (4%)	4 (1%)	0	16 (5%)
Abdominal pain	2 (1%)	2 (1%)	0	4 (1%)
Diarrhoea	1 (< 1%)	1 (< 1%)	0	2 (1%)
Dyspepsia	1 (< 1%)	0	0	1 (< 1%)
Gastrooesophageal reflux disease	1 (< 1%)	0	0	1 (< 1%)
Haemorrhoids	1 (< 1%)	0	0	1 (< 1%)
Nausea	4 (1%)	2 (1%)	0	6 (2%)
Tooth impacted	1 (< 1%)	0	0	1 (< 1%)
Vomiting	2 (1%)	0	0	2 (1%)
General disorders and administration site conditions	11 (4%)	1 (< 1%)	0	12 (4%)
Chest pain	1 (< 1%)	0	0	1 (< 1%)
Fatigue	5 (2%)	1 (< 1%)	0	6 (2%)
Influenza like illness	1 (< 1%)	0	0	1 (< 1%)
Injection site erythema	2 (1%)	0	0	2 (1%)
Injection site induration	2 (1%)	0	0	2 (1%)
Injection site pain	1 (< 1%)	0	0	1 (< 1%)
Injection site pruritus	1 (< 1%)	0	0	1 (< 1%)
Immune system disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)
Hypersensitivity	0	1 (< 1%)	0	1 (< 1%)
Seasonal allergy	1 (< 1%)	0	0	1 (< 1%)
Infections and infestations	19 (6%)	12 (4%)	2 (1%)	33 (11%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Acute sinusitis	1 (< 1%)	2 (1%)	0	3 (1%)
Bronchitis viral	1 (< 1%)	0	0	1 (< 1%)
Cellulitis	1 (< 1%)	0	0	1 (< 1%)
Conjunctivitis	1 (< 1%)	0	0	1 (< 1%)
Cystitis	1 (< 1%)	0	0	1 (< 1%)
Laryngitis	0	1 (< 1%)	0	1 (< 1%)
Nasopharyngitis	7 (2%)	3 (1%)	1 (< 1%)	11 (4%)
Otitis media	0	1 (< 1%)	0	1 (< 1%)
Pharyngitis	1 (< 1%)	0	0	1 (< 1%)
Pneumonia	1 (< 1%)	0	0	1 (< 1%)
Pneumonia bacterial	0	1 (< 1%)	0	1 (< 1%)
Respiratory tract infection viral	1 (< 1%)	0	0	1 (< 1%)
Septic shock	0	0	1 (< 1%)	1 (< 1%)
Sinusitis	0	1 (< 1%)	0	1 (< 1%)
Tonsillitis	0	0	1 (< 1%)	1 (< 1%)
Tooth abscess	0	1 (< 1%)	0	1 (< 1%)
Upper respiratory tract infection	2 (1%)	2 (1%)	0	4 (1%)
Urinary tract infection	1 (< 1%)	0	0	1 (< 1%)
Viral pharyngitis	1 (< 1%)	0	0	1 (< 1%)
Viral rash	0	1 (< 1%)	0	1 (< 1%)
Injury, poisoning and procedural complications	4 (1%)	1 (< 1%)	1 (< 1%)	6 (2%)
Arthropod bite	1 (< 1%)	0	0	1 (< 1%)
Concussion	1 (< 1%)	0	0	1 (< 1%)
Laceration	1 (< 1%)	0	0	1 (< 1%)
Ligament rupture	0	0	1 (< 1%)	1 (< 1%)
Meniscus injury	0	0	1 (< 1%)	1 (< 1%)
Post procedural complication	0	1 (< 1%)	0	1 (< 1%)
Procedural pain	1 (< 1%)	0	0	1 (< 1%)
Road traffic accident	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14.1
Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Decreased appetite	1 (< 1%)	1 (< 1%)	0	2 (1%)
Musculoskeletal and connective tissue disorders	6 (2%)	4 (1%)	1 (< 1%)	9 (3%)
Arthralgia	3 (1%)	1 (< 1%)	1 (< 1%)	5 (2%)
Back pain	0	1 (< 1%)	0	1 (< 1%)
Myalgia	3 (1%)	1 (< 1%)	0	4 (1%)
Myalgia intercostal	1 (< 1%)	0	0	1 (< 1%)
Pain in extremity	0	1 (< 1%)	0	1 (< 1%)
Rheumatoid arthritis	0	1 (< 1%)	0	1 (< 1%)
Synovial cyst	1 (< 1%)	0	0	1 (< 1%)
Nervous system disorders	5 (2%)	4 (1%)	1 (< 1%)	9 (3%)
Headache	4 (1%)	3 (1%)	1 (< 1%)	8 (3%)
Migraine	1 (< 1%)	0	0	1 (< 1%)
Syncope	0	1 (< 1%)	0	1 (< 1%)
Psychiatric disorders	1 (< 1%)	0	0	1 (< 1%)
Attention deficit/hyperactivity disorder	1 (< 1%)	0	0	1 (< 1%)
Renal and urinary disorders	1 (< 1%)	0	0	1 (< 1%)
Dysuria	1 (< 1%)	0	0	1 (< 1%)
Haematuria	1 (< 1%)	0	0	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	6 (2%)	2 (1%)	3 (1%)	11 (4%)
Asthma	1 (< 1%)	1 (< 1%)	1 (< 1%)	3 (1%)
Cough	1 (< 1%)	0	0	1 (< 1%)
Epistaxis	1 (< 1%)	0	0	1 (< 1%)
Nasal congestion	2 (1%)	0	0	2 (1%)
Oropharyngeal pain	1 (< 1%)	1 (< 1%)	1 (< 1%)	3 (1%)
Respiratory disorder	0	0	1 (< 1%)	1 (< 1%)
Sinus congestion	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14.1
Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Skin and subcutaneous tissue disorders	2 (1%)	2 (1%)	0	4 (1%)
Dermatitis contact	1 (< 1%)	0	0	1 (< 1%)
Ecchymosis	1 (< 1%)	0	0	1 (< 1%)
Rash	0	1 (< 1%)	0	1 (< 1%)
Urticaria	0	1 (< 1%)	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14.1
Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	61 (20%)	28 (9%)	4 (1%)	78 (26%)
Eye disorders	1 (< 1%)	0	0	1 (< 1%)
Vision blurred	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	5 (2%)	2 (1%)	1 (< 1%)	8 (3%)
Abdominal pain	0	1 (< 1%)	0	1 (< 1%)
Abdominal pain upper	1 (< 1%)	0	0	1 (< 1%)
Diarrhoea	1 (< 1%)	0	1 (< 1%)	2 (1%)
Food poisoning	2 (1%)	0	0	2 (1%)
Gastritis	0	1 (< 1%)	0	1 (< 1%)
Salivary gland mucocoele	1 (< 1%)	0	0	1 (< 1%)
Vomiting	1 (< 1%)	0	0	1 (< 1%)
General disorders and administration site conditions	16 (5%)	8 (3%)	1 (< 1%)	24 (8%)
Chills	2 (1%)	1 (< 1%)	0	3 (1%)
Fatigue	6 (2%)	5 (2%)	1 (< 1%)	12 (4%)
Injection site erythema	1 (< 1%)	0	0	1 (< 1%)
Injection site induration	1 (< 1%)	0	0	1 (< 1%)
Injection site pain	2 (1%)	0	0	2 (1%)
Injection site pruritus	1 (< 1%)	1 (< 1%)	0	2 (1%)
Injection site swelling	1 (< 1%)	0	0	1 (< 1%)
Peripheral swelling	0	1 (< 1%)	0	1 (< 1%)
Pyrexia	2 (1%)	1 (< 1%)	0	3 (1%)
Vaccination site pruritus	1 (< 1%)	0	0	1 (< 1%)
Immune system disorders	1 (< 1%)	0	0	1 (< 1%)
Allergy to animal	1 (< 1%)	0	0	1 (< 1%)
Infections and infestations	14 (5%)	9 (3%)	0	22 (7%)
Fungal infection	1 (< 1%)	0	0	1 (< 1%)
Gastroenteritis viral	3 (1%)	1 (< 1%)	0	4 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14.1
Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Influenza	1 (< 1%)	0	0	1 (< 1%)
Nasopharyngitis	3 (1%)	1 (< 1%)	0	4 (1%)
Oral herpes	1 (< 1%)	0	0	1 (< 1%)
Otitis media	1 (< 1%)	0	0	1 (< 1%)
Pharyngitis	1 (< 1%)	1 (< 1%)	0	2 (1%)
Pneumonia	0	1 (< 1%)	0	1 (< 1%)
Sinusitis	2 (1%)	1 (< 1%)	0	2 (1%)
Upper respiratory tract infection	2 (1%)	2 (1%)	0	4 (1%)
Urinary tract infection	1 (< 1%)	1 (< 1%)	0	2 (1%)
Viral upper respiratory tract infection	0	1 (< 1%)	0	1 (< 1%)
Injury, poisoning and procedural complications	0	2 (1%)	1 (< 1%)	3 (1%)
Alcohol poisoning	0	0	1 (< 1%)	1 (< 1%)
Joint injury	0	1 (< 1%)	0	1 (< 1%)
Ligament sprain	0	1 (< 1%)	0	1 (< 1%)
Metabolism and nutrition disorders	3 (1%)	2 (1%)	0	5 (2%)
Decreased appetite	3 (1%)	2 (1%)	0	5 (2%)
Musculoskeletal and connective tissue disorders	10 (3%)	4 (1%)	1 (< 1%)	15 (5%)
Arthralgia	6 (2%)	1 (< 1%)	0	7 (2%)
Joint stiffness	1 (< 1%)	0	0	1 (< 1%)
Myalgia	4 (1%)	2 (1%)	1 (< 1%)	7 (2%)
Pain in extremity	0	1 (< 1%)	0	1 (< 1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (< 1%)	0	0	1 (< 1%)
Benign bone neoplasm	1 (< 1%)	0	0	1 (< 1%)
Nervous system disorders	10 (3%)	3 (1%)	2 (1%)	14 (5%)
Dizziness	3 (1%)	1 (< 1%)	0	4 (1%)
Headache	6 (2%)	1 (< 1%)	1 (< 1%)	8 (3%)
Syncope	1 (< 1%)	1 (< 1%)	1 (< 1%)	3 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.14.1
Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Psychiatric disorders	1 (< 1%)	2 (1%)	0	3 (1%)
Anxiety	0	1 (< 1%)	0	1 (< 1%)
Attention deficit/hyperactivity disorder	1 (< 1%)	0	0	1 (< 1%)
Depression	0	1 (< 1%)	0	1 (< 1%)
Reproductive system and breast disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)
Dysmenorrhoea	0	1 (< 1%)	0	1 (< 1%)
Metrorrhagia	1 (< 1%)	0	0	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	15 (5%)	3 (1%)	0	17 (6%)
Cough	1 (< 1%)	2 (1%)	0	3 (1%)
Dysphonia	1 (< 1%)	0	0	1 (< 1%)
Epistaxis	1 (< 1%)	0	0	1 (< 1%)
Nasal congestion	6 (2%)	0	0	6 (2%)
Oropharyngeal pain	4 (1%)	0	0	4 (1%)
Pulmonary congestion	0	1 (< 1%)	0	1 (< 1%)
Rhinorrhoea	0	1 (< 1%)	0	1 (< 1%)
Rhonchi	1 (< 1%)	0	0	1 (< 1%)
Sinus congestion	2 (1%)	0	0	2 (1%)
Upper-airway cough syndrome	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	6 (2%)	1 (< 1%)	0	7 (2%)
Acne	2 (1%)	0	0	2 (1%)
Dermatitis contact	1 (< 1%)	0	0	1 (< 1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Rash	1 (< 1%)	0	0	1 (< 1%)
Rash macular	1 (< 1%)	0	0	1 (< 1%)
Urticaria	0	1 (< 1%)	0	1 (< 1%)
Vascular disorders	1 (< 1%)	0	0	1 (< 1%)
Hot flush	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	18 (18%)	5 (5%)	2 (2%)	22 (22%)
Cardiac disorders	0	1 (1%)	0	1 (1%)
Angina pectoris	0	1 (1%)	0	1 (1%)
Eye disorders	1 (1%)	0	0	1 (1%)
Erythema of eyelid	1 (1%)	0	0	1 (1%)
Gastrointestinal disorders	3 (3%)	0	1 (1%)	4 (4%)
Diarrhoea	1 (1%)	0	1 (1%)	2 (2%)
Nausea	2 (2%)	0	0	2 (2%)
General disorders and administration site conditions	6 (6%)	3 (3%)	0	9 (9%)
Axillary pain	1 (1%)	0	0	1 (1%)
Injection site bruising	1 (1%)	0	0	1 (1%)
Injection site erythema	1 (1%)	3 (3%)	0	4 (4%)
Injection site induration	0	1 (1%)	0	1 (1%)
Injection site pruritus	3 (3%)	0	0	3 (3%)
Pyrexia	1 (1%)	0	0	1 (1%)
Infections and infestations	5 (5%)	1 (1%)	0	6 (6%)
Acute sinusitis	0	1 (1%)	0	1 (1%)
Influenza	1 (1%)	0	0	1 (1%)
Nasopharyngitis	2 (2%)	0	0	2 (2%)
Upper respiratory tract infection	2 (2%)	0	0	2 (2%)
Urinary tract infection	0	1 (1%)	0	1 (1%)
Injury, poisoning and procedural complications	0	0	1 (1%)	1 (1%)
Procedural pain	0	0	1 (1%)	1 (1%)
Musculoskeletal and connective tissue disorders	2 (2%)	0	0	2 (2%)
Muscle tightness	1 (1%)	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Pain in extremity	1 (1%)	0	0	1 (1%)
Nervous system disorders	2 (2%)	1 (1%)	0	3 (3%)
Headache	2 (2%)	1 (1%)	0	3 (3%)
Respiratory, thoracic and mediastinal disorders	3 (3%)	0	0	3 (3%)
Nasal congestion	1 (1%)	0	0	1 (1%)
Oropharyngeal pain	1 (1%)	0	0	1 (1%)
Sinus congestion	1 (1%)	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.15

Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Fatigue	3 (1%)	9 (3%)	12 (2%)	0
Headache	4 (1%)	4 (1%)	8 (1%)	2 (2%)
Myalgia	2 (1%)	6 (2%)	8 (1%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Arthralgia	2 (1%)	4 (1%)	6 (1%)	0
Nasal congestion	2 (1%)	3 (1%)	5 (1%)	1 (1%)
Diarrhoea	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Nausea	3 (1%)	0	3 (< 1%)	1 (1%)
Dizziness	0	3 (1%)	3 (< 1%)	0
Injection site induration	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Injection site pruritus	0	1 (< 1%)	1 (< 1%)	2 (2%)
Cough	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Decreased appetite	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Anxiety	0	1 (< 1%)	1 (< 1%)	0
Chills	0	1 (< 1%)	1 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Nasopharyngitis	0	0	0	1 (1%)
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Oropharyngeal pain	0	1 (< 1%)	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Pyrexia	0	0	0	1 (1%)
Sinus congestion	1 (< 1%)	0	1 (< 1%)	0
Syncope	0	1 (< 1%)	1 (< 1%)	0
Upper respiratory tract infection	0	0	0	1 (1%)
Urticaria	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Viral rash	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Vomiting	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.15.1

Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Fatigue	3 (1%)	9 (3%)	12 (2%)	0
Headache	4 (1%)	4 (1%)	8 (1%)	1 (1%)
Myalgia	2 (1%)	6 (2%)	8 (1%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Arthralgia	2 (1%)	4 (1%)	6 (1%)	0
Nasal congestion	2 (1%)	3 (1%)	5 (1%)	1 (1%)
Diarrhoea	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Nausea	3 (1%)	0	3 (< 1%)	1 (1%)
Dizziness	0	3 (1%)	3 (< 1%)	0
Injection site induration	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Injection site pruritus	0	1 (< 1%)	1 (< 1%)	2 (2%)
Cough	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Decreased appetite	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Anxiety	0	1 (< 1%)	1 (< 1%)	0
Chills	0	1 (< 1%)	1 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Nasopharyngitis	0	0	0	1 (1%)
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Oropharyngeal pain	0	1 (< 1%)	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Pyrexia	0	0	0	1 (1%)
Sinus congestion	1 (< 1%)	0	1 (< 1%)	0
Syncope	0	1 (< 1%)	1 (< 1%)	0
Upper respiratory tract infection	0	0	0	1 (1%)
Urticaria	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Viral rash	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.15.1
Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination Sorted by Overall Frequency
Unsolicited Safety Set

Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Vomiting	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.16
Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	15 (5%)	35 (12%)	50 (8%)	12 (12%)
Blood and lymphatic system disorders	1 (< 1%)	0	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Eye disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Gastrointestinal disorders	4 (1%)	2 (1%)	6 (1%)	2 (2%)
Diarrhoea	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Nausea	3 (1%)	0	3 (< 1%)	1 (1%)
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Vomiting	1 (< 1%)	0	1 (< 1%)	0
General disorders and administration site conditions	5 (2%)	17 (6%)	22 (4%)	8 (8%)
Fatigue	3 (1%)	9 (3%)	12 (2%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Injection site induration	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Injection site pruritus	0	1 (< 1%)	1 (< 1%)	2 (2%)
Chills	0	1 (< 1%)	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Pyrexia	0	0	0	1 (1%)
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Infections and infestations	1 (< 1%)	0	1 (< 1%)	2 (2%)
Nasopharyngitis	0	0	0	1 (1%)
Upper respiratory tract infection	0	0	0	1 (1%)
Viral rash	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.16
Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Metabolism and nutrition disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Decreased appetite	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Musculoskeletal and connective tissue disorders	2 (1%)	11 (4%)	13 (2%)	0
Myalgia	2 (1%)	6 (2%)	8 (1%)	0
Arthralgia	2 (1%)	4 (1%)	6 (1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders	4 (1%)	8 (3%)	12 (2%)	2 (2%)
Headache	4 (1%)	4 (1%)	8 (1%)	2 (2%)
Dizziness	0	3 (1%)	3 (< 1%)	0
Syncope	0	1 (< 1%)	1 (< 1%)	0
Psychiatric disorders	0	1 (< 1%)	1 (< 1%)	0
Anxiety	0	1 (< 1%)	1 (< 1%)	0
Respiratory, thoracic and mediastinal disorders	3 (1%)	4 (1%)	7 (1%)	1 (1%)
Nasal congestion	2 (1%)	3 (1%)	5 (1%)	1 (1%)
Cough	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Oropharyngeal pain	0	1 (< 1%)	1 (< 1%)	0
Sinus congestion	1 (< 1%)	0	1 (< 1%)	0
Skin and subcutaneous tissue disorders	1 (< 1%)	2 (1%)	3 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Urticaria	0	1 (< 1%)	1 (< 1%)	0
Vascular disorders	0	1 (< 1%)	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.16.1
Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	15 (5%)	35 (12%)	50 (8%)	11 (11%)
Blood and lymphatic system disorders	1 (< 1%)	0	1 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Eye disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Gastrointestinal disorders	4 (1%)	2 (1%)	6 (1%)	2 (2%)
Diarrhoea	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Nausea	3 (1%)	0	3 (< 1%)	1 (1%)
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Vomiting	1 (< 1%)	0	1 (< 1%)	0
General disorders and administration site conditions	5 (2%)	17 (6%)	22 (4%)	8 (8%)
Fatigue	3 (1%)	9 (3%)	12 (2%)	0
Injection site erythema	2 (1%)	1 (< 1%)	3 (< 1%)	4 (4%)
Injection site induration	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Injection site pain	1 (< 1%)	2 (1%)	3 (< 1%)	0
Injection site pruritus	0	1 (< 1%)	1 (< 1%)	2 (2%)
Chills	0	1 (< 1%)	1 (< 1%)	0
Injection site bruising	0	0	0	1 (1%)
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Pyrexia	0	0	0	1 (1%)
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Infections and infestations	1 (< 1%)	0	1 (< 1%)	2 (2%)
Nasopharyngitis	0	0	0	1 (1%)
Upper respiratory tract infection	0	0	0	1 (1%)
Viral rash	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.16.1
Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Metabolism and nutrition disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Decreased appetite	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Musculoskeletal and connective tissue disorders	2 (1%)	11 (4%)	13 (2%)	0
Myalgia	2 (1%)	6 (2%)	8 (1%)	0
Arthralgia	2 (1%)	4 (1%)	6 (1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders	4 (1%)	8 (3%)	12 (2%)	1 (1%)
Headache	4 (1%)	4 (1%)	8 (1%)	1 (1%)
Dizziness	0	3 (1%)	3 (< 1%)	0
Syncope	0	1 (< 1%)	1 (< 1%)	0
Psychiatric disorders	0	1 (< 1%)	1 (< 1%)	0
Anxiety	0	1 (< 1%)	1 (< 1%)	0
Respiratory, thoracic and mediastinal disorders	3 (1%)	4 (1%)	7 (1%)	1 (1%)
Nasal congestion	2 (1%)	3 (1%)	5 (1%)	1 (1%)
Cough	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Oropharyngeal pain	0	1 (< 1%)	1 (< 1%)	0
Sinus congestion	1 (< 1%)	0	1 (< 1%)	0
Skin and subcutaneous tissue disorders	1 (< 1%)	2 (1%)	3 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Urticaria	0	1 (< 1%)	1 (< 1%)	0
Vascular disorders	0	1 (< 1%)	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17
Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	11 (4%)	4 (1%)	1 (< 1%)	15 (5%)
Blood and lymphatic system disorders	1 (< 1%)	0	0	1 (< 1%)
Lymphadenopathy	1 (< 1%)	0	0	1 (< 1%)
Eye disorders	1 (< 1%)	0	0	1 (< 1%)
Oculogyric crisis	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	2 (1%)	2 (1%)	0	4 (1%)
Diarrhoea	0	1 (< 1%)	0	1 (< 1%)
Nausea	2 (1%)	1 (< 1%)	0	3 (1%)
Vomiting	1 (< 1%)	0	0	1 (< 1%)
General disorders and administration site conditions	4 (1%)	1 (< 1%)	0	5 (2%)
Fatigue	2 (1%)	1 (< 1%)	0	3 (1%)
Injection site erythema	2 (1%)	0	0	2 (1%)
Injection site induration	1 (< 1%)	0	0	1 (< 1%)
Injection site pain	1 (< 1%)	0	0	1 (< 1%)
Infections and infestations	0	1 (< 1%)	0	1 (< 1%)
Viral rash	0	1 (< 1%)	0	1 (< 1%)
Metabolism and nutrition disorders	0	1 (< 1%)	0	1 (< 1%)
Decreased appetite	0	1 (< 1%)	0	1 (< 1%)
Musculoskeletal and connective tissue disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)
Arthralgia	1 (< 1%)	1 (< 1%)	0	2 (1%)
Myalgia	1 (< 1%)	1 (< 1%)	0	2 (1%)
Nervous system disorders	1 (< 1%)	2 (1%)	1 (< 1%)	4 (1%)
Headache	1 (< 1%)	2 (1%)	1 (< 1%)	4 (1%)
Respiratory, thoracic and mediastinal disorders	3 (1%)	0	0	3 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Cough	1 (< 1%)	0	0	1 (< 1%)
Nasal congestion	2 (1%)	0	0	2 (1%)
Sinus congestion	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	1 (< 1%)	0	0	1 (< 1%)
Ecchymosis	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17

Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	28 (9%)	7 (2%)	2 (1%)	35 (12%)
Eye disorders	1 (< 1%)	0	0	1 (< 1%)
Vision blurred	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	1 (< 1%)	0	1 (< 1%)	2 (1%)
Abdominal pain upper	1 (< 1%)	0	0	1 (< 1%)
Diarrhoea	1 (< 1%)	0	1 (< 1%)	2 (1%)
General disorders and administration site conditions	12 (4%)	4 (1%)	1 (< 1%)	17 (6%)
Chills	1 (< 1%)	0	0	1 (< 1%)
Fatigue	5 (2%)	3 (1%)	1 (< 1%)	9 (3%)
Injection site erythema	1 (< 1%)	0	0	1 (< 1%)
Injection site induration	1 (< 1%)	0	0	1 (< 1%)
Injection site pain	2 (1%)	0	0	2 (1%)
Injection site pruritus	0	1 (< 1%)	0	1 (< 1%)
Injection site swelling	1 (< 1%)	0	0	1 (< 1%)
Vaccination site pruritus	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	1 (< 1%)	0	0	1 (< 1%)
Decreased appetite	1 (< 1%)	0	0	1 (< 1%)
Musculoskeletal and connective tissue disorders	9 (3%)	1 (< 1%)	1 (< 1%)	11 (4%)
Arthralgia	4 (1%)	0	0	4 (1%)
Joint stiffness	1 (< 1%)	0	0	1 (< 1%)
Myalgia	4 (1%)	1 (< 1%)	1 (< 1%)	6 (2%)
Nervous system disorders	6 (2%)	1 (< 1%)	1 (< 1%)	8 (3%)
Dizziness	3 (1%)	0	0	3 (1%)
Headache	3 (1%)	0	1 (< 1%)	4 (1%)
Syncope	0	1 (< 1%)	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Psychiatric disorders	0	1 (< 1%)	0	1 (< 1%)
Anxiety	0	1 (< 1%)	0	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	4 (1%)	0	0	4 (1%)
Cough	1 (< 1%)	0	0	1 (< 1%)
Nasal congestion	3 (1%)	0	0	3 (1%)
Oropharyngeal pain	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Urticaria	0	1 (< 1%)	0	1 (< 1%)
Vascular disorders	1 (< 1%)	0	0	1 (< 1%)
Hot flush	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17

Subjects With Possibly or Probably Related Unsolicited Adverse Events After Vaccination Throughout the Study Period by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	8 (8%)	3 (3%)	1 (1%)	12 (12%)
Gastrointestinal disorders	1 (1%)	0	1 (1%)	2 (2%)
Diarrhoea	0	0	1 (1%)	1 (1%)
Nausea	1 (1%)	0	0	1 (1%)
General disorders and administration site conditions	5 (5%)	3 (3%)	0	8 (8%)
Injection site bruising	1 (1%)	0	0	1 (1%)
Injection site erythema	1 (1%)	3 (3%)	0	4 (4%)
Injection site induration	0	1 (1%)	0	1 (1%)
Injection site pruritus	2 (2%)	0	0	2 (2%)
Pyrexia	1 (1%)	0	0	1 (1%)
Infections and infestations	2 (2%)	0	0	2 (2%)
Nasopharyngitis	1 (1%)	0	0	1 (1%)
Upper respiratory tract infection	1 (1%)	0	0	1 (1%)
Nervous system disorders	2 (2%)	0	0	2 (2%)
Headache	2 (2%)	0	0	2 (2%)
Respiratory, thoracic and mediastinal disorders	1 (1%)	0	0	1 (1%)
Nasal congestion	1 (1%)	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17.1
Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	11 (4%)	4 (1%)	1 (< 1%)	15 (5%)
Blood and lymphatic system disorders	1 (< 1%)	0	0	1 (< 1%)
Lymphadenopathy	1 (< 1%)	0	0	1 (< 1%)
Eye disorders	1 (< 1%)	0	0	1 (< 1%)
Oculogyric crisis	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	2 (1%)	2 (1%)	0	4 (1%)
Diarrhoea	0	1 (< 1%)	0	1 (< 1%)
Nausea	2 (1%)	1 (< 1%)	0	3 (1%)
Vomiting	1 (< 1%)	0	0	1 (< 1%)
General disorders and administration site conditions	4 (1%)	1 (< 1%)	0	5 (2%)
Fatigue	2 (1%)	1 (< 1%)	0	3 (1%)
Injection site erythema	2 (1%)	0	0	2 (1%)
Injection site induration	1 (< 1%)	0	0	1 (< 1%)
Injection site pain	1 (< 1%)	0	0	1 (< 1%)
Infections and infestations	0	1 (< 1%)	0	1 (< 1%)
Viral rash	0	1 (< 1%)	0	1 (< 1%)
Metabolism and nutrition disorders	0	1 (< 1%)	0	1 (< 1%)
Decreased appetite	0	1 (< 1%)	0	1 (< 1%)
Musculoskeletal and connective tissue disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)
Arthralgia	1 (< 1%)	1 (< 1%)	0	2 (1%)
Myalgia	1 (< 1%)	1 (< 1%)	0	2 (1%)
Nervous system disorders	1 (< 1%)	2 (1%)	1 (< 1%)	4 (1%)
Headache	1 (< 1%)	2 (1%)	1 (< 1%)	4 (1%)
Respiratory, thoracic and mediastinal disorders	3 (1%)	0	0	3 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17.1
Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menveo-Menveo (N=301)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Cough	1 (< 1%)	0	0	1 (< 1%)
Nasal congestion	2 (1%)	0	0	2 (1%)
Sinus congestion	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	1 (< 1%)	0	0	1 (< 1%)
Ecchymosis	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	28 (9%)	7 (2%)	2 (1%)	35 (12%)
Eye disorders	1 (< 1%)	0	0	1 (< 1%)
Vision blurred	1 (< 1%)	0	0	1 (< 1%)
Gastrointestinal disorders	1 (< 1%)	0	1 (< 1%)	2 (1%)
Abdominal pain upper	1 (< 1%)	0	0	1 (< 1%)
Diarrhoea	1 (< 1%)	0	1 (< 1%)	2 (1%)
General disorders and administration site conditions	12 (4%)	4 (1%)	1 (< 1%)	17 (6%)
Chills	1 (< 1%)	0	0	1 (< 1%)
Fatigue	5 (2%)	3 (1%)	1 (< 1%)	9 (3%)
Injection site erythema	1 (< 1%)	0	0	1 (< 1%)
Injection site induration	1 (< 1%)	0	0	1 (< 1%)
Injection site pain	2 (1%)	0	0	2 (1%)
Injection site pruritus	0	1 (< 1%)	0	1 (< 1%)
Injection site swelling	1 (< 1%)	0	0	1 (< 1%)
Vaccination site pruritus	1 (< 1%)	0	0	1 (< 1%)
Metabolism and nutrition disorders	1 (< 1%)	0	0	1 (< 1%)
Decreased appetite	1 (< 1%)	0	0	1 (< 1%)
Musculoskeletal and connective tissue disorders	9 (3%)	1 (< 1%)	1 (< 1%)	11 (4%)
Arthralgia	4 (1%)	0	0	4 (1%)
Joint stiffness	1 (< 1%)	0	0	1 (< 1%)
Myalgia	4 (1%)	1 (< 1%)	1 (< 1%)	6 (2%)
Nervous system disorders	6 (2%)	1 (< 1%)	1 (< 1%)	8 (3%)
Dizziness	3 (1%)	0	0	3 (1%)
Headache	3 (1%)	0	1 (< 1%)	4 (1%)
Syncope	0	1 (< 1%)	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17.1
Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Menactra-Menveo (N=300)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Psychiatric disorders	0	1 (< 1%)	0	1 (< 1%)
Anxiety	0	1 (< 1%)	0	1 (< 1%)
Respiratory, thoracic and mediastinal disorders	4 (1%)	0	0	4 (1%)
Cough	1 (< 1%)	0	0	1 (< 1%)
Nasal congestion	3 (1%)	0	0	3 (1%)
Oropharyngeal pain	1 (< 1%)	0	0	1 (< 1%)
Skin and subcutaneous tissue disorders	1 (< 1%)	1 (< 1%)	0	2 (1%)
Pruritus	1 (< 1%)	0	0	1 (< 1%)
Urticaria	0	1 (< 1%)	0	1 (< 1%)
Vascular disorders	1 (< 1%)	0	0	1 (< 1%)
Hot flush	1 (< 1%)	0	0	1 (< 1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.1.17.1

Subjects With Possibly or Probably Related Unsolicited Adverse Events With Onset From Day 1 Through Day 29 After Vaccination by System Organ Class and Preferred Term, by Severity
Unsolicited Safety Set

Group: Naive (N=100)
Vaccination: 1

System Organ Class Preferred Term	MILD	MODERATE	SEVERE	ANY SEVERITY
Any Adverse Event	7 (7%)	3 (3%)	1 (1%)	11 (11%)
Gastrointestinal disorders	1 (1%)	0	1 (1%)	2 (2%)
Diarrhoea	0	0	1 (1%)	1 (1%)
Nausea	1 (1%)	0	0	1 (1%)
General disorders and administration site conditions	5 (5%)	3 (3%)	0	8 (8%)
Injection site bruising	1 (1%)	0	0	1 (1%)
Injection site erythema	1 (1%)	3 (3%)	0	4 (4%)
Injection site induration	0	1 (1%)	0	1 (1%)
Injection site pruritus	2 (2%)	0	0	2 (2%)
Pyrexia	1 (1%)	0	0	1 (1%)
Infections and infestations	2 (2%)	0	0	2 (2%)
Nasopharyngitis	1 (1%)	0	0	1 (1%)
Upper respiratory tract infection	1 (1%)	0	0	1 (1%)
Nervous system disorders	1 (1%)	0	0	1 (1%)
Headache	1 (1%)	0	0	1 (1%)
Respiratory, thoracic and mediastinal disorders	1 (1%)	0	0	1 (1%)
Nasal congestion	1 (1%)	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

14.3.2 Death, Other Serious and Significant Adverse Events

Table 14.3.2.1
Subjects With Unsolicited Adverse Events Leading to Death After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
None Reported				

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.2
Subjects With Serious Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	3 (1%)	2 (1%)	5 (1%)	3 (3%)
Gastrointestinal disorders	1 (< 1%)	0	1 (< 1%)	0
Abdominal pain	1 (< 1%)	0	1 (< 1%)	0
Infections and infestations	1 (< 1%)	0	1 (< 1%)	1 (1%)
Diverticulitis	0	0	0	1 (1%)
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Injury, poisoning and procedural complications	1 (< 1%)	0	1 (< 1%)	0
Intentional overdose	1 (< 1%)	0	1 (< 1%)	0
Nervous system disorders	0	0	0	1 (1%)
Diabetic ketoacidotic hyperglycaemic coma	0	0	0	1 (1%)
Pregnancy, puerperium and perinatal conditions	0	0	0	1 (1%)
Abortion spontaneous	0	0	0	1 (1%)
Psychiatric disorders	2 (1%)	2 (1%)	4 (1%)	0
Suicide attempt	2 (1%)	1 (< 1%)	3 (< 1%)	0
Major depression	1 (< 1%)	0	1 (< 1%)	0
Suicidal ideation	0	1 (< 1%)	1 (< 1%)	0
Respiratory, thoracic and mediastinal disorders	1 (< 1%)	0	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.3
Subjects With Possibly or Probably Related Serious Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
None Reported				

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.4
Subjects With Unsolicited Adverse Events Leading to Premature Withdrawal from Study After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
None Reported				

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.5
Subjects With Unsolicited Adverse Events Leading to Hospitalization After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	2 (1%)	2 (1%)	4 (1%)	2 (2%)
Gastrointestinal disorders	1 (< 1%)	0	1 (< 1%)	0
Abdominal pain	1 (< 1%)	0	1 (< 1%)	0
Infections and infestations	1 (< 1%)	0	1 (< 1%)	1 (1%)
Diverticulitis	0	0	0	1 (1%)
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Nervous system disorders	0	0	0	1 (1%)
Diabetic ketoacidotic hyperglycaemic coma	0	0	0	1 (1%)
Psychiatric disorders	1 (< 1%)	2 (1%)	3 (< 1%)	0
Major depression	1 (< 1%)	0	1 (< 1%)	0
Suicidal ideation	0	1 (< 1%)	1 (< 1%)	0
Suicide attempt	0	1 (< 1%)	1 (< 1%)	0
Respiratory, thoracic and mediastinal disorders	1 (< 1%)	0	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	102 (34%)	79 (26%)	181 (30%)	19 (19%)
Blood and lymphatic system disorders	1 (< 1%)	2 (1%)	3 (< 1%)	0
Anaemia	0	2 (1%)	2 (< 1%)	0
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Cardiac disorders	0	0	0	1 (1%)
Angina pectoris	0	0	0	1 (1%)
Ear and labyrinth disorders	1 (< 1%)	2 (1%)	3 (< 1%)	0
Cerumen impaction	0	1 (< 1%)	1 (< 1%)	0
Middle ear effusion	0	1 (< 1%)	1 (< 1%)	0
Tympanic membrane perforation	1 (< 1%)	0	1 (< 1%)	0
Vertigo	0	1 (< 1%)	1 (< 1%)	0
Eye disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Conjunctivitis allergic	0	1 (< 1%)	1 (< 1%)	0
Erythema of eyelid	0	0	0	1 (1%)
Retinal tear	1 (< 1%)	0	1 (< 1%)	0
Gastrointestinal disorders	14 (5%)	9 (3%)	23 (4%)	2 (2%)
Abdominal pain	6 (2%)	1 (< 1%)	7 (1%)	0
Gastrooesophageal reflux disease	2 (1%)	3 (1%)	5 (1%)	0
Nausea	2 (1%)	0	2 (< 1%)	2 (2%)
Haemorrhoids	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Tooth impacted	2 (1%)	0	2 (< 1%)	0
Abdominal tenderness	1 (< 1%)	0	1 (< 1%)	0
Anal skin tags	0	1 (< 1%)	1 (< 1%)	0
Constipation	0	1 (< 1%)	1 (< 1%)	0
Diarrhoea	0	0	0	1 (1%)
Eosinophilic oesophagitis	0	1 (< 1%)	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Gastritis	0	1 (< 1%)	1 (< 1%)	0
Salivary gland mucocoele	0	1 (< 1%)	1 (< 1%)	0
Umbilical hernia	0	1 (< 1%)	1 (< 1%)	0
Vomiting	1 (< 1%)	0	1 (< 1%)	0
General disorders and administration site conditions	8 (3%)	4 (1%)	12 (2%)	1 (1%)
Fatigue	3 (1%)	2 (1%)	5 (1%)	0
Pyrexia	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Influenza like illness	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Chest pain	1 (< 1%)	0	1 (< 1%)	0
Medical device site erythema	1 (< 1%)	0	1 (< 1%)	0
Medical device site swelling	1 (< 1%)	0	1 (< 1%)	0
Pain	1 (< 1%)	0	1 (< 1%)	0
Hepatobiliary disorders	0	0	0	1 (1%)
Biliary dyskinesia	0	0	0	1 (1%)
Immune system disorders	2 (1%)	2 (1%)	4 (1%)	0
Seasonal allergy	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Anaphylactic reaction	1 (< 1%)	0	1 (< 1%)	0
Hypersensitivity	0	1 (< 1%)	1 (< 1%)	0
Infections and infestations	51 (17%)	47 (16%)	98 (16%)	10 (10%)
Upper respiratory tract infection	9 (3%)	8 (3%)	17 (3%)	1 (1%)
Acute sinusitis	11 (4%)	0	11 (2%)	1 (1%)
Influenza	3 (1%)	6 (2%)	9 (1%)	3 (3%)
Pharyngitis	3 (1%)	5 (2%)	8 (1%)	1 (1%)
Bronchitis	4 (1%)	3 (1%)	7 (1%)	1 (1%)
Otitis media	4 (1%)	4 (1%)	8 (1%)	0
Sinusitis	2 (1%)	5 (2%)	7 (1%)	1 (1%)
Urinary tract infection	2 (1%)	3 (1%)	5 (1%)	2 (2%)
Pharyngitis streptococcal	3 (1%)	3 (1%)	6 (1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Nasopharyngitis	5 (2%)	0	5 (1%)	0
Pneumonia mycoplasmal	4 (1%)	1 (< 1%)	5 (1%)	0
Viral pharyngitis	3 (1%)	2 (1%)	5 (1%)	0
Cellulitis	4 (1%)	0	4 (1%)	0
Gastroenteritis viral	1 (< 1%)	3 (1%)	4 (1%)	0
Otitis media acute	3 (1%)	1 (< 1%)	4 (1%)	0
Conjunctivitis	2 (1%)	1 (< 1%)	3 (< 1%)	0
Otitis externa	2 (1%)	1 (< 1%)	3 (< 1%)	0
Pneumonia	1 (< 1%)	2 (1%)	3 (< 1%)	0
Tooth abscess	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Bacterial vaginosis	0	1 (< 1%)	1 (< 1%)	1 (1%)
Folliculitis	1 (< 1%)	0	1 (< 1%)	1 (1%)
Bartholin's abscess	0	1 (< 1%)	1 (< 1%)	0
Bronchitis viral	1 (< 1%)	0	1 (< 1%)	0
Chlamydial infection	0	1 (< 1%)	1 (< 1%)	0
Croup infectious	1 (< 1%)	0	1 (< 1%)	0
Diverticulitis	0	0	0	1 (1%)
Fungal infection	0	1 (< 1%)	1 (< 1%)	0
Infectious mononucleosis	0	1 (< 1%)	1 (< 1%)	0
Kidney infection	0	0	0	1 (1%)
Laryngitis	1 (< 1%)	0	1 (< 1%)	0
Oral herpes	0	1 (< 1%)	1 (< 1%)	0
Pneumonia bacterial	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection	1 (< 1%)	0	1 (< 1%)	0
Rhinitis	0	1 (< 1%)	1 (< 1%)	0
Septic shock	1 (< 1%)	0	1 (< 1%)	0
Subcutaneous abscess	0	1 (< 1%)	1 (< 1%)	0
Tonsillitis	1 (< 1%)	0	1 (< 1%)	0
Vaginal infection	0	0	0	1 (1%)
Viral upper respiratory tract infection	0	1 (< 1%)	1 (< 1%)	0
Vulvovaginal candidiasis	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal mycotic infection	0	0	0	1 (1%)

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Injury, poisoning and procedural complications	22 (7%)	15 (5%)	37 (6%)	2 (2%)
Ligament sprain	3 (1%)	3 (1%)	6 (1%)	0
Contusion	4 (1%)	1 (< 1%)	5 (1%)	0
Laceration	4 (1%)	1 (< 1%)	5 (1%)	0
Procedural pain	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Arthropod bite	3 (1%)	0	3 (< 1%)	0
Concussion	1 (< 1%)	2 (1%)	3 (< 1%)	0
Meniscus injury	1 (< 1%)	2 (1%)	3 (< 1%)	0
Hand fracture	0	2 (1%)	2 (< 1%)	0
Joint injury	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Limb injury	2 (1%)	0	2 (< 1%)	0
Alcohol poisoning	0	1 (< 1%)	1 (< 1%)	0
Conjunctival abrasion	0	1 (< 1%)	1 (< 1%)	0
Facial bones fracture	0	1 (< 1%)	1 (< 1%)	0
Foot fracture	0	0	0	1 (1%)
Intentional overdose	1 (< 1%)	0	1 (< 1%)	0
Joint dislocation	0	1 (< 1%)	1 (< 1%)	0
Ligament rupture	1 (< 1%)	0	1 (< 1%)	0
Muscle strain	0	1 (< 1%)	1 (< 1%)	0
Post procedural complication	1 (< 1%)	0	1 (< 1%)	0
Pulmonary contusion	0	1 (< 1%)	1 (< 1%)	0
Investigations	0	1 (< 1%)	1 (< 1%)	0
Cardiac murmur	0	1 (< 1%)	1 (< 1%)	0
Metabolism and nutrition disorders	2 (1%)	2 (1%)	4 (1%)	0
Decreased appetite	0	1 (< 1%)	1 (< 1%)	0
Dehydration	0	1 (< 1%)	1 (< 1%)	0
Hypoglycaemia	1 (< 1%)	0	1 (< 1%)	0
Vitamin D deficiency	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Musculoskeletal and connective tissue disorders	12 (4%)	3 (1%)	15 (2%)	2 (2%)
Pain in extremity	4 (1%)	0	4 (1%)	1 (1%)
Arthralgia	4 (1%)	0	4 (1%)	0
Back pain	2 (1%)	0	2 (< 1%)	0
Myalgia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Groin pain	0	0	0	1 (1%)
Metatarsalgia	1 (< 1%)	0	1 (< 1%)	0
Musculoskeletal pain	0	1 (< 1%)	1 (< 1%)	0
Pain in jaw	0	1 (< 1%)	1 (< 1%)	0
Rheumatoid arthritis	1 (< 1%)	0	1 (< 1%)	0
Synovial cyst	1 (< 1%)	0	1 (< 1%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (1%)	2 (< 1%)	0
Benign bone neoplasm	0	1 (< 1%)	1 (< 1%)	0
Skin papilloma	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders	4 (1%)	3 (1%)	7 (1%)	1 (1%)
Migraine	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Syncope	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Diabetic ketoacidotic hyperglycaemic coma	0	0	0	1 (1%)
Dizziness	0	1 (< 1%)	1 (< 1%)	0
Headache	0	1 (< 1%)	1 (< 1%)	0
Migraine with aura	1 (< 1%)	0	1 (< 1%)	0
Presyncope	0	1 (< 1%)	1 (< 1%)	0
Tension headache	1 (< 1%)	0	1 (< 1%)	0
Pregnancy, puerperium and perinatal conditions	0	0	0	1 (1%)
Abortion spontaneous	0	0	0	1 (1%)
Psychiatric disorders	15 (5%)	9 (3%)	24 (4%)	0
Anxiety	5 (2%)	3 (1%)	8 (1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Depression	4 (1%)	1 (< 1%)	5 (1%)	0
Attention deficit/hyperactivity disorder	2 (1%)	2 (1%)	4 (1%)	0
Suicide attempt	2 (1%)	1 (< 1%)	3 (< 1%)	0
Insomnia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Major depression	2 (1%)	0	2 (< 1%)	0
Sleep disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Disruptive mood dysregulation disorder	1 (< 1%)	0	1 (< 1%)	0
Post-traumatic stress disorder	1 (< 1%)	0	1 (< 1%)	0
Suicidal ideation	0	1 (< 1%)	1 (< 1%)	0
Renal and urinary disorders	4 (1%)	1 (< 1%)	5 (1%)	0
Haematuria	2 (1%)	1 (< 1%)	3 (< 1%)	0
Dysuria	1 (< 1%)	0	1 (< 1%)	0
Pollakiuria	1 (< 1%)	0	1 (< 1%)	0
Polyuria	1 (< 1%)	0	1 (< 1%)	0
Proteinuria	1 (< 1%)	0	1 (< 1%)	0
Reproductive system and breast disorders	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Dysmenorrhoea	0	1 (< 1%)	1 (< 1%)	0
Menstruation irregular	1 (< 1%)	0	1 (< 1%)	0
Pelvic congestion	0	0	0	1 (1%)
Respiratory, thoracic and mediastinal disorders	17 (6%)	8 (3%)	25 (4%)	0
Asthma	7 (2%)	1 (< 1%)	8 (1%)	0
Oropharyngeal pain	5 (2%)	1 (< 1%)	6 (1%)	0
Cough	1 (< 1%)	3 (1%)	4 (1%)	0
Rhinitis allergic	1 (< 1%)	2 (1%)	3 (< 1%)	0
Epistaxis	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Wheezing	2 (1%)	0	2 (< 1%)	0
Dyspnoea	0	1 (< 1%)	1 (< 1%)	0
Respiratory disorder	1 (< 1%)	0	1 (< 1%)	0
Snoring	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.6
Subjects With Medically Attended Unsolicited Adverse Events After Vaccination Throughout the Study Period, by System Organ Class and Preferred Term
Unsolicited Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Skin and subcutaneous tissue disorders	8 (3%)	6 (2%)	14 (2%)	0
Acne	3 (1%)	5 (2%)	8 (1%)	0
Dermatitis contact	4 (1%)	0	4 (1%)	0
Alopecia	1 (< 1%)	0	1 (< 1%)	0
Rash	1 (< 1%)	0	1 (< 1%)	0
Urticaria	0	1 (< 1%)	1 (< 1%)	0
Vascular disorders	1 (< 1%)	0	1 (< 1%)	1 (1%)
Essential hypertension	0	0	0	1 (1%)
Lymphangiopathy	1 (< 1%)	0	1 (< 1%)	0

Number and percent of subjects with one or more events (as reported on Adverse Events form) that map to each MedDRA system organ class or MedDRA preferred term.
Hence, MedDRA preferred term counts may not sum to MedDRA system organ class counts, and MedDRA system organ class counts may not sum to overall counts.
Solicited adverse events are reported elsewhere.

PPD

Table 14.3.2.7
Listing of Unsolicited Adverse Events Leading to Death
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
None Reported									

PPD

Table 14.3.2.7.1
Listing of Serious Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Major depression (WORSENING MAJOR DEPRESSIVE DISORDER)	PPD (67)	FOLLOW-UP (36)	16 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		PPD	PPD (67)	FOLLOW-UP (36)	1 (CONT)	Y (5)	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo		PPD (73)	FOLLOW-UP (45)	10 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Diabetic ketoacidotic hyperglycaemic coma (DIABETIC KETOACIDOSIS WITH COMA)	PPD (32)	FOLLOW-UP (11)	6 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS, PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Diverticulitis (ACUTE DIVERTICULITIS)	PPD (168)	FOLLOW-UP (135)	13 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	PPD	PPD (125)	FOLLOW-UP (97)	1 (CONT)	Y (5)	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
			PPD (125)	FOLLOW-UP (97)	1 (CONT)	Y (5)	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive		FEB17	FOLLOW-UP	(CONT)	Y (6)	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo		PPD (33)	TREATMENT (33)	15 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.1
Listing of Serious Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (12)	TREATMENT (12)	6 (CONT)	Y (4)	MOD	(HOSPITALIZATION, IV FLUIDS,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tonsillitis (TONSILLITIS)	PPD (13)	TREATMENT (13)	5 (CONT)	Y (4)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Respiratory disorder (ACUTE RESPIRATORY COMPROMISE)	PPD (15)	TREATMENT (15)	1 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Septic shock (SEPTIC SHOCK)	PPD (15)	TREATMENT (15)	1 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.2
Listing of Possibly or Probably Related Unsolicited Serious Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
None Reported									

PPD

Table 14.3.2.7.3
Listing of Unsolicited Adverse Events Leading to Premature Withdrawal from Study
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset: Start Date (Day)	Onset: Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
None Reported									

PPD

Table 14.3.2.7.4
Listing of Unsolicited Adverse Events Leading to Hospitalization
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Major depression (WORSENING MAJOR DEPRESSIVE DISORDER)	PPD (67)	FOLLOW-UP (36)	16 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	PPD	PPD (73)	FOLLOW-UP (45)	10 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Diabetic ketoacidotic hyperglycaemic coma (DIABETIC KETOACIDOSIS WITH COMA)	PPD (32)	FOLLOW-UP (11)	6 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS, PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Diverticulitis (ACUTE DIVERTICULITIS)	PPD (168)	FOLLOW-UP (135)	13 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	PPD	PPD (33)	TREATMENT (33)	15 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (12)	TREATMENT (12)	6 (CONT)	Y (4)	MOD	(HOSPITALIZATION, IV FLUIDS,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tonsillitis (TONSILLITIS)	PPD (13)	TREATMENT (13)	5 (CONT)	Y (4)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Respiratory disorder (ACUTE RESPIRATORY COMPROMISE)	PPD (15)	TREATMENT (15)	1 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Septic shock (SEPTIC SHOCK)	PPD (15)	TREATMENT (15)	1 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menactra-Menveo	Dizziness (DIZZINESS)	PPD (14)	TREATMENT (14)	105 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Fatigue (FATIGUE)	PPD (14)	TREATMENT (14)	55 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Syncope (SYNCOPE)	PPD (14)	TREATMENT (14)	1 (CONT)	N	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Upper respiratory tract infection (ACUTE UPPER RESPIRATORY INFECTION)	PPD (24)	FOLLOW-UP (2)	9 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Presyncope (NEAR SYNCOPE)	PPD (30)	FOLLOW-UP (8)	51 (CONT)	N	MOD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Vertigo (VERTIGO)	PPD (30)	FOLLOW-UP (8)	39 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Bronchitis (BRONCHITIS)	PPD (117)	FOLLOW-UP (95)	7 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Dyspnoea (TROUBLE BREATHING)	PPD (120)	FOLLOW-UP (98)	1 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Upper respiratory tract infection (ACUTE UPPER RESPIRATORY INFECTION)	PPD (46)	FOLLOW-UP (11)	6 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Otitis externa (UNSPECIFIED OTITIS EXTERNA)	PPD (69)	FOLLOW-UP (40)	7 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Major depression (MAJOR DEPRESSIVE DISORDER)	PPD (32)	TREATMENT (32)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Major depression (WORSENING MAJOR DEPRESSIVE DISORDER)	PPD (67)	FOLLOW-UP (36)	16 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		PPD	PPD (67)	FOLLOW-UP (36)	1 (CONT)	Y (5)	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Upper respiratory tract infection (URI)	PPD (95)	FOLLOW-UP (67)	7 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Viral pharyngitis (VIRAL PHARYNGITIS)	PPD (95)	FOLLOW-UP (67)	7 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Influenza (INFLUENZA)	PPD (43)	FOLLOW-UP (3)	4 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	PPD	PPD (73)	FOLLOW-UP (45)	10 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Anxiety (ANXIETY)	PPD (141)	FOLLOW-UP (113)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Urticaria (HIVES)	PPD (10)	TREATMENT (10)	47 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (POSSIBLY RELATED)
		Fungal infection (YEAST INFECTION)	PPD (28)	TREATMENT (28)	3 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Urticaria (HIVES)	PPD (130)	FOLLOW-UP (102)	74 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (POSSIBLY RELATED)
	Menveo-Menveo	Otitis media (OTITIS MEDIA- RIGHT)	PPD (130)	FOLLOW-UP (102)	10 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Bronchitis (BRONCHITIS)	PPD (130)	FOLLOW-UP (102)	10 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (95)	FOLLOW-UP (66)	20 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Conjunctivitis (CONJUNCTIVITIS- LEFT EYE)	PPD (27)	TREATMENT (27)	6 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (162)	FOLLOW-UP (134)	5 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Attention deficit/hyperactivity disorder (ATTENTION DEFICIT DISORDER)	PPD (105)	FOLLOW-UP (84)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE SINUSITIS)	PPD (115)	FOLLOW-UP (87)	28 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Limb injury (PUNCTURE TO BOTTOM OF RIGHT FOOT)	PPD (61)	FOLLOW-UP (33)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Back pain (BACK PAIN)	PPD (138)	FOLLOW-UP (108)	(INT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Contusion (LEFT FOOT CONTUSION)	PPD (111)	FOLLOW-UP (81)	3 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Pain in extremity (RIGHT ARM PAIN)	PPD (51)	FOLLOW-UP (23)	93 (INT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED WITH SEQUELAE (NONE)
		Acne (ACNE (WORSENING))	PPD (141)	FOLLOW-UP (113)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Laryngitis (LARYNGITIS)	PPD (2)	TREATMENT (2)	6 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Procedural pain (PAIN AFTER WISDOM TEETH EXTRACTION)	PPD (101)	FOLLOW-UP (80)	3 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tooth impacted (WISDOM TEETH IMPACTION)	PPD (101)	FOLLOW-UP (80)	1 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

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PPD	Menveo-Menveo	Cellulitis (CELLULITIS)	PPD (53)	FOLLOW-UP (20)	11 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Laceration (FACIAL LACERATION)	PPD (92)	FOLLOW-UP (59)	7 (CONT)	N	MOD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Urinary tract infection (URINARY TRACT INFECTION)	PPD (120)	FOLLOW-UP (93)	6 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Vulvovaginal mycotic infection (VAGINAL YEAST INFECTION)	PPD (53)	FOLLOW-UP (26)	38 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Sinusitis (SINUSITIS)	PPD (63)	FOLLOW-UP (36)	12 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Bronchitis (BRONCHITIS)	PPD (83)	FOLLOW-UP (56)	7 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Angina pectoris (STABLE ANGINA)	PPD (28)	TREATMENT (28)	(INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Naive	Influenza (INFLUENZA)	PPD (39)	FOLLOW-UP (12)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Bacterial vaginosis (BACTERIAL VAGINOSIS)	PPD (116)	FOLLOW-UP (89)	23 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Benign bone neoplasm (BENIGN NEOPLASM OF MANDIBLE)	PPD (29)	FOLLOW-UP (7)	10 (CONT)	N	MILD	(OTHER,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Constipation (CONSTIPATION)	PPD (80)	FOLLOW-UP (58)	7 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Gastrooesophageal reflux disease (GASTROESOPHOGEAL REFLUX)	PPD (80)	FOLLOW-UP (58)	8 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Salivary gland mucocoele (LOWER LIP MUCOCELE)	PPD (13)	TREATMENT (13)	91 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)

PPD

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Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menactra-Menveo	Acne (ACNE)	PPD (96)	FOLLOW-UP (69)	(INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Ligament sprain (RIGHT KNEE SPRAIN)	PPD (104)	FOLLOW-UP (77)	26 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Acne (ACNE)	PPD (132)	FOLLOW-UP (99)	(INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Fatigue (FATIGUE)	PPD (1)	TREATMENT (1)	12 (INT)	N	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (PROBABLY RELATED)
		Headache (HEADACHE)	PPD (1)	TREATMENT (1)	12 (INT)	N	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (PROBABLY RELATED)
		Myalgia (MUSCLE ACHES)	PPD (4)	TREATMENT (4)	9 (INT)	N	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (POSSIBLY RELATED)
		Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (4)	TREATMENT (4)	9 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Laceration (LEFT HAND LACERATION)	PPD (46)	FOLLOW-UP (20)	12 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Meniscus injury (RIGHT KNEE LATERAL MENISCUC LEAR)	PPD (90)	FOLLOW-UP (64)	(CONT)	N	MOD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (5)	TREATMENT (5)	3 (INT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,OTHER, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Otitis media (RIGHT OTITIS MEDIA)	PPD (65)	FOLLOW-UP (32)	11 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Sinusitis (SINUSITIS)	PPD (65)	FOLLOW-UP (32)	4 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menactra-Menveo	Cerumen impaction (RIGHT EAR CERUMEN IMPACTION)	PPD (63)	FOLLOW-UP (29)	1 (CONT)	N	MOD	(OTHER,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Middle ear effusion (RIGHT MIDDLE EAR EFFUSION)	PPD (63)	FOLLOW-UP (29)	29 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Rhinitis allergic (ALLERGIC RHINITIS)	PPD (63)	FOLLOW-UP (29)	(INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Conjunctivitis allergic (BILATERAL ALLERGIC CONJUNCTIVITIS)	PPD (77)	FOLLOW-UP (43)	15 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Cough (COUGH)	PPD (94)	FOLLOW-UP (60)	39 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Otitis media (LEFT OTITIS MEDIA)	PPD (16)	TREATMENT (16)	11 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Anaemia (ANEMIA)	PPD (98)	FOLLOW-UP (63)	62 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Otitis externa (EXTERNAL OTITIS)	PPD (70)	FOLLOW-UP (43)	1 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (99)	FOLLOW-UP (72)	8 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Haemorrhoids (HEMORRHOID)	PPD (118)	FOLLOW-UP (99)	(CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Anal skin tags (ANAL SKIN TAG)	PPD (130)	FOLLOW-UP (111)	(CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

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PPD	Menactra-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (87)	FOLLOW-UP (51)	21 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Otitis media acute (ACUTE OTITIS MEDIA)	PPD (92)	FOLLOW-UP (56)	16 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Seasonal allergy (SEASONAL ALLERGIC RHINITIS)	PPD (126)	FOLLOW-UP (90)	3 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Asthma (ASTHMA,ACUTE EXACERBATION)	PPD (128)	FOLLOW-UP (92)	2 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Infectious mononucleosis (EPSTEIN-BARRR VIRUS (MONONUCLEOSIS))	PPD (47)	FOLLOW-UP (23)	23 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Pneumonia (BRONCHOPNEUMONIA)	PPD (28)	FOLLOW-UP (3)	20 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Sinusitis (SINUSITIS)	PPD (9)	TREATMENT (9)	9 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Disruptive mood dysregulation disorder (DISRUPTIVE MOOD DISREGULATION DISORDER)	PPD (78)	FOLLOW-UP (52)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Asthma (ASTHMA EXACERBATION)	PPD (82)	FOLLOW-UP (56)	15 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Acute sinusitis (ACUTE MAXILLARY SINUSITIS)	PPD (86)	FOLLOW-UP (60)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Croup infectious (CROUP)	PPD (86)	FOLLOW-UP (60)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Acute sinusitis (ACUTE MAXILLARY SINUSITIS)	PPD (147)	FOLLOW-UP (121)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

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PPD	Naive	Diabetic ketoacidotic hyperglycaemic coma (DIABETIC KETOACIDOSIS WITH COMA)	PPD (32)	FOLLOW-UP (11)	6 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS, PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Folliculitis (FOLLICULITIS OF THE SKIN)	PPD (35)	FOLLOW-UP (14)	9 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Arthralgia (WRIST PAIN)	PPD (11)	TREATMENT (11)	5 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Asthma (ASTHMA EXACERBATION)	PPD (23)	TREATMENT (23)	10 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Back pain (LOW BACK PAIN)	PPD (26)	TREATMENT (26)	16 (INT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pneumonia (PNEUMONIA)	PPD (28)	TREATMENT (28)	12 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Influenza (INFLUENZA)	PPD (55)	FOLLOW-UP (28)	8 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pharyngitis streptococcal (STREP PHARYNGITIS)	PPD (58)	FOLLOW-UP (31)	12 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Viral pharyngitis (VIRAL PHARYNGITIS)	PPD (90)	FOLLOW-UP (63)	68 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Insomnia (INSOMNIA)	PPD (94)	FOLLOW-UP (67)	(INT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
		Snoring (SNORING)	PPD (94)	FOLLOW-UP (67)	(INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Pneumonia mycoplasmal (MYCOPLASMA PNEUMONIA)	PPD (108)	FOLLOW-UP (81)	17 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Seasonal allergy (WORSENING OF SEASONAL ALLERGIES)	PPD (165)	FOLLOW-UP (138)	(INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

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PPD	Menactra-Menveo	Pneumonia (PNEUMONIA)	PPD (84)	FOLLOW-UP (57)	12 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (24)	TREATMENT (24)	15 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pneumonia mycoplasmal (MYCOPLASMA PNEUMONIA)	PPD (59)	FOLLOW-UP (33)	9 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Anxiety (ANXIETY)	PPD (91)	FOLLOW-UP (65)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Depression (DEPRESSION)	PPD (97)	FOLLOW-UP (71)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Dermatitis contact (POISON IVY)	PPD (104)	FOLLOW-UP (78)	5 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Contusion (BRUISING TO LEFT HAND)	PPD (160)	FOLLOW-UP (134)	6 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pain in extremity (PAIN IN LEFT HAND)	PPD (160)	FOLLOW-UP (134)	6 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE SINUSITIS)	PPD (18)	TREATMENT (18)	6 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Migraine with aura (CLASSIC MIGRAINE)	PPD (102)	FOLLOW-UP (76)	3 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pneumonia mycoplasmal (MYCOPLASMA PNEUMONIA)	PPD (152)	FOLLOW-UP (126)	9 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pollakiuria (URINARY FREQUENCY)	PPD (152)	FOLLOW-UP (126)	5 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Synovial cyst (CYST OF GANGLION- LEFT ANKLE)	PPD (15)	TREATMENT (15)	(CONT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

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PPD	Menactra-Menveo	Decreased appetite (LOSS OF APETITE)	PPD (19)	TREATMENT (19)	46 (INT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Gastritis (GASTRITIS)	PPD (19)	TREATMENT (19)	46 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Otitis media (LEFT OTITIS MEDIA)	PPD (48)	FOLLOW-UP (19)	11 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Sleep disorder (SLEEP DISTURBANCE)	PPD (48)	FOLLOW-UP (19)	17 (INT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Laceration (LACERATION TO FINGER)	PPD (65)	FOLLOW-UP (35)	9 (CONT)	N	MILD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE SINUSITIS)	PPD (22)	TREATMENT (22)	15 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Otitis media (LEFT OTITIS MEDIA)	PPD (27)	FOLLOW-UP (6)	10 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Pain in extremity (RIGHT FINGER (5TH DIGIT) PAIN)	PPD (8)	TREATMENT (8)	53 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Rash (RASH ON CHEEKS AND CHIN)	PPD (8)	TREATMENT (8)	23 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Arthralgia (LEFT KNEE PAIN)	PPD (29)	TREATMENT (29)	39 (INT)	N	SEV	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Influenza (INFLUENZA)	PPD (55)	FOLLOW-UP (32)	10 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Respiratory tract infection (ACUTE RESPIRATORY INFECTION)	PPD (55)	FOLLOW-UP (32)	10 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Retinal tear (RETINAL HOLE-BOTH EYES)	PPD (162)	FOLLOW-UP (139)	(CONT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (1)	TREATMENT (1)	7 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Dysuria (DYSURIA)	PPD (1)	TREATMENT (1)	7 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Haematuria (HEMATURIA)	PPD (1)	TREATMENT (1)	7 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Migraine (WORSENING OF MIGRAINES)	PPD (11)	TREATMENT (11)	2 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Gastroenteritis viral (VIRAL GASTROENTERITIS)	PPD (49)	FOLLOW-UP (21)	3 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Urinary tract infection (URINARY TRACT INFECTION)	PPD (27)	FOLLOW-UP (5)	11 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Folliculitis (FOLLICULITIS)	PPD (50)	FOLLOW-UP (28)	10 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Depression (DEPRESSION)	PPD (54)	FOLLOW-UP (32)	31 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Vulvovaginal candidiasis (VAGINAL CANDIDA)	PPD (62)	FOLLOW-UP (40)	8 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menveo-Menveo	Concussion (CONCUSSION WITHOUT LOSS OF CONSCIOUSNESS)	PPD (6)	TREATMENT (6)	6 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Laceration (LACERATION TO TOP OF HEAD)	PPD (6)	TREATMENT (6)	6 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pneumonia bacterial (COMMUNITY ACQUIRED BACTERIAL PNEUMONIA)	PPD (28)	FOLLOW-UP (7)	10 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Vomiting (VOMITING)	PPD (28)	FOLLOW-UP (7)	5 (INT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Cellulitis (CELLULITIS OF RIGHT TOE)	PPD (45)	FOLLOW-UP (32)	17 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Hypoglycaemia (FUNCTIONAL HYPOGLYCEMIC SYNDROME)	PPD (154)	FOLLOW-UP (141)	(INT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Influenza like illness (FLU LIKE SYMPTOMS)	PPD (11)	TREATMENT (11)	8 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Viral pharyngitis (VIRAL PHARYNGITIS)	PPD (11)	TREATMENT (11)	8 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Pain in extremity (LEFT FOOT PAIN)	PPD (148)	FOLLOW-UP (123)	(INT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Joint injury (RIGHT KNEE INJURY)	PPD (5)	TREATMENT (5)	4 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Gastrooesophageal reflux disease (GERD)	PPD (73)	FOLLOW-UP (52)	(INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Naive	Erythema of eyelid (REDNESS OF EYELID)	PPD (7)	TREATMENT (7)	150 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Oropharyngeal pain (SORE THROAT)	PPD (105)	FOLLOW-UP (73)	6 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menactra-Menveo	Upper respiratory tract infection (URI)	PPD (104)	FOLLOW-UP (61)	6 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Viral pharyngitis (VIRAL PHARYNGITIS)	PPD (145)	FOLLOW-UP (117)	6 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Sinusitis (SINUSITIS)	PPD (79)	FOLLOW-UP (25)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Influenza (INFLUENZA)	PPD (110)	FOLLOW-UP (82)	4 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Asthma (ASTHMA ACUTE EXACERBATION)	PPD (2)	TREATMENT (2)	3 (CONT)	N	SEV	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Pharyngitis (PHARYNGITIS)	PPD (111)	FOLLOW-UP (90)	11 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Hypersensitivity (ALLERGIC REACTION)	PPD (86)	FOLLOW-UP (59)	3 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Hand fracture (RIGHT HAND BOWING FRACTURE)	PPD (163)	FOLLOW-UP (136)	58 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Ligament sprain (LEFT ANKLE SPRAIN)	PPD (163)	FOLLOW-UP (136)	93 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Ligament sprain (LEFT FOOT SPRAIN)	PPD (163)	FOLLOW-UP (136)	93 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Naive	Acute sinusitis (ACUTE NON-RECURRENT PANSINUSITIS)	PPD (11)	TREATMENT (11)	14 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Urinary tract infection (URINARY TRACT INFECTION)	PPD (16)	TREATMENT (16)	9 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Nausea (NAUSEA)	PPD (20)	TREATMENT (20)	2 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Diarrhoea (DIARRHEA)	PPD (49)	FOLLOW-UP (16)	4 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Kidney infection (KIDNEY INFECTION)	PPD (49)	FOLLOW-UP (16)	17 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Urinary tract infection (URINARY TRACT INFECTION)	PPD (49)	FOLLOW-UP (16)	6 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (112)	FOLLOW-UP (79)	12 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Urinary tract infection (URINARY TRACT INFECTION)	PPD (112)	FOLLOW-UP (79)	6 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Diverticulitis (DIVERTICULITIS)	PPD (137)	FOLLOW-UP (104)	9 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Nausea (NAUSEA)	PPD (137)	FOLLOW-UP (104)	7 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Diverticulitis (ACUTE DIVERTICULITIS)	PPD (168)	FOLLOW-UP (135)	13 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Ligament sprain (BOTH KNEE- SPRAIN)	PPD (20)	TREATMENT (20)	16 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (123)	FOLLOW-UP (98)	11 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menactra-Menveo	Musculoskeletal pain (RIGHT SHOULDER PAIN)	PPD (114)	FOLLOW-UP (86)	60 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Joint dislocation (RIGHT- ONE DEGREE SEPARATE ACROMIOCLAVICULAR)	PPD (145)	FOLLOW-UP (117)	29 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Sinusitis (SINUSITIS)	PPD (84)	FOLLOW-UP (61)	11 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Concussion (CONCUSSION)	PPD (123)	FOLLOW-UP (100)	53 (INT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Cough (COUGH)	PPD (58)	FOLLOW-UP (37)	32 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Influenza (INFLUENZA)	PPD (47)	FOLLOW-UP (19)	15 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Sinusitis (ACUTE RECURRENT PANSINUSITIS)	PPD (47)	FOLLOW-UP (19)	15 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Procedural pain (PAIN SECONDARY TO ROUTINE WISDOM TOOTH EXTRACTION)	PPD (78)	FOLLOW-UP (57)	8 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Bartholin's abscess (BARTHOLIN'S GLAND INFECTION)	PPD (107)	FOLLOW-UP (86)	14 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (140)	FOLLOW-UP (119)	54 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Vitamin D deficiency (VITAMIN D DEFINCIENCY)	PPD (123)	FOLLOW-UP (94)	73 (CONT)	N	MILD	(PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED WITH SEQUELAE (NONE)
	Menveo-Menveo	Anaphylactic reaction (ANAPHYLACTIC REACTION TO LATEX)	PPD (173)	FOLLOW-UP (145)	1 (CONT)	N	MOD	(OTHER,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Limb injury (RIGHT SHOULDER INJURY)	PPD (84)	FOLLOW-UP (53)	38 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Anxiety (WORSENING OF ANXIETY)	PPD (83)	FOLLOW-UP (55)	64 (INT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Oropharyngeal pain (SORE THROAT)	PPD (1)	TREATMENT (1)	3 (CONT)	N	MOD	(OTHER)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Otitis media (OTITIS MEDIA)	PPD (51)	FOLLOW-UP (24)	18 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Upper respiratory tract infection (URI)	PPD (64)	FOLLOW-UP (37)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (22)	TREATMENT (22)	4 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Sinusitis (SINUSITIS)	PPD (22)	TREATMENT (22)	6 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Bronchitis (BRONCHITIS)	PPD (77)	FOLLOW-UP (49)	12 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Anxiety (ANXIETY)	PPD (61)	FOLLOW-UP (29)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Depression (DEPRESSION)	PPD (61)	FOLLOW-UP (29)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (23)	TREATMENT (23)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Intentional overdose (INTENTIONAL OVERDOSE)	PPD (125)	FOLLOW-UP (97)	1 (CONT)	Y (5)	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Nausea (NAUSEA)	PPD (125)	FOLLOW-UP (97)	1 (CONT)	N	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		PPD	PPD (125)	FOLLOW-UP (97)	1 (CONT)	Y (5)	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

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Unsolicited Safety Set

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PPD	Menveo-Menveo	Syncope (SYNCOPE)	PPD (81)	FOLLOW-UP (53)	1 (CONT)	N	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Anxiety (ANXIETY)	PPD (82)	FOLLOW-UP (54)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Ligament rupture (PARTIAL MEDIAL COLLATERAL LIGAMENT (MCL) TEAR - LEFT KNEE)	PPD (11)	TREATMENT (11)	(CONT)	N	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Ligament rupture (TORN ANTERIOR CRUCIATE LIGAMENT (ACL) - LEFT KNEE, COMPLETE)	PPD (11)	TREATMENT (11)	(CONT)	N	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Meniscus injury (MENISCUS TEAR - LEFT KNEE, COMPLETE)	PPD (11)	TREATMENT (11)	(INT)	N	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Pharyngitis (ACUTE PHARYNGITIS)	PPD (28)	TREATMENT (28)	3 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pyrexia (FEVER)	PPD (28)	TREATMENT (28)	3 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Migraine (MIGRAINE)	PPD (70)	FOLLOW-UP (42)	3 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Influenza like illness (RESPIRATORY FLU-LIKE SYNDROME)	PPD (79)	FOLLOW-UP (50)	7 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Concussion (CONCUSSION)	PPD (99)	FOLLOW-UP (70)	4 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Influenza (FLU)	PPD (99)	FOLLOW-UP (70)	4 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Epistaxis (EPISTAXIS)	PPD (100)	FOLLOW-UP (71)	1 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Pharyngitis (ACUTE PHARYNGITIS)	PPD (24)	TREATMENT (24)	5 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

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PPD	Menactra-Menveo	Conjunctival abrasion (CONJUNCTIVAL ABRASION)	PPD (80)	FOLLOW-UP (52)	2 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Viral upper respiratory tract infection (VIRAL UPPER RESPIRATORY INFECTION)	PPD (84)	FOLLOW-UP (56)	11 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Viral upper respiratory tract infection (VIRAL UPPER RESPIRATORY INFECTION)	PPD (136)	FOLLOW-UP (108)	8 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Pneumonia mycoplasmal (MYCOPLASMA PNEUMONIA)	PPD (52)	FOLLOW-UP (24)	11 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Hand fracture (RIGHT HAND 4TH METACARPAL BONE FRACTURE)	PPD (115)	FOLLOW-UP (86)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Pulmonary contusion (PULMONARY CONTUSION)	PPD (115)	FOLLOW-UP (86)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Sinusitis (SINUSITIS)	PPD (33)	TREATMENT (33)	24 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Bronchitis (BRONCHITIS)	PPD (65)	FOLLOW-UP (32)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	PPD	FEB17	FOLLOW-UP	(CONT)	Y (6)	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Influenza (INFLUENZA)	PPD (50)	FOLLOW-UP (18)	6 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Essential hypertension (ESSENTIAL HYPERTENSION)	PPD (57)	FOLLOW-UP (25)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menactra-Menveo	Dysmenorrhoea (DYSMENORRHEA)	PPD (36)	FOLLOW-UP (13)	(INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Insomnia (INSOMNIA)	PPD (36)	FOLLOW-UP (13)	59 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Gastroenteritis viral (STOMACH VIRUS)	PPD (160)	FOLLOW-UP (137)	3 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Dehydration (DEHYDRATION)	PPD (162)	FOLLOW-UP (139)	1 (CONT)	N	MILD	(IV FLUIDS,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Cough (COUGH)	PPD (72)	FOLLOW-UP (50)	10 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Influenza (INFLUENZA)	PPD (72)	FOLLOW-UP (50)	5 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Pharyngitis streptococcal (STREPTOCOCCAL PHARYNGITIS)	PPD (78)	FOLLOW-UP (50)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Pharyngitis streptococcal (STREPTOCOCCAL PHARYNGITIS)	PPD (78)	FOLLOW-UP (50)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Anxiety (ANXIETY)	PPD (56)	FOLLOW-UP (35)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Attention deficit/hyperactivity disorder (WORSENING ATTENTION DEFICIT HYPERACTIVITY DISORDER)	PPD (56)	FOLLOW-UP (35)	3 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Otitis media (RIGHT OTITIS MEDIA)	PPD (66)	FOLLOW-UP (45)	8 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Influenza (INFLUENZA)	PPD (55)	FOLLOW-UP (22)	6 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Attention deficit/hyperactivity disorder (ATTENTION DEFICIT HYPERACTIVITY DISORDER)	PPD (1)	TREATMENT (1)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menactra-Menveo	Gastroenteritis viral (STOMACH VIRUS)	PPD (33)	FOLLOW-UP (12)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pharyngitis streptococcal (STREPTOCOCCAL PHARYNGITIS)	PPD (33)	FOLLOW-UP (12)	10 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Dermatitis contact (CONTACT DERMATITIS)	PPD (6)	TREATMENT (6)	35 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Urinary tract infection (URINARY TRACT INFECTION)	PPD (22)	TREATMENT (22)	8 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Influenza (FLU)	PPD (19)	TREATMENT (19)	12 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Anxiety (WORSENING ANXIETY)	PPD (22)	TREATMENT (22)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (PROBABLY RELATED)
	Menactra-Menveo	Pharyngitis (PHARYNGITIS)	PPD (65)	FOLLOW-UP (31)	12 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Gastrooesophageal reflux disease (GERD)	PPD (68)	FOLLOW-UP (34)	4 (INT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Skin papilloma (R KNEE WARTS)	MAR17	FOLLOW-UP	(INT)	N	MOD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Bacterial vaginosis (BACTERIAL INFECTION - VAGINOSIS)	PPD (134)	FOLLOW-UP (100)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Chlamydial infection (CHLAMYDIA)	PPD (147)	FOLLOW-UP (113)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Urinary tract infection (URINARY TRACT INFECTION)	PPD (17)	TREATMENT (17)	15 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menactra-Menveo	Urinary tract infection (URINARY TRACT INFECTION)	PPD (44)	FOLLOW-UP (15)	3 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Influenza (INFLUENZA)	PPD (61)	FOLLOW-UP (32)	11 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Vaginal infection (VAGINITIS)	FEB17	FOLLOW-UP	(CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pelvic congestion (PELVIC CONGESTION SYNDROME)	PPD (77)	FOLLOW-UP (43)	(CONT)	N	MOD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Oral herpes (COLD SORE)	PPD (14)	TREATMENT (14)	7 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Acne (FACIAL ACNE)	PPD (72)	FOLLOW-UP (49)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	PPD	PPD (33)	TREATMENT (33)	15 (CONT)	Y (4)	SEV	(HOSPITALIZATION, PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Biliary dyskinesia (BILIARY DYSKINESIA)	PPD (37)	FOLLOW-UP (15)	(INT)	N	MOD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Pharyngitis (ACUTE PHARYNGITIS)	PPD (51)	FOLLOW-UP (13)	4 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Fatigue (FATIGUE)	PPD (39)	FOLLOW-UP (18)	24 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Gastrooesophageal reflux disease (GASTROESOPHAGEAL REFLUX DISEASE)	PPD (40)	FOLLOW-UP (19)	22 (INT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Acute sinusitis (ACUTE MAXILLARY SINUSITIS)	PPD (42)	FOLLOW-UP (21)	21 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Post procedural complication (SYNCOPE EPISODE POST BLOOD DRAW)	PPD (5)	TREATMENT (5)	1 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Oropharyngeal pain (SORE THROAT)	PPD (129)	FOLLOW-UP (108)	6 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

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PPD	Menveo-Menveo	Lymphangiopathy (NONINFECTIVE DISORDER OF LYMPHATIC VESSELS)	PPD (103)	FOLLOW-UP (61)	67 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Acne (ACNE)	PPD (150)	FOLLOW-UP (108)	24 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Alopecia (HAIR LOSS)	PPD (150)	FOLLOW-UP (108)	16 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Sleep disorder (SLEEP DISORDER, UNSPECIFIED)	PPD (150)	FOLLOW-UP (108)	16 (INT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Fatigue (FATIGUE)	PPD (157)	FOLLOW-UP (115)	9 (INT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Ligament sprain (SPRAIN RIGHT THUMB, INTERPHALANGEAL)	PPD (40)	FOLLOW-UP (8)	19 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Abdominal pain (PERIUMBILICAL PAIN)	PPD (89)	FOLLOW-UP (57)	2 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Urinary tract infection (URINARY TRACT INFECTION)	PPD (89)	FOLLOW-UP (57)	2 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Arthralgia (PAIN IN ANKLE AND JOINTS, LEFT FOOT)	PPD (73)	FOLLOW-UP (52)	32 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Contusion (CONTUSION OF LEFT FOOT)	PPD (73)	FOLLOW-UP (52)	32 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Ligament sprain (LEFT ANKLE SPRAIN)	PPD (92)	FOLLOW-UP (70)	32 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Groin pain (INGUINAL PAIN)	PPD (56)	FOLLOW-UP (35)	1 (CONT)	N	MILD	(OTHER)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Cardiac murmur (HEART MURMUR)	PPD (30)	TREATMENT (30)	(CONT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Naive	Pharyngitis (ACUTE PHARYNGITIS)	PPD (124)	FOLLOW-UP (96)	8 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Tooth abscess (TOOTH ABSCESS)	PPD (74)	FOLLOW-UP (53)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

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PPD	Menactra-Menveo	Conjunctivitis (CONJUNCTIVITIS)	PPD (64)	FOLLOW-UP (43)	11 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pain in jaw (JAW PAIN)	PPD (64)	FOLLOW-UP (43)	11 (INT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Facial bones fracture (BILATERAL NASAL BONE FRACTURE)	PPD (77)	FOLLOW-UP (56)	16 (CONT)	N	MILD	(OTHER,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Foot fracture (FRACTURED LEFT BIG TOE)	PPD (82)	FOLLOW-UP (54)	21 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Naive	Procedural pain (LEFT WRIST PAIN DUE TO SURGERY)	PPD (15)	TREATMENT (15)	35 (CONT)	N	SEV	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Nausea (NAUSEA DUE TO PAIN MEDICATION)	PPD (30)	TREATMENT (30)	2 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Acne (ACNE)	DEC16	TREATMENT	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Anaemia (ANEMIA)	PPD (128)	FOLLOW-UP (105)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Eosinophilic oesophagitis (EOSINOPHILIC ESOPHAGITIS)	PPD (128)	FOLLOW-UP (105)	(CONT)	N	MOD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

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Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menactra-Menveo	PPD	PPD (14)	TREATMENT (14)	1 (CONT)	N	SEV	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Depression (DEPRESSION)	PPD (14)	TREATMENT (14)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Abdominal tenderness (EPIGASTRIC TENDERNESS)	PPD (41)	TREATMENT (41)	16 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Subcutaneous abscess (RIGHT AXILLARY ABSCESS)	PPD (57)	FOLLOW-UP (35)	11 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Rhinitis allergic (ALLERGIC RHINITIS)	PPD (37)	FOLLOW-UP (3)	3 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Rhinitis (PURULENT RHINITIS)	PPD (51)	FOLLOW-UP (17)	11 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Acne (ACNE)	PPD (22)	TREATMENT (22)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menactra-Menveo	Contusion (CHEST WALL CONTUSION)	PPD (44)	FOLLOW-UP (16)	6 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Muscle strain (RIGHT SHOULDER STRAIN)	PPD (44)	FOLLOW-UP (16)	6 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

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PPD	Menactra-Menveo	Meniscus injury (TORN LATERAL MENISCUS OF LEFT KNEE)	PPD (124)	FOLLOW-UP (103)	46 (CONT)	N	MOD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tooth abscess (PAIN SECONDARY TO TOOTH ABCESS)	PPD (177)	FOLLOW-UP (156)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
		Tooth abscess (TOOTH ABCESS)	PPD (177)	FOLLOW-UP (156)	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Oropharyngeal pain (SORE THROAT)	PPD (71)	FOLLOW-UP (38)	3 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Tooth impacted (IMPACTED WISDOM TOOTH)	PPD (19)	TREATMENT (19)	1 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Fatigue (FATIGUE)	PPD (69)	FOLLOW-UP (36)	(CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
		Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (139)	FOLLOW-UP (106)	6 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Arthropod bite (INSECT BITE LEFT FOOT)	PPD (73)	FOLLOW-UP (32)	5 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE SINUSITIS)	PPD (16)	TREATMENT (16)	5 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Acute sinusitis (ACUTE SINUSITIS)	PPD (96)	FOLLOW-UP (68)	6 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)

PPD

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PPD	Menveo-Menveo	Depression (DEPRESSION)	FEB17	FOLLOW-UP	(CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Epistaxis (EPISTAXIS)	PPD (127)	FOLLOW-UP (99)	11 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Pharyngitis (ACUTE PHARYNGITIS)	PPD (27)	TREATMENT (27)	6 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Joint injury (KNEE INJURY - RIGHT KNEE)	PPD (153)	FOLLOW-UP (125)	10 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Cellulitis (CELLULITIS LEFT TOE)	APR17	FOLLOW-UP	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Anxiety (ANXIETY)	MAR17	TREATMENT	(CONT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
		Major depression (MAJOR DEPRESSION DISORDER)	PPD (122)	FOLLOW-UP (80)	(CONT)	N	MOD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Acne (ACNE)	JUL17	FOLLOW-UP	(CONT)	N	MILD	(OTHER,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Haemorrhoids (HEMORRHOIDS)	PPD (3)	TREATMENT (3)	10 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Attention deficit/hyperactivity disorder (ATTENTION AND CONCENTRATION DEFICIT)	MAR17	TREATMENT	(CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Abdominal pain (RIGHT ABDOMINAL PAIN)	PPD (173)	FOLLOW-UP (141)	3 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Chest pain (CHEST PAIN)	PPD (10)	TREATMENT (10)	2 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Otitis media (LEFT OTITIS MEDIA)	PPD (85)	FOLLOW-UP (57)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pharyngitis (ACUTE PHARYNGITIS)	PPD (85)	FOLLOW-UP (57)	5 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pharyngitis streptococcal (STREP PHARYNGITIS)	PPD (85)	FOLLOW-UP (57)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menveo-Menveo	Myalgia (MYALGIA)	PPD (84)	FOLLOW-UP (52)	(CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pain (BODY ACHES)	PPD (84)	FOLLOW-UP (52)	(CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Nasopharyngitis (COMMON COLD)	PPD (121)	FOLLOW-UP (93)	9 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Wheezing (WHEEZING)	PPD (123)	FOLLOW-UP (95)	7 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Pyrexia (FEVER)	PPD (126)	FOLLOW-UP (98)	3 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Pharyngitis (ACUTE PHARYNGITIS)	PPD (37)	FOLLOW-UP (9)	5 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Otitis media acute (ACUTE OTITIS MEDIA)	PPD (53)	FOLLOW-UP (18)	5 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Arthropod bite (INSECT BITES)	PPD (73)	FOLLOW-UP (33)	10 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Nasopharyngitis (COLD)	PPD (26)	TREATMENT (26)	5 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Acute sinusitis (ACUTE SINUSITIS)	PPD (115)	FOLLOW-UP (81)	10 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Bronchitis (BRONCHITIS)	PPD (149)	FOLLOW-UP (115)	15 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Medical device site erythema (REDNESS AT PUMP SITE)	PPD (37)	TREATMENT (37)	17 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Medical device site swelling (SWELLING AT PUMP SITE)	PPD (37)	TREATMENT (37)	17 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Arthralgia (PAIN IN ANKLE AND JOINTS, LEFT ANKLE)	PPD (62)	FOLLOW-UP (37)	14 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Ligament sprain (SPRAIN, LEFT ANKLE)	PPD (62)	FOLLOW-UP (37)	14 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Haematuria (GROSS HEMATURIA)	PPD (76)	FOLLOW-UP (43)	12 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Proteinuria (PTROTEINURIA)	PPD (76)	FOLLOW-UP (43)	12 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE SINUSITIS)	PPD (73)	FOLLOW-UP (52)	14 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Nasopharyngitis (ACUTE NASOPHARYNGITIS)	PPD (73)	FOLLOW-UP (52)	14 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Otitis media acute (RIGHT EAR, ACUTE SUPPURATIVE OTITIS MEDIA WITHOUT SPONTANEOUS RUPTURE)	PPD (73)	FOLLOW-UP (52)	14 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tension headache (TENSION HEADACHE)	PPD (73)	FOLLOW-UP (52)	14 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Conjunctivitis (RIGHT EYE, ACUTE FOLLICULAR CONJUNCTIVITIS)	PPD (83)	FOLLOW-UP (62)	7 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Nasopharyngitis (ACUTE NASOPHARYNGITIS)	PPD (99)	FOLLOW-UP (73)	13 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (99)	FOLLOW-UP (73)	13 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menveo-Menveo	Otitis media acute (LEFT EAR ACUTE SUPPURATIVE OTITIS MEDIA)	PPD (90)	FOLLOW-UP (58)	15 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tympanic membrane perforation (LEFT EAR SPONTANEOUS RUPTURE OF EAR DRUM)	PPD (90)	FOLLOW-UP (58)	15 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Naive	Pyrexia (FEVER (102.0 F))	PPD (1)	TREATMENT (1)	2 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (PROBABLY RELATED)
	Menactra-Menveo	Upper respiratory tract infection (UPPER RESPIRATORY INFECTION)	PPD (19)	TREATMENT (19)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Haematuria (HEMATURIA)	PPD (139)	FOLLOW-UP (117)	1 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Gastroenteritis viral (VIRAL GASTROENTERITIS)	PPD (16)	TREATMENT (16)	4 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menactra-Menveo	Umbilical hernia (UMBILICAL HERNIA)	PPD (37)	FOLLOW-UP (11)	31 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Arthropod bite (BUG BITE)	PPD (10)	TREATMENT (10)	3 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Oropharyngeal pain (SORE THROAT)	PPD (172)	FOLLOW-UP (147)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Menstruation irregular (IRREGULAR MENSTRUAL CYCLE)	JUN17	FOLLOW-UP	(INT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Bronchitis viral (VIRAL BRONCHITIS)	PPD (2)	TREATMENT (2)	9 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Asthma (ASTHMA)	PPD (137)	FOLLOW-UP (116)	22 (INT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Tooth abscess (ABCESS TOOTH)	PPD (3)	TREATMENT (3)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (21)	TREATMENT (21)	52 (INT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Otitis externa (OTITIS EXTERNA)	PPD (58)	FOLLOW-UP (27)	12 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pain in extremity (RIGHT SORE TOE)	PPD (121)	FOLLOW-UP (90)	37 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Dermatitis contact (POISON IVY)	PPD (150)	FOLLOW-UP (119)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Laceration (SUTURE REMOVAL/DUE TO LACERATION)	PPD (136)	FOLLOW-UP (107)	1 (CONT)	N	MILD	(PHYSICIAN VISIT,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Viral pharyngitis (VIRAL PHARYNGITIS)	PPD (67)	FOLLOW-UP (39)	10 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Rhinitis allergic (ALLERGIC RHINITIS)	PPD (118)	FOLLOW-UP (90)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Viral pharyngitis (VIRAL PHARYNGITIS)	PPD (118)	FOLLOW-UP (90)	8 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE SINUSITIS)	PPD (148)	FOLLOW-UP (120)	18 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Pharyngitis streptococcal (STREPTOCOCCAL SORE THROAT)	PPD (40)	FOLLOW-UP (19)	13 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Lymphadenopathy (SWOLLEN LYMPH NODE UNDER LEFT ARM)	PPD (3)	TREATMENT (3)	12 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (POSSIBLY RELATED)
		Oropharyngeal pain (SORE THROAT)	PPD (165)	FOLLOW-UP (138)	(CONT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
		Acute sinusitis (ACUTE SINUSITIS)	PPD (169)	FOLLOW-UP (142)	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Acute sinusitis (ACUTE FRONTAL SINUSITIS)	PPD (46)	FOLLOW-UP (16)	31 (CONT)	N	SEV	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Pneumonia mycoplasmal (PNEUMONIA DUE TO MYCOPLASMA PNEUMONIA)	PPD (46)	FOLLOW-UP (16)	51 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Wheezing (WHEEZING)	PPD (46)	FOLLOW-UP (16)	51 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Asthma (COUGH VARIANT ASTHMA)	PPD (58)	FOLLOW-UP (28)	39 (CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Bronchitis (ACUTE BRONCHITIS)	PPD (100)	FOLLOW-UP (79)	16 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Cough (COUGH)	PPD (100)	FOLLOW-UP (79)	16 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset Start Date (Day)	Onset Period (Relative start day)	Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
PPD	Menveo-Menveo	Asthma (MILD INTERMITTENT ASTHMA)	PPD (12)	TREATMENT (12)	9 (INT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Gastrooesophageal reflux disease (GASTROESOPHAGEAL REFLUX DISEASE WITH ESOPHAGITIS)	PPD (12)	TREATMENT (12)	9 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Nasopharyngitis (ACUTE NASOPHARYNGITIS)	PPD (12)	TREATMENT (12)	9 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Nasopharyngitis (COLD)	PPD (12)	TREATMENT (12)	9 (CONT)	N	MILD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Post-traumatic stress disorder (ACUTE POST TRAUMATIC STRESS DISORDER)	PPD (72)	FOLLOW-UP (39)	(CONT)	N	MILD	(PHYSICIAN VISIT)	NOT RECOVERED/NOT RESOLVED (NONE)
		Nasopharyngitis (ACUTE NASOPHARYNGITIS)	PPD (90)	FOLLOW-UP (57)	9 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Nausea (NAUSEA)	PPD (90)	FOLLOW-UP (57)	9 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
		Polyuria (POLYURIA)	PPD (90)	FOLLOW-UP (57)	9 (CONT)	N	MILD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Bronchitis (BRONCHITIS)	PPD (157)	FOLLOW-UP (122)	6 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Cellulitis (CELLULITIS - RIGHT THIGH)	PPD (15)	TREATMENT (15)	12 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

Table 14.3.2.7.5
Listing of Medically Attended Unsolicited Adverse Events
Unsolicited Safety Set

Subject	Group	MedDRA Preferred Term (Reported Term)	Onset		Duration Days (Pattern)	Serious (Seriousness Criteria)	Severity /Intensity	Action Taken Vaccine (Other)	Outcome (Relationship)
			Start Date (Day)	Period (Relative start day)					
PPD	Menveo-Menveo	Abdominal pain (ABDOMINAL PAIN)	PPD (12)	TREATMENT (12)	6 (CONT)	Y (4)	MOD	(HOSPITALIZATION, IV FLUIDS,PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY,PROCEDURE OR PHYSICAL THERAPY)	RECOVERED/ RESOLVED (NONE)
		Tonsillitis (TONSILLITIS)	PPD (13)	TREATMENT (13)	5 (CONT)	Y (4)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Respiratory disorder (ACUTE RESPIRATORY COMPROMISE)	PPD (15)	TREATMENT (15)	1 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Septic shock (SEPTIC SHOCK)	PPD (15)	TREATMENT (15)	1 (CONT)	Y (4,5)	SEV	(HOSPITALIZATION, IV FLUIDS,OTHER, PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Contusion (CONTUSION OF RIGHT FOOT)	PPD (46)	FOLLOW-UP (25)	16 (CONT)	N	MOD	(PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Metatarsalgia (RIGHT FOOT METATARSALGIA)	PPD (41)	FOLLOW-UP (20)	97 (CONT)	N	MOD	(NON-PRESCRIPTION DRUG THERAPY,PHYSICIAN VISIT)	RECOVERED/ RESOLVED (NONE)
	Menveo-Menveo	Rheumatoid arthritis (RHEUMATOID ARTHRITIS)	JUN17	TREATMENT	(CONT)	N	MOD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Procedural pain (POST SURGICAL PAIN- STATUS POST ELECTIVE WISDOM TOOTH EXTRACTION)	PPD (15)	TREATMENT (15)	8 (INT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)
		Asthma (ASTHMA)	SEP17	FOLLOW-UP	(CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	NOT RECOVERED/NOT RESOLVED (NONE)
	Menveo-Menveo	Dermatitis contact (ALLERGIC CONTACT DERMATITIS)	PPD (44)	FOLLOW-UP (23)	7 (CONT)	N	MILD	(PHYSICIAN VISIT,PRESCRIPTION DRUG THERAPY)	RECOVERED/ RESOLVED (NONE)

PPD

14.3.3 Narratives of Deaths, Other Serious and Significant Adverse Events

Subject No. PPD Diabetic ketoacidotic hyperglycaemic coma

Subject PPD was a 36-year-old white non-Hispanic/Latino male who was enrolled in study V59_77, and was vaccinated on 8 December 2016 with Menveo. The subject had a medical history of type I diabetes mellitus and received the following concomitant medications: insulin lispro and insulin glargine.

On PPD (study day 32), 31 days after vaccination this subject developed diabetic ketoacidotic hyperglycemic coma. Prior to the event, the subject had not felt well for several days, had lost weight, and was sleeping more. On 8 January 2017, the subject developed urinary incontinence and became minimally responsive, and was hospitalized. Laboratory tests revealed an anion gap of 37 and the subject's random blood sugar reading was measured at 1131 mg/dL. Laboratory testing revealed abnormal hepatic and renal function parameters, while urinalysis was normal. A CT scan of the head revealed no acute intracranial abnormality. The subject was treated with insulin drip and intravenous (IV) fluids. The subject was subsequently switched to subcutaneous insulin when the abdominal pain, nausea and vomiting stopped, and laboratory parameters improved. The subject became more alert on 10 January 2017 and was able to eat solid food. The subject's blood sugar value dropped to 63 mg/dL and almost all laboratory parameters were within normal ranges by 13 January 2017. The subject was discharged on 13 January 2017.

The investigator considered the event of diabetic ketoacidotic hyperglycemic coma serious due to hospitalization, and due to being medically significant and life-threatening. In the opinion of the investigator, the diabetic ketoacidotic hyperglycemic coma was considered a worsening of a pre-existing condition, unrelated to study vaccine. The SAE was considered resolved, with outcome of recovery, on 13 January 2017.

Subject No. PPD (SAE #1), Major depression (SAE #2)

Subject PPD was a 15-year-old white non-Hispanic/Latino male who was enrolled in study V59_77, and was vaccinated on 30 December 2016 with Menveo. The subject had a medical history of major depression which started 4 months prior to enrolment in the study and concomitant medication included fluoxetine hydrochloride.

On PPD (study day 67), 66 days after vaccination, the subject PPD (SAE #1) by PPD The subject was brought into the ER and was administered PPD The initial electrocardiogram (ECG) on 6 March 2017 showed slightly prolonged QT but when repeated on 7 March 2017, the ECG showed a normal sinus rhythm. Laboratory parameters and urinalysis were within normal ranges. The subject was further treated with midazolam and lorazepam. The worsening of the major depression (SAE #2) ended on 21 March 2017. The medical history event of major depressive disorder continued without worsening.

The investigator considered the PPD (SAE #1) serious due to medical significance and life-threatening, and the worsening of major depression (SAE #2) serious due to medical significance and hospitalization. In the opinion of the investigator, both the PPD and the worsening of the major depression were considered unrelated to study vaccine. The PPD was considered resolved, with outcome of recovery on 6 March 2017; the worsening of the major depression was considered resolved, with outcome of recovery on 21 March 2017.

Subject No. PPD

Subject PPD was a 16-year-old non-Hispanic/Latino white female who was enrolled in study V59_77, and was vaccinated on 15 December 2016 with Menveo. The subject had a medical history that included precordial catch syndrome, migraine and anxiodepressive syndrome, and received the following concomitant medications: fluoxetine hydrochloride, bismuth subsalicylate, macrogol, ibuprofen, ethinyloestradial plus levonorgestrel, and paracetamol.

On PPD (study day 33), 32 days after vaccination, this subject experienced PPD and was hospitalized in a psychiatric facility. The subject was discharged in stable condition with a prescription for fluoxetine hydrochloride on 30 January 2017. The subject was lost to follow-up on 15 March 2017.

The investigator considered the PPD serious because of hospitalization and medical significance. In the opinion of the investigator, the PPD was considered unrelated to study vaccine. The SAE was considered resolved on 30 January 2017, with outcome of recovery.

Subject No. PPD **Diverticulitis**

Subject PPD was a 54-year-old non-Hispanic/Latino white female who was enrolled in study V59_77, and was vaccinated on 8 December 2016 with Menveo. The subject had a medical history of diverticulosis that was ongoing when she enrolled, and received the following concomitant medications during the study: ciprofloxacin hydrochloride, metronidazole and fluconazole (for treatment of non-serious diverticulitis, see below).

On PPD (study day 137), the subject experienced a non-serious diverticulitis, which lasted for 9 days. The subject was treated with the concomitant medications listed above. The subject developed acute diverticulitis (study day 168) 167 days after vaccination, on PPD and was hospitalized for the same from 26 May 2017 to 29 May 2017. On 26 May 2016, a CT scan suggested acute diverticulitis. Medical records confirmed that the SAE resolved on 5 June 2017.

The investigator considered the diverticulitis serious due to hospitalization and medical significance. In the opinion of the investigator, the diverticulitis was considered unrelated to study vaccine. The SAE was considered resolved, with outcome of recovery on 5 June 2017.

Subject No. PPD **(SAE #1),** PPD **(SAE #2)**

Subject PPD was a 16-year-old non-Hispanic/Latino white female who was enrolled in study V59_77, and was vaccinated on 3 February 2017 with Menveo. The subject had no relevant medical history. The subject took isotretinoin for acne PPD starting on 1 May 2017 and ongoing.

On PPD (study day 125), 124 days after vaccination, this subject took an PPD (SAE #1) in an PPD (SAE #2). Laboratory tests were confirmed no other illegal substances or alcohol were used. Other laboratory parameters and metabolic function tests were abnormal. The subject was treated with PPD and ondansetron. The subject was medically cleared after 4 hours.

The investigator considered the PPD (SAE #1) and PPD (SAE #2) serious due to medical significance and life-threatening. In the opinion of the investigator, both SAEs were considered unrelated to study vaccine. The investigator considered the concomitant use of isotretinoin a PPD The SAEs were considered resolved, with outcome of recovery on 7 June 2017.

Subject No. PPD

Subject PPD was a 22-year-old non–Hispanic/Latino white female who was enrolled in study V59_77, and was vaccinated on 9 December 2016 with Menveo. The subject had no relevant medical history.

In February 2017 (exact date unknown), this subject had a PPD The subject had reported a positive urine pregnancy test to the site on 31 January 2017. The date of last menstrual period per subject report was PPD (14 days after vaccination in study V59_77). The subject's medical records showed that the subject had a positive beta hCG quantitative test on 08 February 2017, and subsequently reported PPD on 13 February 2017. A transvaginal ultrasound PPD A second beta hCG quantitative lab test performed on 13 February 2017 was PPD There was no further follow up requested, and the investigator reported this as a PPD The subject reported an end date of 20 February 2017, with the outcome resolved, and did not require medication, intervention or follow-up.

The investigator considered the event of PPD serious due to medical significance. In the opinion of the investigator, the SAE was considered unrelated to study vaccine. The SAE was considered resolved, with outcome of recovery on 20 February 2017.

Subject no. PPD

Subject PPD was a 16-year-old non-Hispanic/Latino white female who was enrolled in study V59_77, and was vaccinated on 9 December 2016 with Menveo. The subject had a medical history that included anxiety, depression, disturbance in attention, memory disturbance, and asthma. The subject was on levosalbutamol and phosphatidyl serine at the time of enrollment in study V59_77.

On PPD (study day 73), 72 days after vaccination, this subject PPD The subject was treated by her primary care physician and the subject was hospitalized on 1 March 2017 and was discharged on 6 March 2017. No other information is available.

The investigator considered the PPD serious due to medical significance and hospitalization. In the opinion of the investigator, the SAE was considered unrelated to study vaccine. The investigator considered the use of PPD The SAE was considered resolved, with outcome of recovery on 6 March 2017.

Subject no. PPD **Abdominal pain (SAE #1), Tonsillitis (SAE #2), Respiratory disorder (SAE #3), Septic shock (SAE#4),**

Subject PPD was a 17-year old non-Hispanic/Latino white male who enrolled in study V59_77, and was vaccinated on 7 June 2017 with Menveo. The subject had no relevant medical history.

On PPD (study day 12), 11 days after vaccination, the subject developed abdominal pain (SAE #1). The subject also complained of nausea and sore throat. On 20 June 2017 the subject was hospitalized for evaluation of the abdominal pain and suspected appendicitis. CT findings were negative for appendicitis. The subject was treated with ciprofloxacin and morphine for the pain, and ondansetron for nausea. A rapid strep test was negative. Diagnostic laparoscopy was planned for the next day (21 June 2017), but the subject had an episode of respiratory distress (SAE #3) overnight. Anaphylaxis was suspected and the subject was treated with epinephrine and intubated. The subject continued to be hypotensive, despite fluid resuscitation. The subject's heart rate was reported in the 30's and his blood pressure was 60/30. He was treated with atropine and epinephrine without improvement, and then started on norepinephrine and taken for emergency surgery. His appendix was removed but was normal. There were no significant findings in surgery. An ear, nose and throat (ENT) doctor was consulted and he felt the swelling and airway compromise was due to tonsillitis (SAE #2) that had started on 19 June 2017. The subject was continued on antibiotics and steroids until it was safe to extubate. The subject was diagnosed with septic shock (SAE #4; unknown source) on 21 June 2017; however, no pathogen was identified by culture. On 23 June 2017 the subject had recovered completely and was discharged.

The investigator considered the abdominal pain (SAE #1) serious due to hospitalization, the tonsillitis (SAE #2) due to hospitalization, and the respiratory disorder (SAE #3) and septic shock (SAE #4) due to being medically significant and life-threatening. In the opinion of the investigator, all SAEs were considered unrelated to study vaccine. The respiratory disorder (SAE # 3) and septic shock (SAE #4) were considered resolved, with outcome of recovery on 21 June 2017, and the abdominal pain (SAE # 1) and tonsillitis (SAE # 4) were considered resolved, with outcome of recovery on 23 June 2017.

14.3.4 Clinical Laboratory Data

Not Applicable

14.3.5 Other Safety Data

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
Subjects with Any Medication	217 (72%)	200 (67%)	79 (79%)
Number of Unique Medications	229	216	166
ACETYLSALICYLIC ACID	0	2 (1%)	4 (4%)
ACETYLSALICYLIC ACID + CAFFEINE + PARACETAMOL	1 (< 1%)	2 (1%)	2 (2%)
ACETYLSALICYLIC ACID + CITRIC ACID + SODIUM BICARBONATE	1 (< 1%)	0	0
ACTIVATED CHARCOAL	1 (< 1%)	0	0
ACYCLOVIR	1 (< 1%)	2 (1%)	0
ADAPALENE	2 (1%)	1 (< 1%)	0
ADAPALENE + BENZOYL PEROXIDE	1 (< 1%)	3 (1%)	0
AFRIN (NOS)	1 (< 1%)	0	0
ALLERGENS (NOS)	3 (1%)	1 (< 1%)	0
ALLIUM SATIVUM OIL	0	1 (< 1%)	0
ALLOPURINOL	0	0	1 (1%)
ALMOTRIPTAN	1 (< 1%)	0	0
ALPRAZOLAM	0	2 (1%)	2 (2%)
ALUMINIUM CHLORIDE	1 (< 1%)	0	0
AMBIGUOUS MEDICATION NOS	0	2 (1%)	1 (1%)
AMFETAMINE ASPARTATE + AMFETAMINE SULFATE + DEXAMFETAMINE SACCHARATE + DEXAMFETAMINE SULFATE	11 (4%)	9 (3%)	6 (6%)
AMITRIPTYLINE	1 (< 1%)	2 (1%)	0
AMITRIPTYLINE HYDROCHLORIDE	1 (< 1%)	0	1 (1%)
AMLODIPINE	0	0	1 (1%)
AMLODIPINE BESILATE	0	0	1 (1%)
AMOXICILLIN	18 (6%)	12 (4%)	4 (4%)
AMOXICILLIN + CLAVULANATE POTASSIUM	0	1 (< 1%)	0
AMOXICILLIN + CLAVULANIC ACID	2 (1%)	3 (1%)	2 (2%)
AMPICILLIN	1 (< 1%)	0	0
ANALGESIC, NOS	0	1 (< 1%)	0
ANTIBIOTICS NOS	0	0	1 (1%)
ARIPIPRAZOLE	1 (< 1%)	1 (< 1%)	1 (1%)
ATENOLOL	2 (1%)	1 (< 1%)	2 (2%)
ATORVASTATIN	0	0	3 (3%)
ATROPINE	1 (< 1%)	0	0
AZELASTINE	0	1 (< 1%)	0
AZELASTINE HYDROCHLORIDE + FLUTICASONE PROPIONATE	1 (< 1%)	0	0
AZITHROMYCIN	14 (5%)	9 (3%)	1 (1%)
BECLOMETASONE DIPROPIONATE	1 (< 1%)	2 (1%)	1 (1%)
BENADRYL (NOS)	13 (4%)	4 (1%)	0

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

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Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
BENAZEPRIL	0	0	1 (1%)
BENZONATATE	4 (1%)	4 (1%)	0
BENZOYL PEROXIDE	1 (< 1%)	0	0
BENZOYL PEROXIDE + CLINDAMYCIN	1 (< 1%)	0	0
BENZOYL PEROXIDE + ERYTHROMYCIN	0	1 (< 1%)	0
BENZYLPENICILLIN	2 (1%)	0	0
BETAMETHASONE	0	1 (< 1%)	0
BIFIDOBACTERIUM INFANTIS	0	1 (< 1%)	0
BIOTIN	0	1 (< 1%)	0
BISMUTH SUBSALICYLATE	0	1 (< 1%)	1 (1%)
BROMFED (NOS)	3 (1%)	0	0
BROMPHENIRAMINE MALEATE + DEXTROMETHORPHAN HYDROBROMIDE + PSEUDOEPHEDRINE HYDROCHLORIDE	4 (1%)	2 (1%)	0
BROMPHENIRAMINE MALEATE + PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (< 1%)	0	0
BUDESONIDE	1 (< 1%)	0	0
BUDESONIDE + FORMOTEROL FUMARATE	4 (1%)	2 (1%)	0
BUPIVACAINE + EPINEPHRINE	0	1 (< 1%)	0
BUPROPION	2 (1%)	2 (1%)	2 (2%)
BUPROPION HYDROCHLORIDE	6 (2%)	4 (1%)	3 (3%)
BUSPIRONE HYDROCHLORIDE	2 (1%)	0	0
CAFFEINE + MEPYRAMINE MALEATE + PARACETAMOL	0	1 (< 1%)	0
CALCIUM	0	1 (< 1%)	2 (2%)
CALCIUM ASCORBATE	0	1 (< 1%)	0
CALCIUM CARBONATE	1 (< 1%)	0	2 (2%)
CALCIUM CHLORIDE + POTASSIUM CHLORIDE + SODIUM CHLORIDE + SODIUM LACTATE	1 (< 1%)	0	0
CALCIUM FOLINATE + DROSPIRENONE + ETHINYLOESTRADIOL	0	2 (1%)	0
CALCIUM MEFOLINATE	1 (< 1%)	0	0
CANAGLIFLOZIN	0	0	1 (1%)
CAROTENOIDS NOS	0	0	1 (1%)
CARVEDILOL	1 (< 1%)	0	2 (2%)
CEFALEXIN	5 (2%)	1 (< 1%)	0
CEFAZOLIN	0	2 (1%)	0
CEFDINIR	3 (1%)	1 (< 1%)	0
CELECOXIB	0	0	2 (2%)
CETIRIZINE	7 (2%)	3 (1%)	0
CETIRIZINE HYDROCHLORIDE	19 (6%)	18 (6%)	2 (2%)
CHLORCYCLIZINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE	1 (< 1%)	1 (< 1%)	0
CHLORPHENAMINE + DEXTROMETHORPHAN + PARACETAMOL + PSEUDOEPHEDRINE	1 (< 1%)	0	0
CHLORPHENAMINE MALEATE	0	0	1 (1%)

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

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Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
CHLORPHENAMINE MALEATE + DEXTROMETHORPHAN HYDROBROMIDE + PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE	1 (< 1%)	0	1 (1%)
CICLOSPORIN	0	0	1 (1%)
CIMETIDINE	0	1 (< 1%)	0
CIPRODEX (NOS)	1 (< 1%)	1 (< 1%)	0
CIPROFLOXACIN	2 (1%)	0	0
CIPROFLOXACIN HYDROCHLORIDE	1 (< 1%)	0	1 (1%)
CITALOPRAM	2 (1%)	2 (1%)	0
CITALOPRAM HYDROBROMIDE	2 (1%)	2 (1%)	2 (2%)
CLINDAMYCIN	7 (2%)	3 (1%)	0
CLINDAMYCIN PHOSPHATE	1 (< 1%)	0	0
CLOBETASOL	0	1 (< 1%)	0
CLONAZEPAM	1 (< 1%)	0	1 (1%)
CLONIDINE	1 (< 1%)	1 (< 1%)	0
CLONIDINE HYDROCHLORIDE	0	1 (< 1%)	0
CLOZAPINE	0	0	1 (1%)
CODEINE + GUAIFENESIN	1 (< 1%)	0	0
CODEINE + PARACETAMOL	0	1 (< 1%)	0
CODEINE + PROMETHAZINE	0	0	1 (1%)
COLCHICINE	0	0	1 (1%)
COLECALCIFEROL	0	1 (< 1%)	0
CONTRACEPTIVE NOS	0	0	1 (1%)
COPPER	0	0	1 (1%)
CULTURELLE (NOS)	1 (< 1%)	0	0
CYANOCOBALAMIN	0	1 (< 1%)	2 (2%)
CYANOCOBALAMIN + PYRIDOXINE HYDROCHLORIDE	0	1 (< 1%)	0
CYCLOBENZAPRINE	1 (< 1%)	1 (< 1%)	1 (1%)
CYCLOBENZAPRINE HYDROCHLORIDE	0	0	1 (1%)
CYPROHEPTADINE	1 (< 1%)	0	0
DAPSONE	1 (< 1%)	0	0
DAYQUIL (NOS)	4 (1%)	4 (1%)	3 (3%)
DESOGESTREL + ETHINYLOESTRADIOL	2 (1%)	2 (1%)	1 (1%)
DESVENLAFAXINE SUCCINATE	1 (< 1%)	1 (< 1%)	1 (1%)
DEXAMETHASONE	3 (1%)	1 (< 1%)	0
DEXAMETHASONE + TOBRAMYCIN	1 (< 1%)	0	0
DEXMETHYLPHENIDATE HYDROCHLORIDE	3 (1%)	1 (< 1%)	0
DEXTROMETHORPHAN	3 (1%)	1 (< 1%)	0
DEXTROMETHORPHAN HYDROBROMIDE + DOXYLAMINE SUCCINATE + PARACETAMOL	0	1 (< 1%)	0
DEXTROMETHORPHAN HYDROBROMIDE + DOXYLAMINE SUCCINATE + PARACETAMOL + PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (< 1%)	0
DEXTROMETHORPHAN HYDROBROMIDE + GUAIFENESIN	2 (1%)	0	0

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The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
DEXTROMETHORPHAN HYDROBROMIDE + GUAIFENESIN + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE	0	1 (< 1%)	1 (1%)
DEXTROMETHORPHAN HYDROBROMIDE + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE	0	1 (< 1%)	0
DEXTROMETHORPHAN HYDROBROMIDE + PROMETHAZINE HYDROCHLORIDE	1 (< 1%)	1 (< 1%)	0
DIAZEPAM	0	1 (< 1%)	0
DICLOFENAC	0	0	1 (1%)
DICLOFENAC POTASSIUM	0	0	1 (1%)
DICLOFENAC SODIUM	0	0	1 (1%)
DICYCLOVERINE	0	1 (< 1%)	0
DIMETICONE, ACTIVATED	1 (< 1%)	0	0
DIPHENHYDRAMINE	3 (1%)	0	1 (1%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (< 1%)	0	1 (1%)
DIPHENHYDRAMINE HYDROCHLORIDE + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE	1 (< 1%)	0	0
DIPHTHERIA TOXOID + PERTUSSIS TOXOID ACELLULAR + TETANUS TOXOID	1 (< 1%)	0	0
DOCOSAHEXANOIC ACID + FISH OIL + ICOSAPENT	0	0	1 (1%)
DORZOLAMIDE	0	1 (< 1%)	0
DOXEPIN	0	0	1 (1%)
DOXYCYCLINE	9 (3%)	4 (1%)	0
DOXYCYCLINE HYCLATE	1 (< 1%)	1 (< 1%)	0
DOXYCYCLINE MONOHYDRATE	1 (< 1%)	0	0
DROSPIRENONE	0	1 (< 1%)	0
DROSPIRENONE + ETHINYLOESTRADIOL	1 (< 1%)	3 (1%)	0
DULOXETINE	2 (1%)	2 (1%)	0
DULOXETINE HYDROCHLORIDE	0	1 (< 1%)	1 (1%)
ECHINACEA (NOS)	1 (< 1%)	0	0
ENOXAPARIN SODIUM	0	0	1 (1%)
EPINEPHRINE	2 (1%)	1 (< 1%)	0
EPINEPHRINE + LIDOCAINE	2 (1%)	0	0
ERYTHROMYCIN	0	0	1 (1%)
ESCITALOPRAM	7 (2%)	6 (2%)	4 (4%)
ESOMEPRAZOLE MAGNESIUM	2 (1%)	2 (1%)	0
ESTRADIOL	0	0	4 (4%)
ESTROGEN NOS	0	0	1 (1%)
ETHINYLOESTRADIOL + ETONOGESTREL	1 (< 1%)	1 (< 1%)	2 (2%)
ETHINYLOESTRADIOL + FERROUS FUMARATE + NORETHISTERONE ACETATE	2 (1%)	1 (< 1%)	2 (2%)
ETHINYLOESTRADIOL + IRON + NORETHISTERONE	0	1 (< 1%)	0
ETHINYLOESTRADIOL + LEVONORGESTREL	5 (2%)	5 (2%)	0
ETHINYLOESTRADIOL + NORELGESTROMIN	2 (1%)	0	0
ETHINYLOESTRADIOL + NORETHISTERONE	2 (1%)	1 (< 1%)	0

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PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
ETHINYLOESTRADIOL + NORETHISTERONE ACETATE	1 (< 1%)	2 (1%)	1 (1%)
ETHINYLOESTRADIOL + NORGESTIMATE	14 (5%)	13 (4%)	1 (1%)
ETONOGESTREL	4 (1%)	5 (2%)	0
EXCEDRIN (NOS)	0	1 (< 1%)	0
FAMOTIDINE	1 (< 1%)	2 (1%)	0
FENTANYL	1 (< 1%)	1 (< 1%)	0
FERROUS SULPHATE	0	1 (< 1%)	2 (2%)
FEXOFENADINE	2 (1%)	0	0
FEXOFENADINE HYDROCHLORIDE	2 (1%)	5 (2%)	0
FEXOFENADINE HYDROCHLORIDE + PSEUDOEPHEDRINE HYDROCHLORIDE	1 (< 1%)	1 (< 1%)	0
FISH OIL	0	1 (< 1%)	2 (2%)
FLONASE (NOS)	6 (2%)	3 (1%)	2 (2%)
FLUCONAZOLE	1 (< 1%)	1 (< 1%)	2 (2%)
FLUOXETINE	3 (1%)	1 (< 1%)	4 (4%)
FLUOXETINE HYDROCHLORIDE	12 (4%)	2 (1%)	4 (4%)
FLUTICASONE	2 (1%)	2 (1%)	3 (3%)
FLUTICASONE PROPIONATE	3 (1%)	2 (1%)	1 (1%)
FLUTICASONE PROPIONATE + SALMETEROL XINAFOATE	1 (< 1%)	1 (< 1%)	0
FOLIC ACID + IRON	0	1 (< 1%)	0
FORMOTEROL FUMARATE + MOMETASONE FUROATE	1 (< 1%)	3 (1%)	0
FUROSEMIDE	0	0	1 (1%)
GABAPENTIN	0	1 (< 1%)	1 (1%)
GLIMEPIRIDE	0	0	1 (1%)
GLUCOSE	0	0	1 (1%)
GLYCOPYRRONIUM BROMIDE	1 (< 1%)	0	0
GUAIFENESIN	2 (1%)	4 (1%)	1 (1%)
GUAIFENESIN + PARACETAMOL + PHENYLEPHRINE HYDROCHLORIDE	1 (< 1%)	1 (< 1%)	0
GUANFACINE	1 (< 1%)	1 (< 1%)	0
GUANFACINE HYDROCHLORIDE	6 (2%)	2 (1%)	0
HEPATITIS A VACCINE	1 (< 1%)	0	0
HUMAN PAPILLOMA VIRUS VACCINE	5 (2%)	4 (1%)	0
HUMAN PAPILLOMAVIRUS TYPE 11 VACCINE (RECOMBINANT) + HUMAN PAPILLOMAVIRUS TYPE 16 VACCINE (RECOMBINANT) + HUMAN PAPILLOMAVIRUS TYPE 18 VACCINE (RECOMBINANT) + HUMAN PAPILLOMAVIRUS TYPE 6 VACCINE (RECO	4 (1%)	1 (< 1%)	0
HYDROCHLOROTHIAZIDE	0	1 (< 1%)	3 (3%)
HYDROCHLOROTHIAZIDE + LOSARTAN POTASSIUM	0	1 (< 1%)	0
HYDROCHLOROTHIAZIDE + TRIAMTERENE	0	0	1 (1%)
HYDROCODONE	2 (1%)	2 (1%)	1 (1%)
HYDROCODONE + PARACETAMOL	2 (1%)	1 (< 1%)	0
HYDROCODONE BITARTRATE + PARACETAMOL	1 (< 1%)	1 (< 1%)	2 (2%)

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PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
HYDROCORTISONE	2 (1%)	3 (1%)	0
HYDROMORPHONE	1 (< 1%)	1 (< 1%)	0
HYDROXYCHLOROQUINE	1 (< 1%)	0	0
HYDROXYZINE	1 (< 1%)	1 (< 1%)	2 (2%)
HYDROXYZINE HYDROCHLORIDE	1 (< 1%)	0	0
HYOSCYAMINE	0	0	1 (1%)
HYOSCYAMINE SULFATE	0	1 (< 1%)	0
IBUPROFEN	53 (18%)	53 (18%)	19 (19%)
INDOMETACIN	0	0	1 (1%)
INFLUENZA VACCINE	7 (2%)	1 (< 1%)	2 (2%)
INFLUENZA VIRUS VACCINE INACTIVATED	4 (1%)	5 (2%)	0
INSULIN ASPART	0	1 (< 1%)	0
INSULIN GLARGINE	0	1 (< 1%)	1 (1%)
INSULIN LISPRO	0	0	1 (1%)
INSULIN NOS	2 (1%)	0	1 (1%)
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (< 1%)	0
INTRAVENOUS FLUID (NOS)	0	1 (< 1%)	0
IOHEXOL	1 (< 1%)	0	0
IPRATROPIUM + SALBUTAMOL	1 (< 1%)	0	0
IPRATROPIUM BROMIDE	0	1 (< 1%)	0
IRON	1 (< 1%)	0	2 (2%)
ISOTRETINOIN	6 (2%)	3 (1%)	0
KETOCONAZOLE	1 (< 1%)	0	0
KETOROLAC TROMETAMOL	2 (1%)	1 (< 1%)	1 (1%)
KETOTIFEN FUMARATE	1 (< 1%)	0	0
LABETALOL	0	0	1 (1%)
LAMOTRIGINE	1 (< 1%)	2 (1%)	1 (1%)
LANSOPRAZOLE	1 (< 1%)	0	0
LEUPRORELIN ACETATE	0	0	1 (1%)
LEVOCETIRIZINE	1 (< 1%)	0	0
LEVOCETIRIZINE HYDROCHLORIDE	2 (1%)	1 (< 1%)	0
LEVOFLOXACIN	1 (< 1%)	0	2 (2%)
LEVONORGESTREL	3 (1%)	3 (1%)	6 (6%)
LEVOSALBUTAMOL HYDROCHLORIDE	0	1 (< 1%)	0
LEVOSALBUTAMOL TARTRATE	1 (< 1%)	1 (< 1%)	0
LEVOTHYROXINE	3 (1%)	2 (1%)	1 (1%)
LEVOTHYROXINE SODIUM	0	2 (1%)	4 (4%)
LIDOCAINE	0	1 (< 1%)	0
LIRAGLUTIDE	0	0	1 (1%)
LISDEXAMFETAMINE	0	1 (< 1%)	0

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
LISDEXAMFETAMINE MESILATE	12 (4%)	11 (4%)	0
LISINOPRIL	1 (< 1%)	0	3 (3%)
LIVE VARICELLA VIRUS VACCINE	0	1 (< 1%)	0
LOPERAMIDE HYDROCHLORIDE	0	1 (< 1%)	2 (2%)
LOPRAZOLAM	0	1 (< 1%)	0
LORATADINE	10 (3%)	14 (5%)	2 (2%)
LORATADINE + PSEUDOEPHEDRINE SULFATE	2 (1%)	1 (< 1%)	0
LORAZEPAM	3 (1%)	1 (< 1%)	4 (4%)
LOSARTAN	0	1 (< 1%)	2 (2%)
LURASIDONE HYDROCHLORIDE	1 (< 1%)	1 (< 1%)	0
MACROBID (NOS)	0	0	1 (1%)
MACROGOL	0	3 (1%)	0
MAGNESIUM	0	0	1 (1%)
MECLOZINE	0	1 (< 1%)	0
MEDICATION UNKNOWN	1 (< 1%)	0	0
MEDROXYPROGESTERONE	0	1 (< 1%)	0
MEDROXYPROGESTERONE ACETATE	2 (1%)	5 (2%)	0
MELATONIN	3 (1%)	5 (2%)	0
MELOXICAM	2 (1%)	1 (< 1%)	5 (5%)
MENINGOCOCCAL B VACCINE	5 (2%)	0	0
MENINGOCOCCAL POLYSACCHARIDE A + MENINGOCOCCAL POLYSACCHARIDE C + MENINGOCOCCAL POLYSACCHARIDE W135 + MENINGOCOCCAL POLYSACCHARIDE Y	0	1 (< 1%)	0
METAXALONE	0	0	1 (1%)
METFORMIN	1 (< 1%)	2 (1%)	2 (2%)
METFORMIN HYDROCHLORIDE	0	0	1 (1%)
METHADONE	0	0	1 (1%)
METHOCARBAMOL	1 (< 1%)	2 (1%)	0
METHYLPHENIDATE	3 (1%)	2 (1%)	0
METHYLPHENIDATE HYDROCHLORIDE	9 (3%)	8 (3%)	0
METHYLPREDNISOLONE	3 (1%)	1 (< 1%)	0
METHYLPREDNISOLONE ACETATE	1 (< 1%)	1 (< 1%)	1 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (< 1%)	0	0
METOCLOPRAMIDE HYDROCHLORIDE	1 (< 1%)	0	0
METOPROLOL	0	1 (< 1%)	2 (2%)
METRONIDAZOLE	1 (< 1%)	1 (< 1%)	2 (2%)
MICONAZOLE NITRATE	0	0	1 (1%)
MIDAZOLAM	2 (1%)	1 (< 1%)	0
MIDOL (NOS)	1 (< 1%)	1 (< 1%)	0
MINERALS NOS + VITAMINS NOS	0	0	1 (1%)
MINOCYCLINE	1 (< 1%)	1 (< 1%)	0

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.
PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
MINOCYCLINE HYDROCHLORIDE	0	1 (< 1%)	0
MOMETASONE	1 (< 1%)	1 (< 1%)	0
MOMETASONE FUROATE	3 (1%)	1 (< 1%)	0
MONTELUKAST	0	2 (1%)	0
MONTELUKAST SODIUM	11 (4%)	7 (2%)	2 (2%)
MORPHINE	1 (< 1%)	1 (< 1%)	1 (1%)
MUPIROCIN	1 (< 1%)	0	0
NAPROXEN	8 (3%)	7 (2%)	2 (2%)
NAPROXEN SODIUM	1 (< 1%)	0	0
NAPROXEN SODIUM + SUMATRIPTAN SUCCINATE	1 (< 1%)	0	0
NEOSPORIN (NOS)	1 (< 1%)	0	0
NEOSTIGMINE	1 (< 1%)	0	0
NICOTINE	0	0	1 (1%)
NICOTINIC ACID	0	0	1 (1%)
NIFEDIPINE	0	0	1 (1%)
NITROFURANTOIN	0	0	1 (1%)
NOREPINEPHRINE	1 (< 1%)	0	0
NOREPINEPHRINE BITARTRATE	1 (< 1%)	0	0
NORETHISTERONE	0	0	1 (1%)
NORTRIPTYLINE	1 (< 1%)	1 (< 1%)	0
NYQUIL (NOS)	5 (2%)	3 (1%)	1 (1%)
OCUFLOX (NOS)	1 (< 1%)	0	0
OFLOXACIN	1 (< 1%)	0	0
OLANZAPINE	0	0	1 (1%)
OLOPATADINE HYDROCHLORIDE	0	0	1 (1%)
OMALIZUMAB	1 (< 1%)	0	0
OMEPRAZOLE	5 (2%)	9 (3%)	5 (5%)
OMNICEF (NOS)	1 (< 1%)	0	0
ONDANSETRON	4 (1%)	3 (1%)	3 (3%)
ONDANSETRON HYDROCHLORIDE	0	0	1 (1%)
OSELTAMIVIR	0	2 (1%)	1 (1%)
OSELTAMIVIR PHOSPHATE	2 (1%)	3 (1%)	1 (1%)
OXCARBAZEPINE	1 (< 1%)	0	0
OXYCODONE + PARACETAMOL	0	1 (< 1%)	0
OXYCODONE HYDROCHLORIDE + PARACETAMOL	1 (< 1%)	1 (< 1%)	3 (3%)
PANTOPRAZOLE	1 (< 1%)	0	0
PARACETAMOL	20 (7%)	24 (8%)	5 (5%)
PAROXETINE HYDROCHLORIDE	1 (< 1%)	0	1 (1%)
PHENAZOPYRIDINE HYDROCHLORIDE	1 (< 1%)	0	0
PHENOL	1 (< 1%)	0	0

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (< 1%)	0	1 (1%)
PHENTERMINE	0	1 (< 1%)	1 (1%)
PHENYLEPHRINE	0	1 (< 1%)	0
PHOSPHATIDYL SERINE	0	1 (< 1%)	0
POLYMYXIN B SULFATE + TRIMETHOPRIM	2 (1%)	0	0
POTASSIUM CHLORIDE	0	0	1 (1%)
POTASSIUM NOS + SODIUM CHLORIDE	0	0	1 (1%)
POTASSIUM PHOSPHATE DIBASIC	0	0	1 (1%)
PRAMIPEXOLE DIHYDROCHLORIDE	0	0	1 (1%)
PRAVASTATIN	0	0	1 (1%)
PREDNISONE	13 (4%)	11 (4%)	1 (1%)
PROAIR (NOS)	1 (< 1%)	2 (1%)	0
PROMETHAZINE	2 (1%)	2 (1%)	1 (1%)
PROPOFOL	1 (< 1%)	0	0
PROPRANOLOL	1 (< 1%)	0	0
PROTONIX (NOS)	0	0	1 (1%)
PSEUDOEPHEDRINE	1 (< 1%)	1 (< 1%)	0
PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (< 1%)	0
QUETIAPINE FUMARATE	1 (< 1%)	0	2 (2%)
RANITIDINE	2 (1%)	0	0
RANITIDINE HYDROCHLORIDE	2 (1%)	1 (< 1%)	0
RIBOFLAVIN	0	1 (< 1%)	0
RISPERIDONE	1 (< 1%)	0	1 (1%)
RIZATRIPTAN	1 (< 1%)	1 (< 1%)	0
RIZATRIPTAN BENZOATE	1 (< 1%)	1 (< 1%)	0
ROBITUSSIN (NOS)	0	2 (1%)	1 (1%)
ROCURONIUM	1 (< 1%)	0	0
SALBUTAMOL	20 (7%)	9 (3%)	2 (2%)
SALBUTAMOL SULFATE	4 (1%)	6 (2%)	0
SERTRALINE	5 (2%)	2 (1%)	0
SERTRALINE HYDROCHLORIDE	4 (1%)	6 (2%)	3 (3%)
SEVOFLURANE	1 (< 1%)	0	0
SIMVASTATIN	0	0	1 (1%)
SODIUM CHLORIDE	1 (< 1%)	1 (< 1%)	0
SOMA (NOS)	0	0	1 (1%)
SPIRONOLACTONE	0	4 (1%)	1 (1%)
SUDAFED (NOS)	6 (2%)	4 (1%)	1 (1%)
SULFAMETHOXAZOLE + TRIMETHOPRIM	3 (1%)	3 (1%)	1 (1%)
SUMATRIPTAN	3 (1%)	3 (1%)	1 (1%)
TAMOXIFEN	0	0	1 (1%)

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

PPD

Table 14.3.5.1
Concomitant Medications
Overall Safety Set

Generic Drug Name	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Naive (N=100)
TAZAROTENE	1 (< 1%)	0	0
TIOTROPIUM BROMIDE	0	1 (< 1%)	0
TIZANIDINE HYDROCHLORIDE	0	1 (< 1%)	0
TOBRAMYCIN	0	1 (< 1%)	0
TOMEXETINE HYDROCHLORIDE	2 (1%)	0	0
TOPIRAMATE	3 (1%)	1 (< 1%)	1 (1%)
TRAMADOL	0	1 (< 1%)	2 (2%)
TRAMADOL HYDROCHLORIDE	1 (< 1%)	1 (< 1%)	0
TRAZODONE	2 (1%)	0	1 (1%)
TRETINOIN	1 (< 1%)	0	0
TRIAMCINOLONE	1 (< 1%)	1 (< 1%)	0
TRIAMCINOLONE ACETONIDE	2 (1%)	3 (1%)	1 (1%)
TYLENOL COLD AND SINUS (NOS)	1 (< 1%)	0	0
VACCINIUM MACROCARPON	1 (< 1%)	0	0
VALACICLOVIR	0	1 (< 1%)	0
VALACICLOVIR HYDROCHLORIDE	0	0	1 (1%)
VANCOMYCIN	0	0	1 (1%)
VENLAFAXINE	1 (< 1%)	0	0
VENLAFAXINE HYDROCHLORIDE	2 (1%)	0	1 (1%)
VERAPAMIL	0	0	1 (1%)
VITAMIN D NOS	3 (1%)	3 (1%)	0
VITAMINS NOS	6 (2%)	5 (2%)	3 (3%)
ZINC	0	1 (< 1%)	0
ZINC GLUCONATE	0	1 (< 1%)	0
ZOLPIDEM TARTRATE	0	1 (< 1%)	3 (3%)

Terminology was derived from the World Health Organization (WHO) drug dictionary when available.
The generic term, for a single ingredient drug, is the WHO dictionary International Nonproprietary Names (INN) term.

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Any Adverse Event	243 (81%)	211 (70%)	454 (76%)	60 (60%)
Blood and lymphatic system disorders				
Lymphadenopathy	1 (< 1%)	0	1 (< 1%)	0
Anaemia	0	2 (1%)	2 (< 1%)	0
Cardiac disorders				
Angina pectoris	0	0	0	1 (1%)
Ear and labyrinth disorders				
Ear pain	1 (< 1%)	0	1 (< 1%)	0
Tympanic membrane perforation	1 (< 1%)	0	1 (< 1%)	0
Cerumen impaction	0	1 (< 1%)	1 (< 1%)	0
Middle ear effusion	0	1 (< 1%)	1 (< 1%)	0
Vertigo	0	1 (< 1%)	1 (< 1%)	0
Eye disorders				
Oculogyric crisis	1 (< 1%)	0	1 (< 1%)	0
Retinal tear	1 (< 1%)	0	1 (< 1%)	0
Conjunctivitis allergic	0	1 (< 1%)	1 (< 1%)	0
Eye disorder	0	1 (< 1%)	1 (< 1%)	0
Vision blurred	0	1 (< 1%)	1 (< 1%)	0
Erythema of eyelid	0	0	0	1 (1%)
Gastrointestinal disorders				
Nausea	51 (17%)	44 (15%)	95 (16%)	15 (15%)
Abdominal pain	5 (2%)	1 (< 1%)	6 (1%)	1 (1%)
Gastrooesophageal reflux disease	2 (1%)	3 (1%)	5 (1%)	0
Diarrhoea	2 (1%)	2 (1%)	4 (1%)	3 (3%)
Vomiting	2 (1%)	1 (< 1%)	3 (< 1%)	0
Tooth impacted	2 (1%)	0	2 (< 1%)	0
Haemorrhoids	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Abdominal tenderness	1 (< 1%)	0	1 (< 1%)	0
Dyspepsia	1 (< 1%)	0	1 (< 1%)	0
Food poisoning	0	2 (1%)	2 (< 1%)	0

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Abdominal pain upper	0	1 (< 1%)	1 (< 1%)	0
Anal skin tags	0	1 (< 1%)	1 (< 1%)	0
Constipation	0	1 (< 1%)	1 (< 1%)	0
Eosinophilic oesophagitis	0	1 (< 1%)	1 (< 1%)	0
Gastritis	0	1 (< 1%)	1 (< 1%)	0
Salivary gland mucocoele	0	1 (< 1%)	1 (< 1%)	0
Umbilical hernia	0	1 (< 1%)	1 (< 1%)	0
General disorders and administration site conditions				
Injection site pain	119 (40%)	106 (35%)	225 (37%)	41 (41%)
Fatigue	116 (39%)	111 (37%)	227 (38%)	19 (19%)
Chills	34 (11%)	37 (12%)	71 (12%)	10 (10%)
Injection site induration	17 (6%)	10 (3%)	27 (4%)	8 (8%)
Injection site erythema	14 (5%)	10 (3%)	24 (4%)	11 (11%)
Pyrexia	3 (1%)	7 (2%)	10 (2%)	1 (1%)
Injection site pruritus	1 (< 1%)	2 (1%)	3 (< 1%)	3 (3%)
Influenza like illness	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Chest pain	1 (< 1%)	0	1 (< 1%)	0
Medical device site erythema	1 (< 1%)	0	1 (< 1%)	0
Medical device site swelling	1 (< 1%)	0	1 (< 1%)	0
Pain	1 (< 1%)	0	1 (< 1%)	0
Injection site swelling	0	1 (< 1%)	1 (< 1%)	0
Peripheral swelling	0	1 (< 1%)	1 (< 1%)	0
Vaccination site pruritus	0	1 (< 1%)	1 (< 1%)	0
Axillary pain	0	0	0	1 (1%)
Injection site bruising	0	0	0	1 (1%)
Hepatobiliary disorders				
Biliary dyskinesia	0	0	0	1 (1%)
Immune system disorders				
Seasonal allergy	2 (1%)	1 (< 1%)	3 (< 1%)	0
Hypersensitivity	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Anaphylactic reaction	1 (< 1%)	0	1 (< 1%)	0
Allergy to animal	0	1 (< 1%)	1 (< 1%)	0

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Infections and infestations				
Nasopharyngitis	13 (4%)	5 (2%)	18 (3%)	2 (2%)
Upper respiratory tract infection	12 (4%)	9 (3%)	21 (3%)	3 (3%)
Acute sinusitis	11 (4%)	0	11 (2%)	1 (1%)
Otitis media	4 (1%)	4 (1%)	8 (1%)	0
Bronchitis	4 (1%)	3 (1%)	7 (1%)	1 (1%)
Pneumonia mycoplasmal	4 (1%)	1 (< 1%)	5 (1%)	0
Cellulitis	4 (1%)	0	4 (1%)	0
Influenza	3 (1%)	7 (2%)	10 (2%)	3 (3%)
Pharyngitis	3 (1%)	5 (2%)	8 (1%)	1 (1%)
Pharyngitis streptococcal	3 (1%)	3 (1%)	6 (1%)	0
Viral pharyngitis	3 (1%)	2 (1%)	5 (1%)	0
Otitis media acute	3 (1%)	1 (< 1%)	4 (1%)	0
Sinusitis	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Urinary tract infection	2 (1%)	3 (1%)	5 (1%)	2 (2%)
Conjunctivitis	2 (1%)	1 (< 1%)	3 (< 1%)	0
Otitis externa	2 (1%)	1 (< 1%)	3 (< 1%)	0
Gastroenteritis viral	1 (< 1%)	6 (2%)	7 (1%)	0
Pneumonia	1 (< 1%)	2 (1%)	3 (< 1%)	0
Tooth abscess	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (1%)
Folliculitis	1 (< 1%)	0	1 (< 1%)	1 (1%)
Bronchitis viral	1 (< 1%)	0	1 (< 1%)	0
Croup infectious	1 (< 1%)	0	1 (< 1%)	0
Cystitis	1 (< 1%)	0	1 (< 1%)	0
Hordeolum	1 (< 1%)	0	1 (< 1%)	0
Laryngitis	1 (< 1%)	0	1 (< 1%)	0
Pneumonia bacterial	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection	1 (< 1%)	0	1 (< 1%)	0
Respiratory tract infection viral	1 (< 1%)	0	1 (< 1%)	0
Viral rash	1 (< 1%)	0	1 (< 1%)	0
Vulvovaginal candidiasis	1 (< 1%)	0	1 (< 1%)	0
Viral upper respiratory tract infection	0	2 (1%)	2 (< 1%)	0
Bacterial vaginosis	0	1 (< 1%)	1 (< 1%)	1 (1%)
Bartholin's abscess	0	1 (< 1%)	1 (< 1%)	0

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Chlamydial infection	0	1 (< 1%)	1 (< 1%)	0
Fungal infection	0	1 (< 1%)	1 (< 1%)	0
Infectious mononucleosis	0	1 (< 1%)	1 (< 1%)	0
Oral herpes	0	1 (< 1%)	1 (< 1%)	0
Rhinitis	0	1 (< 1%)	1 (< 1%)	0
Subcutaneous abscess	0	1 (< 1%)	1 (< 1%)	0
Diverticulitis	0	0	0	1 (1%)
Kidney infection	0	0	0	1 (1%)
Vaginal infection	0	0	0	1 (1%)
Vulvovaginal mycotic infection	0	0	0	1 (1%)
Injury, poisoning and procedural complications				
Contusion	4 (1%)	1 (< 1%)	5 (1%)	0
Laceration	4 (1%)	1 (< 1%)	5 (1%)	0
Ligament sprain	3 (1%)	3 (1%)	6 (1%)	0
Arthropod bite	3 (1%)	0	3 (< 1%)	0
Concussion	2 (1%)	2 (1%)	4 (1%)	0
Procedural pain	2 (1%)	1 (< 1%)	3 (< 1%)	1 (1%)
Limb injury	2 (1%)	0	2 (< 1%)	0
Meniscus injury	1 (< 1%)	2 (1%)	3 (< 1%)	0
Joint injury	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Arthropod sting	1 (< 1%)	0	1 (< 1%)	0
Ligament rupture	1 (< 1%)	0	1 (< 1%)	0
Post procedural complication	1 (< 1%)	0	1 (< 1%)	0
Road traffic accident	1 (< 1%)	0	1 (< 1%)	0
Hand fracture	0	2 (1%)	2 (< 1%)	0
Alcohol poisoning	0	1 (< 1%)	1 (< 1%)	0
Conjunctival abrasion	0	1 (< 1%)	1 (< 1%)	0
Facial bones fracture	0	1 (< 1%)	1 (< 1%)	0
Joint dislocation	0	1 (< 1%)	1 (< 1%)	0
Muscle strain	0	1 (< 1%)	1 (< 1%)	0
Pulmonary contusion	0	1 (< 1%)	1 (< 1%)	0
Foot fracture	0	0	0	1 (1%)
Investigations				

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Cardiac murmur	0	1 (< 1%)	1 (< 1%)	0
Metabolism and nutrition disorders				
Decreased appetite	37 (12%)	48 (16%)	85 (14%)	6 (6%)
Hypoglycaemia	1 (< 1%)	0	1 (< 1%)	0
Vitamin D deficiency	1 (< 1%)	0	1 (< 1%)	0
Dehydration	0	1 (< 1%)	1 (< 1%)	0
Musculoskeletal and connective tissue disorders				
Myalgia	57 (19%)	55 (18%)	112 (19%)	15 (15%)
Arthralgia	46 (15%)	41 (14%)	87 (14%)	13 (13%)
Pain in extremity	4 (1%)	1 (< 1%)	5 (1%)	1 (1%)
Back pain	2 (1%)	0	2 (< 1%)	0
Metatarsalgia	1 (< 1%)	0	1 (< 1%)	0
Myalgia intercostal	1 (< 1%)	0	1 (< 1%)	0
Rheumatoid arthritis	1 (< 1%)	0	1 (< 1%)	0
Synovial cyst	1 (< 1%)	0	1 (< 1%)	0
Joint stiffness	0	1 (< 1%)	1 (< 1%)	0
Musculoskeletal pain	0	1 (< 1%)	1 (< 1%)	0
Pain in jaw	0	1 (< 1%)	1 (< 1%)	0
Groin pain	0	0	0	1 (1%)
Muscle tightness	0	0	0	1 (1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Benign bone neoplasm	0	1 (< 1%)	1 (< 1%)	0
Skin papilloma	0	1 (< 1%)	1 (< 1%)	0
Nervous system disorders				
Headache	103 (34%)	84 (28%)	187 (31%)	23 (23%)
Syncope	2 (1%)	3 (1%)	5 (1%)	0
Migraine	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Loss of consciousness	1 (< 1%)	0	1 (< 1%)	0
Migraine with aura	1 (< 1%)	0	1 (< 1%)	0
Tension headache	1 (< 1%)	0	1 (< 1%)	0

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Dizziness	0	4 (1%)	4 (1%)	0
Presyncope	0	1 (< 1%)	1 (< 1%)	0
Psychiatric disorders				
Anxiety	5 (2%)	3 (1%)	8 (1%)	0
Depression	4 (1%)	1 (< 1%)	5 (1%)	0
Attention deficit/hyperactivity disorder	2 (1%)	2 (1%)	4 (1%)	0
Major depression	2 (1%)	0	2 (< 1%)	0
Insomnia	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Sleep disorder	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Disruptive mood dysregulation disorder	1 (< 1%)	0	1 (< 1%)	0
Post-traumatic stress disorder	1 (< 1%)	0	1 (< 1%)	0
Renal and urinary disorders				
Haematuria	2 (1%)	1 (< 1%)	3 (< 1%)	0
Dysuria	1 (< 1%)	0	1 (< 1%)	0
Pollakiuria	1 (< 1%)	0	1 (< 1%)	0
Polyuria	1 (< 1%)	0	1 (< 1%)	0
Proteinuria	1 (< 1%)	0	1 (< 1%)	0
Reproductive system and breast disorders				
Menstruation irregular	1 (< 1%)	0	1 (< 1%)	0
Dysmenorrhoea	0	2 (1%)	2 (< 1%)	0
Metrorrhagia	0	1 (< 1%)	1 (< 1%)	0
Pelvic congestion	0	0	0	1 (1%)
Respiratory, thoracic and mediastinal disorders				
Oropharyngeal pain	7 (2%)	5 (2%)	12 (2%)	1 (1%)
Asthma	7 (2%)	1 (< 1%)	8 (1%)	0
Nasal congestion	2 (1%)	6 (2%)	8 (1%)	1 (1%)
Cough	2 (1%)	6 (2%)	8 (1%)	0
Epistaxis	2 (1%)	2 (1%)	4 (1%)	0
Wheezing	2 (1%)	0	2 (< 1%)	0
Sinus congestion	1 (< 1%)	2 (1%)	3 (< 1%)	1 (1%)
Rhinitis allergic	1 (< 1%)	2 (1%)	3 (< 1%)	0

PPD

Table 14.3.5.2
Subjects With Solicited and Unsolicited Adverse Events (Excluding SAEs) Reported by >0% of Subjects From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

Vaccination: 1

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Snoring	1 (< 1%)	0	1 (< 1%)	0
Dysphonia	0	1 (< 1%)	1 (< 1%)	0
Dyspnoea	0	1 (< 1%)	1 (< 1%)	0
Pulmonary congestion	0	1 (< 1%)	1 (< 1%)	0
Rhinorrhoea	0	1 (< 1%)	1 (< 1%)	0
Rhonchi	0	1 (< 1%)	1 (< 1%)	0
Upper-airway cough syndrome	0	1 (< 1%)	1 (< 1%)	0
Skin and subcutaneous tissue disorders				
Dermatitis contact	4 (1%)	1 (< 1%)	5 (1%)	0
Acne	3 (1%)	5 (2%)	8 (1%)	0
Rash	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Urticaria	1 (< 1%)	1 (< 1%)	2 (< 1%)	0
Alopecia	1 (< 1%)	0	1 (< 1%)	0
Ecchymosis	1 (< 1%)	0	1 (< 1%)	0
Pruritus	0	1 (< 1%)	1 (< 1%)	0
Rash macular	0	1 (< 1%)	1 (< 1%)	0
Vascular disorders				
Lymphangiopathy	1 (< 1%)	0	1 (< 1%)	0
Hot flush	0	1 (< 1%)	1 (< 1%)	0
Essential hypertension	0	0	0	1 (1%)

PPD

Table 14.3.5.3

Occurrences of Serious Adverse Events Sorted by System Organ Class and Preferred Term Throughout the Study Period
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term		Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
	Total no of deaths	0	0	0	0	0
	Total no of deaths from AEs	0	0	0	0	0
Gastrointestinal disorders						
Abdominal pain	Occurrences - all	1	0	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Infections and infestations						
Diverticulitis	Occurrences - all	0	0	0	1	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Septic shock	Occurrences - all	1	0	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Tonsillitis	Occurrences - all	1	0	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Injury, poisoning and procedural complications						
Intentional overdose	Occurrences - all	1	0	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Nervous system disorders						
Diabetic ketoacidotic hyperglycaemic coma	Occurrences - all	0	0	0	1	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Pregnancy, puerperium and perinatal conditions						
Abortion spontaneous	Occurrences - all	0	0	0	1	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Psychiatric disorders						

PPD

Table 14.3.5.3
Occurrences of Serious Adverse Events Sorted by System Organ Class and Preferred Term Throughout the Study Period
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term		Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)	Total (N=701)
Major depression	Occurrences - all	1	0	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Suicidal ideation	Occurrences - all	0	1	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Suicide attempt	Occurrences - all	2	1	3	0	3
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders						
Respiratory disorder	Occurrences - all	1	0	1	0	1
	Occurrences related to treatment	0	0	0	0	0
	Fatalities	0	0	0	0	0
	Fatalities related to treatment	0	0	0	0	0

PPD

Table 14.3.5.4
Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Blood and lymphatic system disorders				
Anaemia	0	2	2	0
Lymphadenopathy	1	0	1	0
Cardiac disorders				
Angina pectoris	0	0	0	1
Ear and labyrinth disorders				
Cerumen impaction	0	1	1	0
Ear pain	1	0	1	0
Middle ear effusion	0	1	1	0
Tympanic membrane perforation	1	0	1	0
Vertigo	0	1	1	0
Eye disorders				
Conjunctivitis allergic	0	1	1	0
Erythema of eyelid	0	0	0	1
Eye disorder	0	1	1	0
Oculogyric crisis	1	0	1	0
Retinal tear	1	0	1	0
Vision blurred	0	1	1	0
Gastrointestinal disorders				
Abdominal pain	5	1	6	1
Abdominal pain upper	0	1	1	0
Abdominal tenderness	1	0	1	0
Anal skin tags	0	1	1	0
Constipation	0	1	1	0
Diarrhoea	2	2	4	3
Dyspepsia	1	0	1	0
Eosinophilic oesophagitis	0	1	1	0
Food poisoning	0	2	2	0
Gastritis	0	1	1	0
Gastrooesophageal reflux disease	2	3	5	0
Haemorrhoids	1	1	2	0
Nausea	65	55	120	17
Salivary gland mucocoele	0	1	1	0

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.

PPD

Table 14.3.5.4

Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Tooth impacted	2	0	2	0
Umbilical hernia	0	1	1	0
Vomiting	2	1	3	0
General disorders and administration site conditions				
Axillary pain	0	0	0	1
Chest pain	1	0	1	0
Chills	36	50	86	10
Fatigue	146	159	305	21
Influenza like illness	1	1	2	0
Injection site bruising	0	0	0	1
Injection site erythema	16	10	26	14
Injection site induration	17	11	28	9
Injection site pain	124	113	237	41
Injection site pruritus	1	2	3	3
Injection site swelling	0	1	1	0
Medical device site erythema	1	0	1	0
Medical device site swelling	1	0	1	0
Pain	1	0	1	0
Peripheral swelling	0	1	1	0
Pyrexia	4	8	12	1
Vaccination site pruritus	0	1	1	0
Hepatobiliary disorders				
Biliary dyskinesia	0	0	0	1
Immune system disorders				
Allergy to animal	0	1	1	0
Anaphylactic reaction	1	0	1	0
Hypersensitivity	1	1	2	0
Seasonal allergy	2	1	3	0
Infections and infestations				
Acute sinusitis	13	0	13	1
Bacterial vaginosis	0	1	1	1
Bartholin's abscess	0	1	1	0
Bronchitis	4	3	7	1

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.

PPD

Table 14.3.5.4

Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Bronchitis viral	1	0	1	0
Cellulitis	4	0	4	0
Chlamydial infection	0	1	1	0
Conjunctivitis	2	1	3	0
Croup infectious	1	0	1	0
Cystitis	1	0	1	0
Diverticulitis	0	0	0	1
Folliculitis	1	0	1	1
Fungal infection	0	1	1	0
Gastroenteritis viral	1	6	7	0
Hordeolum	1	0	1	0
Infectious mononucleosis	0	1	1	0
Influenza	3	7	10	3
Kidney infection	0	0	0	1
Laryngitis	1	0	1	0
Nasopharyngitis	16	5	21	2
Oral herpes	0	1	1	0
Otitis externa	2	1	3	0
Otitis media	4	4	8	0
Otitis media acute	3	1	4	0
Pharyngitis	3	5	8	1
Pharyngitis streptococcal	3	3	6	0
Pneumonia	1	2	3	0
Pneumonia bacterial	1	0	1	0
Pneumonia mycoplasmal	4	1	5	0
Respiratory tract infection	1	0	1	0
Respiratory tract infection viral	1	0	1	0
Rhinitis	0	1	1	0
Sinusitis	2	7	9	1
Subcutaneous abscess	0	1	1	0
Tooth abscess	1	1	2	1
Upper respiratory tract infection	12	9	21	3
Urinary tract infection	2	3	5	4
Vaginal infection	0	0	0	1
Viral pharyngitis	4	2	6	0
Viral rash	1	0	1	0
Viral upper respiratory tract infection	0	3	3	0

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.

PPD

Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Vulvovaginal candidiasis	1	0	1	0
Vulvovaginal mycotic infection	0	0	0	1
Injury, poisoning and procedural complications				
Alcohol poisoning	0	1	1	0
Arthropod bite	3	0	3	0
Arthropod sting	1	0	1	0
Concussion	2	2	4	0
Conjunctival abrasion	0	1	1	0
Contusion	4	1	5	0
Facial bones fracture	0	1	1	0
Foot fracture	0	0	0	1
Hand fracture	0	2	2	0
Joint dislocation	0	1	1	0
Joint injury	1	1	2	0
Laceration	4	1	5	0
Ligament rupture	1	0	1	0
Ligament sprain	3	3	6	0
Limb injury	2	0	2	0
Meniscus injury	1	2	3	0
Muscle strain	0	1	1	0
Post procedural complication	1	0	1	0
Procedural pain	2	1	3	1
Pulmonary contusion	0	1	1	0
Road traffic accident	1	0	1	0
Investigations				
Cardiac murmur	0	1	1	0
Metabolism and nutrition disorders				
Decreased appetite	50	63	113	6
Dehydration	0	1	1	0
Hypoglycaemia	1	0	1	0
Vitamin D deficiency	1	0	1	0
Musculoskeletal and connective tissue disorders				
Arthralgia	60	50	110	13

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.

PPD

Table 14.3.5.4

Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Back pain	2	0	2	0
Groin pain	0	0	0	1
Joint stiffness	0	1	1	0
Metatarsalgia	1	0	1	0
Muscle tightness	0	0	0	1
Musculoskeletal pain	0	1	1	0
Myalgia	63	72	135	15
Myalgia intercostal	1	0	1	0
Pain in extremity	4	1	5	2
Pain in jaw	0	1	1	0
Rheumatoid arthritis	1	0	1	0
Synovial cyst	1	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Benign bone neoplasm	0	1	1	0
Skin papilloma	0	1	1	0
Nervous system disorders				
Dizziness	0	4	4	0
Headache	135	118	253	27
Loss of consciousness	1	0	1	0
Migraine	1	1	2	0
Migraine with aura	1	0	1	0
Presyncope	0	1	1	0
Syncope	2	3	5	0
Tension headache	1	0	1	0
Psychiatric disorders				
Anxiety	5	3	8	0
Attention deficit/hyperactivity disorder	2	2	4	0
Depression	4	1	5	0
Disruptive mood dysregulation disorder	1	0	1	0
Insomnia	1	1	2	0
Major depression	2	0	2	0
Post-traumatic stress disorder	1	0	1	0
Sleep disorder	1	1	2	0

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.

PPD

Table 14.3.5.4

Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Renal and urinary disorders				
Dysuria	1	0	1	0
Haematuria	2	1	3	0
Pollakiuria	1	0	1	0
Polyuria	1	0	1	0
Proteinuria	1	0	1	0
Reproductive system and breast disorders				
Dysmenorrhoea	0	2	2	0
Menstruation irregular	1	0	1	0
Metrorrhagia	0	1	1	0
Pelvic congestion	0	0	0	1
Respiratory, thoracic and mediastinal disorders				
Asthma	7	1	8	0
Cough	2	6	8	0
Dysphonia	0	1	1	0
Dyspnoea	0	1	1	0
Epistaxis	2	2	4	0
Nasal congestion	2	6	8	1
Oropharyngeal pain	7	5	12	1
Pulmonary congestion	0	1	1	0
Rhinitis allergic	1	2	3	0
Rhinorrhoea	0	1	1	0
Rhonchi	0	1	1	0
Sinus congestion	1	2	3	1
Snoring	1	0	1	0
Upper-airway cough syndrome	0	1	1	0
Wheezing	2	0	2	0
Skin and subcutaneous tissue disorders				
Acne	3	5	8	0
Alopecia	1	0	1	0
Dermatitis contact	4	1	5	0
Ecchymosis	1	0	1	0
Pruritus	0	1	1	0

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.

PPD

Table 14.3.5.4

Occurrences of Solicited and Unsolicited Adverse Events (Excluding SAEs) From Day 1 Through Day 29 Sorted by System Organ Class and Preferred Term
[table created for posting purposes]
Overall Safety Set

System Organ Class Preferred Term	Menveo-Menveo (N=301)	Menactra-Menveo (N=300)	Pooled Menveo/Menactra-Menveo (N=601)	Naive (N=100)
Rash	1	1	2	0
Rash macular	0	1	1	0
Urticaria	1	2	3	0
Vascular disorders				
Essential hypertension	0	0	0	1
Hot flush	0	1	1	0
Lymphangiopathy	1	0	1	0

Even though the sites are instructed to enter the same event only once, and the monitors look for duplicates, there remains the possibility of double-counting in scenarios that cannot be checked programmatically.
PPD

15.0 REFERENCE LIST

15.0 REFERENCE LIST

Code of Federal Regulations (1997): Food and Drug Administration, U.S. Department of Health and Human Services: Title 21, Part 11: Electronic Records Electronic Signatures. Federal Register 62: 13464.

ICH (1997) ICH Harmonised Tripartite ICH Guideline for Good Clinical Practices E6 (R1). Federal Register, 62 (90): 25691-25709.

16.0 APPENDICES

16.1 Study Information

16.1.1 Protocol and Protocol Amendments

CLINICAL STUDY PROTOCOL V59_77 Version 1

A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.

Safety and Immunogenicity Study of a Single Dose of Menveo, Administered to Subjects 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination

PRO-01 TEMP 06 / Atlas No. 293620
Version No.4 / Version Date: January 29, 2015

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PROTOCOL SYNOPSIS V59_77

Name of Sponsor:	**Protocol number:**	**Generic name of study vaccine(s):**
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine
Title of Study: A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.		
Study Period: Approximately 180 days (six months).		**Clinical Phase:** 3b

Background and Rationale:

Neisseria meningitidis is a leading cause of bacterial meningitis and sepsis worldwide, capable of causing outbreaks and epidemics of invasive disease. Meningococcal disease is associated with high morbidity and mortality even among patients who receive early antibiotic treatment. Most cases of invasive disease worldwide are caused by serogroups A, B, C, W and Y.

The quadrivalent meningococcal oligosaccharide diphtheria CRM-197 conjugate vaccine (MenACWY-CRM; Menveo, GSK Vaccines) is approved for active immunization of individuals from 2 months through 55 years of age in the United States, and in over 60 other countries. As of February 2015, more than 30,000 of subjects have been exposed to MenACWY-CRM vaccine in completed clinical studies and more than 24 million doses of the vaccine have been distributed globally.

The US Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with a quadrivalent conjugated meningococcal vaccine for adolescents at 11-12 years of age with a booster dose administered 5 years later. While a substantial body of data exists showing a robust immune response and good antibody persistence after a single dose of MenACWY-CRM in adolescents, the response to a booster dose of MenACWY-CRM in this age group has only been evaluated in 2 clinical studies with limited number of subjects.

A robust anamnestic immune response to a booster dose of Menveo vaccine administered at approximately 5 years after previous vaccination with the same vaccine or a licensed meningococcal polysaccharide vaccine (Menomune®) was demonstrated in

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

the phase 2 clinical study V59P6E1. High titers of bactericidal antibodies against the vaccine serogroups were achieved at 7 and 30 days after booster dose in MenACWY-primed subjects. However, the number of subjects included in this study was relatively small (N=101, including 50 subjects who received a booster dose after the primary MenACWY-CRM vaccination).

In the phase 3b clinical study V59P13E1, a booster dose of MenACWY-CRM was given 3 years after primary vaccination with either MenACWY-CRM or Menactra® (a meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) in adolescents. A booster dose was able to substantially increase antibody titers against all 4 serogroups irrespective of the priming vaccine. Again, only a small number of subjects (N=160) received the MenACWY-CRM booster, (83 who received primary MenACWY-CRM and 77 who received MenACWY-D).

In the light of the current ACIP recommendation for a booster dose of MenACWY-CRM, there exists a need to evaluate the response to a MenACWY-CRM booster given at ~5 years after primary vaccination in meningococcal-vaccine primed adolescents. Generation of this data would also be of relevance in outbreak management and vaccination of travelers to endemic areas.

The purpose/aim of this study is to assess the safety and antibody response to vaccination with a booster dose of Menveo given 4-6 years after primary vaccination and the response to a single dose given to vaccine-naive subjects, and to describe the immune response over time after a booster dose of Menveo, administered to subjects previously vaccinated with Menveo or Menactra, and after a single dose of Menveo to vaccine-naive subjects. The inclusion of vaccine-naive subjects in a separate study arm is to enable comparison of the rapidity and magnitude of an anamnestic response to a booster dose (in primed individuals) or the primary response to a first dose (in naive individuals) of MenACWY-CRM.

Study Objectives:

Primary Objective(s): Immunogenicity objective:

1. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

received Menveo, as measured by the percentage of subjects with hSBA seroresponse1 against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination.

2. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse1 against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination

Criteria to demonstrate immune response sufficiency: The immune response sufficiency will be tested sequentially; first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra . The immune response will be considered as sufficient if the lower limit of the one-sided 97.5% CI for percentage of subjects with hSBA seroresponse[1] against serogroups A, C, W and Y is greater than 75%. The study will be considered successful if the immune response sufficiency will be demonstrated at least in the group of subjects who received primary vaccination with Menveo.

Secondary Objective(s):

Immunogenicity objectives:

1. To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo, subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled vaccine group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA seroresponse[1], hSBA titers ≥8 and ≥16, and hSBA GMTs against *N. meningitidis* serogroups A, C, W and Y at Day 1, Day 4, Day 6, and Day 29

[1] Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

after vaccination.

2. To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the primary vaccination with Menactra in comparison with naturally-acquired levels in vaccine-naive individuals, as measured by the percentages of subjects with hSBA titers ≥8 and hSBA GMTs at Day 1.

Safety objectives:

1. To assess reactogenicity and safety of MenACWY-CRM vaccine when administered to subjects who previously received Menveo or Menactra and vaccine-naive individuals.

Study Design:

This is a phase 3b, controlled, open-label, multi-center study to evaluate safety and immunogenicity of MenACWY-CRM after a single vaccination in healthy individuals who were vaccinated with Menveo or Menactra 4 to 6 years before and in vaccine-naive individuals.

Study population: Approximately 700 healthy subjects 15 through 55 years of age will be enrolled in the study.

Duration of the study: The duration of this study is approximately 6 months per subject.

Written informed consent and, as applicable according to local guidelines, written assent will be obtained before conducting any study-specific procedures.

Vaccination schedule: All subjects will receive a single dose of MenACWY-CRM at Day 1.

Study groups:

- Group Menveo-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menveo 4 to 6 years before, will receive one dose of MenACWY-CRM.
- Group Menactra-Menveo: approximately 300 subjects, who were vaccinated with a

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

single dose of Menactra 4 to 6 years before, will receive one dose of MenACWY-CRM.

- Group Naive: approximately 100 subjects, of similar age to subjects enrolled in other primed groups, with enrolment distributed across all clinical sites, who have not received any meningococcal vaccination, will receive one dose of MenACWY-CRM.

Randomization / Stratification:

Within each study group, subjects will be randomized into one of two different blood draw schedules according to a 1:1 ratio, described as follows:

- Subjects getting blood draws at Day 1, Day 4 and Day 29.
- Subjects getting blood draws at Day 1, Day 6 and Day 29.

For a schematic overview, see Table 1.

Table 1: Schematic diagram of the V59_77 study groups

Vaccine History	Vaccination in current study	Blood draw schedule
Menveo N=300	Menveo	Blood draw Day 1, 4, 29 (N=150)
		Blood draw Day 1, 6, 29 (N=150)
Menactra N=300	Menveo	Blood draw Day 1, 4, 29 (N=150)
		Blood draw Day 1, 6, 29 (N=150)
Vaccine-Naive N=100	Menveo	Blood draw Day 1, 4, 29 (N=50)
		Blood draw Day 1, 6, 29 (N=50)

Blinding: open-label study.

Blood samples: Three (3) blood samples of approximately 10 mL each will be collected according to the blood draw schedule in Table 1.

Data collection: Electronic Case Report Form (eCRF).

Study clinic visits: Three (3) clinic visits at Day 1, Day 4 or Day 6 and Day 29 are

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

planned for each subject.

Reminder Phone calls: Two (2) reminder phone calls will be conducted at Day 3 and Day 5 after the study vaccination to remind the subject/ legal guardian to complete the diary card.

Safety phone calls: Three (3) safety phone calls (at Day 15, Day 91 and Day 181) will be conducted to collect any medically-attended AEs, AEs leading to withdrawal, SAEs, related medications and any vaccinations. In addition, all unsolicited AEs and related medications occurring after the vaccination will be collected during the safety call at Day 15. The Day 181 Safety Phone call will also serve as the termination visit.

Solicited Adverse Events (injection site pain, erythema, induration, fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever) occurring on the day of vaccination and the following six days (Day 1 through Day 7) will be recorded daily using a Diary Card for all subjects.

Unsolicited AEs occurring within 28 days after study vaccination will be collected. Qualified site staff will interview the subject by phone approximately 14 days after vaccination and in person at the study site approximately 28 days after study vaccination to assess the occurrence of any unsolicited AEs.

Medically-attended AEs, AEs leading to study withdrawal and SAEs will be collected during the entire study period. These data will be captured by interviewing the subject and/or subjects' parents / guardian (as applicable) during the site visits and phone calls and by review of available medical records. Subjects and/or parents / guardian will be encouraged to call the site in the event of any medically-attended AEs or any AEs which they perceive as being of concern during the entire study period.

Table 2: Schematic diagram of the V59_77 study design.

Day 1	Day 4	Day 6	Day 15	Day 29	Day 91	Day 181
Blood draw (all subjects) Menveo	Blood draw (50% of subjects)	Blood draw (50% of subjects)	Safety Phone call	Blood draw (all subjects)	Safety Phone call	Safety Phone call Study termination

Number of Subjects planned: Approximately 700 subjects are planned for enrolment

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Name of Sponsor:	**Protocol number:**	**Generic name of study vaccine(s):**
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine
into this study, approximately 300 subjects who previously received Menveo (Menveo-Menveo group), 300 subjects who previously received Menactra (Menactra-Menveo group) and 100 meningococcal vaccine-naive subjects (Naive group). Assuming a 10% drop-out rate that should provide approximately 630 evaluable subjects.		
Study Population and Subject Characteristics: The list of inclusion and exclusion criteria is included in protocol section 4, Selection of Study Population.		
Study Procedures: The study includes three clinic visits, one vaccination, three blood draws, and three safety phone calls for each subject. All study procedures associated with the pre-vaccination, vaccination, post-vaccination and study termination visit are described in section 5.0.		
Study Vaccines: **GlaxoSmithKline Meningococcal MenACWY-CRM vaccine (Menveo):** Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine is supplied as a vial that contains 10 µg of serogroup A oligosaccharides and 5 µg of serogroups C, W and Y oligosaccharides, conjugated to *Corynebacterium diphtheriae* CRM_{197} protein. Overall injection volume of 0.5 mL. The vaccine will be administered intramuscularly, preferably in the deltoid area of the non-dominant arm.		
Primary Endpoint(s): **Immunogenicity Endpoints:** The following measures will be summarized for Menveo-Menveo and Menactra-		

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

Menveo groups:

1. Percentage of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 29.

Secondary Endpoints:

Immunogenicity endpoints:

The following measures will be summarized for Menveo-Menveo, Menactra-Menveo, Naive and the pooled (Menveo-Menveo and Menactra-Menveo) groups :

1. Percentage of subjects with hSBA titer ≥8 and ≥16 against *N. meningitidis* serogroups A, C, W and Y at Day 1, Day 4, Day 6 and Day 29 and between-group differences;
2. Percentages of subjects with hSBA seroresponse[2] against *N. meningitidis* serogroups A, C, W and Y at Day 4, Day 6 and Day 29 and between-group differences;
3. hSBA GMTs against *N. meningitidis* serogroup A, C, W and Y at Day 1, Day 4, Day 6 and Day 29;
4. Ratios of hSBA GMTs at Day 1, Day 4, Day 6 and Day 29 (between study groups).
5. hSBA Geometric Mean Ratios (GMRs) at Day 4, Day 6, and Day 29 compared to Day 1 (within study groups).

Safety endpoints:

Safety of the study vaccine will be asses sed in the Menveo-Menveo and Menactra-Menveo groups and the pooled vaccine group (Menveo-Menveo and Menactra - Menveo) and the vaccine-naive group in terms of the frequencies (percentages) of

[1]-[2] Seroresponse is defined for this study as follows: For subjects with prevaccination titers <4, post-vaccination titers ≥ 16; for subjects with prevaccination titers ≥4, post vaccination titers 4 times the pre-vaccination titers.

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

reported adverse events including:

1. Any unsolicited AEs reported within 30 minutes after vaccination;
2. Solicited local and systemic AEs reported from Day 1 (6 hours) through Day 7 after vaccination;
3. Other indicators of reactogenicity (e.g. use of analgesics / antipyretics, body temperature) within 7 days after vaccination;
4. All unsolicited AEs reported from Day 1 through Day 29 after vaccination;
5. Medically-attended AEs, AEs leading to withdrawal and SAEs reported from Day 1 through Day 181 (during the entire study period).

Statistical Analyses:

Primary Immunogenicity Objective

The primary population for the analysis of sufficient immune response is the Per Protocol Set (PPS), and will consist of the Menveo-Menveo group (n=270 evaluable subjects) and Menactra-Menveo group (n=270 evaluable subjects).To demonstrate immune response sufficiency after MenACWY-CRM booster vaccine administration, the lower limit of the one-sided 97.5% Confidence Interval (CI) for percentage of subjects with hSBA seroresponse against each of serogroups A, C, W and Y must be greater than 75%. This will be tested sequentially first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra.

Hypothesis:

Null hypothesis *versus* Alternative hypothesis

$P_{ij} \leq 0.75$ $P_{ij} > 0.75$

Where: P_{ij} is the population booster seroresponse rate; $j = 1,2$ refer to group Menveo-Menveo (first test) and Menactra-Menveo (second test) respectively; $i = 1,2,3,4$ refer to serogroup A, C, W and Y respectively.

Name of Sponsor:	Protocol number:	Generic name of study vaccine(s):
GlaxoSmithKline Biologicals S.A	V59_77	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine

Sample Size:

Statistical power was estimated based on observed data from study V59P13E1.

Assuming the true booster seroresponse rates in the Menveo-Menveo group range from 90% to 97% (alternative hypothesis) for each serotype, a sample size of n=270 will have at least 96% power to show sufficiency of immune response to a booster dose of MenACWY-CRM, compared with a pre-specified reference booster seroresponse of 75% (null hypothesis) using an exact test with 0.025 one-sided significance level.

Assuming the true booster seroresponse rates in the Menactra-Menveo group range from 91% to 100% (alternative hypothesis) for each serotype, a sample size of n=270 will have at least 96% power to show sufficiency of immune response to a booster dose of MenACWY-CRM, compared with a pre-specified reference booster seroresponse of 75% (null hypothesis) using an exact test with 0.025 one-sided significance level.

Overall statistical power to show sufficiency of immune response to a booster dose of MenACWY-CRM for each serotype in both the Menveo-Menveo and the Menactra-Menveo group will be at least 92%.

When taking a 10% dropout rate into account, N=300 previously vaccinated subjects with Menveo and N=300 previously vaccinated subjects with Menactra have to be enrolled in the study.

Calculations have been done with nQuery Advisor (Version 7.0).

Interim Analysis: No interim analysis is planned for this study.

Data Monitoring Committee: No DMC will be utilized for the study.

Table 4 Time and Events Table

Visit Type		Clinic Visit	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Phone Call
Study period		Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Follow-up	Follow-up
Study Day			1	3, 5	4/6[a]	15	29	91	181
Visit Window (Days)		-5 to 1	0	2 days (-1/+1), 4 days (0/+2) after vacc	3/5 days (-1/+1) after vacc	14 days (-2/+2) after vacc	28 days (-7/+14) after vacc	90 days (-14/+14) after vacc	180 days (-14/+14) after vacc
Visit Number		Pre-vaccination	1	N/A	2	3	4	5	6
Study Event	**References**								
Study Treatment									
Vaccination (vacc)	Section 5.2		X						
Screening and Safety									
Informed Consent[b]	Section 5.1.1	X							
Medical History	Section 5.1.2	X							
Physical Exam	Sections 5.1.2 and 5.3.1	X	X[c]		X		X		
Pregnancy Test	Sections 3.5 and 5.1.2	X	X[c]						
Exclusion/Inclusion Criteria[d]	Section 4	X	X						
Randomization	Section 5.1.4		X[c]						
30 Minutes Post Injection Assessment	Section 5.2.1		X						

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Visit Type		Clinic Visit	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Phone Call
Study period		Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Follow-up	Follow-up
Study Day			1	3, 5	4/6[a]	15	29	91	181
Visit Window (Days)		-5 to 1	0	2 days (-1/+1), 4 days (0/+2) after vacc	3/5 days (-1/+1) after vacc	14 days (-2/+2) after vacc	28 days (-7/+14) after vacc	90 days (-14/+14) after vacc	180 days (-14/+14) after vacc
Visit Number		Pre-vaccination	1	N/A	2	3	4	5	6
Study Event	**References**								
Subject Diary Dispensed with Training	Section 5.2.1		X						
Subject Diary Reminder Call	Section 5.2.2			X[e]	X[e]				
Subject Diary Reviewed and Collected	Section 5.3.1						X		
Assess Unsolicited AEs	Section 7.1		X		X	X	X		
Assess SAEs	Section 7.1.4		X		X	X	X	X	X
Assess for medically attended AEs and AEs leading to withdrawal	Sections 7.1.4.1 and 7.1.3		X		X	X	X	X	X
Assess relevant medications/ vaccinations	Sections 5.1.2 and 6.5	X	X		X	X	X	X	X

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Visit Type		Clinic Visit	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Clinic Visit	Phone Call	Phone Call
Study period		Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Follow-up	Follow-up
Study Day			1	3, 5	4/6[a]	15	29	91	181
Visit Window (Days)		-5 to 1	0	2 days (-1/+1), 4 days (0/+2) after vacc	3/5 days (-1/+1) after vacc	14 days (-2/+2) after vacc	28 days (-7/+14) after vacc	90 days (-14/+14) after vacc	180 days (-14/+14) after vacc
Visit Number		Pre-vaccination	1	N/A	2	3	4	5	6
Study Event	**References**								
Immunogenicity									
Serology blood draw	Section 3.5		X[b]		X		X		
Study Completion Procedure									
Study Termination[f]	Section 5.5								X

Notes:

[a] Subject will be randomized into a blood draw schedule in a 1:1 ratio. The second clinic visit will occur at Day 4 OR Day 6.

[b] Confirm consent form(s) signed prior to any procedures.

[c] Procedure to be performed prior to vaccination

[d] Reminder: for previously vaccinated subjects, appropriate written documentation of the identity of the primary meningococcal vaccination (Menveo or Menactra) and vaccination date must be provided prior to enrollment.

[e] If the clinic visit at Day 4 is overlapping with the specified window of the Day 3 reminder call, the Day 3 reminder call may be omitted.
If the clinic visit at Day 6 is overlapping with the specified window of the Day 5 reminder call, the Day 5 reminder call may be omitted.

[f] Subjects who terminate the study early are recommended to complete certain study-related procedures. See section 5.5 for further details.

LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
CI	Confidence Interval
CBER	Center for Biologics Evaluation and Research
CRM	Cross Reactive material
CRO	Contract Research Organization
EC	Ethics Committee
EoS	End of Study
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FAS	Full Analysis Set
FDA	Food and Drug Administration
GCP	Good Clinical Practices
GMR	Geometric Mean Ratio
GMT	Geometric Mean Titer
GSK	GlaxoSmithKline Biologicals
HIPAA	Health Insurance Portability and AccountabilityAct
hSBA	Human Serum Bactericidal Assay
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IM	Intramuscular
IRB	Institutional Review Board
LSLV	Last Subject Last Visit
MedDRA	Medical Dictionary for Regulatory Activities
PP	Per Protocol
Ref.	Reference
SAE	Serious Adverse Event
SDAF	Source Documentation Agreement Form
SBIR	Source Data Base for Internet Randomization
SOC	System Organ Class
SOP	Standard Operating Procedure

1. BACKGROUND AND RATIONALE

1.1 Background

Neisseria meningitidis is a leading cause of bacterial meningitis and sepsis worldwide, capable of causing outbreaks and epidemics of invasive disease. Meningococcal disease is associated with high morbidity and mortality even among patients who receive early antibiotic treatment. Most cases of invasive disease worldwide are caused by serogroups A, B, C, W and Y.

The quadrivalent meningococcal oligosaccharide diphtheria CRM-197 conjugate vaccine (MenACWY-CRM; Menveo, GSK Biologicals) is approved for active immunization of individuals from 2 months through 55 years of age in the United States. As of February 2015, more than 30,000 of subjects have been exposed to MenACWY-CRM vaccine in completed clinical studies and more than 24 million doses of the vaccine have been distributed globally.

The US Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination with a quadrivalent conjugated meningococcal vaccine for adolescents at 11-12 years of age with a booster dose administered 5 years later. While a substantial body of data exists showing a robust immune response and good antibody persistence after a single dose of MenACWY-CRM in adolescents, the response to a booster dose of MenACWY-CRM in this age group has only been evaluated in 2 clinical studies with limited number of subjects.

A robust anamnestic immune response to a booster dose of Menveo vaccine administered at approximately 5 years after previous vaccination with the same vaccine or a licensed meningococcal polysaccharide vaccine (Menomune®) was demonstrated in the phase 2 clinical study V59P6E1. High titers of bactericidal antibodies against the vaccine serogroups were achieved at 7 and 30 days after booster dose in MenACWY-CRM-primed subjects. However, the number of subjects included in this study was relatively small (N=101, including 50 subjects who received a booster dose after the primary MenACWY-CRM vaccination).

In the phase 3b clinical study V59P13E1, a booster dose of MenACWY-CRM was given 3 years after primary vaccination with either MenACWY-CRM or Menactra® (a meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) in adolescents. A booster dose was able to substantially increase antibody titers against all 4 serogroups irrespective of the priming vaccine. Again, only small number of subjects (N=160) received the MenACWY-CRM booster, (83 who received primary MenACWY-CRM and 77 who received MenACWY-D).

In the light of the current ACIP recommendation for a booster dose of MenACWY-CRM, there exists a need to evaluate the response to a MenACWY-CRM booster given at ~5 years after primary vaccination in meningococcal-vaccine primed adolescents. Generation of this data would also be of relevance in outbreak management and vaccination of travelers to endemic areas.

1.2 Rationale

The purpose/aim of this study is to assess the safety and antibody response to vaccination with a booster dose of Menveo given 4-6 years after primary vaccination and the response to a single dose given to vaccine-naive subjects, and to describe the immune response over time after a booster dose of Menveo, administered to subjects previously vaccinated with Menveo or Menactra, and after a single dose of Menveo to vaccine-naive subjects. The inclusion of vaccine-naive subjects in a separate study arm is to enable comparison of the rapidity and magnitude of an anamnestic response to a booster dose (in primed individuals) or the primary response to a first dose (in naive individuals) of MenACWY-CRM.

2. OBJECTIVES

2.1 Primary Objective(s)

Immunogenicity objective:

1. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 29 after vaccination
2. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 29 after vaccination

   Criteria to demonstrate immune response sufficiency: The immune response sufficiency will be tested sequentially; first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra . The immune response will be considered as sufficient if the lower limit of the one-sided 97.5% CI for percentage of subjects with hSBA seroresponse[1] against serogroups A, C, W and Y is greater than 75%. The study will be considered successful if the immune response sufficiency will be demonstrated at least in the group of subjects who received primary vaccination with Menveo.

2.2 Secondary Objective(s)

Secondary Immunogenicity objectives:

1. To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo, subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled vaccine group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA

[1] Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

seroresponse[1], hSBA titers ≥8 and ≥16, and hSBA GMTs against *N. meningitidis* serogroups A, C, W and Y at Day 1, Day 4, Day 6, and Day 29 after vaccination.

2. To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the primary vaccination with Menactra in comparison with naturally-acquired level in vaccine-naive individuals, as measured by the percentages of subjects with hSBA titers ≥8 and hSBA GMTs at Day 1.

Secondary Safety objectives:

To assess the reactogenicity and safety of MenACWY-CRM vaccine when administered to subjects who previously received Menveo or Menactra and vaccine-naive individuals.

2.3 Exploratory Objective(s)

There are no exploratory objectives.

3. STUDY DESIGN

3.1 Overview of Study Design

This is a phase 3b, controlled, open-label, multi-center study to evaluate safety and immunogenicity of MenACWY-CRM after a single vaccination in healthy individuals who were vaccinated with Menveo or Menactra 4 to 6 years before and in vaccine-naive individuals.

Study population: Approximately 700 healthy subjects 15 through 55 years of age will be enrolled in the study.

Duration of the study: The duration of this study is approximately 6 months per subject.

Written informed consent and, as applicable according to local guidelines, written assent will be obtained before conducting any study-specific procedures.

Vaccination schedule: All subjects will receive a single dose of MenACWY-CRM at Day 1.

Study groups:

Group Menveo-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menveo 4 to 6 years before, will receive one dose of MenACWY-CRM.

Group Menactra-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menactra 4 to 6 years before, will receive one dose of MenACWY-CRM.

Group Naive: approximately 100 subjects equally enrolled across all clinical sites, who have not received any meningococcal vaccination, will receive one dose of MenACWY-CRM.

Randomization / Stratification:

Within each study group, subjects will be randomized into one of two different blood draw schedules according to a 1:1 ratio, described as follows:

- Subjects getting blood draws at Day 1, Day 4 and Day 29.
- Subjects getting blood draws at Day 1, Day 6 and Day 29.

For a schematic overview, see Table 1

Table 3.1-1: Schematic diagram of the V59_77 study groups

Vaccine History	Vaccination in current study	Blood draw schedule
Menveo N=300	Menveo	Blood draw Day 1, 4, 29 (N=150)
		Blood draw Day 1, 6, 29 (N=150)
Menactra N=300	Menveo	Blood draw Day 1, 4, 29 (N=150)
		Blood draw Day 1, 6, 29 (N=150)
Vaccine-Naive N=100	Menveo	Blood draw Day 1, 4, 29 (N=50)
		Blood draw Day 1, 6, 29 (N=50)

Blinding: open-label study.

Blood samples: Three (3) blood samples of approximately 10 mL each will be collected according to the blood draw schedule in Table 3.1.1.

Data collection: Electronic Case Report Form (eCRF).

Study clinic visits: Three (3) clinic visits at Day 1, Day 4 or Day 6 and Day 29 are planned for each subject.

Reminder Phone calls: Two (2) reminder phone calls will be conducted at Day 3 and Day 5 after the study vaccination to remind the subject/legal guardian to complete the diary card.

Safety phone calls: Three (3) safety phone calls (at Day 15, Day 91 and Day 181) will be conducted to collect any medically-attended AEs, AEs leading to withdrawal, SAEs, related medications and any vaccinations. In addition, all unsolicited AEs and related medications occurring after the vaccination will be collected during the safety call at Day 15. The Day 181 Safety Phone call will also serve as the termination visit.

Solicited Adverse Events (injection site pain, erythema, induration, fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever) occurring on the day of vaccination and the following six days (Day 1 through Day 7) will be recorded daily using a Diary Card for all subjects.

Unsolicited AEs occurring within 28 days after study vaccination will be collected. Qualified site staff will interview the subject by phone approximately 14 days after vaccination and in person at the study site approximately 28 days after study vaccination to assess the occurrence of any unsolicited AEs.

Medically-attended AEs, AEs leading to study withdrawal and SAEs will be collected during the entire study period. These data will be captured by interviewing the subject and/or subjects' parents / guardian (as applicable) during the site visits and phone calls and by review of available medical records. Subjects and/or parents / guardian will be encouraged to call the site in the event of any medically-attended AEs or any AEs which they perceive as being of concern during the entire study period.

Table 3.1-2: Schematic diagram of the V59_77 study design

Day 1	Day 4	Day 6	Day 15	Day 29	Day 91	Day 181
Blood draw (all subjects) Menveo	Blood draw (50% of subjects)	Blood draw (50% of subjects)	Safety Phone call	Blood draw (all subjects)	Safety Phone call	Safety Phone call Study termination

3.2 Study Period

Each subject should expect to participate in the study for 6 months, from the time of enrolment through the last study visit.

3.3 Blinding Procedures

The trial is designed as an open-label study.

3.4 Data Collection

3.4.1 Data Collected from Subjects

The following data will be collected from each subject over the duration of their study participation:

- Demographic Information
- Adverse Events
- Medical History
- Concomitant Medications/Vaccinations
- Information on the blood samples

All data collected must only be identified using the Subject ID, as described in section 5.1.4, Randomization.

3.4.2 Tools Used for Data Collection

Data will be recorded in the Subject Diary and collected on electronic Case Report Forms (eCRFs).

Subject Diary

Paper Diaries (pDiaries), hereafter referred to as Subject Diaries will be the only source document allowed for solicited local and systemic adverse events (including body temperature measurements), starting after the initial, 30minute post-vaccination period at the clinic. The following additional rules apply to documentation of safety information collected in the Subject Diary.

The Investigator or delegated staff should monitor the Subject's Diary status throughout the study for compliance and any solicited local and systemic adverse events that were of concern to the subject.

- No corrections or additions to the information recorded by the subject or parent(s)/legal guardian(s) within the Subject Diary will be allowed after it is delivered to the site.
- Any blank or illegible fields on the Subject Diary must be described as missing in the eCRF.

Case Report Forms

This study utilizes electronic Case Report Forms (eCRFs) to collect study-related data from each subject. A qualified site staff member(s) is required to enter subject data in the eCRFs in English based on the medical information available in each subject's source record.

Data should be entered into the eCRF in a timely fashion following each subject's clinic visit, study procedure, or phone call. Each subject's eCRF casebook will be compared with the subject's source records by a GSK-approved study monitor (or designee) over the duration of the study in order to ensure data collection accuracy.

The following additional rules apply to documentation of Subject Diary information collected in the eCRFs:

- The site must enter all readable entries in the Subject Diary into the eCRF, including those values that may be biologically implausible (e.g. body temperature: 400°C).
- Any illegible or implausible data should be reviewed with the subject and/or parent(s)/legal guardian(s). If an underlying solicited or unsolicited adverse event is

described on review with the subject, this should be described in the source document and reported as an unsolicited adverse event in the Adverse Event eCRF (e.g., if the subject above confirms body temperature of 40°C on the day in which body temperature: 400°C was written into his/her Subject Diary, this fever of 40°C should be recorded in the Adverse Event eCRF).

- Any newly described safety information (including a solicited adverse event) must not be written into the Subject Diary and must be described in the study file as a verbally reported adverse event. Any adverse event reported in this fashion must be described as an unsolicited adverse event and therefore entered on the Adverse Event eCRF.

3.5 Collection of Clinical Specimens

- Collected samples will be used for protocol mandated research and purposes related to the improvement, development and quality assurance of the laboratory tests described in this protocol. This may include the management of the quality of these tests, the maintenance or improvement of these tests, the development of new test methods, as well as making sure that new tests are comparable to previous methods and work reliably.
- It is also possible that future findings may make it desirable to use the samples acquired in this study for future research, not described in this protocol. Therefore, all subjects in countries where this is allowedwill be asked to give a specific consent to allow GSK or a contracted partner to use the samples for future research. Future research will be subject to the laws and regulations in the USAand will only be performed once an independent Ethics Committee or Review Board has approved this research.

Information on further investigations and their rationale can be obtained from GSK.

Any sample testing will be done in line with the consent of the individual subject/subject's parent(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 the table below may be changed.

The following clinical specimens are required to be collected from each subject in this study:

- Blood.

- Urine for pregnancy testing (As per routine practice, specimens will be tested at each site).

Processing of a specimen should be completed by a qualified site member and in accordance with the study-specific Laboratory Manual. Testing of serum specimens will be performed by a GSK or a designated laboratory. Refer to the study-specific Clinical Specimen Laboratory Manual for additional details.

Blood Specimens

Approximately 10 mL sample of blood will be drawn from all subjects at visit Day 1 before vaccination, and at visit Day 4 or Day 6 and visit Day 29. The blood volume will not exceed 10 mL at each time point in order to provide the necessary serum volume (approximately half of the blood draw volume) for the serology assays.

The blood will be used for immunological assays. See section 7, Assessments for additional details.

The total amount of blood collected over the study period per subject will be approximately 30 mL.

Urine Specimens

Urine will be collected for pregnancy testing in females of child bearing potential. Urine will be collected at visit Day 1 before vaccination and the results recorded in the source document and eCRF.

3.6 Stopping/Pausing Guidelines

There are no predetermined stopping rules in this study. Subjects may be withdrawn from the study according to investigator discretion as described in section 3.8, Premature Withdrawal from Study.

3.7 Data Monitoring Committee

No DMC will be utilized for the study.

3.8 Premature Withdrawal from Study

Subjects may withdraw at any time, or be dropped from the study at the discretion of the investigator should any untoward effects occur and/or for safety reasons. In addition, a subject may be withdrawn by the investigator or the Sponsor if he/she violates the study

plan or for administrative reasons. The investigator or study coordinator must notify the Sponsor immediately when a subject has been withdrawn due to an adverse event.

The circumstances above are referred to as premature withdrawal from the study, and the reason for premature withdrawal should be clearly documented and detailed in the source documentation. The investigator should make every attempt to evaluate the subject's safety, including resolution of ongoing AEs, at the time of premature withdrawal. If a subject wants to withdraw from the study before or prior to the last planned study visit, the subject will be asked to be followed for safety for the duration of the study. When a subject withdraws, or is withdrawn, from the study, the procedures described in section 5.5.1, Early Termination Visit should be completed if possible.

The reasons for premature withdrawal from the study include: Adverse event, death, withdrawal of consent, lost to follow-up, administrative reason, and protocol deviation. These reasons are described in greater detail below.

Adverse Event

For any subject withdrawn from study participation prior to the planned Study Termination Visit, it is important to determine if an AE was associated with the reason for discontinuing the study. This AE must be identified on the AE eCRF page by indicating "Withdrawn from study due to AE". Any ongoing AEs at the time of study withdrawal must be followed until resolution or stabilization.

Death

For any subject withdrawn from study participation due to death, this should be noted on the Study Termination eCRF page and the associated SAE that led to the death must be reported.

Withdrawal of consent

The subject and/or parent(s)/legal guardian(s) can withdraw consent for participation in the study at any time without penalty or loss of benefit to which the subject is otherwise entitled. Reason for early termination should be deemed as "withdrawal of consent" if the subject withdraws from participation due to a non-medical reason (i.e., reason other than AE). If the subject and/or parent(s)/legal guardian(s) intends to withdraw consent from the study, the investigator should clarify if the subject will withdraw completely from the study or if the subject will continue study participation for safety, or a subset of other study procedures. If the subject requests complete withdrawal from the study, no further study interventions will be performed with the subject.

If a subject and/or parent(s)/legal guardian(s) withdraws consent but does not revoke the HIPAA authorization, the Sponsor will have full access to the subject's medical records, including termination visit information. If a subject and/or parent(s)/legal guardian(s) revokes only the HIPAA authorization, the Sponsor will have full access to all of the subject's medical records prior to the date and time of written revocation.

Lost to Follow-Up

For subjects who fail to show up for final visits (clinic or telephone contacts), or for three consecutive visits, study staff are encouraged to make at least three documented attempts to contact the subject by telephone and at least one documented written attempt to contact the subject and/or parent(s)/legal guardian(s) to encourage the completion of study termination procedures. These efforts to contact the subject should be recorded in the source document. The termination date for the subject to be captured on the Study Termination eCRF page is the date of the last successful contact (clinic visit or telephone) with the subject.

Administrative Reason

Examples for subjects withdrawn from the study due to administrative reason can include: Sponsor decision to terminate the study, subject discontinuation for insurance issues, moving, no time, etc. This reason should be noted in the Study Termination eCRF page and any ongoing AEs at the time of study withdrawal should be followed until resolution/stabilization, if possible.

If the clinical study is prematurely terminated by the Sponsor, the investigator is to promptly inform the study subjects and local EC/IRB and should assure appropriate therapy and follow up for the subjects. All procedures and requirements pertaining to the archiving of study documents should be followed. All other study materials (study medication/vaccines, etc.) must be returned to the Sponsor.

For subjects who are withdrawn from the study due to receipt of an excluded medication/vaccination or due to significant protocol non-compliance, this reason should be noted in the Study Termination eCRF page.

Protocol Deviation

A protocol deviation is any change, divergence, or departure from the study design or procedures of a study protocol. In general, subjects associated with protocol deviations may remain in the study unless continuation in the study jeopardizes the subject's health, safety, or rights.

Investigators will apply due diligence to avoid protocol deviations. Under no circumstances should the investigator contact GSK or its agents, if any, monitoring the study to request approval of a protocol deviation, as no authorized deviations are permitted. If the investigator feels a change to the protocol would improve the conduct of the study this must be considered a protocol amendment, and unless such an amendment is agreed upon by GSK and approved by the IRB/EC and health authorities it cannot be implemented.

Any subject who becomes pregnant during the study, despite the protocol requirement for adequate contraception should be encouraged to continue participating in the study for safety follow-up only. The site must complete a Pregnancy Report CRF (initial report) as soon as possible after learning of pregnancy occurrence (see section 7.1.6, Pregnancies for further details). If the subject withdraws from the study for any of the above categories except death, the site will obtain permission from the subject to continue to remain in contact with her until the outcome of the pregnancy is known, even if the outcome is not known until after the subject reaches the end of follow-up period.

3.9 End of Study

Most clinical trials intended to support the efficacy/immunogenicity and safety of an Investigational Product proceed to full completion of planned sample size accrual. For the purpose of this protocol, End of Study (EoS) is defined as the date of the last testing/reading released of human biologicals samples, related to primary and secondary end points, to be achieved no later than 8 months after Last Subject Last Visit (LSLV).

If the completion of testing occurs prior the completion of the Last Subject Last Visit (LSLV) the latter date defines the end of study visit.

4. SELECTION OF STUDY POPULATION

4.1 Inclusion Criteria

In order to participate in this study, all subjects must meet ALL of the inclusion criteria described.

1. Individuals of 15 through 55 years of age on the day of informed consent or assent.
2. Individuals who received Menveo 4 to 6 years prior to enrolment at an age of 11 years or older (Menveo-Menveo group)

   OR

   Individuals who received Menactra 4 to 6 years prior to enrolment at an age of 11 years or older (Menactra-Menveo group)

   OR

   Individuals who have not received any previous meningococcal vaccine (Naive group).
3. Individuals who have voluntarily given written informed consent (and/or assent, if applicable) after the nature of the study has been explained according to local regulatory requirements, prior to study entry. If the subject is under age 18 at the time of enrolment, the parent*(s)*/legal guardian*(s)* of the subject should have voluntarily given written informed consent.
4. Individuals who can comply with study procedures including follow-up[1].
5. Males

   Or

   Females of non-childbearing potential[2]

   Or

[1] A subject and/or parent(s)/legal guardian(s) is/are considered to be compliant if the Investigator judges that the subject will complete the Subject Diary and return for all the follow-up visits scheduled in the study.

[2] A female is considered to be of non-childbearing potential prior to menarche and after natural or induced menopause. Natural menopause is recognized to have occurred after 12 consecutive months of amenorrhea for which there is no other obvious pathological or physiological cause. Induced menopause is recognized to have occurred after hysterectomy, after bilateral oophorectomy, or iatrogenic ablation of ovarian function.

Females of childbearing potential who are using an effective birth control method[1] which they intend to use for at least 30 days after the study vaccination.

4.2 Exclusion Criteria

Each subject must not have:

1. History of any meningococcal vaccine administration other than the single vaccination given 4 to 6 years before (Menveo-Menveo and Menactra-Menveo groups)

   OR

   History of any meningococcal vaccine administration (Naive group).
2. Current or previous, confirmed or suspected disease caused by *N. meningitidis*.
3. Household contact with and/or intimate exposure to an individual with any laboratory confirmed *N. meningitidis* infection within 60 days prior to study vaccination.
4. Progressive, unstable or uncontrolled clinical conditions.
5. Hypersensitivity, including allergy, to any component of vaccines, medicinal products or medical equipment whose use is foreseen in this study.
6. Clinical conditions representing a contraindication to intramuscular vaccination (IM) and blood draws.
7. Abnormal function of the immune system resulting from:
   a. Clinical conditions.
   b. Systemic administration of corticosteroids (PO/IV/IM) for more than 14 consecutive days within 90 days prior to study vaccination.
   c. Administration of antineoplastic and immunomodulating agents or radiotherapy within 90 days prior to study vaccination.

[1] The following birth control methods are considered effective:
- Abstinence
- Hormonal contraceptive (such as oral, injection, transdermal patch, implant) if used for at least 30 days prior to informed consent
- Diaphragm preferably with spermicide, tubal occlusion device
- Intrauterine device (IUD)
- Tubal ligation
- Male partner using condom preferably with spermicide
- Male partner having been vasectomized at least six months prior to informed consent

8. Received immunoglobulins or any blood products within 180 days prior to informed consent.
9. Received systemic antibiotic treatment (PO/IV/IM) within 3 days prior to study vaccination or blood draw.
10. Received an investigational or non-registered medicinal product within 30 days prior to study vaccination.
11. Study personnel as an immediate family or household member.
12. Individuals who have received any other vaccines within 7 days (for inactivated vaccines) or 14 days (for live vaccines) prior to vaccination in this study or who are planning to receive any vaccine within 28 days from the study vaccination.
13. Individuals who have experienced a moderate or severe acute infection and/or fever defined as a temperature ≥38°C (100.4°F) within 3 days prior to study vaccination.
14. Any other clinical condition that, in the opinion of the investigator, might pose additional risk to the subject due to participation in the study.

4.3 Criteria for Delay of Vaccination and/or Blood Sampling

There may be instances when individuals meet all eligibility criteria for vaccination yet have a transient clinical circumstance which may warrant delay of vaccination: body temperature elevation [≥38.0° C (≥ 100.4° F) within 3 days prior to intended study vaccination], systemic antibiotic treatment within 3 days prior to study vaccination or blood draw. Under such circumstances, a subject may be considered eligible for study enrolment after the appropriate window for delay has passed and inclusion/exclusion criteria have been rechecked, and if the subject is confirmed to be eligible.

There is a clinical circumstance that warrants delay of blood collection for immunogenicity assessments in this study: subject has received a dose of systemic antibiotics less than 3 days before the intended blood collection. In the event that a subject meets this criterion for delay of blood collection, blood collection may proceed once the window for delay has passed.

5. STUDY PROCEDURES

The sections that follow provide an overview of the procedures that are to be followed in enrolling, evaluating, and following subjects who participate in this clinical study. Visits can be either clinic visits or safety follow-up telephone calls, as specified in the Table below and in the Time and Events Table4.

Table 5-1 Study Procedures

Visit Category	Procedures
Pre-vaccination Clinic Visit(s)	Section 5.1 describes procedures to be followed prior to study vaccination: informed consent/assent, screening, enrolment, and randomization
Vaccination Clinic Visit(s)	Section 5.2 describes procedures to be followed during each clinic visit involving vaccination: vaccination, post-vaccination procedures, and post-vaccination reminders
Post-vaccination Visit(s)	Section 5.3 describes follow-up clinic visits and safety follow-up calls
Unscheduled Visit(s)	Section 5.4 Unscheduled visits are not expected within this protocol.
Study Termination Visit	Section 5.5 describes procedures to be followed at the last study visit for a subject (may include early termination visit)

5.1 Pre-vaccination Clinic Visit(s)

This section describes the procedures that must be performed for each potential subject prior to vaccination, including obtaining informed consent/assent, screening, enrolment and randomization.

5.1.1 Informed Consent/Assent

"Informed consent" is the voluntary agreement of an individual or his/her legal guardian(s) to participate in research. Consent must be given with free will of choice, and without undue inducement. The individual must have sufficient knowledge and understanding of the nature of the proposed research, the anticipated risks and potential benefits, and the requirements of the research to be able to make an informed decision.

"Assent" is a term used to express willingness to participate in research by persons who are by definition too young to give informed consent but who are old enough to

understand the proposed research in general, its expected risks and possible benefits, and the activities expected of them as subjects. Assent by itself is not sufficient, however. If assent is given, informed consent must still be obtained from the subject's parent(s) or legal guardian(s). Local laws define who constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a protocol (Levine 1988).

Informed consent of the parent(s)/legal guardian(s) and assent of subject following local IRB/EC guidance **must** be obtained before conducting any study-specific procedures (i.e., all of the procedures described in the protocol). The process of obtaining informed consent and assent should be documented in the subject source document in addition to maintaining a copy of the signed and dated informed consent. Additional specifics regarding the informed consent and assent processes are located in section 13.2, Informed Consent Procedures.

If a subject and/or parent(s)/legal guardian(s) is unable to read, an impartial witness should be present during the entire informed consent and assent discussion. An impartial witness is defined as a person who is independent from study conduct, who cannot be unfairly influenced by those involved with the study, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject and/or parent(s)/legal guardian(s) and after the subject and/or parent(s)/legal guardian(s) has verbally consented to the subject’s participation in the study and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject and/or parent(s)/legal guardian(s) and that informed consent was freely given by the subject and/or parent(s)/legal guardian(s).

5.1.2 Screening

Subject identification numbers will be assigned sequentially to the subjects who have consented to participate in the study, according to the range of subject identification numbers allocated to each study center. The eligibility of the subject will be determined based on the inclusion and exclusion criteria listed in section 4, Selection of Study Population and evaluated during this screening procedure.

Prior to study enrolment, demographic data will be collected from the subject, including: date of birth, gender, race, ethnicity, prior vaccination against meningitis. Note: Appropriate written documentation of the brand of primary vaccination (Menveo or Menactra) and vaccination date must be provided prior to enrollment.

Medical history will also be collected, including but not limited to any medical history that may be relevant to subject eligibility for study participation such as prior vaccinations, concomitant medications, and previous and ongoing illnesses or injuries. Relevant medical history can also include any medical history that contributes to the understanding of an adverse event that occurs during study participation, if it represents an exacerbation of an underlying disease/pre-existing problem.

Review of systems is a structured interview that queries the subject and/or parent(s)/legal guardian(s) as to any complaints the subject has experienced across each organ system. This will be performed before enrolment and used to guide physical examination.

If applicable, prior and concomitant medications or vaccinations taken prior to start of study should be collected (refer to section 6.5, Prior and Concomitant Medications and Vaccines for further details).

Collect vital signs (heart rate, blood pressure, and temperature (preferably taken orally). Measure height and weight.

Perform pregnancy testing in women of childbearing potential (refer to section 3.5, Collection of Clinical Specimens for additional information)

A general physical examination is to be performed by a qualified health care practitioner. “Qualified health care practitioner” refers to any licensed health care professional who is permitted by institutional policy to perform physical examinations and who is identified within the Study Staff Signature Log.

The data collected through study assessments listed above will be written in the source document (see section 9.1, Source Documentation). Should the physical assessment reveal any abnormal values or events, these must be documented in the CRF Adverse Events Form.

Prior to vaccination, approximately 10 mL of blood will be drawn from all subjects for the immunological testing: see section 3.5, Collection of Clinical Specimens.

In the event that the individual is determined ineligible for study participation, he/she is considered a screen failure. The reason for screen failure must be documented in the Screening and Enrolment log. If the individual is determined to be eligible for the study, he/she will be enrolled into the study.

5.1.3 Enrolment

After signing the informed consent, if an individual is determined to be eligible for study participation, the investigator will enroll the subject and enter the subject information into randomization system, Source Data Base for Internet Randomization (SBIR).

5.1.4 Randomization

5.1.4.1 Randomization of supplies

The randomization of supplies within blocks will be performed at GSK, using MATerial EXcellence (MATEX), a program developed for use in Statistical Analysis System (SAS®) (Cary, NC, USA) by GSK. Entire blocks will be shipped to the study centre.

5.1.4.2 Study group and treatment number allocation

Enrolled subjects will be randomized in the SBIR system to one of two different blood draw schedules according to a 1:1 ratio, described as follows:

- Subjects getting blood draws at Day 1, Day 4 and Day 29.
- Subjects getting blood draws at Day 1, Day 6 and Day 29.

Allocation of the subject to a blood draw schedules at the investigator site will be performed using a central randomization system on internet (SBIR).

The randomization algorithm will use a minimization procedure accounting for the previous vaccination status (Menveo, Menactra or Vaccine-Naïve study group).

For each dose, the study staff in charge of vaccine administration will access SBIR, provide the subject ID, and the system will provide a treatment number consistent with the allocated treatment arms.

SBIR will also be used to ensure adequate and appropriate distribution of enrolment of naive subjects across all sites.

For any question regarding SBIR, please refer to the SBIR user guide and SBIR Manual for specific instructions. If for any reason, after signing the informed consent form (ICF), the subject who is eligible and enrolled fails to be randomized, this is called a randomization failure and the early termination study procedures must be applied. The reason for all randomization failures should be recorded in the Screening and Enrolment Log and in the source document as specified in the Source Documentation Agreement Form (SDAF). The information on subjects who are randomization failures should be

kept distinct from subjects who are screen failures, as described in section 5.1.2, Screening.

If for any reason, after enrolment the subject fails to undergo treatment/study procedures this is an Early Termination and the reason should be recorded in source document as specified in the Source Documentation Agreement (SDAF). The information on these Early Termination subjects should be kept distinct in the source documentation from subjects who are screen failures, as described in section 5.1.2, Screening.

5.2 Vaccination Clinic Visit

The first vaccination will be performed on Day 1.

For studies which have visits for concomitant vaccinations or treatments, see section 6.5, Prior and Concomitant Medications and Vaccines for those visit procedures.

Ensure all blood samples are taken **prior** to the vaccination.

After completing the pre-vaccination procedures on day 1, administer the vaccine to the subject according to the procedures described in section 6.3, Vaccine Preparation and Administration. Observe the blinding procedures described in section 3.3, Blinding Procedures.

Prior to administration of study vaccination, confirm that the subject does not meet any criteria for delaying additional study vaccinations as described in section 4, Selection of Study Population.

5.2.1 Post-vaccination Procedures

The following post-vaccination procedures will be performed on day 1.

- After vaccination, the subject will be observed for at least 30 minutes including observation for unsolicited adverse events, solicited adverse events, and body temperature measurement. Record all safety data collected during this time in the subject's source document.
- A Subject Diary will be used in this study to document solicited adverse events. The Subject Diary is the only source for collection of these data; therefore, it is critical that the subject completes the Subject Diary correctly. The subject should be trained on how and when to complete each field of the Subject Diary.
- The subject and/or parent(s)/legal guardian(s) should be trained on how to self-measure local solicited adverse events. The measurement of solicited local adverse events is to be performed using the ruler provided by the site.

- The subject and/or parent(s)/legal guardian(s) should be instructed how to perform body temperature measurement using the thermometer provided by the site. If the subject feels unusually hot or cold during the day, the subject and/or parent(s)/legal guardian(s) should check body temperature. If the subject has fever, the highest body temperature observed that day should be recorded in the Subject Diary.

Subject Diary training should be directed at the individual(s) who will perform the measurements of adverse events and who will enter the information into the Subject Diary. This individual may not be the subject and/or parent(s)/legal guardian(s), but if a person other than the subject and/or parent(s)/legal guardian(s) enters information into the Subject Diary, this person's identity must be documented in the Subject Diary or subject's source record. Any individual that makes entries into the Subject Diary must receive training on completion of the Subject Diary at the time of the visit. This training must be documented in the subject's source record.

The same individual should complete the Subject Diary throughout the course of the study.

- The site should schedule the next study activity clinic visit on Day 4 or Day 6 depending to which blood draw schedule subject was randomized to with the subject and/or parent(s)/legal guardian(s).

The subject and/or parent(s)/legal guardian(s) will be reminded to complete the Subject Diary and to contact the site if there are any questions, and to contact the site immediately (or as soon as the subject is medically stable) if the subject has a medical condition that leads to a hospitalization or an emergency room visit or to a visit to/by a doctor or is of concern.

5.2.2 Post-vaccination Reminders

Reminder calls or alerts are not intended to be an interview for collection of safety data. If the subject and/or parent(s)/legal guardian(s) wishes to describe safety information, this information should only be collected by a healthcare professional at the site, and the safety data described must be written down in the subject's medical chart.

Subject Diary Reminder Calls

Subject Diary reminder calls will be performed on day 3 and day 5. The purpose of this call is to remind the subject and/or parent(s)/legal guardian(s) about completion of the Subject Diary. The call follows the Subject Diary Reminder Telephone Call Script provided to the site. The subject and/or parent(s)/legal guardian(s) should be reminded to contact the site via the telephone number provided in the informed consent to discuss

medical questions. If the clinic visit at Day 4 or Day 6 overlaps with the specified window of the Day 3 or Day 5 reminder call, the Day 3/Day 5 reminder call may be omitted.

5.3 Post-vaccination Visit(s)

Post-vaccination visits will be performed on Day 4 or Day 6 according to the blood draw schedule to which subject was randomized and Day 29.

5.3.1 Follow-up Clinic Visit(s)

Follow-up clinic visits will be performed on Day 4 or Day 6 according to the blood draw schedule to which subject was randomized and on Day 29. During the follow-up clinic visit:

- Subject Diary will be reviewed at Day 29. No changes to the information recorded within the Subject Diary are permissible. For details on the Subject Diary see sections 3.4.2, Tools Used for Data Collection and 5.2.1, Post-vaccination Procedures. The subject and/or parent(s)/legal guardian(s) will be interviewed to determine if any unsolicited adverse events occurred and if any concomitant medications or vaccines were taken/received in the time since the last clinic visit. This interview will follow a script which will facilitate the collection of relevant safety information. The healthcare professional reviewing these data will discuss the symptoms (if any) reported by the subject and will determine if any additional diagnoses and/or adverse events are present. Adverse events reported by the subject and/or parent(s)/legal guardian(s) at this follow-up clinic visit must be recorded in the subject's source document and on an Adverse Events CRF, as specified in section 7.1, Safety Assessment, and not written on the script used for the interview.
- Perform a brief symptom-directed physical examination if necessary according to symptoms the subject has reported. This is a physical examination that will include an examination of organ systems that are relevant to the investigator based on review of the subject's reported adverse events and concomitant medication use. This assessment may include: measurement of vital signs, body temperature and a check of general appearance. The physical assessment must be performed by the investigator or designee of the investigator, who is qualified to perform a physical assessment in accordance with their institutional policy. Corresponding information is documented in the subject's source document and CRF(s).
- Collect a blood sample (see section 3.5, Collection of Clinical Specimens for additional information).

The site should schedule the next study activity safety call with the subject and/or parent(s)/legal guardian(s).

The subject and/or parent(s)/legal guardian(s) will receive a written reminder of the next planned study activity. The subject and/or parent(s)/legal guardian(s) will be reminded to contact the site if there are any questions and to contact the site immediately (or as soon as the subject is medically stable) if the subject has a medical condition that leads to a hospitalization or an emergency room visit.

5.3.2 Safety Follow-up Calls

Safety follow-up call will be performed on Day 15, Day 91 and Day 181.

Safety follow-up calls are calls made to the subject by a healthcare professional designated on the site log. These calls will follow a script which will facilitate the collection of relevant safety information. The subject and/or parent(s)/legal guardian(s) will be interviewed according to the script, and information related to unsolicited adverse events (only at Day 15), serious adverse events (SAEs), medically attended adverse events, AEs leading to withdrawal and concomitant medications or vaccinations associated with those events will be reviewed. All safety information described by the subject must be written down in a designated location within the source document and not written on the script used for the telephone call.

The site should schedule the next study activity with the subject and/or parent(s)/legal guardian(s).

The subject and/or parent(s)/legal guardian(s) will be reminded to contact the site if there are any questions and to contact the site immediately (or as soon as the subject is medically stable) if the subject has a medical condition that leads to a hospitalization or an emergency room visit.

5.4 Unscheduled Visits

Unscheduled visits are not expected within this protocol.

5.5 Study Termination Visit

The study termination visit will occur on Day 181. The termination visit will be a telephone call. The date of termination is the date of the last contact (clinic visit or telephone call) in which the subject's health status was assessed or, in cases where the subject does not agree to any further safety follow-up, it is the date consent is withdrawn. This date should be recorded on the termination CRF page. For visit procedures to be performed for a subject whose planned study participation ends prematurely, please see section 5.5.1, Early Termination Visit.

During the telephone call, the following procedures will be performed: interview of subject and/or parent(s)/legal guardian(s) to collect medically attended adverse events, AEs leading to withdrawal, SAEs, as well as interview of subject and/or parent(s)/legal guardian(s) to collect concomitant medications/ vaccinations associated with those events. All safety information described by the subject must be written down in a designated location within the source document and not written on the script used for the telephone call.

The site will review with the subject and/or parent(s)/legal guardian(s) the plan of when information relating to the subject's participation in the study may be available (e.g., study results, treatment assignments). It will also be discussed how information relating to the subject's participation in the study will be shared with the subject's healthcare provider, if the subject and/or parent(s)/legal guardian(s) chooses to share this information.

The site will complete the termination CRF page, and this will mark the completion of the subject's participation in the study.

5.5.1 Early Termination Visit

When a subject is withdrawn from treatment or withdraws from the study, the investigator will notify the Sponsor and, when possible, will perform the procedures listed below. The reason(s) for the early termination will be included in the subject's source documentation. If the Early Termination Visit is a telephone call, collect as much information as possible. Early Termination Visits include subjects who were randomized but not treated.

At the clinic visit or during the telephone call, the following procedures will be performed: interview of subject and/or parent(s)/legal guardian(s) to collect adverse events, medically attended adverse events, AEs leading to withdrawal, SAEs, interview of subject and/or parent(s)/legal guardian(s) to collect concomitant medications/ vaccinations.

The site will review with the subject and/or parent(s)/legal guardian(s) the plan of when information relating to the subject's participation in the study may be available (e.g., study results, treatment assignments). It will also be discussed how information relating to the subject's participation in the study will be shared with the subject's healthcare provider, if the subject and/or parent(s)/legal guardian(s) chooses to share this information.

The site will complete the termination CRF page and this will mark the completion of the subject's participation in the study.

6. TREATMENT OF SUBJECTS

All vaccines associated with this study are to be stored separately from other vaccines and medications in a secure location under appropriate storage conditions with temperature monitoring. **All vaccines associated with this study must be checked for expiration date prior to use. Expired vaccines must not be administered to subjects.**

6.1 Study Vaccine(s)

The term 'study vaccine' refers to those vaccines provided by the Sponsor, which will be evaluated as part of the study objectives. The study vaccines specific to this study are described below. The study vaccines specific to this study is the MenACWY-CRM vaccine (Menveo®, GSK Biologicals).

The Meningococcal ACWY conjugate vaccine is obtained by extemporaneous mixing just before injection of the lyophilized MenA-CRM component with the MenCWY-CRM full liquid vaccine. The pharmaceutical form is Powder and solution for solution for injection. Menveo® is provided as vial/vial presentation. MenA lyophilised conjugate component (glass vial) and MenCWY liquid conjugate component (glass vial). After reconstitution, MenACWY-CRM will have the following composition per 0.5 mL of injectable solution (See Table 6.1-1):

Table 6.1-1: MenACWY-CRM Composition

Name of Ingredient	Unit and/or Percentage Formula (Dose 0.5 mL)
Drug Substances	
CRM_{197}-MenA conjugate	10 µg MenA, 16.7 – 33.3 µg CRM_{197}
CRM_{197}-MenC conjugate	5 µg MenC, 7.1 - 12.5 µg CRM_{197}
CRM_{197}-MenW conjugate	5 µg MenW, 3.3 – 8.3 µg CRM_{197}
CRM_{197}-MenY conjugate	5 µg MenY, 5.6 – 10 µg CRM_{197}
Sodium chloride	4.5 mg
Excipients	
Sucrose	12.5 mg
Sodium phosphate buffer Sodium dihydrogen phosphate Disodium hydrogen phosphate dehydrate	10 mM 2.5 mM 7.5mM
Potassium dihydrogen phosphate	5 mM
Water for Injection	q.s 0.5 mL
Volume of Formulation	0.6 mL

Name of Ingredient	Unit and/or Percentage Formula (Dose 0.5 mL)
Appearance	Colorless to light yellow
Vaccine Presentation	A single dose of two vials

One 0.5 mL dose of MenACWY will be administered by intramuscular (IM) injection in the deltoid area of non-dominant arm (preferably).

For more detailed information, refer to the latest version of Investigator Brochure and SPC for Menveo®, which are included in the investigator site file.

6.2 Non-Study Vaccines

Not applicable.

6.3 Vaccine Preparation and Administration

The investigator or designee will be responsible for oversight of the administration of vaccine to subjects enrolled in the study according to the procedures stipulated in this study protocol. All vaccines will be administered only by personnel who are qualified to perform that function under applicable local laws and regulations for the specific study site.

All study vaccines to be administered to the subjects must be stored in a safe and locked place with no access by unauthorized personnel.

The study vaccines will be stored at the defined temperature range (i.e. +2 to +8 C). The storage temperature of the vaccines will be monitored daily with temperature monitoring devices and will be recorded.

Any temperature deviation, i.e. temperature outside the range (+2 to +8°C), must be reported to the sponsor as soon as detected. Following the exposure to such a temperature deviation, vaccines will not be used until written approval has been given by the sponsor.

The study vaccine should be allowed to reach room temperature before administration, according to local vaccination practice.

MenACWY-CRM (Menveo) vaccine is prepared by aseptically withdrawing all fluid from the vial containing the MenCWY-CRM liquid conjugate component and injecting the liquid into the vial containing the MenA-CRM lyophilized portion. Invert and shake the vial well until the vaccine is dissolved. The final mixed vaccine is then ready for administration of the MenACWY formulation (0.5 mL/dose of injectable solution).

Detailed vaccine preparation and administration instructions will be provided to investigators in the Clinical Trials Supply Manual prior to study start.

PRECAUTIONS TO BE OBSERVED IN ADMINISTERING STUDY VACCINE:

Prior to vaccination, subjects must be determined to be eligible for study vaccination and it must be clinically appropriate in the judgment of the investigator to vaccinate. Eligibility for vaccination prior to first study vaccine administration is determined by evaluating the entry criteria outlined in protocol sections 4.1, Inclusion Criteria and 4.2, Exclusion Criteria.

Eligibility for non-study vaccines should be determined by the investigator, pending the review of the package insert of the relevant vaccine.

Study vaccines should not be administered to individuals with known hypersensitivity to any component of the vaccines.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from fainting.

Standard immunization practices are to be observed and care should be taken to administer the injection intramuscularly. Before administering vaccine, the vaccination site is to be disinfected with a skin disinfectant (e.g., 70% alcohol). Allow the skin to dry. **DO NOT inject intravascularly**.

As with all injectable vaccines, trained medical personnel and appropriate medical treatment should be readily available in case of anaphylactic reactions following vaccine administration. For example, epinephrine 1:1000, diphenhydramine, and/or other medications for treating anaphylaxis should be available.

6.3.1 Replacement of unusable vaccines

In addition to the vaccine doses provided for the planned number of subjects (including extra doses to allow flexibility in enrolment at the different sites), at least 15% additional vaccine doses will be supplied to replace those that are unusable.

6.4 Vaccine Administration Error or Overdose of Vaccine

Vaccine administration error is defined as receiving a dose of study vaccine that was not reconstituted as instructed or administered by a different route from the intended route of administration. An overdose of study vaccine (whether accidental or intentional) is

defined when a dosage higher than the recommended dosage is administered in one dose of study vaccine.

6.5 Prior and Concomitant Medications and Vaccines

All medications, vaccines and blood products taken or received by the subject within 30 days prior to the start of the study are to be recorded on the Prior and Concomitant Medications CRF.

In addition, the following are considered prior medications for this protocol: all medication/vaccines described in the inclusion and exclusion criteria of this protocol including:

- Systemic administration of corticosteroids (PO/IV/IM) for more than 14 consecutive days within 90 days prior to study vaccination;
- Administration of antineoplastic and immunomodulating agents or radiotherapy within 90 days prior to study vaccination;
- Immunoglobulins or any blood products within 180 days prior to informed consent;
- Systemic antibiotic treatment within 3 days prior to study vaccination or blood draw;
- Any investigational or non-registered medicinal product within 30 days prior to study vaccination;
- Administration of vaccines within 7 days (for inactivated vaccines) or 14 days (for live vaccines) prior to vaccination in this study or who are planning to receive any vaccine within 28 days from the study vaccination.

Use of analgesics/antipyretics to prevent or treat solicited AEs will be captured in the Subject Diary from day 1-7 following each vaccination. Medications taken for prophylaxis are those intended to prevent the onset of symptoms. Medications taken for treatment are intended to reduce or eliminate the presence of symptoms that are present.

Concomitant medications include all prescription and non-prescription medications (including vaccines) taken by/administered to the subject during the 30 days after study vaccination and must be documented on the Concomitant Medications CRF. Mineral supplements and vitamins are not considered concomitant medications.

When recording concomitant medications/vaccines, they should be checked against the study entry and continuation criteria in section 4, Selection of Study Population to ensure that the subject should be enrolled/continue in the study.

Concomitant medication administered for treatment of AEs with medically-attended visits, AEs leading to study withdrawal and SAEs must be documented during the entire study period.

Any vaccine not foreseen in the study protocol in the period starting at Day 1 and ending at Day 181 must be recorded in the eCRF.

6.6 Vaccine Supply, Labeling, Storage and Tracking

Detailed vaccine supply, labeling, storage and tracking instructions will be provided to investigators in the Clinical Trials Supply Manual prior to study start.

7. ASSESSMENTS

7.1 Safety Assessment

The measures of safety used in this study are routine clinical procedures. They include a close vigilance for, and stringent reporting of, selected local and systemic adverse events routinely monitored in vaccine clinical studies as indicators of reactogenicity.

An adverse event (AE) is defined as any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product at any dose that does not necessarily have to have a causal relationship with this treatment. Therefore, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of an investigational product, whether or not considered related to the investigational product. This definition includes intercurrent illnesses or injuries and exacerbation of pre-existing conditions.

The period of observation for AEs extends from the time the subject signs informed consent until he or she completes the specified safety follow-up period of 180 days or terminates the study early (whichever comes first). AEs occurring after the informed consent form is signed but prior to receiving study vaccine/product will be documented as an adverse event and recorded within source document. However, any AEs occurring prior to receipt of any study vaccine will be analyzed separately from "treatment emergent" AEs (AEs occurring after administration of the first study vaccine).

Adverse events are collected as either solicited or unsolicited adverse events. Solicited events are derived from organized data collection systems, such as Subject Diaries.

7.1.1 Solicited Adverse Events

The term "reactogenicity" refers to solicited signs and symptoms ("solicited adverse events") occurring in the hours and days following a vaccination, to be collected by the subject and/or parent(s)/legal guardian(s) for 7 consecutive days, using a pre-defined Subject Diary.

The following solicited adverse events are included in the Subject Diary. Each adverse event is to be assessed using the scoring system reported in parentheses below:

Solicited Local Adverse Events

Injection site pain, erythema, induration

Solicited Systemic Adverse Events

Fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills, and fever.

Table 7.1.1-1 Severity grading for solicited local and systemic AEs

	Mild	Moderate	Severe
Pain	No interference with daily activity	Interferes with daily activity	Prevents daily activity
Erythema	25-50mm	51-100mm	> 100 mm
Induration	25-50 mm	51-100 mm	> 100 mm
Fatigue	No interference with daily activity	Interferes with daily activity	Prevents daily activity
Headache	No interference with activity	Interferes with daily activity	Prevents daily a activity
Myalgia	No interference with activity	Interferes with daily activity	Prevents daily activities
Arthralgia	No interference with activity	Interferes with daily activity	Prevents daily activity
Loss of appetite	Eating less than usual with no effect on normal activity	Eating less than usual / interfered with normal activity	Not eating at all
Nausea	No interference with daily activity	Interferes with daily activity	Prevents daily activity
Chills	No interference with activity	Interferes with daily activity	prevents daily activity

Fever is defined and measured by a body temperature ≥ 38.0°C (100.4°F). Route of temperature measurement is preferably oral.

Other Indicators of Reactogenicity:

- Use of analgesics / antipyretics for prophylaxis (Days 1-7)
- Use of analgesics / antipyretics for treatment (Days 1-7)
- Body temperature, described in degrees Celsius and summarized by route of measurement and in 0.5°C increments from ≥36.0°C.

The study staff must review the data entered into the Subject Diary as described in section 3.4.2, Tools Used for Data Collection and section 5.3.1, Follow-up Clinic Visit(s).

Note: Any solicited adverse event that meets any of the following criteria must be entered into subjects' source document (see section 9.1, Source Documentation) and also as an adverse event on the Adverse Event CRF:

- Solicited local or systemic adverse event that continues beyond day 7 after vaccination.
- Solicited local or systemic adverse event that leads to a visit to a healthcare provider (medically attended adverse event, see section 7.1.3, Evaluation of Adverse Events).
- Solicited local or systemic adverse event leading to the subject withdrawing from the study or the subject being withdrawn from the study by the investigator (adverse event leading to withdrawal, see section 7.1.3, Evaluation of Adverse Events).
- Solicited local or systemic adverse event that otherwise meets the definition of a serious adverse event (see section 7.1.4, Serious Adverse Events).

7.1.2 Unsolicited Adverse Events

An unsolicited adverse event is an adverse event that was not solicited using a Subject Diary and that was spontaneously communicated by a subject and/or parent(s)/legal guardian(s) who has signed the informed consent.

Potential unsolicited AEs may be medically attended (defined as symptoms or illnesses requiring hospitalization, or emergency room visit, or visit to/by a health care provider), or were of concern to the subject and/or parent(s)/legal guardian(s). In case of such events, subjects and/or parent(s)/legal guardian(s) will be instructed to contact the site as soon as possible to report the event(s). The detailed information about the reported unsolicited AEs will be collected by the qualified site personnel during the interview and will be documented in the subject's records.

Unsolicited AEs that are not medically attended nor perceived as a concern by subjects and/or parent(s)/legal guardian(s) will be collected during interview with the subject [and/or parent(s)/legal guardian(s) and by review of available medical records at the next visit (see section 5.3, Post-vaccination Visit(s)).

7.1.3 Evaluation of Adverse Events

Adverse events, reported at a clinic visit or at a scheduled safety call, should be recorded in the eCRF verbatim, as reported by the subject.

The severity of events reported on the Adverse Events CRF will be determined by the investigator as:

Mild: transient with no limitation in normal daily activity.
Moderate: some limitation in normal daily activity.
Severe: unable to perform normal daily activity.

The relationship of the study treatment to an AE will be determined by the investigator based on the following definitions:

1. Not Related

The AE is not related to an investigational vaccine if there is evidence that clearly indicates an alternative explanation. If the subject has not received the vaccine, the timing of the exposure to the vaccine and the onset of the AE are not reasonably related in time, or other facts, evidence or arguments exist that reasonably suggest an alternative explanation, then the AE is not related.

2. Possibly Related

The administration of the investigational vaccine and AE are considered reasonably related in time and the AE could be explained by exposure to the investigational vaccine or by other causes.

3. Probably Related

Exposure to the investigational vaccine and AE are reasonably related in time and no alternative explanation has been identified.

The relationship of the study treatment to an unsolicited AE will be determined by the investigator.

Note: solicited AEs will not be evaluated for relationship to study treatment. Grading for severity of solicited local and systemic AEs is described in section 7.1.1, Solicited Adverse Events.

Adverse events will also be evaluated by the investigator for the co-existence of any of the other following conditions:

- "Medically attended adverse event": an adverse event that leads to a visit to a healthcare provider.
- AEs leading to withdrawal: adverse events leading to study or vaccine withdrawal.

If solicited or unsolicited adverse events have been reported and the subject and/or parent(s)/legal guardian(s)] indicated that the symptoms required medical attendance or were of concern, the subject and/or parent(s)/legal guardian(s) must be contacted for further information.

When the subject and/or parent(s)/legal guardian(s) is contacted for any of these reasons, the contact must be documented in the subject's source documentation.

All AEs, regardless of severity, will be monitored until resolution or until the investigator assesses them as chronic or stable. All subjects experiencing AEs - whether considered associated with the use of the study vaccine or not - must be monitored until symptoms subside and any abnormal laboratory values have returned to baseline, or until there is a satisfactory explanation for the changes observed, or until death, in which case a full pathologist's report should be supplied, if possible. The investigator's assessment of ongoing Adverse Events at the time of each subject's last visit should be documented in the subject's medical chart.

7.1.4 Serious Adverse Events

A serious adverse event (SAE) is defined as any untoward medical occurrence that at any dose results in one or more of the following:

- Death.
- Is life-threatening (i.e., the subject was, in the opinion of the investigator, at immediate risk of death from the event as it occurred); it does not refer to an event which hypothetically might have caused death if it were more severe.
- Required or prolonged hospitalization.
- Persistent or significant disability/incapacity (i.e., the event causes a substantial disruption of a person's ability to conduct normal life functions).
- Congenital anomaly/or birth defect.
- An important and significant medical event that may not be immediately life threatening or resulting in death or hospitalization but, based upon appropriate medical judgment, may jeopardize the subject or may require intervention to prevent one of the other outcomes listed above.

Adverse events which do not fall into these categories are defined as non-serious.

It should be noted that a severe adverse event need not be serious in nature and that a serious adverse event need not, by definition, be severe.

Serious adverse events will be captured both on the Vaccines Serious Adverse Event (VSAE) form as well as on the AE CRF. All SAEs will be evaluated by the investigator for relationship of the event to study vaccine. SAEs that are judged to be possibly or probably related to the study vaccine should be reported to the Sponsor as related events.

The relationship of the study treatment to an SAE will be determined by the investigator based on the following definitions:

1. Related

The SAE is judged by the investigator to be possibly or probably related to the study vaccine on the AE CRF page (see section 7.1.3, Evaluation of Adverse Events).

2. Not Related

The SAE is not related if exposure to the study vaccine has not occurred, **or** the occurrence of the SAE is not reasonably related in time, **or** the SAE is considered unlikely to be related to use of the study vaccine, i.e., there are no facts (evidence) or arguments to suggest a causal relationship.

The relationship of the study vaccine to an SAE will be determined by the investigator.

In addition, SAEs will be evaluated by the Sponsor or designee for "expectedness." An unexpected AE is one that is not listed in the current Summary of Product Characteristics or the Investigator's Brochure or an event that is by nature more specific or more severe than a listed event.

In addition, a pre-existing event or condition that results in hospitalization should be recorded on the Medical History CRF. If the onset of an event occurred before the subject entered the study (e.g., any pre-planned hospitalization for conditions like cosmetic treatments or for non-emergency routine visits for a pre-existing condition), the hospitalization would not lead to an AE being classified as serious unless, in the view of the investigator, hospitalization was prolonged as a result of participation in the clinical study or was necessary due to a worsening of the pre-existing condition.

7.1.4.1 Adverse Events of Special Interest

Adverse Events of Special Interest (AESIs) will not be assessed during the study.

7.1.5 Methods for Recording Adverse Events and Serious Adverse Events

Findings regarding Adverse Events must be reported on an Adverse Events CRF, as specified in section 7.1.1, Solicited Adverse Events, and on the VSAE form, if applicable,

which is part of the Investigator Site File. All findings in subjects experiencing AEs must be reported also in the subject's source document.

All SAEs which occur during the course of the study, whether considered to be associated with the study vaccination or not, must be reported **within 24 hours of the site becoming aware of the event** to GSK or its designee. Specific instructions and contact details for collecting and reporting SAEs to GSK will be provided to the investigator. Specifically, once an investigator becomes aware that a SAE has occurred in a study subject, the investigator (or designate) must complete a paper expedited Adverse Events report and forward it to GSK WITHIN 24 HOURS. The report will always be completed as thoroughly as possible with all available details of the event and then dated and signed by the investigator (or designate). Even if the investigator does not have all information regarding a SAE, the report should still be completed and forwarded to GSK within 24 hours. Once additional relevant information is received, the report should be updated and forwarded to GSK WITHIN 24 HOURS. The investigator will always provide an assessment of causality at the time of the initial report. All SAEs are also to be documented on the Adverse Events CRF. Any medication or other therapeutic measures used to treat the AE will be recorded on the appropriate CRF(s) in addition to the outcome of the AE.

After receipt of the initial report, representatives of GSK or its designee will contact the investigator if it is necessary to obtain further information for assessment of the event. Of note, 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, and within 2 weeks for pregnancies).

All SAEs must be reported by the investigator to his/her corresponding EC/ IRB applicable regulatory authorities in accordance with institutional policy/regulatory requirements and adequate documentation of this notification must be provided to the Sponsor.

GSK or its designee must also comply with the applicable regulatory requirement(s) related to the reporting of suspected unexpected serious adverse vaccine reactions (also known as SUSARs) to the regulatory authority(ies) and the IRB/EC. If a SUSAR or other safety signal relating to use of one of the study vaccines is reported to GSK or its designee, the Sponsor will communicate the information to the investigator and the investigator will be responsible for submitting this information to the EC/IRB and other relevant authorities.

7.1.5.1 Post-Study Events

Any SAE that occurs outside of the protocol-specified follow-up period and considered to be caused by the study vaccine must be reported to GSK or its designee. These SAEs will be processed by GSK or its designee as during the course of the study, until 1 month after Last Subject Last Visit (LSLV). Instructions and contact details for collecting and reporting these suspected SAEs will be provided to the investigator.

7.1.6 Pregnancies

To ensure subjects' safety, each pregnancy in a subject after study vaccination must be reported to GSK or delegate in due time of the site learning of its occurrence. If the subject agrees to submit this information, the pregnancy must be followed to determine outcome, including spontaneous or voluntary termination, details of the birth, and the presence or absence of any birth defects, congenital abnormalities, or maternal and/or newborn complications. This follow-up should occur even if intended duration of safety follow-up for the study has ended.

Pregnancy data must be recorded on a Pregnancy Report CRF (initial report) and Pregnancy Follow-Up CRF (outcome report) and reported to GSK or delegate. Instructions and contact details for submitting the Pregnancy CRFs will be provided to the investigator.

Any pregnancy outcome meeting the definition of a SAE (see section 7.1.4, Serious Adverse Events) must also be reported on the VSAE Report Form. The following should always be considered as SAE.

- Spontaneous pregnancy loss, including:
  - spontaneous abortion, (spontaneous pregnancy loss before/at 22 weeks of gestation)
  - ectopic and molar pregnancy
  - still birth (intrauterine death of foetus after 22 weeks of gestation).

  Note: the 22 weeks cut-off in gestational age is based on WHO-ICD 10 noted in the EMA Guideline on pregnancy exposure. It is recognized that national regulations might be different.
- Any early neonatal death (i.e. death of a live born infant occurring within the first 7 days of life).
- Any congenital anomaly or birth defect (as per the Metropolitan Atlanta Congenital Defects Program (**Error! Reference source not found.**) guidelines) identified in the offspring of a study subject (either during pregnancy, at birth or later) regardless of

whether the foetus is delivered dead or alive. This includes anomalies identified by prenatal ultrasound, amniocentesis or examination of the products of conception after elective or spontaneous abortion.

7.1.7 Safety Laboratory Measurements

No safety laboratory measurements will be done in this study.

7.2 Efficacy Assessment

This section is not applicable. This study has no efficacy measurements.

7.3 Immunogenicity Assessment

The functional measure of immunogenicity used in this study, Serum Bactericidal Assay (SBA), is a measure of the ability of antibodies, in concert with human complement, to kill meningococci, and is widely used and generally recognized as the serological correlate of protection. The key measures of immunogenicity will be the percentages of subjects with seroresponse [1], percentages of subjects who achieve hSBA titers ≥8 and, and the hSBA GMTs against serogroups A, C, W and Y reference strains

These measurements will be assessed in serology samples collected at Visit Day 1, 4 or 6 and Day 29. The measures of immunogenicity used in this study are standard, i.e., widely used and generally recognized as reliable, accurate, and relevant (able to describe the quality and extent of the immune response).

All subjects will have a blood draw at Day 1, before vaccination. Subsequent blood draws will be at either Day 4 or Day 6 post vaccination, and at Day 29 post vaccination.

Testing will be conducted by qualified and certified laboratories. All assays will be performed in GSK Clinical Laboratory Sciences or delegate laboratory, as provided in the protocol ancillary document.

[1] Seroresponse is defined for this study as follows: Seroresponse to N. meningitidis serogroups A, C, W and Y is defined as: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

8. STATISTICAL CONSIDERATIONS

8.1 Endpoints

8.1.1 Primary Endpoint(s)

8.1.1.1 Primary Safety Endpoint(s)

There are no primary safety endpoints in this study.

8.1.1.2 Primary Efficacy Endpoint(s)

There are no primary efficacy endpoints in this study.

8.1.1.3 Primary Immunogenicity Endpoint(s)

The following measure will be summarized for the Menveo-Menveo and Menactra-Menveo groups:

1. Percentage of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 29.

8.1.2 Secondary Endpoint(s)

8.1.2.1 Secondary Safety Endpoint(s)

Safety of the study vaccine will be assessed in the Menveo-Menveo, Menactra-Menveo, Naive and the pooled (Menveo-Menveo and Menactra-Menveo) groups in terms of the frequencies (percentages) of reported adverse events including:

1. Any unsolicited AEs reported within 30 minutes after vaccination;
2. Solicited local and systemic AEs reported from Day 1 (6 hours) through Day 7 after vaccination;
3. Other indicators of reactogenicity (e.g. use of analgesics / antipyretics, body temperature) within 7 days after vaccination;
4. All unsolicited AEs reported from Day 1 through Day 29 after vaccination;

[1] Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.titers.

5. Medically-attended AEs, AEs leading to withdrawal and SAEs reported from Day 1 through Day 181 (entire study period).

Adverse events will be coded using MedDRA preferred terms as applicable.

8.1.2.2 Secondary Efficacy Endpoint(s)

There are no secondary efficacy endpoints in this study.

8.1.2.3 Secondary Immunogenicity Endpoint(s)

The following measures will be summarized for Menveo-Menveo, Menactra-Menveo, Naive and the pooled (Menveo-Menveo and Menactra-Menveo) groups:

1. Percentage of subjects with hSBA titer ≥8 and ≥16 against *N. meningitidis* serogroups A, C, W and Y at Day 1, Day 4, Day 6 and Day 29 and between-group differences;
2. Percentages of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 4, Day 6 and Day 29 and between-group differences;
3. hSBA GMTs against *N. meningitidis* serogroup A, C, W and Y at Day 1, Day 4, Day 6 and Day 29;
4. Ratios of hSBA GMTs at Day 1, Day 4, Day 6 and Day 29 (between study groups).
5. hSBA Geometric Mean Ratios (GMRs) at Day 4, Day 6, and Day 29 compared to Day 1 (within study groups).

8.1.3 Exploratory Endpoint(s)

8.1.3.1 Exploratory Safety Endpoint(s)

There are no exploratory safety endpoints in this study.

8.1.3.2 Exploratory Efficacy Endpoint(s)

There are no exploratory efficacy endpoints in this study.

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[1] Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

8.1.3.3 Exploratory Immunogenicity Endpoint(s)

There are no exploratory immunogenicity endpoints in this study.

8.2 Success Criteria

8.2.1 Success Criteria for Primary Objective(s)

8.2.1.1 Success Criteria for Primary Safety Objective(s)

There are no primary safety objectives in this study.

8.2.1.2 Success Criteria for Primary Efficacy Objective(s)

There are no primary efficacy objectives in this study.

8.2.1.3 Success Criteria for Primary Immunogenicity Objective(s)

To demonstrate immune response sufficiency after MenACWY-CRM booster vaccine administration, the lower limit of the one-sided 97.5% Confidence Interval (CI) for percentage of subjects with hSBA booster seroresponse against each of serogroups A, C, W and Y must be greater than 75%. This will be tested sequentially first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra.

8.2.2 Success Criteria for Secondary Objective(s)

8.2.2.1 Success Criteria for Secondary Safety Objective(s)

There are no success criteria associated with the secondary safety objectives.

8.2.2.2 Success Criteria for Secondary Efficacy Objective(s)

There are no secondary efficacy objectives in this study.

8.2.2.3 Success Criteria for Secondary Immunogenicity Objective(s)

There are no success criteria associated with the secondary immunogenicity objectives in this study.

8.3 Analysis Sets

8.3.1 All Enrolled Set

All screened subjects who provide informed consent and provide demographic and/or baseline screening assessments, regardless of the subject's randomization and treatment status in the study, and received a Subject ID.

8.3.2 All Exposed Set

All subjects in the enrolled set who receive a study vaccination.

8.3.3 Safety Set

Solicited Safety Set (solicited local and systemic adverse events and other solicited adverse events)

All subjects in the Exposed Set with any solicited adverse event data.

Unsolicited Safety Set (unsolicited adverse events)

All subjects in the Exposed Set with unsolicited adverse event data.

Overall Safety Set

All subjects who are in the Solicited Safety Set and/or Unsolicited Safety Set.

8.3.4 Full Analysis Set (FAS) Efficacy/Immunogenicity Set

Full Analysis Set Immunogenicity

FAS (Day 1)

All subjects in the All Enrolled Set who:

- are randomized;
- provide evaluable serum samples at Day 1 whose result is available for at least one serogroup.

FAS (Day 29)

All subjects in the All Enrolled Set who:

- are randomized;
- receive the study vaccination;

- provide evaluable serum samples at Day 1 whose result is available for at least one serogroup (except for hSBA titer ≥8 and ≥16, GMTs and GMRs calculated at specific timepoints);
- provide evaluable serum samples at Day 29 whose result is available for at least one serogroup.

8.3.5 Per Protocol (PP) Set Efficacy/Immunogenicity Set

A PPS will be defined for each FAS described in the previous Section with additional criteria specified below.

All subjects in the FAS Immunogenicity who:

- Have no protocol deviations leading to exclusion (see section 8.3.8, Protocol Deviations) as defined prior to unblinding / analysis.
- Are not excluded due to other reasons defined prior to unblinding or analysis (see section 8.3.8, Protocol Deviations)

Examples for subjects excluded due to other reasons than protocol deviations are:

- Subjects who withdrew informed consent.

8.3.6 Other Analysis Sets

There are no other analysis sets used in this study.

8.3.7 Subgroups

Using the PPS (Day 29), the analyses of the primary objectives will be replicated by sex and race.

8.3.8 Protocol Deviations

A protocol deviation is any change, divergence, or departure from the study design or procedures of a study protocol. A protocol deviation may be a reason to remove data from an analysis set at the time of analysis. CSR-reportable protocol deviations will be defined as exclusionary from the analysis according to protocol objectives and endpoints, which will be specified in the statistical analysis plan. In some cases exclusion of data may be due to a reason other than a protocol deviation, e.g. early termination.

8.4 Statistical Analysis Plan

8.4.1 Analysis of Demographic and Baseline Characteristics

Descriptive statistics (mean, standard deviation, median, minimum and maximum) for age, height and weight at enrolment will be calculated overall and by study group.

Distributions of subjects by sex, race and ethnic origin will be summarized overall and by study group.

8.4.2 Analysis of Primary Objective(s)

8.4.2.1 Analysis of Primary Safety Objective(s)

There are no primary safety objectives in this study.

8.4.2.2 Analysis of Primary Efficacy Objective(s)

There are no primary efficacy objectives in this study.

8.4.2.3 Analysis of Primary Immunogenicity Objective(s)

8.4.2.3.1 Statistical Hypotheses

Null hypothesis: $P_{ij} \leq 0.75$

versus

Alternative hypothesis: $P_{ij} > 0.75$

Where: P_{ij} is the population booster seroresponse rate; $j = 1,2$ refer to group Menveo-Menveo (first test) and Menactra-Menveo (second test) respectively; $i = 1,2,3,4$ refer to serogroup A, C, W and Y respectively. The level of significance is fixed at one-sided 0.025.

8.4.2.3.2 Analysis Sets

The analysis population to be used for the primary objectives is the PPS (Day 29). Analyses of primary objectives will be repeated on the FAS (Day 29) to assess robustness of results.

8.4.2.3.3 Statistical Methods

General

Missing immunogenicity values are assumed MCAR (Missing Completely At Random) and therefore may not contain information that impact the result of the analysis (i.e., not informative). Imputation methods will therefore not be used.

Overall significance level for all hypothesis tests is one-sided $\alpha = 2.5\%$.

Seroresponse (Day 29)

Seroresponse for this booster study is defined as: a) post-vaccination hSBA titer ≥ 16 for subjects with a pre-vaccination hSBA titer <4; b) for subjects with a pre-vaccination hSBA titer ≥ 4, an increase of at least four times the pre-vaccination hSBA titer.

For each individual vaccine group (Menveo-Menveo and Menactra-Menveo) and each ACWY serogroup, the percentage of subjects with seroresponse will be computed, along with associated two-sided 95% Clopper-Pearson CIs.

Further details of the statistical methods will be provided in the SAP.

8.4.3 Analysis of Secondary Objective(s)

8.4.3.1 Analysis of Secondary Safety Objective(s)

8.4.3.1.1 Analysis of Extent of Exposure

Subjects will be analyzed to the extent that they were exposed to study vaccines and according to the available safety data for the subject during any study period. Subjects who withdraw early or who are lost to follow-up will be removed from the summary table denominator for the time period in which they have no available safety data collected.

8.4.3.1.2 Analysis of Solicited Local, Systemic and Other Adverse Events

All solicited adverse events will be summarized according to defined severity grading scales.

Frequencies and percentages of subjects experiencing each adverse event will be presented for each symptom severity. Summary tables showing the occurrence of any local or systemic adverse event overall and at each time point will also be presented.

Post-vaccination solicited adverse events reported from Day 1 to Day 7 will be summarized for the intervals Day 1 (6 hours) – Day 3, Days 4-7, Day 1 (6 hours) – Day 7 by maximal severity and by study group. Separate analyses will be performed for solicited AEs reported 30 minutes after vaccination. The severity of solicited local adverse events, including injection-site erythema and induration, will be categorized based on linear measurement: None (0-24 mm), Mild (25-50 mm), Moderate (51-100 mm), Severe (> 100mm).

Injection site pain and systemic reactions, including fatigue, headache, myalgia, arthralgia, chills, nausea, loss of appetite, occurring up to 7 days after each vaccination will be summarized according to "mild", "moderate" or "severe".

Each solicited local and systemic adverse event will also be further summarized as "none" versus "any".

Use of antipyretics and analgesics will be summarized by frequency, by type of use (prophylactic versus treatment) and percentage of subjects reporting use.

Body temperature will be summarized separately according to the 3 schemes described below and will be broken down according to route of measurement:

- by 0.5 °C increments from 36.0°C up to ≥40°C;
- by 1°C increments: <36.0, 36.0-36.9, 37.0-37.9, 38.0-38.9, 39.0-39.9, ≥40°C;
- According to different cut-offs (< versus ≥): 38.0, 38.5, 39.0, 39.5, 40.0°C.

8.4.3.1.3 Analysis of Unsolicited Adverse Events

This analysis applies to all adverse events occurring during the study, judged either as probably related, possibly related, or not related to vaccination by the investigator, recorded in AE CRF, with a start date on or after the date of first vaccination. AE starting prior to the first vaccination will only be listed. The original verbatim terms used by investigators to identify adverse events in the CRFs will be mapped to preferred terms using the MedDRA dictionary. The adverse events will then be grouped by MedDRA preferred terms into frequency tables according to system organ class (SOC).

All reported adverse events, as well as adverse events judged by the investigator as at least possibly related to study vaccine, will be summarized according to SOC and preferred term within SOC. These summaries will be presented by study group and by interval of study observation. When an adverse event occurs more than once for a subject, the maximal severity and strongest relationship to the vaccine will be counted.

Separate summaries will be produced for the following categories:

- Adverse events that are possibly or probably related to vaccine
- Unsolicited AEs reported within 30 minutes after vaccination
- Unsolicited AEs reported within 29 days after vaccination
- Adverse events leading to withdrawal
- Adverse events leading to a medically attended visit
- Serious adverse events
-

Data listings of all adverse events will be provided by subject. In addition, adverse events in the categories above will be provided as listed data.

8.4.3.1.4 Statistical Hypotheses

There are no statistical hypotheses associated with the secondary safety objectives.

8.4.3.1.5 Analysis Sets

Analyses of solicited adverse events - and other solicited reactions - and unsolicited adverse events will be performed on the relevant safety sets.

8.4.3.1.6 Statistical Methods

For unsolicited adverse events, the entire study period will be divided into the following intervals: onset within 30 minutes after vaccination, onset within 28 days after vaccination; and from Day 1 through Day 181. For solicited adverse events, the solicited study period will be divided into intervals: from 6 hours through day 3; from day 4 through day 7; and from 6 hours through day 7.

No imputation methods will be used to address missing safety data.

Summaries of safety will be presented using frequencies and percentages within each study group. No statistical comparisons among the study groups with respect to any of the safety parameters will be performed.

8.4.3.2 Analysis of Secondary Efficacy Objective(s)

There are no secondary efficacy objectives associated with this study.

8.4.3.3 Analysis of Secondary Immunogenicity Objective(s)

8.4.3.3.1 Statistical Hypotheses

Analyses related to the secondary immunogenicity objectives will be descriptive; no formal statistical tests will be performed.

8.4.3.3.2 Analysis Sets

Analyses of secondary immunogenicity will be based on the PPS and repeated on the FAS.

8.4.3.3.3 Statistical Methods

General

The hSBA titers at each visit will be logarithmically transformed (base10) to obtain approximately normally distributed data.

For comparison of percentages and GMT ratios, unadjusted estimates will be obtained along with adjusted estimates from regression models to account for potential baseline imbalance between study groups.

For each *N. meningitidis* serogroup A, C, W and Y, unadjusted GMTs will be calculated, with their associated two-sided 95% CIs, by exponentiating the corresponding log-transformed means and their 95% CIs. Adjusted GMTs will be obtained from Analysis of Covariance (ANCOVA) models.

See section 8.4.2.3.3 for other relevant details.

Seroresponse (Day 4, Day 6, and Day 29)

The percentage of subjects with seroresponse and associated two-sided 95% Clopper-Pearson CIs will be computed by group (Menveo-Menveo, Menactra-Menveo, the Naïve and the pooled [Menveo-Menveo and Menactra-Menveo] groups) and *N. meningitidis* serogroups A, C, W and Y test strains. Differences in percentages and associated 95% CIs between study groups will be calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - each of the previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) will be compared to the naïve group. Also the two previously vaccinated study groups will be compared to each other.

As sensitivity analyses, the difference in percentages will also be obtained from a log-linear model adjusting for pre-vaccination titer. Please see SAP for technical details.

Percentage of Subjects With hSBA titer≥8 (Day 1, Day 4, Day 6, and Day 29)

For each study group and in the pooled group (Menveo-Menveo and Menactra-Menveo), the percentage of subjects with hSBA titer ≥8 and ≥16 and associated two-sided 95% Clopper-Pearson CIs will be computed by the *N. meningitidis* serogroups A, C, W and Y test strains on Day 1, Day 4, Day 6 and Day 29 (as applicable, depending on blood draw schedule).

Differences in percentages and associated 95% CIs between study groups will be calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - the previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) will be compared to the naïve group. Also the two previously vaccinated groups will be compared to each other.

As sensitivity analyses, the difference in percentages will also be obtained from a log-linear model adjusting for pre-vaccination titer. Please see SAP for technical details.

Between-group Ratios of GMTs (Adjusted and Unadjusted)

The between-group ratio of hSBA GMTs and corresponding 95% CI, at each of Visit Day 1 (Persistence), Day 4, Day 6 and Day 29 against each *N. meningitidis* serogroups A, C, W and Y test strains will be obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified.

Additionally, adjusted ratio of GMTs will be obtained from ANCOVA models including pre-vaccination titer as factors in the model.

The previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) will be compared to the naïve group at each timepoint – descriptively – using the ratios of GMTs.

The two previously vaccinated groups will be compared at each timepoint using GMT ratios.

Within-group GMRs (Adjusted and Unadjusted)

Within each study group and for each serogroup, GMRs will be calculated, as applicable, at:

- Visit Day 4 versus at Visit Day 1;
- Visit Day 6 versus at Visit Day 1; and
- Visit Day 29 versus at Visit Day 1.

The unadjusted GMRs and 95% CIs will be constructed by exponentiating the mean within-group differences in log-transformed titers and the corresponding 95% CIs.

Further details of the statistical methods will be provided in the Statistical Analysis Plan (SAP).

8.4.4 Analysis of Exploratory Objectives

8.4.4.1 Analysis of Exploratory Safety Objective(s)

There are no exploratory safety objectives in this study.

8.4.4.2 Analysis of Exploratory Efficacy Objective(s)

There are no exploratory efficacy objectives in this study.

8.4.4.3 Analysis of Exploratory Immunogenicity Objective(s)

There are no exploratory immunogenicity objectives in this study.

8.5 Sample Size and Power Considerations of Primary and Secondary Objectives

Statistical power was estimated based on observed data from a previous study (V59P13E1) assessing the immunogenicity of a booster dose of Menveo among subjects who had previously been vaccinated with either Menveo or Menactra 3 years prior in another study (V59P13) while subjects were 11-18 years old. Data from study V59P13E1, were used to compute booster seroresponse rates at one-month post booster dose of MenACWY-CRM using the following definition of booster seroresponse: a) post-vaccination hSBA titer ≥ 16 for subjects with a pre-vaccination hSBA titer <4; b) for subjects with a pre-vaccination hSBA titer ≥4, an increase of at least four times the pre-vaccination hSBA titer (cf. table 8.5-1).

Table 8.5-1: hSBA Seroresponse at One Month Following the Booster at 3 Years After Vaccination, by Serogroup - Booster- PP Population

	Vaccination	ACWY/ACWY Group IV	Menactra/ACWY Group V
Serogroup A	Overall Seroresponse	68 (97%) (90-100) N=70	70 (100%) (95-100) N=70
Serogroup C	Overall Seroresponse	66 (93%) (84-98) N=71	65 (93%) (84-98) N=70
Serogroup W	Overall Seroresponse	63 (91%) (82-97) N=69	64 (93%) (84-98) N=69
Serogroup Y	Overall Seroresponse	63 (90%) (80-96) N=70	64 (91%) (82-97) N=70

Assuming the true booster seroresponse rates in the Menveo-Menveo group range from 90% to 97% (alternative hypothesis) for each serotype, a sample size of n=270 will have at least 96% power to show sufficiency of immune response to a booster dose of MenACWY-CRM, compared with a pre-specified reference booster seroresponse of 75% (null hypothesis) using an exact test with 0.025 one-sided significance level (cf. table 8.5-2a).

Assuming the true booster seroresponse rates in the Menactra-Menveo group range from 91% to 100% (alternative hypothesis) for each serotype, a sample size of n=270 will have at least 96% power to show sufficiency of immune response to a booster dose of

MenACWY-CRM, compared with a pre-specified reference booster seroresponse of 75% (null hypothesis) using an exact test with 0.025 one-sided significance level (cf. table 8.5-2b).

Table 8.5-2a: Statistical Power to Test for Sufficiency of Immune Response Given a Range of True Booster Seroresponse Rates for Evaluable Sample Size of 270 subjects in the Menveo-Menveo group

Serotype	True Seroresponse Rate	Power
A	0.97	0.99
C	0.93	0.99
W	0.91	0.99
Y	0.90	0.99
Total Power		0.96

Calculations have been done with nQuery Advisor (Version 7.0).

Table 8.5-2b: Statistical Power to Test for Sufficiency of Immune Response Given a Range of True Booster Seroresponse Rates for Evaluable Sample Size of 270 subjects in the Menactra-Menveo group

Serotype	True Seroresponse Rate	Power
A	>0.99	0.99
C	0.93	0.99
W	0.93	0.99
Y	0.91	0.99
Total Power		0.96

Calculations have been done with nQuery Advisor (Version 7.0).

Overall statistical power to show sufficiency of immune response to a booster dose of MenACWY-CRM for each serotype in both the Menveo-Menveo and the Menactra-Menveo group will be at least 92%.

When taking a 10% dropout rate into account, N=300 previously vaccinated subjects with Menveo and N=300 previously vaccinated subjects with Menactra have to be enrolled in the study.

A total of 100 meningococcal vaccine-naïve subjects are planned to be enrolled in the study for comparison of immune responses after a single dose in unprimed subjects with the booster response in primed subjects. The sample size of 100 naïve subjects is based on

previous MenACWY studies examining the response to a booster and to ensure a minimum sample size of ~50 subjects in each blood draw schedule for adequate comparisons.

8.6 Interim Analysis

No interim analysis of data from this study is planned.

9. SOURCE DOCUMENTATION, STUDY MONITORING AND AUDITING

In order to ensure consistency across sites, study monitoring and auditing will be standardized and performed in accordance with the Sponsor's or delegated contract research organization's (CRO) standard operating procedures and applicable regulatory requirements (e.g., FDA, EMA, and ICH guidelines).

Prior to enrolment of the first study subject, GSK or delegate will train investigators and/or their study staff on the study protocol, all applicable study procedures, documentation practices and all electronic systems. CRFs supplied by the Sponsor must be completed for each randomized subject (see section 8.3.1, All Enrolled Set for definition of enrolled subject). Documentation of screened but not enrolled subjects must be maintained at the site and made available for review by the site monitor. Data and documents will be checked by the Sponsor and/or monitor.

9.1 Source Documentation

Prior to the start of the study, the site staff participating in the study conduct will be instructed on what documents will be required for review as source documents. The kinds of documents that will serve as source documents will be agreed between Sponsor or delegate and investigator and designees and specified in the SDAF prior to subject enrolment.

In addition, source documentation **must** include all of the following: subject identification (on each page), eligibility and participation, proper informed consent procedures, dates of visits, adherence to protocol procedures, adequate reporting and follow-up of adverse events,: documentation of prior/concomitant medication/vaccines, study vaccine receipt/dispensing/return records, study vaccine administration information, any data collected by a telephone conversation with the subject and/or parent(s)/legal guardian(s) and date of completion and reason.

The subject and/or parent(s)/legal guardian(s) must also allow access to the subject's medical records. Each subject and/or the parent(s)/legal guardian(s) must be informed of this prior to the start of the study and consent for access to medical records may be required in accordance with local regulations.

All safety data reported by subjects must be written down in source documents prior to entry of the data into CRFs. If there are multiple sources of information (e.g., Subject Diary, verbal report of the subject, telephone contact details, medical chart) supporting the diagnosis of an adverse event, these sources must be identified in the source documents, discrepancies between sources clarified, the ultimate diagnosis must be justified and written in the source documents, and this diagnosis must be captured in the

Adverse Event CRF (AE CRF). The AE CRF must also capture which source(s) of information were used to determine the adverse event (e.g., subject recall, medical chart, Subject Diary).

9.2 Study Monitoring, Auditing and Source Data Verification

Prior to enrolment of the first study subject, GSK or its designee (e.g., a CRO) will develop a Clinical Monitoring Plan to specify how centralized and/or on-site monitoring, including clinical specimens reconciliation, will be performed for the study. Study progress will be monitored by GSK or its designee as frequently as necessary to ensure:

- that the rights and well-being of human subjects are protected,
- the reported study data are accurate, complete, and verifiable from the source documents and
- the conduct of the study is in compliance with the current approved protocol/amendment(s), GCP and applicable regulatory requirements.

Contact details for the GSK team or its designee involved in study monitoring will be provided to the investigator. Study data recorded on CRFs will be verified by checking the CRF entries against source documents in order to ensure data completeness and accuracy as required by study protocol. .

Data verification may also be performed through a centralized review of data (e.g., checking for outliers or other anomalies). Additional documents such as the investigator site file, pharmacy records, and informed consent documentation must also be available for review if requested. Arrangements for monitoring visits will be made in advance in accordance with the monitoring plan, except in case of emergency.

The investigator and/or site staff must make source documents of subjects enrolled in this study available for inspection by GSK or its representative at the time of each monitoring visit and Sponsor audits, when applicable. These documents must also be available for inspection, verification and copying, as required by regulations, by officials of the regulatory health authorities (e.g., FDA, EMA and others) and/or ECs/IRBs. The investigator and study site staff must comply with applicable privacy, data protection and medical confidentiality laws for use and disclosure of information related to the study and enrolled subjects.

10. DATA MANAGEMENT

10.1 Data Entry and Management

In this study, all clinical data (including, but not limited to, AE/SAEs, concomitant medications, medical history, and physical assessments), safety data, and immunogenicity data will be entered onto case report forms (CRFs) in a timely fashion by the investigator and/or the investigator's dedicated site staff. Data entered onto CRFs are stored on a secure website. The data collected on this secure website are assimilated into an electronic data capture (EDC) system, which is compliant with Title 21 Part 11 policies of the Code of Federal Regulations (FDA 1997). The data system includes password protection and internal quality checks. The EDC system will be designed and validated by the Sponsor prior to activation for data entry by sites. The investigator or designated delegate must review data entered and electronically sign the CRFs to verify their accuracy.

Access to the EDC system for data entry or review will require training and distinct individual access code assignments to those site staff members who will be entering study data and those involved in study oversight who may review study data. Data are collected within the EDC system, to which the Sponsor and site monitors have exclusively "read only" access.

10.2 Data Clarification

As part of the conduct of the trial, the Sponsor may have questions about the data entered by the site, referred to as queries. The monitors and the Sponsor are the only parties that can generate a query. All corrections and clarifications will be entered into the EDC system and will be identified by the person entering the information, the reason for the change, as well as the time of the changes made. If changes are made to a previously and electronically signed CRF, the investigator must confirm and endorse the changes.

10.3 Data Protection

GSK respects the subjects' rights to privacy and will ensure the confidentiality of their medical information in accordance with all applicable laws and regulations.

11. 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. 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 25 years after completion of the study report.

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.

The principles for the storage of laboratory samples are provided below:

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.

12. USE OF INFORMATION AND PUBLICATION

GSK assures that the key design elements of this protocol will be posted in a publicly accessible database such as clinicaltrials.gov, and in compliance with current regulations.

GSK also assures that key results of this clinical study will be posted in a publicly accessible database within the required time-frame from the end of study as defined in section 3.9, End of Study.

In accordance with standard editorial, ethical practices and current guidelines of Good Publication Practice (Graf 2009), GSK will generally support publication of multicenter studies only in their entirety and not as individual center data. In this case, a coordinating investigator will be designated by mutual agreement prior to the start of the study. The coordinating investigator will also sign the clinical study report on behalf of the principal investigators (CPMP/EWP/2747/00). Authorship will be determined by mutual agreement and in line with International Committee of Medical Journal Editors authorship requirements. Any formal publication of the study in which contribution of GSK personnel exceeded that of conventional monitoring will be considered as a joint publication by the investigator and the appropriate GSK personnel.

GSK must be notified of any intent to publish data collected from the study and prior approval from GSK must be obtained prior to submission for publication.

13. ETHICAL CONSIDERATIONS

13.1 Regulatory and Ethical Compliance

The study will be conducted in compliance with the protocol, GCP and applicable regulatory requirement(s).

This clinical study was designed and shall be implemented and reported in accordance with the ICH Harmonized Tripartite Guidelines for Good Clinical Practice, with applicable local regulations including European Directive 2001/20/EC, US Code of Federal Regulations Title 21, and Japanese Ministry of Health, Labor, and Welfare, GSK codes on protection of human rights, and with the ethical principles laid down in the Declaration of Helsinki (European Council 2001, US Code of Federal Regulations, ICH 1997).

13.2 Informed Consent Procedures

Eligible subjects may be included in the study only after providing written informed consent or assent, as described in section 5.1.1, Informed Consent/Assent. Before the start of the study, the investigator will have the informed consent and any other materials that will be provided to the subjects reviewed and approved by the IRB/EC. This review and approval will be documented and stored with other study documents. The investigator or designee must fully inform the subject or legal guardian of all pertinent aspects of the study. A copy of the written informed consent will be given to the subject or the designee. The subject/designee must be allowed ample time to ask about the details of the study and to make a decision as to whether or not to participate in the study. The subject and/or legal guardian(s) **must** sign the consent form indicating their agreement to participate in the study before any study-related procedures are conducted. The informed consent process may be conducted up to 5 days prior to vaccination on Day 1. If the subject and/or legal guardian(s) is unable to read and write, a witness must be present during the informed consent discussion and at the time of informed consent signature.

Prior to the start of the study, GSK will provide to investigators a proposed informed consent form that complies with the ICH GCP guideline and regulatory requirements and is considered appropriate for this study. Any changes to the proposed consent form suggested by the investigator must be agreed to by GSK before submission to the IRB/EC and a copy of the approved version must be provided to the GSK monitor after IRB/EC approval.

Women of childbearing potential should be informed that taking the study medication may involve unknown risks to the fetus if pregnancy were to occur during the study and agree that in order to participate in the study they must adhere to the contraception

requirements indicated in the protocol for the duration of the study. In case of doubts on the ability of a subject to adhere to these requirements, that subject should not be allowed in the study

Before the start of the study, the investigator will have the informed assent, the informed consent, and any other materials that will be provided to the subject and/or parent(s)/legal guardian(s) reviewed and approved by the IRB/EC. This review and approval will be documented and stored with other study documents. The investigator or designee must fully inform the subject and/or parent(s)/legal guardian(s) of all pertinent aspects of the study. A copy of the written informed consent and informed assent will be given to the subject and/or parent(s)/legal guardian(s).

In addition, the investigator or designee should explain pertinent aspects of the study in an age appropriate manner to pediatric subjects who are eligible for informed assent in accordance with local policies. The subject and parent(s)/legal guardian(s) must be allowed ample time to ask about the details of the study and to make a decision as to whether or not to participate in the study. The subject and parent(s)/legal guardian(s) must sign the consent/assent forms indicating their agreement to participate in the study before any study-related procedures are conducted. If the subject and/or parent(s)/legal guardian(s) are unable to read and write, a witness must be present during the informed consent/assent discussion and at the time of informed consent/assent signature.

13.3 Responsibilities of the Investigator and IRB/EC

The protocol and the proposed informed consent form must be reviewed and approved by a properly constituted IRB/EC before study start. Properly constituted IRB/EC is defined in ICH Guideline for Good Clinical Practice E6 (R1), Section 3 (ICH 1997). A signed and dated statement that the protocol and informed consent have been approved by the IRB/EC must be given to GSK before study initiation. Prior to study start and at any time the protocol is amended during study conduct, the investigator is required to sign a protocol signature page confirming his/her agreement to conduct the study in accordance with these documents and all of the instructions and procedures found in this protocol and to give access to all relevant data and records to GSK monitors, auditors, GSK Clinical Quality Assurance representatives, designated agents of GSK, IRBs/ECs, and regulatory authorities as required. If an inspection of the clinical site is requested by a regulatory authority, the investigator must inform GSK immediately that this request has been made.

The investigator also responsible for the following:

- Maintaining a list of appropriately qualified persons to whom the investigator has delegated significant study-related duties.

- Demonstrating the capability of recruiting the required number of suitable subjects within the recruitment period.
- Demonstrating sufficient time and staffing to properly conduct and complete the study within the agreed study period.
- Ensuring that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their study-related duties and functions.
- Ensuring that appropriately trained health care professionals are responsible for all study-related medical decisions and for ensuring appropriate medical care of subjects experiencing any adverse event related to the study.
- If permission to do so is given by the subject and/or parent(s)/legal guardian(s), ensuring that the subject's primary healthcare provider is informed of the subject's participation in the study.

The investigator should not implement any deviation from, or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to study subjects, or when the change(s) involves only logistical or administrative aspects of the study (e.g., change in monitor(s), change of telephone number(s)). In addition, the investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to study subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

(a) to the IRB/IEC for review and approval/favourable opinion,

(b) to the Sponsor for agreement and, if required,

(c) to the regulatory authority(ies).

13.4 Protocol Amendments

An amendment is a written description of change(s) to or formal clarification of a study protocol which may impact on the conduct of the clinical study, potential benefit of the clinical study, or may affect subject safety, including changes of study objectives, study design, subject population, sample sizes, study procedures, or significant administrative aspects. An administrative change of a study protocol is a minor correction or clarification that has no significant impact on the way the clinical study is to be conducted

and no effect on subject safety (e.g., change of telephone number(s), logistical changes). Protocol amendments must be approved by GSK, health authorities where required, and the IRB/EC. In cases when the amendment is required in order to protect the subject safety, the amendment can be implemented prior to IRB/EC approval. Notwithstanding, the need for formal approval of a protocol amendment, the investigator is expected to take any immediate action required for the safety of any subject included in this study, even if this action represents a deviation from the protocol. In such cases, GSK should be notified of this action, the IRB/EC at the study site, and, if required by local regulations, the relevant health authority) should be informed within 10 working days.

14. REFERENCE LIST

Code of Federal Regulations (1997): Food and Drug Administration, U.S. Department of Health and Human Services: Title 21, Part 11: Electronic Records Electronic Signatures. Federal Register 62: 13464

European Medicines Agency (2005): EMEA/CHMP/313666/2005 Guideline on the exposure to medicinal products during pregnancy: need for post-authorisation data, London, 14 November 2005

European Parliament (1995): Directive 95/46/EC of the European Parliament and of the Council of 4 April 2001. Official Journal of the European Communities. L 281/31-39

European Parliament (2001): Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001. Official Journal of the European Communities. L 121/34-44

Graf C, Battisti WP, Bridges D (2009). Good publication practice for communicating company Sponsored medical research: the GPP2 guidelines. BMJ; 339: b4330

ICH (1997) ICH Harmonised Tripartite ICH Guideline for Good Clinical Practices E6 (R1). Federal Register, 62 (90): 25691-25709

ICH (1998) ICH Harmonised Tripartite ICH Guideline for Statistical Principles for Clinical Trials E9. Federal Register, 63 (179): 49583

Levine RJ. (1988) Ethics and Regulations of Clinical Research. New Haven: Yale University Press.

Metropolitan Atlanta Congenital Defects Program (MACDP)
http://www.cdc.gov/ncbddd/birthdefects/documents/macdpcode0807.pdf

U.S. Department of Health and Human Services, Food and Drug Administration, CBER (2009): Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

59th World Medical Association General Assembly (October 2008) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Seoul, Korea

Appendix 1: 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' study vaccine(s)/product(s) and other study-related duties and functions as described in the protocol.
- To acquire the reference ranges for laboratory tests performed locally and, if required by local regulations, obtain the laboratory's current certification or Quality Assurance procedure manual.
- To ensure that no clinical samples (including serum samples) are retained onsite or elsewhere without the approval of GSK Biologicals and the express written informed consent of the 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(s)/product(s), 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.

PRO-01 TEMP 06 / Atlas No. 293620
Version No.4 / Version Date: January 29, 2015

- 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	*205352 (MENACWY CONJ-038 (V59_77))*
IND number:	*IND 11278*
Date of protocol:	
Detailed Title:	*A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.*
Investigator name:	_____
Signature:	_____
Date:	_____

PRO-01 TEMP 06 / Atlas No. 293620
Version No.4 / Version Date: January 29, 2015

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Certificazione per l'approvazione di un documento

The individuals listed have approved this document for implementation using an electronic signature in the Atlas EDMS. / Die aufgeführten Personen haben durch ihre elektronische Unterschrift, dieses Dokument im Atlas EDMS genehmigt. / Le persone sotto riportate hanno approvato questo documento per consentirne l'utilizzo (l'approvazione avviene mediante firma elettronica su sistema Atlas EDMS).

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16.1.2 Sample case report form

PREGNANCY REPORT

Protocol Number	Site Number	Subject Number	Subject Code
V59_77			

Date of last menstrual period: dd mmm yyyy

Date pregnancy confirmed: dd mmm yyyy

Estimated date of confinement: dd mmm yyyy

Has subject had any previous children born with congenital abnormalities? ☐ 1 Yes ☐ 2 No

Has subject had any previous spontaneous abortions? ☐ 1 Yes ☐ 2 No

Complete Pregnancy Follow-up form after completion of pregnancy.

"I have reviewed the data contained in this case report and attest to the accuracy and completeness thereof."

_____
Investigator's Signature

dd mmm yyyy

PREGNANCY FOLLOW UP

Protocol Number	Site Number	Subject Number	Subject Code
V59_77			

Specify below the pregnancy outcome:

Date of Delivery or Termination: ☐☐ ☐☐☐ ☐☐☐☐
dd mmm yyyy

Check if date is unknown ☐

Please check one:

		Trimester:	
Spontaneous abortion (miscarriage)	☐ 1	☐ 1	☐ 2
Therapeutic abortion	☐ 2		
Ectopic Pregnancy	☐ 3		
Stillborn delivery	☐ 4		
Liveborn delivery	☐ 5		
Unknown	☐ 6		

If Liveborn delivery, provide information below:

Number of infants: _____

Did the infant(s) have any congenital abnormalities? ☐ 1 Yes ☐ 2 No

If Yes, contact company immediately and complete the Abnormal Outcome-Mother and Abnormal Pregnancy Outcome - Infant forms.

"I have reviewed the data contained in this case report and attest to the accuracy and completeness thereof."

_____
Investigator's Signature

☐☐ ☐☐☐ ☐☐☐☐
dd mmm yyyy

ABNORMAL PREGNANCY OUTCOME MOTHER

Protocol Number	Site Number	Subject Number	Subject Code
V59_77			

Were there any complications during pregnancy, labor or delivery? ☐ 1 Yes ☐ 2 No

Describe: _____

PRENATAL CARE:

☐ 0 None ☐ 1 1-3 visits ☐ 2 4 or more visits ☐ 3 unknown

INFECTIONS/ILLNESSES:

Did any infections/illnesses occur during this pregnancy? ☐ 1 Yes ☐ 2 No

If Yes, record below:

	Trimester of Occurence		
	1	2	3
Diabetes			
High Blood Pressure			
Epilepsy/Seizures			
Rubella			
CMV			
Toxoplasmosis			
Hepatitis B			
Sexually Transmitted Diseases Specify: _____			
Other:			
Other:			

MEDICATIONS:

Were any medications taken during this pregnancy? ☐ 1 Yes ☐ 2 No

If Yes, record all medications below:

	Trimester of Occurence		
	1	2	3

Did this subject smoke during pregnancy? ☐ 1 Yes ☐ 2 No

Did this subject drink alcohol (any amount) during pregnancy? ☐ 1 Yes ☐ 2 No

Did this subject use recreational drugs during pregnancy? ☐ 1 Yes ☐ 2 No

Is there any additional information that might have an impact on the outcome of this pregnancy (e.g., drugs, infections, medical, economic, or other exposures or conditions)? ☐ 1 Yes ☐ 2 No

If Yes, comment: _____

ABNORMAL PREGNANCY OUTCOME INFANT

If any congenital abnormalities exist, complete the following for each infant:

Estimated gestational age at delivery: _____ weeks

Sex: ☐ 1 Male ☐ 2 Female

Birth Weight: ☐☐ lbs ☐☐ oz ☐☐☐☐ grams

Describe abnormalities: _____

_____

_____

To what do you attribute the abnormalities: _____

_____

_____

"I have reviewed the data contained in this case report and attest to the accuracy and completeness thereof."

_____
Investigator's Signature

☐☐ dd ☐☐☐ mmm ☐☐☐☐ yyyy

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16.1.3 List of IECs and Sample Consent Forms

LIST OF ETHICS COMMITTES / IRB

Date and Version of Final Issued Protocol: 24 Jun 16, Version 1

Protocol Number: V59_77

Protocol Title: A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination

United States of America & Puerto Rico			
EC / IRB	**Address**	**Contact details**	**Chair**
Chesapeake IRB	6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046	PPD	PPD PhD, RN; PPD PhD, DABT, RAC; PPD BA, JD; PPD PhD
Kaiser Permanente Northern California Institutional Review Board	1800 Harrison Street, 16th Floor, Oakland, CA 94612	PPD	Names are not provided for anonymity

Assent Form Model

Study Title:	A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.
Study Number:	V59_77
Assent Form Version, Date, and Status:	Assent Form version 1.0 (Master Country, English). 08 SEP 16, Final
Study Sponsor:	GlaxoSmithKline Biologicals S.A
Investigator:	*[For site-specific Assent insert Investigator's name]*
Institution:	*[For site-specific Assent insert institution name and address]*

INFORMATION SHEET

What Is a Vaccine Research Study

This document contains information about a research study on Menveo; a vaccine licensed to prevent a kind of bacterial meningitis (infection of the surface of the brain), a rare disease caused by a family of germs called the "meningococcus" that can be life-threatening and lead to permanent disability. The vaccine that is being studied prevents disease caused by meningococcal bacteria (*Neisseria meningitidis*) groups A, C, W and Y.

A vaccine (also known as a "vaccination" or "shot") is a type of medicine that helps protect you against getting a specific disease.

Assent Form Model

Vaccines have to be studied to make sure they don't cause harm and that they work as they should.

The doctor and the manufacturer of the vaccine want to learn more about how the body reacts when this vaccine is given to healthy children like you. The doctor would like to know if you would like to help them with this research and agree to participate in this study.

If you do not understand what the doctor tells you, always ask the doctor to explain again or ask clarifications to your parent / guardian or nurses in the clinic.

What Do I Need to Do if I Participate

You will come to the clinic 3 times during the next month. You will be given 1 injection in the arm. Since you need to be in good health to be vaccinated, on the first visit, before the vaccination the doctor will check your health to see if it is okay to give you the vaccine.

You and your parents will be asked if you are feeling well, if you have had any disease recently and if you have taken or are taking any medicines. You will also be examined and your temperature will be measured.

The doctor / nurse will take a little blood sample from your arm. Other blood samples will be taken again at two different time points after the first blood sample.

You will be given the shot after the blood sample has been taken on the first day. You will stay in the clinic for at least 30 minutes afterwards so that the study doctor can check if you are feeling well.

You need to complete a diary each day, for 6 days following the shot. You will also be called by the study doctor or nurse 2 times to remind you to complete the diary.

You will also be called by the study doctor or nurse again 3 times over a 6 month time period following the shot. These calls are to ask how you are feeling since you've had the vaccination.

Assent Form Model

Will Other Children Be Taking Part in this Study?

Yes. Approximately 700 healthy adolescents and adult volunteers are being asked if they want to join this study. So far a lot of people have helped to test this vaccine.

Can I Feel Bad After the Vaccination?

After you have been given the shot, you might feel warmth or pain or see redness, swelling, skin hardness, or bruising where the shot was given. You may feel tired or have a fever, a headache, chills, or your body may ache for a few days after getting the shot. You may also feel sick after the shot and not be able to eat for a short while.

You may feel sore where the shot was given and may have some bruising where the blood was taken. You may feel faint or light-headed for a while after the blood draw.

You may feel other effects not mentioned here. You must tell your parents / guardian and the doctor if you feel any other effects that are not mentioned here.

It is very important that you tell your parents / guardian and the doctor if you feel sick or ill at any time.

You will be carefully looked after.

What Are the Benefits if I Am in the Study?

If you are in this research study you will help the doctor and manufacturer of the vaccine to learn more about vaccines, so you may help other children to not get ill in the future.

There may not be a direct medical benefit to you as a result of taking part in this study; however you may be protected against meningitis caused by meningococcal bacteria groups A, C, W and Y.

Can Anyone See Information Collected About Me?

Any information that the doctor or nurses collect about you during the study will be kept secret. This means that nobody will know your name and where you live, except the doctor and the nurses.

Assent Form Model

All information collected about you will be associated to a "code" consisting of letters or numbers, not to your name. This code will be used for all the information collected about you.

Do I Need to Participate in this Research Study?

Participation in this study is not mandatory, and you can take your time to make a decision. Also, you can change your mind and stop being part of this study at any time later.

This will make no difference to the doctor, so even if you do not want to join this study you will continue to receive his care.

The doctor asked your parents/guardian if they agree that you participate in the study and you cannot participate unless they also agree.

But if you don't want to participate in the study, you can say no and this will be accepted by your parents / guardian.

Who Do I Ask for Questions?

If there is anything you do not understand, please ask your parent/ guardian or the study staff.

Your parents/guardian will be given more information from the study doctor and study team. They can contact the study staff at any time, if you have questions about this study.

Assent Form Model

My Approval / Assent

If you agree to participate in this research study, write your full name in BLOCK letters and your age below.

Participant name (print)	Age

Write your signature and the date below.

Participant signature	Date (DD MMM YY)

Person Obtaining Assent

I confirm that I have explained this research study to the participant to the extent compatible with the participant's understanding, and that the participant assented to be included in the study.

Name of person obtaining assent (print)	

Signature of person obtaining assent	Date (DD MMM YY)

Informed Consent Form Model

Study Title:	A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.
Study Number:	V59_77
Informed Consent Form Version, Date, Status and Number:	ICF version 2.0 (Master Country, English). 11 AUG 16 Final
Study Sponsor:	GlaxoSmithKline Biologicals S.A
Investigator:	*[For site-specific ICF: Insert Investigator's name and contact information (i.e. phone number and address if different from institution address below)]*
Institution:	*[For site-specific ICF: Insert institution name and address]*

Informed Consent Form Model

INFORMATION SHEET

Request to Participate in the Study

You *[Your child] [is]* are being invited to take part in a medical research study sponsored by GlaxoSmithKline Biologicals S.A. (hereafter referred to as GSK) investigating a vaccine for the prevention of bacterial meningitis. Before making your decision to *[allow your child to]* be part of this study, please take your time to read this information sheet carefully. If there is anything in this information sheet that you do not understand, please ask the study doctor or study staff for clarifications.

Participation is Voluntary

Taking part in this study is voluntary. You are free to refuse or discontinue your *[child's]* participation in the study without giving any reason at any time. Your decision to not *[allow your child to]* participate will not affect the care that you *[your child]* would normally get from your *[his/her]* doctor.

Other vaccines against bacterial meningitis are available. You should discuss with the study doctor other options that may be right for you *[your child]*.

If you agree to take part in this study *[or to allow your child to participate in this study, as applicable]*, you *[as applicable: a parent or both parents, legal representative]* will be asked to sign this consent form. By signing this form you *[your child]* will not be giving up any legal rights to which you *[your child]* are *[is]* entitled as a participant in a research study.

Study procedures will only be performed after you have signed this informed consent form.

A copy of the signed consent form will be given to you to keep.

Informed Consent Form Model

Background and Purpose of the Study

This study is being conducted to learn more about the safety, and immune response of the study vaccine Menveo, in healthy individuals from 15 through 55 years of age when given as a single booster dose 4-6 years after receiving a previous meningitis vaccine.

Menveo is a vaccine licensed to prevent meningitis caused by meningococcal bacteria *(Neisseria meningitidis)* groups called A, C, W and Y.

Booster doses are additional doses of a vaccine needed to be injected periodically to "boost" the immune system.

An additional objective of this study is to evaluate the response to a single dose of the study vaccine given to subjects who have not received any previous meningococcal vaccine in the past (vaccine-naïve subjects), and to describe their immune response. You *[your child]* will be allocated to one of 3 study arms according to your *[their]* meningitis vaccination history.

A vaccine (also known as a "vaccination" or "shot") is a type of medicine that helps protect you *[your child]* against getting a specific disease.

Immune response refers to your *[child's]* body's defense system producing substances (antibodies) to fight off germs after you have *[your child has]* been in contact with them. Germs are microorganisms like bacteria, viruses and parasites that can cause diseases. The aim of this research study is to understand if and how well the study vaccine helps your *[child's]* body to produce antibodies that specifically recognize and fight off germs causing meningitis. This will be done by measuring the antibody levels in your *[child's]* blood

Approximately 700 healthy adolescents and adult volunteers in the USA will take part in this study. Among those, approximately 300 subjects who previously received Menveo vaccine (Menveo-Menveo group), 300 subjects who previously received Menactra vaccine (Menactra-Menveo group) and 100 subjects who have not received any previous meningococcal vaccine in the past (naïve group).

Informed Consent Form Model

What Is the Disease and What Is the Vaccine?

Meningitis, caused, among others, by a family of germs (or bacteria) called the "meningococcus", is a rare infection of the surface of the brain, but it can be life-threatening and lead to permanent disability. The same family of germs can also cause an infection of the blood called sepsis. Meningococcal meningitis and sepsis are most common in babies and adolescents. About 0.4 to 0.5 adolescents per 100,000 get meningococcal meningitis or sepsis, and more than 10% of these illnesses are fatal. In the US, the most common groups of germs in the meningococcus family that can cause disease are called A, B, C, W and Y.

MenACWY-CRM (Menveo) is a GSK vaccine intended for protection against disease caused by meningococcal bacteria groups called A, C, W and Y in infants, children and adults. In clinical studies more than 39,000 people have been vaccinated with Menveo, including more than 12,600 adults and adolescents (≥11 years of age), 5200 children (1 to 10 years of age) and 13,900 infants (less than 1 year of age) as of February 2016.

This vaccine has been approved for use in your country as a primary vaccination to protect against bacterial meningitis. This study will, however, help understand how the vaccine works when given as a booster in those who have already received a previous dose of meningococcal vaccine.

Study Methods and Study Procedures

This is an open-label, male/female, healthy volunteers, single dose study.

Randomized: means you *[your child]* will be assigned by chance (like flipping of a coin) to have a blood sample taken on either Day 4 or Day 6 *(e.g., half of the* participants will be assigned to have a blood sample taken on Day 4 and the rest on Day 6*)*. Assignment to one of these groups is done by a computer and the study doctor cannot choose what group you *[your child]* will be in.

Open-label: means that both you and the study doctor know which study vaccine you *[your child]* received.

Dose: administration of a vaccine at one time or stated intervals (as in dosing regimen).

Informed Consent Form Model

Adults and adolescents that meet requirements and volunteer to participate in the study, will receive one dose of Menveo vaccine.

My *[And My Child]* Duties as Study Participant

If you volunteer *[allow your child]* to participate in the study, you *[and your child]* are agreeing to:

- come to the clinic for the scheduled visits and be available for the planned telephone calls
- complete Subject Diary
- follow the study doctor's and study staff's directions and instructions
- tell the study doctor and study staff about any changes in your *[child's]* health
- tell the study doctor about any medicines and other vaccines taken during the study
- have the study doctor perform some tests to assess your *[child's]* health for participation in the research study.

If the study doctor is not your *[child's]* regular doctor, you and the study doctor can inform your *[child's]* regular doctor of your *[their]* study participation unless you do not wish to do so.

Taking part to the study will last about 180 days (6 months).

There are 3 clinic visits and 5 follow-up telephone calls included in this study.

A list of all activities that will be performed during the study is presented in the **Attachment 1** to this document.

Possible Risks or Side Effects

There are possible risks or side effects listed below that you *[your child]* might experience from participating in this study. Also, there may be other risks and side effects that are not yet known.

Informed Consent Form Model

All risks and side effects will be monitored throughout the study. For this reason, please contact the study doctor if you think you *[your child]* are *[is]* having side effects or experiencing a change in your *[their]* health condition.

Study Vaccine Related Risks: You *[your child]* may have some side effects from the vaccine. The most commonly experienced (in at least 10% of the subjects) localized side effects (also known as local reactions) that were noticed in clinical trials were pain, redness and hardness at the injection site. Most of these side effects occurred within the first several days after vaccination and were not usually severe.

The most common whole-body reactions (or systemic reactions) were fever, tiredness (fatigue), headaches, muscle pain (myalgia), joint pain (arthralgia), loss of appetite, queasiness (nausea) and chills.

Some people have reported allergic reactions (sometimes severe), fainting, or feeling faint after injection with the MenACWY.

As for all vaccines, severe allergic reactions may occur. These kinds of reactions are usually rare, however can be life-threatening. Medications are available at the clinic in order to treat the possible allergic reactions.

If you *[your child]* have *[has]* had allergic reactions in the past after vaccinations, or you are *[your child is]* allergic to latex you must tell the study doctor or site staff and you *[your child]* will not be able to take part in this study.

Risks Related to Blood Sample Collection: When blood samples are taken from a vein, there is a risk of bruising at the site, soreness, possibly bleeding. Sometimes a person may become dizzy or faint for a short period of time. There is a rare possibility of infection or of nerve injury.

Reproductive Risks: The effect of the study vaccine used in this study on an unborn child or female and male fertility is not known.

If you think you *[your child]* might be pregnant during the study, you must contact the study doctor immediately. If you *[your child]* become *[s]* pregnant during the course of the study, you may be asked to continue participation. During the course of pregnancy, the study staff will contact you for information about your *[child's]* health during the pregnancy and the health of any baby conceived.

Informed Consent Form Model

Other Risks: In addition to the side effects listed above, there is a chance that you *[your child]* might experience a side effect which was not seen in previous clinical studies. This could be an allergic reaction or interaction with another drug. Medical treatment will be given to you *[your child]* in case of an allergic reaction to the vaccine.

Possible Benefits

There may not be a direct medical benefit to you *[your child]* as a result of taking part in this study; however , you *[your child]* may be protected against meningitis caused by meningococcal bacteria groups called A, C, W and Y.

In addition, data from this study may help us to learn more about the safety of the vaccine.

Communication of New Information on this Vaccine

Any new important information or findings that relate to for example the safety of the study vaccine that develop during the conduct of the study will be made available to you *[your child]* in a timely manner as these new findings may influence your willingness to *[allow your child]* remain in the study.

Costs Associated to Study Participation

There is no cost involved to take part in this study. You *[your child]* will receive the Menveo vaccine at no cost and the costs of all clinic visits related to the study will be covered by the sponsor.

You *[your child]* will receive compensation for the reasonable travel costs. Beyond this compensation, you *[your child]* will not receive any additional payments relating to this study. Your study doctor and study personnel will be compensated for his/her/their work on the study.

Handling of Injuries During Study Participation

If you *[your child]* are *[is]* injured as a direct result of a study related procedure or because you *[your child]* received the study vaccine, appropriate medical care for the treatment of the illness or injury will be given to you/your child.

Informed Consent Form Model

[LDL: please explain if insurance is provided and how this relates to compensation for injury and whom to contact in the event that a research related injury to the subject occurs. For the local ICFs, the LDL should include the appropriate compensation-for-injury terms applicable to their country. The LDL should ensure that the language provided below is compliant with the local rules and regulations and that any changes to the ICF are reviewed by the local legal team, and tracked in the ICF Change Tracking form.]

GSK (the study Sponsor) agrees to pay for medical treatment needed to treat an injury if:

(1) Expenses are not otherwise paid by medical insurance,
(2) You have followed the directions of the study doctors and,
(3) You did nothing to cause or contribute to the injury.

GSK will offer no other form of compensation. GSK does not usually pay for such things as lost wages, disability or discomfort due to injury.

Medical expenses from illness or injuries that are not directly related to the administration of the investigational study vaccine will not be covered by the study.

If you *[your child]* experience *[s]* an injury or have *[has]* any questions or concerns, you should contact the study doctor at:

[Enter study doctor's name and contact details. Include a 24-hour phone number if one is available]

By signing this consent form you will not waive the legal rights to which you *[your child]* are *[is]* entitled as a participant in a research study.

Collection and Treatment of Personal / Sensitive Data During the Study

During this study the study doctor or *[insert name of institution]* office staff will record information about you *[your child]*, your *[your child's]* health, and participation in the study in an electronic system provided by GSK *[or delegate representative]*.

The information collected about you *[your child]*, will be held by *[insert name of site]*, *[name of CRO]* and *[GSK and/or the controller of the data]*. The information will be analyzed and used for the purposes of this study and for training purposes. To ensure that

Informed Consent Form Model

your *[child's]* personal information is kept confidential, your *[their]* name, and any other information that allows you *[your child]* to be identified, will not be entered on the electronic systems or included in any records or samples the study doctor provides to *[insert name of CRO]* or GSK and/or controller of the data. Instead, you *[your child]* will only be identifiable by a code. Your *[child's]* study information will be labeled with a code number (for example, PPD It will not include your *[child's]* name or address. The study doctor/members of the study staff will have the link between your *[child's]* name and the code number.

The link between your *[child's]*name and the code number will not be shared. Only the code number and coded information will be provided to GSK.

GSK will use your *[child's]* coded information for research only. This may include research looking at improving the quality and efficiency in conducting clinical research trials in general.

Representatives from government agencies, Ethics Committees, Institutional Review Boards, GSK or its agents (e.g., auditors, monitors) and *[insert name of CRO]* will consult your *[child's]* medical and study participation records for the purpose of verifying completeness and correctness of the information collected for the purposes of this research study, without violating your *[child's]* confidentiality. By signing the consent form, you authorize this access.

Documents generated as part of this study will be stored under the custody of GSK. Your *[child's]*coded personal information will also, from time to time, be transferred to, stored in or otherwise processed in electronic databases owned or operated by GSK companies or third parties involved in the technical administration and maintenance of the databases. These databases may be located in the United States, or any other country where GSK conducts business. Be aware that some countries may not offer the same level of privacy protection as you are used to in the country where you live or where this study is conducted.

GSK and other third party companies working for GSK will take all reasonable measures to keep any information they receive confidential within the limits of the local laws. GSK will keep any information it receives to the same standard of confidentiality as far as permitted by applicable local law. GSK has entered into agreements with the third parties working for GSK to secure adequate protection of your data and samples.

Informed Consent Form Model

Once the study is complete and the data from the study has been analyzed, you have the right to ask the investigator for information collected from you *[your child]* during study participation. If the results of this study are published in medical publications or presented in a meeting, nothing will identify you *[your child]*. You *[your child]* will not be named and no one will be able to tell that you were in the study from the publication or presentation.

A description of this research will be available on a public website http//www.ClinicalTrials.gov, as required by GSK policy and local health authorities. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

[LDL: Insert Country specific language related to the confidentiality. The LDL is responsible for ensuring that the language provided is compliant with the local rules and regulations. The LDL should obtain approval for the text to be implemented from the local Legal representative/Data Privacy Officer before finalization of the country specific ICF.]

Handling of Samples for the purpose of this Study

As part of the study, you *[your child]* will be asked to give samples of your *[their]* blood and, if female of childbearing potential, also urine. Your *[childs's]* blood samples may be sent to GSK or other laboratories working with GSK including those outside *[insert name of country]* to:

- measure how your *[their]* body reacts to the study vaccine
- ensure the quality over time of the tests we use for the study vaccine and/ or disease,
- improve tests and develop new tests linked to the study vaccine(s)/product(s) and/or disease(s). These tests will never include testing related to your *[child's]* genes' hereditary characteristics.

Your *[child's]* samples will be given a code so that it does not directly identify you.

Informed Consent Form Model

Handling of Samples Left Over After the Study

Future Use Related to the Purpose of this Study

The samples that are left over after testing will be stored for up to 20 years, for purposes limited to additional analyses related to this study that GSK may need to conduct in future, to further understand the body response to the vaccine or to meningitis.

By signing the consent form you agree to have left over of your *[child's]* samples to be retained and used for the purposes described above.

Future Use of Samples Not Related to the Purpose of this Study

We ask for your consent to donate the left overs of your *[child's]* samples for future research use **not** related to this study. The future use of your *[child's]* samples may result in new discoveries that are important to the understanding of the vaccine(s) or disease. However, the results of these additional research studies will not be shared with you.

The leftover samples that are stored will **not** be used for testing related to your *[child's]* genes' hereditary characteristics.

If you decide to be part of this study but do not agree to donate your *[child's]* leftover samples to be used for future research not related to this study, please indicate this on the consent form.

Withdrawal From the Study After Signing the Informed Consent

If you *[or your child]* decide*[s]* to withdraw from the study, please tell the study doctor or member of the study staff right away and let them know of any medical problems you *[your child]* experienced or medications you *[your child]* have *[has]* taken since the last study contact. If you withdraw your *[child's]* consent, you will be asked to come to the clinic for a final study visit and to return the completed Subject Diary.

After you have told your study doctor or a member of the study staff to stop your *[child's]* participation to the study, no further data will be collected from you *[your child]*, but any information collected before that time will remain a part of the study data. This also applies for the samples already collected from you *[your child]* unless you inform your study doctor to have these destroyed. GSK will only keep and use any

research results that have already been obtained from the testing of your *[child]* samples. In any case, these results are coded (i.e. not associated with your *[child's]* name or identity) and you *[your child]* cannot be identified from them.

At any time during the study, the study doctor or the study sponsor may end your *[child's]* participation in the study. This may happen if:

- You *[Your child]* develop *[s]* an illness which may negatively affect your *[their]* health
- You *[Your child]* require *[s]* a medication or vaccine that is not allowed during the study
- You *[Your child]* do *[does]* not follow the study instructions given by the study staff
- GSK decides to suspend or terminate the study or the participation of this site in the study
- Other unanticipated circumstances

Whom to Contact for Questions

If you have any questions about the collection and use of information about you *[your child]* or would like to exercise rights that you *[your child]* may have with respect to this information, you should ask your study doctor.

During this study, if you have any questions about the kind of research involved in this study or your *[child's]* rights as participant to this research study, you should contact *[insert IRB/EC contact details]*.

If you have any medical or study related questions or feel you *[your child]* have *[has]* been hurt or injured as a result of taking part in the study and in case of any symptoms or illnesses that require hospitalization, emergency room visit or visit to/by a health care provider during the entire study period you should contact *[insert contact details of study doctor or person assigned to handle medical questions]*.

Attachments

Attachment 1: Study Related Procedures and Time & Events Table.

Informed Consent Form Model

Informed Consent Form *[* Subject Number: _____*]*

My signature indicates that I agree to *[have my child]* participate in the research study mentioned above and that:

- The study procedures have been explained to me.
- I have read and understood the written study information and study procedures. I have been given enough time to ask questions and all my questions have been answered satisfactory.
- I am aware that participation in the study is voluntary and that I am free to withdraw *[my child's]* participation at any time, without giving any reason, and without my *[child's]* medical care or legal rights being affected.
- I am aware that other people, as mentioned in the Informed Consent, may have access to my *[child's]* personal data.
- I am aware that if I decide to withdraw *[my child]* from this study, data collected about me *[my child]* before my *[child's]* withdrawal will be used in the analysis of the study results.
- I agree that data collected from me *[my child]* during this study may be transferred to other countries as described in this Informed Consent.

☐	I **agree** to my *[child's]* leftover samples being used in future research not related to this study.
☐	I **do not agree** to my *[child's]* leftover samples being used in future research not related to this study.
☐	I give permission for my *[child's]* General Practitioner and/or Pediatrician to be informed about my *[child's]* participation in this study.
☐	I **do not give** permission for my General Practitioner and/or Pediatrician to be informed about my *[child's]* participation in this study.
☐	I *[my child]* **do*[es]* not** have a General Practitioner and/or Pediatrician.

Informed Consent Form Model

Section only to be completed by the participant or person signing on behalf of the participant			
NAME PARTICIPANT	NAME OF PERSON SIGNING* ***if other than participant***	DATE (DD MMM YY)	SIGNATURE
			Participant Signature
* Relation to the participant OF PERSON SIGNING **(ONLY when applicable):** ☐ Parent ☐ Legal representative ☐ Independent Witness (1)			Parent/Legal Representative/ Independent Witness Signature
1) I as independent witness declare that by signing this document, the written information has been read out to the participant and to the best of my knowledge is understood by the participant and consent to participate has been given voluntarily. *Only applicable if the participant [or the child's parent or legal representative] is not able to read this written information, however does understand the language.*			

This section is only to be completed by the person obtaining the Informed Consent		
I declare that the participant/person signing mentioned above has been fully informed, both verbally and in writing, and all her/his questions about participation in this study have been answered. If new information becomes available during the study that might influence the participant's/person signing earlier consent I will inform her/him about this as soon as possible.		
NAME	DATE (DD MMM YY)	SIGNATURE

NOTE: Preferably to be signed at the same time by the participant/delegate and person obtaining the Consent form

Informed Consent Form Model

Attachment 1: Study Related Procedures and Time & Events

The following activities will be performed during the study to make sure you are *[your child is]* able to participate and that you *[your child]* can continue to participate until the end of the study. These activities will also be used to assess your *[child's]* safety and any side effects after you have received the study vaccine.

General Information and Medical History: You will be asked to provide general information about yourself *[your child]*, your *[child's]* medical history and to describe all medications including prescription medications, non-prescription (over the counter) medications and vaccinations you are *[your child is]* currently taking and may have taken recently in the past. You may be requested to get medical records from other doctors.

Based on your *[child's]* meningococcal vaccination history and if already primed in the past with a meningococcal vaccination, you *[your child]* will be asked for the proof that you *[your child]* have *[has]* received appropriate meningitis vaccination approximately 4 to 6 years ago.

Physical Exam: There are three planned clinic visits. During each clinic visit (Day 1, Day 4 or 6 and Day 29). Qualified site personnel will give you *[your child]* a physical exam, which may include examination of head, neck, thyroid, ears, eyes, nose, throat, chest, lungs, heart, lymph nodes, abdomen, skin, muscles and skeleton, nervous system.

Vital Signs: Measurement of blood pressure, body temperature, heart rate (beat) will be checked at each clinic visit. Your *[child's]* height and weight will also be measured at first clinic visit, on Day 1.

Pregnancy Test: Before the vaccination females of child-bearing age will be asked to provide a urine sample for testing to confirm that you *[your child is]* are not pregnant.

Birth Control: Females who are pregnant may not enter this study. Therefore, if you are *[your child is]* a female that could become pregnant, you *[your child]* must confirm that you *[your child]* will practice acceptable birth control during this study.

The study doctor will discuss which methods are considered acceptable birth control. In order to participate in this study, you must be willing to use one of these birth control methods for at least 30 days after getting the study vaccine.

Informed Consent Form Model

Laboratory: At different study visits the following clinical specimens will be obtained from you *[your child]*

- Blood samples will be taken at three clinic visits (Day 1 before vaccination, Day 4 or 6 and Day 29). At the first clinic visit, you *[your child]* will be randomly assigned a blood sample schedule, which means that for your *[child's]* second clinic visit you *[your child]* will have to come to the clinic either on Day 4 or Day 6. Half of the subjects will be asked to come back to the clinic on Day 4 and the other half of the subjects on Day 6. Blood samples will be tested for the antibody responses. The total amount of blood that will be collected from you *[your child]* during the study will be approximately 30ml (6 teaspoons).
- Urine samples only from females of childbearing potential, which will be used to check whether you *[your child]* are *[is]* pregnant will be collected at first clinic visit (Day 1).

Vaccination: You *[your child]* will be given the study vaccine at the first Clinic Visit. A member of the site staff will inject the vaccine into the upper muscle of preferably the arm you *[your child]* use the least.

After Vaccination (Post Injection Side Effects): After injection, you *[your child]* will have to stay in the clinic for approximately 30 minutes so that the study doctor or his/her staff can observe whether you *[your child]* have any side effects from the injection. During this time, the staff will ask questions, measure vital signs, and may examine you *[your child]*. The site will also provide you with instructions for what to do after you leave the clinic and when to return to the clinic next.

Subject Diary: You will be asked to report certain information following your *[child's]* study vaccination on a Subject Diary. This diary reminds you to report specific types of side effects that we look for after vaccination.

The Subject Diary used in this study is a paper document.

During visit 1 the site staff will provide you *[your child's]* with the Subject Diary to take home with you and also will explain to you *[and your child]* how to use it and make entries for 7 days following the study vaccination. You *[your child]* will also be asked to:

Informed Consent Form Model

- Look at the place where you *[your child]* received the study vaccine and measure specific reactions you may see.
- Indicate if you *[your child]* experience*[s]* other kinds of reactions that are sometimes seen after vaccination, pain, redness, hardness, tiredness, headache, muscle pain, joint pain, loss of appetite, nausea, chills.
- Measure your *[child's]* body temperature orally preferably. You may also be asked questions about your *[child's]* health, vaccine experience
- Call the site staff if you experience symptoms that concern you or require you to visit a doctor or medical professional
- Bring the Subject Diary back with you at your *[child's]* next visit.

Subject Diary Reminder Telephone Calls: The study doctor or a member of his/her staff will make a telephone call to you 2 and 4 days after vaccination (on Day 3 and Day 5) to remind you to complete the Subject Diary and to remind you to bring the Subject Diary back at your next visit. If you are scheduled to come back to the clinic on Day 4, you will be called by the study staff on Day 3 but they will remind you at the clinic visit to complete diary card.

You *[Your child]* will be also called on Day 15 to remind you *[your child]* to call the study doctor if you have a medical condition that leads to a hospitalization or an emergency room visit or any visit to a physician or any medical concerns.

Safety Telephone Call: At Day 91 and Day 181 (approximately 3 and 6 months after your *[child]* vaccination), the study staff will call you in order to review with you your *[child's]* general safety information, such as any visits to the doctor for any new and/or serious health problems since the last visit to the study center. The call at 180 days after the study vaccination will be the last phone call made to you.

Informed Consent Form Model

Table 1: Schedule of Events

Study duration: approximately 180 days/6 months					
Clinic Visit 1	**Phone calls**	**Clinic Visit 2**	**Phone call**	**Clinic Visit 3**	**Phone calls**
Day 1	Day 3, Day 5	Day 4 or Day 6*	Day 15	Day 29	Day 91 and Day 181
	2 and 4 days after vaccination	*3 or 5 days after vaccination*	*14 days after vaccination*	*28 days after vaccination*	*Approximately 3 and 6 months after vaccination*
- Medical history review -Physical exam -Vital signs -Pregnancy test -Blood sample -Vaccination	Subject Diary reminder phone calls	- Physical exam - Blood sample	-Safety review	-Physical exam -Blood sample	-Safety review - Study termination (Day 181) only

*Your study doctor will let you know whether you/your child should come back to the clinic at Day 4 or Day 6. It is planned that half of the participants have to come back to the clinic at Day 4 and half at Day 6. In case the date of the diary reminder phone call (Day 3 or Day 5) will overlap with the date of clinic Visit 2, the phone call may be omitted.

Novartis

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Freigabenachweis Dokument /
Certificazione per l'approvazione di un documento

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16.1.4 List of Investigators Including CVs

Study Administrative Structure

Clinical and Epidemiology Research and Development Project Lead (CEPL): PPD
Manager who translates strategies into clinical development plans; ensures that the protocols, reports and publications of the studies included in clinical development plans and the integrated clinical documents for regulatory submissions are of the highest scientific, operational and ethical standards.

Lead Statistician: PPD
GSK employee responsible for providing technical and operational leadership for biostatistical issues pertaining to the planning and implementation of vaccine projects, ensuring high quality, innovative and effective statistical support.

Clinical Research and Development Lead (CRDL): PPD
Contributes to the clinical strategy of the cluster and to its translation into sound clinical development plans; serves as lead author or key contributor to clinical documents, including clinical trial protocols, reports and publications and integrated clinical documents for regulatory submissions.

Local Medical Lead (LML): PPD
Member of the regional organization responsible for medical related and safety aspects of the trial. Responsible for interacting with investigators including study feasibility assessments. Supports the conduct of clinical trials in the assigned countries in the region ensuring that the conduct of trials is in compliance with GCP guidelines, local regulations and GSK Vaccines SOPs.

Study Delivery Lead (SDL): PPD
Senior member of the cluster who coordinates the global clinical trial team and has overall responsibility for a clinical trial.

Local Delivery Lead LDL: PPD
Senior member of the regional organization who is allocated to lead and to coordinate the regional clinical team for a given trial and may undertake some monitoring responsibilities. Some of the CTM's responsibilities can be delegated to certain members of regional team, as agreed with line manager.

Study Centers: 1 center in Puerto Rico; 39 centers in US

Clinical Research Organization (CRO): ICON, Dublin, Ireland for DM.

Study Administrative Structure

Activity	Name	Responsibilities and Scope/Sites of Manufacture/Release/TMF
Study Monitoring	PPD	Verified that: the rights and well-being of human subjects were protected; the reported trial data were accurate, complete, and verifiable from source documents; the conduct of the trial was in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).
Data Management		Coordinated generation of trial specific database setup requirements, based on established standards, and validation of all trial specific database deliverables. Coordinated and performed discrepancy management for CRF and laboratory data, including coordination of coding of medical verbatim. Prepared database lock. Maintained all document management-related documents.
Statistician		Provided consultation and advice in quantitative/statistical design, experimental design and data management issues. Worked with the clinical monitor to develop clinical protocols, analysis plans and final study reports for clinical development projects. Planned, coordinated and produced statistical analyses and summaries in support of product development.
Laboratory Assessments		Laboratory analysis of specimens and laboratory results data release.
Statistical Programmer		Provided and contributed to finalization of quality specifications, analysis plans, and other relevant documents. Provided timely implementation of clinical trial analysis plans in collaboration with the study biostatistician.
Sites of Manufacture		GSK Vaccines Rosia S.r.l.; Bellaria-Rosia; 53018 Sovicille (SI); Italy
Sites of Release		GlaxoSmithKline Biologicals; Rue de l'Institut 89; 1330 Rixensart; Belgium
Scientific Writer		Coordinated the various activities and functions to draft, review and finalize the Clinical Study Report
Site of TMF	N/A	eTMF used

[a]GlaxoSmithKline, 14200 Shady Grove Road, Rockville, Maryland 20850, Unites States; [b]GSK Vccines B.V., Amsterdam, The Netherlands; [c]ICON, Dublin, Ireland; [d]GlaxoSmithKline, Rue de l'Institut 89, 1330 Rixensart, Belgium; [e f]GlaxoSmithKline, Clinical Serology Laboratory, Marburg, Germany; [f]GlaxoSmithKline Srl, Via Fiorentina 1, 53100, Siena (SI), Italy.
Note: eTMF is routinely used for all Novartis Vaccines studies
Note: Sites of Manufacture and Sites of Release refer to Novartis Vaccines products only

Country Name	Site Ref. No.	Site Name	Investigator Forename	Investigator Surname	Investigator Address	Investigator Zip Code	Investigator City	Investigator Province/State
Puerto Rico	PPD	Ponce School of Medicine	Elizabeth	Barranco Santana	280 Monterrey Street	00716	Ponce	Puerto Rico
United States		Kentucky Pediatric/Adult Research	Stanley	Block	201 South 5th Street	40004	Bardstown	Kentucky
United States		J. Lewis Research Inc.	Stephen	Coleman	13953 S. Bangerter Parkway	84020	Draper	Utah
United States		Columbine Family Practice	Emily	Crockett	7335 South Pierce St.	80128	Littleton	Colorado
United States		Brownsboro Park Pediatrics	Wendy	Daly	6002 Brownsboro Park Blvd	40207	Louisville	Kentucky
United States		North Texas Family Medicine	Adam	Kaplan	4001 W 15th Street, MOB III	75093	Plano	Texas
United States		Simon Williamson Clinic	William	Kirby	832 Princeton Ave SW	35211	Birmingham	Alabama
United States		East Valley Family Physicians	Donna	DeSantis	1455 W Chandler Blvd	85224	Chandler	Arizona
United States		Benchmark Research	William	Douglas	4345 Arden Way	95864	Sacramento	California
United States		Quality Clinical Research LLC	Michael	Dunn	10040 Regency Circle	68114	Omaha	Nebraska
United States		United Medical Associates	Frank	Eder	1290 Upper Front Street	13901	Binghamton	New York
United States		Optimal Resarch	Randle	Middleton	Suite 203, 2089 Cecil Ashburn Drive	35802	Huntsville	Alabama
United States		Emmaus Research Center, Inc.	Elizabeth	Reyes	408 South Beach Boulevard	92804	Anaheim	California
United States		Benchmark Research	William	Seger	4504 Boat Club Road	76135	Fort Worth	Texas
United		Senders Pediatrics	Shelly	Senders	2054 South Green	44121	Cleveland	Ohio

Country Name	Site Ref. No.	Site Name	Investigator Forename	Investigator Surname	Investigator Address	Investigator Zip Code	Investigator City	Investigator Province/State
States					Road			
United States	PPD	Ford Simpson Lively & Rice Pediatrics	William	Stewart	2933 Maplewood Avenue	27103	Winston-Salem	North Carolina
United States		Capitol Pediatric and Adolescent Center	Earl	Franklin	3801 Computer Drive	27609	Raleigh	North Carolina
United States		Benchmark Research	Darrell	Herrington	3555 Knickerbocker Road	76904	San Angelo	Texas
United States		Medical Research South	Donald	Hurley	1481 Tobias Gadson Blvd	29407	Charleston	South Carolina
United States		J Lewis Research, Inc.	Katie	Julien	1868 West 9800 South	84095	South Jordan	Utah
United States		J. Lewis Research, Inc.	John Edward	Witbeck	6360 South 3000 East	84121	Salt Lake City	Utah
United States		CopperView Medical Center	Mary	Tipton	3556 W. 9800 S.	84095	South Jordan	Utah
United States		Analab Clinical Research Inc.	Stephen	Maddock	15335 W 95th St	66219	Lenexa	Kansas
United States		Palm Beach Research Center	Isaac	Marcadis	2277 Palm Beach Lakes Blvd	33409	West Palm Beach	Florida
United States		Martin Diagnostic Clinic	Earl	Martin	710 Lawrence Street	77375	Tomball	Texas
United States		Radiant Research	Linda	Murray	6010 Park Blvd	33781	Pinellas Park	Florida
United States		Village Health Partners	Madhavi	Ampajwala	5425 West Spring Creek Parkway	75024	Plano	Texas
United States		Meridian Clinical Research, LLC	Brandon	Essink	3319 North 107th Street	68134	Omaha	Nebraska
United States		Michigan Avenue Internists	Louis	Hiotis	200 South Michigan Avenue	60604	Chicago	Illinois

Country Name	Site Ref. No.	Site Name	Investigator Forename	Investigator Surname	Investigator Address	Investigator Zip Code	Investigator City	Investigator Province/State
United States	PPD	Soma Medical Center	Rafael	Nunez-Avila	3255 Forest Hill Blvd, Suite 103	33406	West Palm Beach	Florida
United States		J. Lewis Research, Inc.	James	Peterson	2295 Foothill Drive	84109	Salt Lake City	Utah
United States		Sylvana Research	Paul	Ratner	7711 Louis Pasteur Drive, Suite 406	78229	San Antonio	Texas
United States		Clinix Health Services of Colorado	Scott	Kaiser	7030 S Yosemite	80112	Centennial	Colorado
United States		Kaiser Permanente Sacramento	Nicola	Klein	1650 Response Road	95815	Sacramento	California
United States		Kaiser Permanente San Jose	Nicola	Klein	276 International Circle	95119	San Jose	California
United States		Kaiser Permanente Roseville	Nicola	Klein	1840 Sierra Gardens Dr	95661	Roseville	California
United States		Kaiser Permanente So Sacramento	Nicola	Klein	6600 Bruceville Road	95823	Sacramento	California
United States		Advanced Clinical Research - Jordan Ridge Family Medicine	Mark	Johnson	6321 S. Redwood Rd.	84123	Salt Lake City	Utah
United States		Advanced Clinical Research, Center For Lifetime Health	John	Eck	300 E Bannock St	83712	Boise	Idaho
United States		Clinical Research Advantage Inc	Jennifer	Kay	11020 Prairie Brook Roas	68144	Omaha	Nebraska
United States		Professional Research Network of Kansas LLC	William	Simon	2260 N Ridge Road	67205-1138	Wichita	Kansas

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16.1.5 Signatures of Principal or Coordinating Investigator(s) or Sponsor's Responsible Medical Officer

APPROVER'S SIGNATURE

SPONSOR: GlaxoSmithKline Biologicals S.A.

STUDY NUMBER: V59_77

REPORT TYPE: Clinical Study Report

DATE: 22 MAY 18

STUDY TITLE: A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.

STUDY AUTHORS: PPD (Sr. CRDL), PPD (Biostatistician), PPD (Lead Scientific Writer)

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Clinical and Epidemiology Project Lead: PPD

SIGNATURE: PPD

DATE: 23 MAY 2018

APPROVER'S SIGNATURE

SPONSOR: GlaxoSmithKline Biologicals S.A.

STUDY NUMBER: V59_77

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STUDY AUTHORS: PPD (Sr. CRDL), PPD (Biostatistician), PPD (Lead Scientific Writer)

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Director Biostatistics and Statistical Programming: PPD

SIGNATURE: PPD

DATE: PPD 23 May 2018

INVESTIGATOR'S SIGNATURE

SPONSOR: GlaxoSmithKline Biologicals S.A.

STUDY NUMBER: V59_77

REPORT TYPE: Clinical Study Report

DATE: 22 MAY 18

STUDY TITLE: A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.

STUDY AUTHORS: PPD (Sr. CRDL), PPD (Biostatistician), PPD (Lead Scientific Writer)

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Investigator: Mary Tipton, M.D.

SIGNATURE: PPD

DATE: 5/24/18

16.1.6 Listing of Patients Receiving Investigational Product(s) From Specific Batches

Not Applicable

16.1.7 Randomization Scheme

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Not Treated	Not Treated
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE

PPD

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE

PPD

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE

PPD

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD [redacted]	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Not Treated	Not Treated
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE

PPD [redacted]

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE

PPD

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE

PPD

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Naive	1-6-29 SCHEDULE	Not Treated	Not Treated
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE

PPD

Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Naive	1-4-29 SCHEDULE	Naive	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Naive	1-6-29 SCHEDULE	Naive	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menactra-Menveo	1-6-29 SCHEDULE	Menactra-Menveo	1-6-29 SCHEDULE
	Menactra-Menveo	1-4-29 SCHEDULE	Menactra-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE

PPD

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE

PPD

Appendix 16.1.7
Randomization Scheme and Codes - Randomized Subjects Only

Subject	Planned Group	Planned Group Description	Actual Group	Actual Group Description
PPD	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-4-29 SCHEDULE	Menveo-Menveo	1-4-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE
	Menveo-Menveo	1-6-29 SCHEDULE	Menveo-Menveo	1-6-29 SCHEDULE

PPD

16.1.8 Audit Certificates

AUDIT CERTIFICATE

Study Number: V59-77 (205352)

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 wellbeing 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
V59-77 (205352)	Investigator Site	GSK-CQA-US	PPD	USA	21-23 March, 2017
V59-77 (205352)	Investigator Site	GSK-CQA-US		USA	12-14 July, 2017

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:** 15-May-2018

Role: Manager, Clinical Quality Assurance

Clinical Quality Assurance
GlaxoSmithKline Research and Development

16.1.9 Documentation of Statistical Methods

16.1.9 DOCUMENTATION OF STATISTICAL METHODS

16.1.9.1 Introduction

The purpose of this section is two-fold: firstly, to provide additional technical details not provided in the body of the report and secondly, to present sensitivity analyses in support of our main study findings.

All statistical analyses were performed by GSK using SAS version 9.3 on SAS Drug Development version 4.3. Unless specified otherwise, all tests of hypotheses are two-tailed and were conducted at an α-level of 0.05.

16.1.9.2 Immunogenicity Analyses

Analyses of the immunogenicity endpoints were grouped into two types:

(1) analyses of vaccine specific titers as continuous variables, and

(2) analyses of binary variables derived from immunogenicity titers

The primary analysis set is the Per Protocol (*PP)* population at one month after booster vaccination or first vaccination. However, the analysis was also run using the Full Analysis Set (FAS) population for the primary endpoint as a measure of the robustness of the results.

16.1.9.2.1 Analyses Addressing hSBA Titers as Continuous Variables

These analyses relate to the following study objectives:

hSBA Geometric Mean Titers (GMTs) against *N. meningitidis* serogroup A, C, W and Y at Day 1, Day 4, Day 6 and Day 29;

Ratio of hSBA GMTs at Day 1, Day 4, Day 6 and Day 29 (between study groups);

hSBA Geometric Mean Ratios (GMRs) at Day 4, Day 6, and Day 29 compared to Day 1 (within study groups).

Statistical considerations

Distributions of titers are typically skewed to the right (Nauta, 2010) which is problematic as most standard statistical techniques rely on the assumption that observations are normally distributed. However, log-transformed immunogenicity values are usually

approximately normally distributed and so this transformation (base 10) was applied to all titers.

Titers below the limit of detection were set to half that limit (e.g., an hSBA titer of < 4 was set to 2 for the analysis).

The Geometric Mean Titer and Geometric Mean Ratio

Unadjusted GMTs and GMRs were constructed by exponentiation (base 10) of the means of the logarithmically transformed (base 10) hSBA titer and differences in the logarithmically transformed titers with corresponding two-sided 95% CIs.

Unadjusted GMTs and GMRs were calculated by fitting the following fixed effects analysis of variance (ANOVA) model,

$$y_{ij} = \mu + \alpha_i + \varepsilon_{ij}$$

where y_{ij} represents either the log-transformed (base 10) titer (for GMTs) or the difference in log-transformed titers for GMRs of the *j*th subject in study group *i* ($i = 1,\mathrm{K},3$ study groups; $j = 1,\mathrm{K},n_i$ and subjects in study group *i*); μ is the overall mean; α_i is the main effect of study group *i;* and ε_{ij} are error terms which are normally distributed with a mean of zero and variance σ^2 ($\varepsilon_{ij} \sim N\left(0,\sigma^2\right)$).

Adjusted GMT/GMCs and GMRs were calculated by fitting the following fixed effects analysis of covariance (ANCOVA) model,

$$y_{ij} = \mu + \alpha_i + \beta\, x_{ij} + \varepsilon_{ij}$$

where y_{ij} represents either the log-transformed (base 10) titer (for GMTs) or the difference in log-transformed titers for GMRs of the *j*th subject in study group *i* ($i = 1,\mathrm{K},3$ study groups; $j = 1,\mathrm{K},n_i$ and subjects in study group *i*); μ is the overall mean; α_i is the main effect of study group *i;* β is a parameter included to adjust for the baseline titer x_{ij} for subject *j* in study group *i* and ε_{ij} are error terms which are normally distributed with a mean of zero and variance σ^2 ($\varepsilon_{ij} \sim N\left(0,\sigma^2\right)$).

The GMTs and GMRs were constructed by exponentiation (base 10) of the least square means of the logarithmically transformed (base 10) hSBA titers and differences in the logarithmically transformed titers with corresponding two-sided 95% CIs obtained from the ANCOVA model.

Between-group ratios of GMTs were calculated by exponentiating the between-group difference in the least square means of the log-transformed titers and the 95% CIs.

Procedures

The (un) adjusted hSBA GMTs against N. meningitidis serogroup A, C, W and Y at Day 1, 4, 6 and 29 after booster vaccination were calculated.

In addition, median, minimum and maximum values were calculated for each study group, for each serogroup at each time-point.

SAS code

The SAS statements used to calculate the unadjusted GMT and GMRs were similar to:

```
PROC glm;
  BY serogroup visit;
  CLASS group;
  MODEL logtiter=group;
  LSMEANS group / tdiff stderr;
RUN;
```

The SAS statements used to calculate the adjusted GMT were similar to:

```
PROC glm;
  BY serogroup visit;
  CLASS group;
  MODEL logtiter=group basetitr;
  LSMEANS group / tdiff stderr;
RUN;
```

Between-group ratios of GMTs were calculated by including additional SAS statements within PROC GLM, similar to:

```
ESTIMATE 'Group 1 – Group 2' group 1 -1;
```

Median, minimum, and maximum titers/concentrations were obtained using PROC UNIVARIATE on the actual titer values:

```
PROC univariate DATA=analdat NOPRINT;
  BY visitnum group;
  VAR titer;
```

```
    OUTPUT out = univlab
           median = medvar1 – medvar8
           min = minvar1 – minvar8
           max = maxvar1 – maxvar8
             n = nvar1 – nvar8
        nmiss = nmiss1 – nmiss8;
RUN;
```

SAS outputs

ANOVA: 16.1.9.8.1, 16.1.9.8.3, 16.1.9.8.4, 16.1.9.8.5

ANCOVA: 16.1.9.8.2,

16.1.9.2.2 Analyses of Binary Variables Derived from Immunogenicity Titers or Antibody Concentrations

These analyses relate to the following study objectives:

To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with hSBA seroresponse[1] against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination.

To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination.

To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo, subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled study group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA seroresponse, hSBA titers ≥8 and ≥16 against N. meningitidis serogroups A, C, W and Y at Day 1, Day 4, Day 6, and Day 29 after vaccination.

[1] Seroresponse is defined for this booster study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the primary vaccination with Menactra in comparison with naturally-acquired level in vaccine-naive individuals, as measured by the percentages of subjects with hSBA titers ≥8.

Statistical considerations

The above study objectives were achieved with binary endpoints and so summaries of proportions.

For each of these proportions, two-sided $(1-\alpha)$% Clopper-Pearson CIs (Clopper and Pearson, 1934) were calculated. These intervals correspond to the following intersection:

$$\{\pi : P[Bin(n,\pi) \le x] \ge \alpha/2\} \cap \{\pi : P[Bin(n,\pi) \ge x] \ge \alpha/2\}$$

where x is the number of observed events (numerator of the proportion), $Bin(n,\pi)$ is a Binomial random variable with n trials (denominator of the proportion) and probability of an event occurring, π.

It can be shown that the Binomial cumulative distribution function can be rewritten in terms of the Beta distribution (Hald, 1952; Leemis and Trivedi, 1996):

$$\sum_{k=0}^{y} \binom{n}{k} \pi^k (1-\pi)^{n-k} = 1 - F(\pi; y+1, n-y),$$

where $F(\pi; y+1, n-y)$ is the Beta cumulative distribution function for Beta-distributed variable Π with shape parameters $y+1$ and $n-y$.

Therefore, the Clopper-Pearson interval can be presented in terms of quantiles of the Beta distribution:

$$B(\alpha/2;\, x,\, n-x+1) < \pi < B(1-\alpha/2;\, x+1,\, n-x),$$

where $B(p; v,w)$ is the pth quantile from a Beta distribution with shape parameters v and w.

Between-group differences in proportions were calculated using a binomial distribution. For constructing the two-sided 95% CIs, the usual normal approximation was not considered to be appropriate because these proportions could be close to 1. Therefore, the method of Miettinen and Nurminen was used (known as the MN method, 1985) which performs well when rates are close to 0 or close to 1 and in comparison with the Wald

statistic (Newcombe and Nurminen, 2011). In analyzing differences in proportions, the MN method assumes normality of the test statistic (or a chi-square distribution for the squared version) under the null hypothesis, as does the usual method, the difference is in the method of estimating variance.

SAS code

The Clopper-Pearson CIs were calculated using SAS code similar to:

```
data events;
   set events; * containing – for each group – numbers of subjects (n) and
'events' (e);
   p=round(100*e/n);
   lo=round(100*betainv(.025, e, n-e+1));
   up=round(100*betainv(.975, e+1, n-e));
   if  lo=. then lo=0;
   if  up=. then up=100;
run;
```

SAS outputs

Not applicable

16.1.9.3 Efficacy Analyses

Not applicable

16.1.9.4 Safety Analyses

These analyses relate to the following study objectives:

To assess the reactogenicity and safety of MenACWY-CRM vaccine when administered to subjects who previously received Menveo or Menactra and vaccine-naive individuals.

Statistical considerations

No statistical comparisons among the study groups with respect to any of the safety parameters were performed.

Summaries of safety were essentially reflected by frequencies and percentages within each study group.

Procedures

Please refer to the Statistical Analysis Plan (Section 6.4) for a detailed description of the safety summaries produced.

SAS code

Safety summaries were produced using SAS code similar to:

```
PROC FREQ;
TABLES group*reaction;
RUN;
```

SAS outputs

Not applicable

16.1.9.5 Multiplicity Adjustments

Not applicable

16.1.9.6 Sensitivity Analyses

16.1.9.6.1 Analyses of Different Study Populations

FAS versus PP

The primary analysis population was the PP population, below is the summary of the analysis corresponding to the primary and secondary objectives based on the FAS population.

Results for FAS were comparable to results for PPS.

Results

PPS: 14.2.1.1, 14.1.2.1 - 14.2.1.2.3, 14.2.1.3, 14.2.1.4

Seroresponse: 14.2.1.1.4

hSBA titer ≥8: 14.2.1.2.4

hSBA titer ≥16: 14.2.1.2.5

Persistence (hSBA titer ≥8): 14.2.1.3.1

Unadjusted GMT: 14.2.1.4.2

Persistence (unadjusted GMT): 14.2.1.5.1

16.1.9.6.2 Subgroup Analyses

The analyses of the primary objectives were replicated by sex and race (see tables 14.2.1.1.1 to 14.2.1.1.2). There was no meaningful effect of these factors seen on the percentages of subjects with hSBA seroresponse against any of the serogroups. However, there were very few subjects enrolled in some of the race categories, making the assessment difficult.

16.1.9.6.3 Alternative Analyses

Sensitivity analyses were performed for percentage of subjects with seroresponse (primary endpoint), percentage of subjects with hSBA titers≥8 and hSBA titers ≥16.

To calculate adjusted between-group differences in proportions, proportions were modelled using a binary model (Agresti, 2002) with a logarithmically transformed (base 10) baseline titer and study group as independent variables. Adjusted percentages were calculated by fitting the following fixed effects binary model,

$$\text{logit}(\pi_{ij}) = \log\left(\frac{\pi_{ij}}{1-\pi_{ij}}\right) = \mu + \beta\ x_{ij} + \alpha_i$$

where $\pi_{ij} = P(y_{ij} = 1) \sim \text{Bin}(1,\ \pi_{ij}(1-\ \pi_{ij}))$ represents the probability that subject j in study group i ($i = 1,\text{K},3$ study groups; $j = 1,\text{K},n_i$ and subjects in study group i) has seroresponse or has hSBA titer ≥8 or has hSBA titer ≥16; μ is the overall mean; α_i is the main effect of study group i; β is a parameter included to adjust for the baseline titer x_{ij} for subject j in study group i.

The model is fitted in SAS using the GLIMMIX procedure. The probability is calculated from the logit link $\log\left(\frac{\pi_{ij}}{1-\pi_{ij}}\right)$ and it is given by

$$\pi_{ij} = \frac{\exp(\mu + \beta\ x_{ij} + \alpha_i)}{1 + \exp(\mu + \beta\ x_{ij} + \alpha_i)}$$

The difference between two study groups is, for example given by:

$$d_{12} = \pi_{1\bullet} - \pi_{2\bullet}$$
$$\text{var}(d_{12}) = \text{var}(\pi_{1\bullet} - \pi_{2\bullet})$$

where $\pi_{i\bullet}$ is the probability for study group *i* over all subjects. The confidence interval is then approximated as $d_{12} \pm z_{\alpha/2}\sqrt{\text{var}(d_{12})}$.

Adjusted between-group differences in proportions were calculated using SAS code similar to:

```
PROC glimmix data=data;
     BY param avisitn avisit;
     CLASS trt01p;
     MODEL response (event="Y") = logbase trt01p / s dist=binary link=logit;

/* To obtain individual group estimates. The ilink option directly gives the
probabilities needed. The differences between groups will be calculated using
these estimates and their standard errors */

     LSMEANS trt01p  / CL ilink;

     ODS output LSMeans=LSMeans;
RUN;
```

Results from the sensitivity analyses varied across timepoints and study groups. Some of the results were slightly higher than or lower than those obtained using the standard approaches.

SAS outputs

Seroresponse: *14.2.1.1.3,*

hSBA titer ≥ 8: *14.2.1.2.2*

hSBA titer ≥ 16: *14.2.1.2.2.3*

16.1.9.7 Missing Data

Immunogenicity data

For immunogenicity data, it may be reasonable to consider missing immunogenicity values as missing completely at random (MCAR), i.e., not informative. Therefore, a complete case analysis was considered sufficient, without concern for bias (under/over-estimation of the true effect). Analyses of primary and key secondary objectives were, in any case, carried out on both the FAS and the PPS (see Section 16.1.9.6.1).

REFERENCES FOR STATISTICAL APPENDIX 16.1.9

Agresti, A. Categorical Data Analysis. 2nd ed. 2002. Hoboken, NJ: Wiley. Page 77.

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

Hald, A. Statistical Theory with Engineering Applications. 1952. New York: JohnWiley.

Leemis LM, Trivedi KS. A comparison of approximate interval estimators for the Bernoulli parameter. *The American Statistician* **50**:63-68, 1996

Mee, RW. Confidence bounds for the difference between two probabilities. *Biometrics* 1984; **40**:1175-1176/

Miettinen O., Nurminen M. Comparative analysis of two rates. *Stat*istics in Medicine 1985; **4**(2):213-226.

Nauta J. *Statistics in Clinical Vaccine Trials*. 2010. Heidelberg: Springer.

Newcombe R.G., Nurminen M.M. In defence of score intervals for proportions and their differences. *Communications in Statistics – Theory and Methods* 2011; **40**(7): 1271-1282.

Statistical Analysis Plan

Study alias & e-track number(s): V59_77 (205352)

Version: 1 Date: 19-09-2016

Detailed Title:	A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.
Scope:	All data pertaining to the above study.
Co-ordinating author:	PPD
Other author(s):	N.A.
Reviewed by:	PPD (Clinical and Epidemiology Project Lead) PPD (Clinical Research and Development Lead) PPD (Manager Statistics) PPD (Lead statistical analyst) PPD (Scientific writer)
Approved by:	PPD (Clinical and Epidemiology Project Lead) PPD (Manager Statistics) PPD

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LIST OF ABBREVIATIONS

AE	Adverse event
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
CI	Confidence Interval
CRF	Case Report Form
CSR	Clinical Study Report
CTRS	Clinical Trial Registry Summary
ES	Exposed Set
FAS	Full Analysis Set
GMT	Geometric mean antibody titer
GSK	GlaxoSmithKline
LL	Lower Limit of the confidence interval
MedDRA	Medical Dictionary for Regulatory Activities
N.A.	Not Applicable
PD	Protocol Deviation
PPS	Per Protocol Set
PT	Preferred Term
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SR	Study Report
TFL	Tables Figures and Listings
TOC	Table of Content

1. DOCUMENT HISTORY

Date	Description	Protocol Version
19-SEP-2016	Version 1: first version	Final Version 1 – 24-JUN-2016

2. STUDY DESIGN

This is a phase 3b, controlled, open-label, multi-center study to evaluate safety and immunogenicity of MenACWY-CRM after a single vaccination in healthy individuals who were vaccinated with Menveo or Menactra 4 to 6 years before and in vaccine-naive individuals.

Study population: Approximately 700 healthy subjects 15 through 55 years of age will be enrolled in the study.

Duration of the study: The duration of this study is approximately 6 months per subject.

Written informed consent and, as applicable according to local guidelines, written assent will be obtained before conducting any study-specific procedures.

Vaccination schedule: All subjects will receive a single dose of MenACWY-CRM at Day 1.

Study groups:

Group Menveo-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menveo 4 to 6 years before, will receive one dose of MenACWY-CRM.

Group Menactra-Menveo: approximately 300 subjects, who were vaccinated with a single dose of Menactra 4 to 6 years before, will receive one dose of MenACWY-CRM.

Group Naive: approximately 100 subjects equally enrolled across all clinical sites, who have not received any meningococcal vaccination, will receive one dose of MenACWY-CRM.

Randomization / Stratification:

Within each study group, subjects will be randomized into one of two different blood draw schedules according to a 1:1 ratio, described as follows:

- Subjects getting blood draws at Day 1, Day 4 and Day 29.
- Subjects getting blood draws at Day 1, Day 6 and Day 29.

Table 2-1: Schematic diagram of the V59_77 study groups

Vaccine History	Vaccination in current study	Blood draw schedule
Menveo N=300	Menveo	Blood draw Day 1, 4, 29 (N=150)
		Blood draw Day 1, 6, 29 (N=150)
Menactra N=300	Menveo	Blood draw Day 1, 4, 29 (N=150)
		Blood draw Day 1, 6, 29 (N=150)
Vaccine-Naive N=100	Menveo	Blood draw Day 1, 4, 29 (N=50)
		Blood draw Day 1, 6, 29 (N=50)

Blinding: open-label study.

Blood samples: Three (3) blood samples of approximately 10 mL each will be collected according to the blood draw schedule in Table 2-1.

Data collection: Electronic Case Report Form (eCRF).

Study clinic visits: Three (3) clinic visits at Day 1, Day 4 or Day 6 and Day 29 are planned for each subject.

Reminder Phone calls: Two (2) reminder phone calls will be conducted at Day 3 and Day 5 after the study vaccination to remind the subject/legal guardian to complete the diary card.

Safety phone calls: Three (3) safety phone calls (at Day 15, Day 91 and Day 181) will be conducted to collect any medically-attended AEs, AEs leading to withdrawal, SAEs, related medications and any vaccinations. In addition, all unsolicited AEs and related medications occurring after the vaccination will be collected during the safety call at Day 15. The Day 181 Safety Phone call will also serve as the termination visit.

Solicited Adverse Events (injection site pain, erythema, induration, fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever) occurring on the day of vaccination and the following six days (Day 1 through Day 7) will be recorded daily using a Diary Card for all subjects.

Unsolicited AEs occurring within 28 days after study vaccination will be collected. Qualified site staff will interview the subject by phone approximately 14 days after vaccination and in person at the study site approximately 28 days after study vaccination to assess the occurrence of any unsolicited AEs.

Medically-attended AEs, AEs leading to study withdrawal and SAEs will be collected during the entire study period. These data will be captured by interviewing the subject and/or subjects' parents / guardian (as applicable) during the site visits and phone calls and by review of available medical records. Subjects and/or parents / guardian will be encouraged to call the site in the event of any medically-attended AEs or any AEs which they perceive as being of concern during the entire study period.

Table 2-2: Schematic diagram of the V59_77 study design

Day 1	**Day 4 (-1/+1)**	**Day 6 (-1/+1)**	**Day 15 (-2/+2)**	**Day 29 (-7/+14)**	**Day 91 (-14/+14)**	**Day 181 (-14/+14)**
Blood draw (all subjects) Menveo	Blood draw (50% of subjects)	Blood draw (50% of subjects)	Safety Phone call	Blood draw (all subjects)	Safety Phone call	Safety Phone call Study termination

3. OBJECTIVES

3.1. Primary Objective(s)

Immunogenicity objective:

1. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 29 after vaccination
2. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse[1] against *N. meningitidis* serogroups A, C, W and Y at Day 29 after vaccination

   Criteria to demonstrate immune response sufficiency: The immune response sufficiency will be tested sequentially; first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra . The immune response will be considered as sufficient if the lower limit of the one-sided 97.5% CI for percentage of subjects with hSBA seroresponse[1] against serogroups A, C, W and Y is greater than 75%. The study will be considered successful if the immune response sufficiency will be demonstrated at least in the group of subjects who received primary vaccination with Menveo.

3.2. Secondary Objective(s)

Secondary Immunogenicity objectives:

1. To compare the immune responses over time following a booster dose of MenACWY-CRM vaccine, between subjects who previously received Menveo,

[1] Seroresponse is defined for this booster study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

subjects who previously received Menactra, and subjects who previously received Menveo or Menactra (pooled vaccine group) and following a single dose in vaccine-naive individuals, as measured by the percentages of subjects with hSBA seroresponse[1], hSBA titers ≥8 and ≥16, and hSBA GMTs against *N. meningitidis* serogroups A, C, W and Y at Day 1, Day 4, Day 6, and Day 29 after vaccination.

2. To assess persistence of bactericidal antibodies against serogroups A, C, W and Y at approximately 4-6 years after the primary vaccination with Menveo and after the primary vaccination with Menactra in comparison with naturally-acquired level in vaccine-naive individuals, as measured by the percentages of subjects with hSBA titers ≥8 and hSBA GMTs at Day 1.

Secondary Safety objectives:

To assess the reactogenicity and safety of MenACWY-CRM vaccine when administered to subjects who previously received Menveo or Menactra and vaccine-naive individuals.

4. ENDPOINTS

4.1. Primary Endpoints

Primary Immunogenicity Endpoint

The following measure will be summarized for the Menveo-Menveo and Menactra-Menveo groups:

1. Percentage of subjects with hSBA seroresponse[2] against *N. meningitidis* serogroups A, C, W and Y at Day 29.

[2] Seroresponse is defined for this booster study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.titers.

4.2. Secondary Endpoints

Secondary Safety Endpoints

Safety of the study vaccine will be assessed in the Menveo-Menveo, Menactra-Menveo, Naive and the pooled (Menveo-Menveo and Menactra-Menveo) groups in terms of the frequencies (percentages) of reported adverse events including:

1. Any unsolicited AEs reported within 30 minutes after vaccination;
2. Solicited local and systemic AEs reported from Day 1 (6 hours) through Day 7 after vaccination;
3. Other indicators of reactogenicity (e.g. use of analgesics / antipyretics, body temperature) within 7 days after vaccination;
4. All unsolicited AEs reported from Day 1 through Day 29 after vaccination;
5. Medically-attended AEs, AEs leading to withdrawal and SAEs reported from Day 1 through Day 181 (entire study period).

Adverse events will be coded using MedDRA preferred terms as applicable.

Secondary Immunogenicity Endpoints

The following measures will be summarized for Menveo-Menveo, Menactra-Menveo, Naive and the pooled (Menveo-Menveo and Menactra-Menveo) groups:

1. Percentage of subjects with hSBA titer ≥8 and ≥16 against *N. meningitidis* serogroups A, C, W and Y at Day 1, Day 4, Day 6 and Day 29 and between-group differences;
2. Percentages of subjects with hSBA seroresponse[3] against *N. meningitidis* serogroups A, C, W and Y at Day 4, Day 6 and Day 29 and between-group differences;

[3] Seroresponse is defined for this booster study as follows: For subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

3. hSBA GMTs against *N. meningitidis* serogroup A, C, W and Y at Day 1, Day 4, Day 6 and Day 29;
4. Ratios of hSBA GMTs at Day 1, Day 4, Day 6 and Day 29 (between study groups).
5. hSBA Geometric Mean Ratios (GMRs) at Day 4, Day 6, and Day 29 compared to Day 1 (within study groups).

5. ANALYSIS SETS

5.1. Definition

5.1.1. All Enrolled Set

All screened subjects who provide informed consent and provide demographic and/or baseline screening assessments, regardless of the subject's randomization and treatment status in the study, and received a Subject ID.

5.1.2. All Exposed Set

All subjects in the enrolled set who receive a study vaccination.

5.1.3. Safety Sets

Solicited Safety Set (solicited local and systemic adverse events and other solicited adverse events)

All subjects in the Exposed Set with any solicited adverse event data.

Unsolicited Safety Set (unsolicited adverse events)

All subjects in the Exposed Set with unsolicited adverse event data.

Overall Safety Set

All subjects who are in the Solicited Safety Set and/or Unsolicited Safety Set.

5.1.4. Immunogenicity Sets

Full Analysis Set (FAS)

FAS (Day 1)

All subjects in the All Enrolled Set who:

- are randomized;
- provide evaluable serum samples at Day 1 whose result is available for at least one serogroup.

FAS (Day 29)

All subjects in the All Enrolled Set who:

- are randomized;
- receive the study vaccination;
- provide evaluable serum samples at Day 1 whose result is available for at least one serogroup (this condition is not required for the analyses on hSBA titer ≥8 and ≥16, GMTs and GMRs calculated at specific timepoints);
- provide evaluable serum samples at Day 29 whose result is available for at least one serogroup.

Per Protocol (PP) Set

A PPS will be defined for each FAS described in the previous Section with additional criteria specified below.

All subjects in the FAS Immunogenicity who:

- Have no protocol deviations leading to exclusion (see section 5.2.3) as defined prior to unblinding / analysis.
- Are not excluded due to other reasons defined prior to the analysis (see section 5.2.3)

Examples for subjects excluded due to other reasons than protocol deviations are:

- Subjects who withdrew informed consent.

5.2. Criteria for eliminating data from Analysis Sets

Elimination codes are used to identify subjects to be eliminated from analysis. Detail is provided below for each sets. A consolidated table is also available in Annex 2.

5.2.1. Elimination from Exposed Set (ES)

Code 100 (Study vaccine not administered at all) will be used for identifying subjects eliminated from ES.

5.2.2. Elimination from Full Analysis Set (FAS)

Code 110.x (Serological results not available at Day x) will be used for identifying subjects eliminated from FAS Day x.

5.2.3. Elimination from Per-protocol analysis Set (PPS)

5.2.3.1. Excluded subjects

A subject will be excluded from the PPS analysis under the following conditions:

Code	Condition under which the code is used
120	Randomization failure
140	Vaccination not according to protocol
150	Administration of forbidden vaccine
200	Subject did not meet entry criteria
230	Administration of forbidden medication
240	Underlying medical condition forbidden by the protocol
250	Concomitant infection related to the vaccine which may influence immune response

260	Did not comply with study vaccination schedule

5.2.4. Right censored Data

Not applicable.

5.2.5. Visit-specific censored Data

Data from visit x will be censored for the PPS analysis under the following conditions.

Code	Condition under which the code is used
112.x	Obvious deviation from Laboratory Manual or error in laboratory data at Day x
270.x	Did not comply with blood draw schedule at Day x

5.3. Important protocol deviation not leading to elimination from per-protocol analysis set

Not applicable.

6. STATISTICAL ANALYSES

Note that standard data derivation rule and stat methods are described in annex 1 and will not be repeated below.

6.1. Demography

6.1.1. Analysis of demographics/baseline characteristics planned in the protocol

Descriptive statistics (mean, standard deviation, median, minimum and maximum) for age, height and weight at enrolment will be calculated overall and by study group.

Distributions of subjects by sex, race and ethnic origin will be summarized overall and by study group.

6.1.2. Additional considerations

The frequencies and percentages of subjects with medical history will be presented by MedDRA system organ class and preferred term, by study group and overall.

Medical history and demographic data will be tabulated for the All Enrolled, PPS (Day 29) and Overall Safety set.

6.2. Exposure

6.2.1. Analysis of exposure planned in the protocol

Subjects will be analyzed to the extent that they were exposed to study vaccines and according to the available safety data for the subject during any study period. Subjects who withdraw early or who are lost to follow-up will be removed from the summary table denominator for the time period in which they have no available safety data collected.

6.2.2. Additional considerations

The frequencies and percentages of subjects with vaccination will be summarized overall and by study group. Data will be tabulated for the All Enrolled Set.

6.3. Immunogenicity

6.3.1. Analysis of immunogenicity planned in the protocol

The analysis population to be used for the primary objectives is the PPS (Day 29). Analyses of primary objectives will be repeated on the FAS (Day 29) to assess robustness of results. Analyses of secondary immunogenicity will be based on the PPS and repeated on the FAS.

Missing immunogenicity values are assumed MCAR (Missing Completely At Random) and therefore may not contain information that impact the result of the analysis (i.e., not informative). Imputation methods will therefore not be used.

The hSBA titers at each visit will be logarithmically transformed (base10) to obtain approximately normally distributed data.

For comparison of percentages and GMT ratios, unadjusted estimates will be obtained along with adjusted estimates from regression models to account for potential baseline imbalance between study groups. For each *N. meningitidis* serogroup A, C, W and Y, unadjusted GMTs will be calculated, with their associated two-sided 95% CIs, by exponentiating the corresponding log-transformed means and their 95% CIs. Adjusted GMTs will be obtained from Analysis of Covariance (ANCOVA) models.

Seroresponse (Day 4, Day 6, and Day 29)

The percentage of subjects with seroresponse and associated two-sided 95% Clopper-Pearson CIs will be computed by group (Menveo-Menveo, Menactra-Menveo, the Naïve and the pooled [Menveo-Menveo and Menactra-Menveo] groups) and *N. meningitidis* serogroups A, C, W and Y test strains. Differences in percentages and associated 95% CIs between study groups will be calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - each of the previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) will be compared to the naïve group. Also the two previously vaccinated study groups will be compared to each other.

As sensitivity analyses, the difference in percentages will also be obtained from a log-linear model adjusting for pre-vaccination titer.

Percentage of Subjects With hSBA titer≥8 and ≥16 (Day 1, Day 4, Day 6, and Day 29)

For each study group and in the pooled group (Menveo-Menveo and Menactra-Menveo), the percentage of subjects with hSBA titer ≥8 and ≥16 and associated two-sided 95% Clopper-Pearson CIs will be computed by the *N. meningitidis* serogroups A, C, W and Y test strains on Day 1, Day 4, Day 6 and Day 29 (as applicable, depending on blood draw schedule).

Differences in percentages and associated 95% CIs between study groups will be calculated using the Miettinen & Nurminen score method.

In a descriptive fashion - using the difference in percentages and 95% CIs - the previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) will be compared to the naïve group. Also the two previously vaccinated groups will be compared to each other.

As sensitivity analyses, the difference in percentages will also be obtained from a log-linear model adjusting for pre-vaccination titer.

Between-group Ratios of GMTs (Adjusted and Unadjusted)

The between-group ratio of hSBA GMTs and corresponding 95% CI, at each of Visit Day 1 (Persistence), Day 4, Day 6 and Day 29 against each *N. meningitidis* serogroups A, C, W and Y test strains will be obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified.

Additionally, adjusted ratio of GMTs will be obtained from ANCOVA models including pre-vaccination titer as factors in the model.

The previously vaccinated groups (individually and pooled [Menveo-Menveo and Menactra-Menveo]) will be compared to the naïve group at each timepoint – descriptively – using the ratios of GMTs.

The two previously vaccinated groups will be compared at each timepoint using GMT ratios.

Within-group GMRs (Adjusted and Unadjusted)

Within each study group and for each serogroup, GMRs will be calculated, as applicable, at:

- Visit Day 4 versus at Visit Day 1;
- Visit Day 6 versus at Visit Day 1; and
- Visit Day 29 versus at Visit Day 1.

The unadjusted GMRs and 95% CIs will be constructed by exponentiating the mean within-group differences in log-transformed titers and the corresponding 95% CIs.

6.3.2. Additional considerations

Using the PPS (Day 29), the analyses of the primary objectives will be replicated by sex and race.

All sensitivity analyses will be performed on the PPS.

Reverse Cumulative Distributions Curves of hSBA Titers against *N. Meningitidis* serogroups A, C, W and Y will be produced at Days 1, 4, 6 and 29 for all study groups (Menveo-Menveo, Menactra-Menveo and the Naïve) on both the PPS and the FAS.

The adjusted ratio of GMTs, obtained from ANCOVA models including pre-vaccination titer as factors in the model, will be only computed as secondary analyses. The group titers of naïve subjects will be anyway always summarized without any adjustment (i.e. unadjusted GMTs and percentages).

6.4. Analysis of safety

6.4.1. Analysis of safety planned in the protocol

Analyses of solicited adverse events - and other solicited reactions - and unsolicited adverse events will be performed on the relevant safety sets.

For unsolicited adverse events, the entire study period will be divided into the following intervals: onset within 30 minutes after vaccination, onset within 28 days after vaccination; and from Day 1 through Day 181. For solicited adverse events, the solicited study period will be divided into intervals: from 6 hours through day 3; from day 4 through day 7; and from 6 hours through day 7.

No imputation methods will be used to address missing safety data.

Summaries of safety will be presented using frequencies and percentages within each study group. No statistical comparisons among the study groups with respect to any of the safety parameters will be performed.

Analysis of Solicited Local, Systemic and Other Adverse Events

All solicited adverse events will be summarized according to defined severity grading scales.

Frequencies and percentages of subjects experiencing each adverse event will be presented for each symptom severity. Summary tables showing the occurrence of any local or systemic adverse event overall and at each time point will also be presented.

Post-vaccination solicited adverse events reported from Day 1 to Day 7 will be summarized for the intervals Day 1 (6 hours) – Day 3, Days 4-7, Day 1 (6 hours) – Day 7 by maximal severity and by study group. Separate analyses will be performed for solicited AEs reported 30 minutes after vaccination. The severity of solicited local adverse events, including injection-site erythema and induration, will be categorized based on linear measurement: None (0-24 mm), Mild (25-50 mm), Moderate (51-100 mm), Severe (> 100mm).

Injection site pain and systemic reactions, including fatigue, headache, myalgia, arthralgia, chills, nausea, loss of appetite, occurring up to 7 days after each vaccination will be summarized according to “mild”, “moderate” or “severe”.

Each solicited local and systemic adverse event will also be further summarized as “none” versus “any”.

Use of antipyretics and analgesics will be summarized by frequency, by type of use (prophylactic versus treatment) and percentage of subjects reporting use.

Body temperature will be summarized separately according to the 3 schemes described below and will be broken down according to route of measurement:

- by 0.5 °C increments from 36.0°C up to ≥40°C;
- by 1°C increments: <36.0, 36.0-36.9, 37.0-37.9, 38.0-38.9, 39.0-39.9, ≥40°C;
- According to different cut-offs (< versus ≥): 38.0, 38.5, 39.0, 39.5, 40.0°C.

Analysis of Unsolicited Adverse Events

This analysis applies to all adverse events occurring during the study, judged either as probably related, possibly related, or not related to vaccination by the investigator, recorded in AE CRF, with a start date on or after the date of first vaccination. AE starting prior to the first vaccination will only be listed. The original verbatim terms used by investigators to identify adverse events in the CRFs will be mapped to preferred terms using the MedDRA dictionary. The adverse events will then be grouped by MedDRA preferred terms into frequency tables according to system organ class (SOC).

All reported adverse events, as well as adverse events judged by the investigator as at least possibly related to study vaccine, will be summarized according to SOC and preferred term within SOC. These summaries will be presented by study group and by interval of study observation. When an adverse event occurs more than once for a subject, the maximal severity and strongest relationship to the vaccine will be counted.

Separate summaries will be produced for the following categories:

- Adverse events that are possibly or probably related to vaccine
- Unsolicited AEs reported within 30 minutes after vaccination
- Unsolicited AEs reported within 29 days after vaccination
- Adverse events leading to withdrawal
- Adverse events leading to a medically attended visit
- Serious adverse events

Data listings of all adverse events will be provided by subject. In addition, adverse events in the categories above will be provided as listed data.

6.4.2. Additional considerations

6.4.2.1. Exclusion of implausible solicited Adverse Event

Some local and systemic adverse events will be directly measured by the subject and will not be subject to a reconciliation process, even if they are biologically implausible.

Therefore these implausible measurements will be removed from the analysis but included in listings. Implausible measurements are summarized in the table below:

Table 6.5.2.1-1: Implausible Solicited Adverse Events

Parameter	Implausible measurements
Body temperature	≤ 33°C or ≥ 42°C
Erythema	For subjects ≥ 6 years: ≥ 900 mm Measurements < 0 mm
Induration	For subjects ≥ 6 years: ≥ 500 mm Measurements < 0 mm

6.4.2.2. Solicited Adverse Events

For details please refer to section 7.1.1 of the protocol.

Fever, defined as a body temperature of ≥38°C irrespective of route of measurement, will be integrated to the summaries as a systemic adverse event.

The analyses will encompass summaries of the data on five levels:

1. Daily reports of subjects with solicited adverse events.
2. Time of first onset of solicited adverse events (excluding 30 min measurement).
3. Solicited adverse events, maximum event severity by event and interval [6h - day 3, day 4 -7, and 6h - day 7, each without 30 min].
4. Duration of solicited adverse events, including ongoing AE after Day 7.
5. Solicited adverse events and indicators of solicited adverse events, occurrence of at least one event by category (local, systemic) and interval 6h-Day 3, Day 4-7 and 6h-Day 7, each without 30 min].

For each of the time points or time intervals presented in the summaries, only subjects with at least one plausible observation (i.e., any non-missing values but excluding “Not done/unknown” and implausible values) for the solicited adverse events in the interval of interest will be considered. Subjects without plausible data (i.e. missing values or reported as “Not done/unknown” and implausible values) will be removed from the denominator to prevent a downward bias (towards zero).

Level 1: Daily reports of solicited adverse event

For each of the time points (30 min, 6h, days 2, 3, 4, 5, 6 and 7) only subjects with at least one plausible observation (i.e., any non-missing values but excluding "Not done/unknown" and implausible values) for the solicited adverse event in the interval of interest will be considered. Subjects without plausible data (i.e. missing values or reported as "Not done/unknown" and implausible values) will be removed from the denominator in order to prevent a downward bias (towards zero). Data collected will be summarized (frequencies and percentages of subjects) by study group, solicited adverse event and time point.

Level 2: Time of first onset of solicited adverse events

The **time of first onset** is defined, for each subject, for each solicited adverse event, as the time point at which the respective solicited adverse event first occurred. For erythema, and induration the following threshold will be used: ≥ 25 mm. The summary will provide the frequencies and percentages of subjects with first onset of each solicited adverse events by study group and by each time point (30 min, 6h, days 2, 3, 4, 5, 6 and 7). Note, 'not done' is treated identical to 'missing'.

Level 3: Solicited adverse events, maximum event severity by event and interval

The **maximum event severity** will be defined if there is at least one plausible non-missing observation (excluding "Not done/unknown" and implausible values) within this time interval. Each subject's data will be aggregated across the time points of the interval and summarized according to the maximal severity observed for each adverse event, followed by a summary across subjects for each vaccine. Subjects without any solicited adverse events in the interval, i.e., missing values at each of the requested time points, will be removed from the denominator.

Level 4: Number of days with solicited adverse events

The number of days with the adverse event is defined irrespective of severity. This means at least 'mild' solicited adverse event that are assessed qualitatively and ≥ 25 mm for erythema and induration. If a solicited adverse event continues beyond day 7 the period after day 7 is added.

The frequency distribution of the number of days will be provided in a summary table by vaccine and by adverse event.

Level 5: Solicited adverse events, occurrence of at least one event by category (local, systemic) and interval.

The **occurrence of at least one solicited adverse event** is defined as "any" for a subject if he/she reports greater than "none" (≥ 25 mm, for erythema and induration) for the respective event and "none" otherwise. The occurrence of at least one solicited adverse event (i.e., none versus any) will be summarized by category (i.e., local, systemic, any), by study group and by time interval.

Medications to treat or prevent pain or fever will be summarized by frequencies and percentages of subjects reporting use of the medications by interval (30min, 6h - day 3, day 4 - 7, 6h - day 7).

Safety completeness analysis

The safety completeness analysis on solicited adverse events aims to identify subjects who completed diary cards, irrespective of severity. The analysis will show the number of subjects with *valid data* by solicited adverse event and time point. *Valid data* in the context of the safety completeness analysis are all data entered in the diary card (including implausible values) except "Not done/unknown".

Four summaries will be produced:

1. The frequencies of subjects who provide diary cards by study group.
2. For each solicited adverse event, the frequencies of subjects with *valid data* will be presented by study group and timepoint: 30 min, 6h, days 2, 3, 4, 5, 6 and 7.
3. For each type of solicited adverse event (local, systemic) and indicators of solicited adverse events, such as analgesic use the frequencies of subjects *with valid data* by study group, aggregated over time points: 6h - day 7.
4. For each solicited adverse event, the frequencies of subjects *with valid data* by study group, aggregated over time points: 6h - day 7.

For the corresponding percentages, the denominator will be the respective numbers of exposed subjects, i.e., subjects who received a vaccination and were still in-study for that time point or time interval, irrespective of whether a diary card was present or not.

6.4.2.3. Unsolicited Adverse Events

All AEs occurring during the first 28 days after vaccination, including the day of vaccination, and all medically attended unsolicited adverse events, adverse events leading to study withdrawal and serious adverse events occurring at any time during the study will be recorded according to the protocol-specified reporting rules.

Only vaccine-emergent adverse events (see section 11.2 for definition) will be analyzed, i.e., excluding those after a subject has given informed consent but before vaccination. The selection of unsolicited adverse events and the assignment to time intervals will be done by day of onset and not by days ongoing/persisting.

The analysis of unsolicited adverse events comprises the following categories:

- Any unsolicited adverse event.
- Possibly or probably related unsolicited adverse events.
- Unsolicited adverse events leading to death.
- Serious adverse events.
- Possibly or probably related serious adverse event.
- Unsolicited adverse events leading to premature withdrawal from study.
- Unsolicited adverse events leading to hospitalization.
- Medically attended adverse events.

Solicited adverse events continuing beyond day 7 will be coded by MedDRA and combined with the respective unsolicited adverse events.

6.4.2.4. Combined Solicited and Unsolicited Adverse Events

A summary of subjects with all combined solicited (regardless of their duration) and unsolicited adverse events will be provided. Solicited adverse events will be coded by MedDRA as per the following codes:

Solicited symptom	Lower level code	Lower level term
Pain	10022086	Injection site pain
Fever	10016558	Fever
Loss of appetite	10003028	Appetite lost
Erythema	10022061	Injection site erythema
Induration	10022075	Injection site induration
Fatigue	10016256	Fatigue
Headache	10019211	Headache
Myalgia	10028411	Myalgia
Arthralgia	10003239	Arthralgia
Nausea	10028813	Nausea
Chills	10008531	Chills

For clintrial.gov and EudraCT posting purposes, a summary of combined solicited and unsolicited non-serious adverse events will be produced by System Organ Class and according to occurrence of each event.

6.4.2.5. Clinical Safety Laboratory Investigations

Not applicable.

6.4.2.6. Concomitant Medication

The frequencies and percentages of subjects reporting concomitant medications will be tabulated overall and by study group. Medications (generic drug name) will be coded using the WHODRUG dictionary (see section 11.2 for definition).

7. ANALYSIS INTERPRETATION

Except for analysis on primary immunogenicity objective with predefined success criterion, comparative analyses are descriptive with the aim to characterize the difference between groups. The use of these descriptive analyses should be limited to supportive analysis of confirmatory analyses or hypothesis generation. There are no success criteria associated with the secondary immunogenicity objectives in this study.

With respect to confirmatory analyses the interpretation must be done in a hierarchical manner. To demonstrate immune response sufficiency after MenACWY-CRM booster vaccine administration, the lower limit of the one-sided 97.5% Confidence Interval (CI) for percentage of subjects with hSBA booster seroresponse against each of serogroups A, C, W and Y must be greater than 75%. This will be tested sequentially first in the group of subjects who received primary vaccination with Menveo and, if met, also in the group of subjects who received primary vaccination with Menactra.

Null hypothesis: $P_{ij} \leq 0.75$

versus

Alternative hypothesis: $P_{ij} > 0.75$

Where: P_{ij} is the population booster seroresponse rate; $j = 1,2$ refer to group Menveo-Menveo (first test) and Menactra-Menveo (second test) respectively; $i = 1,2,3,4$ refer to serogroup A, C, W and Y respectively. Overall significance level for all hypothesis tests is one-sided $\alpha = 2.5\%$.

Note that the lower limit of the 1-sided 97.5% CI corresponds to the lower limit of the 2-sided 95% CI that will be presented in the statistical output.

The study will be considered successful if the immune response sufficiency will be demonstrated at least in the group of subjects who received primary vaccination with Menveo.

8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

Description	Analysis ID	Disclosure Purpose (CTRS=web posting, SR=study report, internal)	Dry run review needed (Y/N)	*Study Headline Summary (SHS)*requiring expedited communication to upper management (Yes/No)	Reference for TF
Final analysis	E1_01	SR and CTRS	Y	Yes	All tables from TF 25-JUL-2016

8.2. Statistical considerations for interim analyses

No interim analysis of data from this study is planned.

9. CHANGES FROM PLANNED ANALYSES

None

10. LIST OF FINAL REPORT TABLES, LISTINGS AND FIGURES

The TFL TOC provides the list of tables/listings and figures needed for the study report. It also identifies the tables eligible for each analyses and their role (synopsis, in-text, post-text, SHS…)

The mock tables referred under column named 'layout' can be found in the legacy-NV SDD dedicated folder for standard tables.

The following group names will be used in the TFLs:

Group order in tables	Group label in tables	Group definition for footnote	Pooled Groups label in tables	Pooled definition for footnote
1	Menveo-Menveo	Subjects previously vaccinated with Menveo	Pooled Menveo/Menactra - Menveo	Subjects previously vaccinated with Menveo/Menactra
2	Menactra-Menveo	Subjects previously vaccinated with Menactra	Pooled Menveo/Menactra - Menveo	Subjects previously vaccinated with Menveo/Menactra
3	Naive	Naive subjects	Naive	Naive subjects

11. ANNEX 1 STANDARD DATA DERIVATION RULE AND STAT METHODS

11.1. Statistical method references

Nauta J. Statistics in Clinical Vaccine Trials. 2010. Heidelberg: Springer.

U.S. Department of Health and Human Services, Food and Drug Administration, CBER (2007): Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials

Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of binomial. *Biometrika*. 1934;26:404-413.Miettinen O., Nurminen M. Comparative analysis of two rates. Statistics in Medicine 1985; 4(2):213-226.

11.2. Standard data derivation

Immunogenicity

Values below the limit of quantification (recorded as "< LQ") will be set to half that limit.

Seroresponse is defined for this booster study as follows:

- for subjects with pre-vaccination titers <4, post-vaccination titers ≥ 16;
- for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

Duration in the Study

Duration in the study is defined in days as:

Last visit date (visit x)[a] – Enrollment date (visit 1) + 1

[a]or premature discontinuation date (in case of withdrawal from the study)

The duration is missing if one of the dates is missing or incomplete.

Unsolicited Adverse Events

All adverse events will be characterized according to the date of occurrence related to the vaccination phase as follows:

- **Emergence before vaccination phase**: start date before the first date of injection of study vaccine.
- **Emergence during vaccination phase**: start date on or after the first date of injection of study vaccine or, adverse event increase in severity including to "serious" adverse event.

If start date is equal to the first date of injection then "timing" variable ("On injection day, before injection"/"On injection day, after injection") will be used to define whether the adverse event occur before or after the injection.

If an adverse event start date is missing or unknown, the adverse event will be considered as emergent.

When start and/or end dates of an adverse event are only partially known, adverse events will be categorized as emergent before, during, or after vaccination phase using the following rules:

- If the partial end date is before (<) the first study vaccination (i.e., year or year & month is/are before the first study vaccination year or year & month) then the adverse event is emergent before vaccination phase.
- If the partial start date is equal or after (≥) the first study vaccination (i.e., year or year & month is/are after or the same as the first study injection year or year & month) then the adverse event is emergent during vaccination phase.

The **maximum event severity** is the greatest severity associated with a preferred term for a reported adverse event according to the following order: Mild < Moderate < Severe. Unknown/ Missing severity is considered as severe (except for the definition of emergence).

Multiple AEs with the same PT for the same subject are counted only once.

Vaccination-related Adverse Events are those for which the cause has been evaluated by the investigator, and recorded either as possibly related, probably related or unknown/ missing.

Prestudy, Concomitant and Post-Vaccination Medications

A **previous medication** is a medication used only before the first study vaccination (i.e. medication end date < first study vaccination date).

A **post-vaccination medication** is a medication used only after study vaccination + 28 days (i.e. medication start date > last study vaccination date + 28 days).

All other medications are **concomitant**.

When start and/or end dates of a medication intake are missing, the medication is considered as concomitant with the study vaccination schedule.

If the first study vaccination date is missing then the medication is considered as concomitant with the study vaccination schedule, provided that the study vaccine was administered to the subject.

The business rule can be consulting by clicking on the following icon:

NV business rule.docx

12. ANNEX 2: SUMMARY ON ELIMINATION CODES

Table 12-1 Safety Sets

PD code	PD Description	Study Period	*All Exposed Set*	*Safety Set, Unsolicited AEs*	*Safety Set, Solicited AEs*
	Exclusion code		***EXPFL***	***SSUFL***	***SSSFL***
100	**Study vaccine not administered AT ALL**	**D1-D181**	*EXC*	*EXC*	*EXC*
115	**Subject did not provide any post-vaccination unsolicited safety data**	**D1-D181**	*None*	*EXC*	*None*
116	**Subject did not provide any post-vaccination solicited safety data**	**D1**	*None*	*None*	*EXC*

EXC = excluded from this analysis set.

Table 12-2 Immunogenicity Sets

PD code	PD Description	Study Period	*FAS Day 1*	*FAS Day 29*	*PPS Day 1*	*PPS Day 29*
	Exclusion code		***FAS01FL***	***FAS29FL***	***PPS01FL***	***PPS29FL***
100	**Study vaccine not administered AT ALL**	**D1-D181**	*EXC*	*EXC*	*EXC*	*EXC*
110.1	**Serological results are not available at Day 1 for none of the serogroups**	**D1**	*EXC*	*EXC (for serorespo nse only)*	*EXC*	*EXC (for serorespo nse only)*
110.2	**Serological results are not available at Day 29 for none of the serogroups**	**D29**	*None*	*EXC*	*None*	*EXC*
112.1	**Obvious deviation from Laboratory Manual or error in laboratory data at D1**	**D1**	*None*	*None*	*EXC*	*EXC (for serorespo nse only)*
112.2	**Obvious deviation from Laboratory Manual or error in laboratory data at D29**	**D29**	*None*	*None*	*None*	*EXC*
120	**Randomization failure**	**D1- D29**	*None*	*None*	*None*	*EXC (for analysis at D4 and D6 only)*

PD code	PD Description	Study Period	*FAS Day 1*	*FAS Day 29*	*PPS Day 1*	*PPS Day 29*
	Exclusion code		***FAS01FL***	***FAS29FL***	***PPS01FL***	***PPS29FL***
140	**Vaccination not according to protocol**	**D1**	*None*	*None*	*None*	*EXC*
150	**Administration of forbidden vaccine**	**D1- D29**	*None*	*None*	*None*	*EXC*
200	**Subject did not meet entry criteria**	**D1- D29**	*None*	*None*	*EXC*	*EXC*
230	**Administration of forbidden medication**	**D1- D29**	*None*	*None*	*None*	*EXC*
240	**Underlying medical condition forbidden by the protocol**	**D1- D29**	*None*	*None*	*EXC*	*EXC*
250	**Concomitant infection related to the vaccine which may influence immune response**	**D1- D29**	*None*	*None*	*None*	*EXC*
260	**Did not comply with study vaccination schedule**	**D1**	*None*	*None*	*None*	*EXC*
270.1	**Did not comply with blood draw schedule at Day 1**	**D1**	*None*	*None*	*EXC*	*None*

PD code	PD Description	Study Period	*FAS Day 1*	*FAS Day 29*	*PPS Day 1*	*PPS Day 29*
	Exclusion code		***FAS01FL***	***FAS29FL***	***PPS01FL***	***PPS29FL***
270.2	**Did not comply with blood draw schedule at Day 4 or Day 6**	**D4/D6**	*None*	*None*	*None*	*EXC (for analysis at D4 and D6 only)*
270.3	**Did not comply with blood draw schedule at Day 29**	**D29**	*None*	*None*	*None*	*EXC*

FAS = Full Analysis Set; PPS=Per Protocol Set; EXC = excluded from this analysis set.

13. ANNEX 3: STUDY SPECIFIC MOCK TFL

Not applicable

PPD

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ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0016AB	Menveo-Menveo	289	0	0.45	0.386	0.023	0.149	2.00	2.0	140.0	1.968	2.810	2.535	3.114
Day 1	M0016AB	Menactra-Menveo	282	0	0.47	0.407	0.024	0.165	2.00	2.0	173.0	1.968	2.954	2.647	3.296
Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	571	0	0.46	0.396	0.017	0.157	2.00	2.0	173.0	1.964	2.880	2.672	3.104
Day 1	M0016AB	Naive	93	0	0.36	0.211	0.022	0.044	2.00	2.0	71.0	1.986	2.272	2.056	2.511
Day 4	M0016AB	Menveo-Menveo	144	0	0.45	0.417	0.035	0.174	2.00	2.0	244.0	1.977	2.826	2.412	3.310
Day 4	M0016AB	Menactra-Menveo	138	0	0.48	0.428	0.036	0.183	2.00	2.0	453.0	1.977	3.004	2.545	3.547
Day 4	M0016AB	Pooled Menveo/ Menactra-Menveo	282	0	0.46	0.422	0.025	0.178	2.00	2.0	453.0	1.968	2.912	2.598	3.263
Day 4	M0016AB	Naive	48	0	0.35	0.266	0.038	0.071	2.00	2.0	101.0	2.012	2.249	1.882	2.686
Day 6	M0016AB	Menveo-Menveo	146	0	1.11	0.823	0.068	0.677	11.00	2.0	817.0	1.976	12.867	9.439	17.542
Day 6	M0016AB	Menactra-Menveo	140	0	1.01	0.819	0.069	0.670	2.00	2.0	1688.0	1.977	10.168	7.421	13.931
Day 6	M0016AB	Pooled Menveo/ Menactra-Menveo	286	0	1.06	0.821	0.049	0.674	8.00	2.0	1688.0	1.968	11.466	9.202	14.288
Day 6	M0016AB	Naive	44	0	0.39	0.294	0.044	0.086	2.00	2.0	36.0	2.017	2.480	2.019	3.046

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0016AB	Menveo-Menveo	290	0	2.32	0.476	0.028	0.226	215.00	2.0	7250.0	1.968	210.102	185.114	238.462
Day 29	M0016AB	Menactra-Menveo	282	0	2.37	0.497	0.030	0.247	215.00	2.0	3861.0	1.968	236.685	206.948	270.695
Day 29	M0016AB	Pooled Menveo/ Menactra-Menveo	572	0	2.35	0.487	0.020	0.237	215.00	2.0	7250.0	1.964	222.812	203.216	244.298
Day 29	M0016AB	Naive	93	0	1.51	0.889	0.092	0.790	37.00	2.0	1999.0	1.986	32.115	21.070	48.949
Day 4/Day 1	M0016AB	Menveo-Menveo	144	0	0.01	0.260	0.022	0.068	1.00	0.1	122.0	1.977	1.019	0.923	1.125
Day 4/Day 1	M0016AB	Menactra-Menveo	138	0	0.03	0.266	0.023	0.071	1.00	0.1	226.5	1.977	1.067	0.962	1.182
Day 4/Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	282	0	0.02	0.263	0.016	0.069	1.00	0.1	226.5	1.968	1.042	0.971	1.119
Day 4/Day 1	M0016AB	Naive	48	0	-0.00	0.062	0.009	0.004	1.00	0.4	1.4	2.012	0.990	0.950	1.032
Day 6/Day 1	M0016AB	Menveo-Menveo	145	0	0.66	0.790	0.066	0.624	1.67	0.1	408.5	1.977	4.578	3.396	6.170
Day 6/Day 1	M0016AB	Menactra-Menveo	140	0	0.51	0.746	0.063	0.557	1.00	0.1	267.5	1.977	3.248	2.437	4.328
Day 6/Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	285	0	0.59	0.771	0.046	0.594	1.00	0.1	408.5	1.968	3.868	3.145	4.757
Day 6/Day 1	M0016AB	Naive	44	0	0.04	0.237	0.036	0.056	1.00	0.4	18.0	2.017	1.088	0.921	1.285

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0016AB	Menveo-Menveo	289	0	1.88	0.542	0.032	0.293	93.00	1.0	862.5	1.968	75.020	64.932	86.676
Day 29/Day 1	M0016AB	Menactra-Menveo	282	0	1.90	0.560	0.033	0.314	90.25	1.0	1930.5	1.968	80.130	68.886	93.209
Day 29/Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	571	0	1.89	0.551	0.023	0.303	91.50	1.0	1930.5	1.964	77.502	69.832	86.014
Day 29/Day 1	M0016AB	Naive	93	0	1.15	0.867	0.090	0.753	17.50	1.0	999.5	1.986	14.136	9.369	21.330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0019AB	Menveo-Menveo	288	0	1.21	0.789	0.046	0.622	13.00	2.0	1590.0	1.968	16.112	13.052	19.889
Day 1	M0019AB	Menactra-Menveo	281	0	1.03	0.724	0.043	0.525	10.00	2.0	1848.0	1.968	10.718	8.812	13.037
Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	569	0	1.12	0.762	0.032	0.581	11.00	2.0	1848.0	1.964	13.174	11.402	15.222
Day 1	M0019AB	Naive	93	0	0.70	0.470	0.049	0.221	4.00	2.0	208.0	1.986	5.057	4.046	6.320
Day 4	M0019AB	Menveo-Menveo	144	0	1.36	0.787	0.066	0.620	20.50	2.0	1457.0	1.977	22.959	17.033	30.946
Day 4	M0019AB	Menactra-Menveo	138	0	1.16	0.771	0.066	0.594	12.50	2.0	3385.0	1.977	14.295	10.603	19.272
Day 4	M0019AB	Pooled Menveo/ Menactra-Menveo	282	0	1.26	0.785	0.047	0.616	15.00	2.0	3385.0	1.968	18.207	14.733	22.502
Day 4	M0019AB	Naive	48	0	0.83	0.522	0.075	0.273	6.00	2.0	232.0	2.012	6.687	4.716	9.480
Day 6	M0019AB	Menveo-Menveo	145	0	1.97	0.827	0.069	0.683	115.00	2.0	3663.0	1.977	92.272	67.514	126.109
Day 6	M0019AB	Menactra-Menveo	139	0	1.95	0.773	0.066	0.597	99.00	2.0	3859.0	1.977	90.061	66.820	121.388
Day 6	M0019AB	Pooled Menveo/ Menactra-Menveo	284	0	1.96	0.799	0.047	0.639	104.50	2.0	3859.0	1.968	91.183	73.544	113.054
Day 6	M0019AB	Naive	44	0	0.83	0.589	0.089	0.347	5.00	2.0	351.0	2.017	6.709	4.442	10.134

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0019AB	Menveo-Menveo	290	0	3.06	0.569	0.033	0.323	1425.00	13.0	19263	1.968	1159.926	997.061	1349.394
Day 29	M0019AB	Menactra-Menveo	281	0	3.02	0.593	0.035	0.352	1122.00	2.0	33272	1.968	1057.660	900.961	1241.613
Day 29	M0019AB	Pooled Menveo/ Menactra-Menveo	571	0	3.04	0.581	0.024	0.337	1234.00	2.0	33272	1.964	1108.419	993.081	1237.154
Day 29	M0019AB	Naive	93	0	1.78	0.951	0.099	0.905	50.00	2.0	41043	1.986	59.697	38.024	93.722
Day 4/Day 1	M0019AB	Menveo-Menveo	143	0	0.05	0.247	0.021	0.061	1.00	0.3	30.3	1.977	1.123	1.023	1.234
Day 4/Day 1	M0019AB	Menactra-Menveo	137	0	0.13	0.436	0.037	0.190	1.00	0.1	178.2	1.978	1.353	1.142	1.603
Day 4/Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	280	0	0.09	0.354	0.021	0.125	1.00	0.1	178.2	1.969	1.230	1.118	1.354
Day 4/Day 1	M0019AB	Naive	48	0	0.08	0.253	0.036	0.064	1.00	0.4	10.5	2.012	1.212	1.024	1.435
Day 6/Day 1	M0019AB	Menveo-Menveo	144	0	0.86	0.838	0.070	0.703	5.63	0.0	923.0	1.977	7.252	5.277	9.967
Day 6/Day 1	M0019AB	Menactra-Menveo	139	0	0.90	0.819	0.069	0.670	5.85	0.7	1929.5	1.977	7.939	5.787	10.891
Day 6/Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	283	0	0.88	0.828	0.049	0.685	5.76	0.0	1929.5	1.968	7.582	6.066	9.475
Day 6/Day 1	M0019AB	Naive	44	0	0.16	0.395	0.060	0.156	1.00	0.4	59.0	2.017	1.451	1.100	1.913

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0019AB	Menveo-Menveo	288	0	1.86	0.710	0.042	0.504	69.50	0.5	3265.0	1.968	71.723	59.331	86.703
Day 29/Day 1	M0019AB	Menactra-Menveo	280	0	1.99	0.740	0.044	0.547	98.98	0.3	8361.5	1.969	97.130	79.494	118.679
Day 29/Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	568	0	1.92	0.727	0.031	0.529	83.75	0.3	8361.5	1.964	83.287	72.550	95.613
Day 29/Day 1	M0019AB	Naive	93	0	1.07	0.832	0.086	0.691	8.80	0.8	4178.5	1.986	11.805	7.958	17.512

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0021AB	Menveo-Menveo	289	0	1.34	0.634	0.037	0.402	28.00	2.0	761.0	1.968	22.075	18.641	26.141
Day 1	M0021AB	Menactra-Menveo	282	0	1.37	0.678	0.040	0.459	31.00	2.0	6726.0	1.968	23.463	19.540	28.173
Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	571	0	1.36	0.656	0.027	0.430	29.00	2.0	6726.0	1.964	22.750	20.094	25.755
Day 1	M0021AB	Naive	93	0	1.09	0.661	0.069	0.437	14.00	2.0	200.0	1.986	12.213	8.927	16.709
Day 4	M0021AB	Menveo-Menveo	144	0	1.41	0.622	0.052	0.387	33.00	2.0	763.0	1.977	25.896	20.456	32.783
Day 4	M0021AB	Menactra-Menveo	138	0	1.53	0.706	0.060	0.498	42.00	2.0	7353.0	1.977	33.873	25.769	44.526
Day 4	M0021AB	Pooled Menveo/ Menactra-Menveo	282	0	1.47	0.665	0.040	0.443	36.00	2.0	7353.0	1.968	29.533	24.677	35.343
Day 4	M0021AB	Naive	48	0	1.14	0.690	0.100	0.476	23.00	2.0	186.0	2.012	13.797	8.700	21.878
Day 6	M0021AB	Menveo-Menveo	146	0	2.05	0.714	0.059	0.510	146.50	2.0	6974.0	1.976	112.493	85.960	147.216
Day 6	M0021AB	Menactra-Menveo	140	0	2.16	0.700	0.059	0.490	164.50	2.0	22491	1.977	143.754	109.819	188.174
Day 6	M0021AB	Pooled Menveo/ Menactra-Menveo	286	0	2.10	0.708	0.042	0.501	150.50	2.0	22491	1.968	126.840	104.919	153.340
Day 6	M0021AB	Naive	44	0	1.20	0.716	0.108	0.513	20.00	2.0	577.0	2.017	15.984	9.681	26.391

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0021AB	Menveo-Menveo	290	0	3.14	0.535	0.031	0.286	1521.00	20.0	87078	1.968	1394.646	1209.519	1608.108
Day 29	M0021AB	Menactra-Menveo	281	0	3.28	0.653	0.039	0.427	2057.00	18.0	78040	1.968	1883.963	1578.934	2247.920
Day 29	M0021AB	Pooled Menveo/ Menactra-Menveo	571	0	3.21	0.599	0.025	0.359	1680.00	18.0	87078	1.964	1617.107	1443.722	1811.316
Day 29	M0021AB	Naive	92	0	1.74	0.867	0.090	0.752	57.50	2.0	29145	1.986	55.311	36.581	83.630
Day 4/Day 1	M0021AB	Menveo-Menveo	144	0	0.02	0.354	0.030	0.126	1.00	0.0	64.0	1.977	1.054	0.922	1.206
Day 4/Day 1	M0021AB	Menactra-Menveo	138	0	0.15	0.422	0.036	0.178	1.04	0.2	68.7	1.977	1.398	1.187	1.647
Day 4/Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	282	0	0.08	0.393	0.023	0.154	1.00	0.0	68.7	1.968	1.211	1.089	1.346
Day 4/Day 1	M0021AB	Naive	48	0	0.06	0.471	0.068	0.222	1.00	0.1	51.0	2.012	1.141	0.833	1.564
Day 6/Day 1	M0021AB	Menveo-Menveo	145	0	0.76	0.709	0.059	0.503	4.37	0.2	646.5	1.977	5.709	4.367	7.464
Day 6/Day 1	M0021AB	Menactra-Menveo	140	0	0.80	0.739	0.062	0.546	5.04	0.5	346.0	1.977	6.274	4.722	8.338
Day 6/Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	285	0	0.78	0.723	0.043	0.523	4.50	0.2	646.5	1.968	5.980	4.925	7.261
Day 6/Day 1	M0021AB	Naive	44	0	0.12	0.601	0.091	0.361	1.00	0.1	288.5	2.017	1.322	0.868	2.014

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0021AB	Menveo-Menveo	289	0	1.80	0.693	0.041	0.480	73.11	1.7	6382.5	1.968	63.627	52.897	76.533
Day 29/Day 1	M0021AB	Menactra-Menveo	281	0	1.91	0.881	0.053	0.777	83.26	0.4	6902.0	1.968	80.605	63.514	102.296
Day 29/Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	570	0	1.85	0.792	0.033	0.628	73.95	0.4	6902.0	1.964	71.496	61.531	83.074
Day 29/Day 1	M0021AB	Naive	92	0	0.66	0.882	0.092	0.778	2.11	0.3	14573	1.986	4.575	3.004	6.967

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0023AB	Menveo-Menveo	287	0	0.97	0.645	0.038	0.416	10.00	2.0	350.0	1.968	9.244	7.779	10.985
Day 1	M0023AB	Menactra-Menveo	281	0	0.91	0.663	0.040	0.439	6.00	2.0	5173.0	1.968	8.220	6.871	9.834
Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	568	0	0.94	0.654	0.027	0.427	8.00	2.0	5173.0	1.964	8.723	7.705	9.875
Day 1	M0023AB	Naive	93	0	0.66	0.466	0.048	0.217	2.00	2.0	72.0	1.986	4.557	3.653	5.685
Day 4	M0023AB	Menveo-Menveo	143	0	1.04	0.730	0.061	0.532	10.00	2.0	381.0	1.977	10.873	8.237	14.353
Day 4	M0023AB	Menactra-Menveo	138	0	1.08	0.787	0.067	0.619	11.00	2.0	12288	1.977	12.120	8.935	16.442
Day 4	M0023AB	Pooled Menveo/ Menactra-Menveo	281	0	1.06	0.757	0.045	0.573	10.00	2.0	12288	1.968	11.469	9.345	14.074
Day 4	M0023AB	Naive	48	0	0.67	0.496	0.072	0.246	2.00	2.0	84.0	2.012	4.628	3.322	6.446
Day 6	M0023AB	Menveo-Menveo	145	0	1.80	0.760	0.063	0.578	80.00	2.0	2563.0	1.977	63.301	47.496	84.365
Day 6	M0023AB	Menactra-Menveo	140	0	1.79	0.777	0.066	0.604	61.50	2.0	23434	1.977	61.557	45.642	83.022
Day 6	M0023AB	Pooled Menveo/ Menactra-Menveo	285	0	1.80	0.767	0.045	0.589	72.00	2.0	23434	1.968	62.438	50.814	76.721
Day 6	M0023AB	Naive	44	0	0.81	0.618	0.093	0.382	2.00	2.0	184.0	2.017	6.443	4.179	9.934

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0023AB	Menveo-Menveo	290	0	3.03	0.537	0.032	0.289	879.00	45.0	26324	1.968	1066.662	924.562	1230.602
Day 29	M0023AB	Menactra-Menveo	281	0	3.00	0.615	0.037	0.378	965.00	2.0	22572	1.968	1007.622	853.324	1189.822
Day 29	M0023AB	Pooled Menveo/ Menactra-Menveo	571	0	3.02	0.576	0.024	0.332	912.00	2.0	26324	1.964	1037.187	930.013	1156.712
Day 29	M0023AB	Naive	93	0	1.57	0.927	0.096	0.860	30.00	2.0	6607.0	1.986	37.403	24.096	58.061
Day 4/Day 1	M0023AB	Menveo-Menveo	142	0	0.13	0.455	0.038	0.207	1.00	0.1	177.0	1.977	1.354	1.138	1.610
Day 4/Day 1	M0023AB	Menactra-Menveo	137	0	0.12	0.449	0.038	0.202	1.00	0.0	77.5	1.978	1.307	1.097	1.556
Day 4/Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	279	0	0.12	0.451	0.027	0.204	1.00	0.0	177.0	1.969	1.330	1.177	1.504
Day 4/Day 1	M0023AB	Naive	48	0	-0.00	0.194	0.028	0.038	1.00	0.2	2.3	2.012	0.993	0.872	1.131
Day 6/Day 1	M0023AB	Menveo-Menveo	143	0	0.78	0.794	0.066	0.630	4.78	0.0	621.0	1.977	6.093	4.504	8.241
Day 6/Day 1	M0023AB	Menactra-Menveo	140	0	0.93	0.845	0.071	0.714	9.00	0.1	639.5	1.977	8.593	6.208	11.894
Day 6/Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	283	0	0.86	0.821	0.049	0.675	6.00	0.0	639.5	1.968	7.222	5.789	9.011
Day 6/Day 1	M0023AB	Naive	44	0	0.17	0.460	0.069	0.212	1.00	0.3	88.0	2.017	1.478	1.071	2.040

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0023AB	Menveo-Menveo	287	0	2.07	0.717	0.042	0.515	137.17	1.2	5831.0	1.968	116.584	96.226	141.250
Day 29/Day 1	M0023AB	Menactra-Menveo	280	0	2.09	0.813	0.049	0.660	132.19	0.8	7755.5	1.969	123.408	99.023	153.798
Day 29/Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	567	0	2.08	0.765	0.032	0.586	135.31	0.8	7755.5	1.964	119.906	103.683	138.666
Day 29/Day 1	M0023AB	Naive	93	0	0.91	0.925	0.096	0.855	6.00	0.1	3303.5	1.986	8.207	5.294	12.724

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.91589301	0.45794651	3.24	0.0398
Error	661	93.44966627	0.14137620		
Corrected Total	663	94.36555928			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.009706	84.50199	0.376000	0.444960

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.91589301	0.45794651	3.24	0.0398

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.91589301	0.45794651	3.24	0.0398

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.44866467	0.02211766	<.0001
2	0.47037711	0.02239049	<.0001
4	0.35637820	0.03898941	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.448665	0.405235	0.492094
2	0.470377	0.426412	0.514342
4	0.356378	0.279820	0.432936

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	662
Number of Observations Used	662

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	18.2795845	9.1397922	17.42	<.0001
Error	659	345.7392151	0.5246422		
Corrected Total	661	364.0187996			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.050216	68.24863	0.724322	1.061299

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.27958446	9.13979223	17.42	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.27958446	9.13979223	17.42	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.20713672	0.04268108	<.0001
2	1.03012182	0.04320942	<.0001
4	0.70387272	0.07510868	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.207137	1.123329	1.290944
2	1.030122	0.945277	1.114967
4	0.703873	0.556392	0.851354

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	5.9364803	2.9682401	6.88	0.0011
Error	661	285.1547673	0.4313990		
Corrected Total	663	291.0912476			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.020394	49.79092	0.656810	1.319136

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.93648027	2.96824014	6.88	0.0011

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.93648027	2.96824014	6.88	0.0011

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.34389254	0.03863587	<.0001
2	1.37037614	0.03911245	<.0001
4	1.08682756	0.06810800	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.343893	1.268029	1.419756
2	1.370376	1.293577	1.447176
4	1.086828	0.953093	1.220562

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	661
Number of Observations Used	661

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.7219221	3.3609610	8.44	0.0002
Error	658	262.0201932	0.3982070		
Corrected Total	660	268.7421153			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.025013	70.03918	0.631036	0.900976

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.72192207	3.36096104	8.44	0.0002

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.72192207	3.36096104	8.44	0.0002

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.96587579	0.03724890	<.0001
2	0.91487444	0.03764448	<.0001
4	0.65870176	0.06543543	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.965876	0.892735	1.039017
2	0.914874	0.840957	0.988792
4	0.658702	0.530214	0.787189

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.56634457	0.28317228	1.74	0.1777
Error	327	53.31988202	0.16305774		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.010510	90.16919	0.403804	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.56634457	0.28317228	1.74	0.1777

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.56634457	0.28317228	1.74	0.1777

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.45113311	0.03365034	<.0001
2	0.47773488	0.03437409	<.0001
4	0.35193946	0.05828410	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.451133	0.384935	0.517332
2	0.477735	0.410113	0.545357
4	0.351939	0.237280	0.466599

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	17.6073235	8.8036617	14.76	<.0001
Error	327	194.9859572	0.5962873		
Corrected Total	329	212.5932807			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.082822	79.54482	0.772196	0.970769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60732348	8.80366174	14.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60732348	8.80366174	14.76	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.10948742	0.06390743	<.0001
2	1.00721914	0.06526251	<.0001
4	0.39449829	0.11641299	0.0008

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.109487	0.983766	1.235209
2	1.007219	0.878832	1.135606
4	0.394498	0.165485	0.623511

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 665
Number of Observations Used 665

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	56.9921134	28.4960567	90.86	<.0001
Error	662	207.6235223	0.3136307		
Corrected Total	664	264.6156357			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.215377	25.11004	0.560027	2.230293

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	56.99211336	28.49605668	90.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	56.99211336	28.49605668	90.86	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	2.32242917	0.03288594	<.0001
2	2.37417124	0.03334915	<.0001
4	1.50670714	0.05807214	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	2.322429	2.257856	2.387002
2	2.374171	2.308688	2.439654
4	1.506707	1.392679	1.620735

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	10.7469338	5.3734669	9.61	<.0001
Error	327	182.8100969	0.5590523		
Corrected Total	329	193.5570307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.055523	62.46584	0.747698	1.196971

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.74693381	5.37346690	9.61	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.74693381	5.37346690	9.61	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.36094719	0.06230817	<.0001
2	1.15517433	0.06364828	<.0001
4	0.82520848	0.10792091	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.360947	1.238372	1.483523
2	1.155174	1.029963	1.280386
4	0.825208	0.612902	1.037515

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	328
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	48.9347252	24.4673626	40.62	<.0001
Error	325	195.7593502	0.6023365		
Corrected Total	327	244.6940754			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.199983	42.92858	0.776103	1.807894

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	48.93472516	24.46736258	40.62	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	48.93472516	24.46736258	40.62	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.96506921	0.06445188	<.0001
2	1.95453889	0.06582823	<.0001
4	0.82666701	0.11700199	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.965069	1.838274	2.091865
2	1.954539	1.825036	2.084042
4	0.826667	0.596490	1.056844

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	128.9671983	64.4835991	154.93	<.0001
Error	661	275.1208628	0.4162192		
Corrected Total	663	404.0880610			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.319156	22.50262	0.645150	2.867002

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.9671983	64.4835991	154.93	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.9671983	64.4835991	154.93	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.06443015	0.03788454	<.0001
2	3.02434615	0.03848645	<.0001
4	1.77594920	0.06689899	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.064430	2.990042	3.138819
2	3.024346	2.948776	3.099917
4	1.775949	1.644589	1.907309

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	5.4396506	2.7198253	6.10	0.0025
Error	327	145.8232391	0.4459426		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.035962	46.95385	0.667789	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.43965064	2.71982532	6.10	0.0025

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.43965064	2.71982532	6.10	0.0025

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.41323372	0.05564911	<.0001
2	1.52985192	0.05684601	<.0001
4	1.13977003	0.09638709	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.413234	1.303758	1.522709
2	1.529852	1.418022	1.641682
4	1.139770	0.950153	1.329387

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	31.6683612	15.8341806	31.55	<.0001
Error	327	164.1033695	0.5018452		
Corrected Total	329	195.7717307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.161762	35.71852	0.708410	1.983314

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.66836119	15.83418059	31.55	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.66836119	15.83418059	31.55	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	2.05112525	0.05862845	<.0001
2	2.15761926	0.05987160	<.0001
4	1.20369471	0.10679687	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	2.051125	1.935789	2.166462
2	2.157619	2.039837	2.275401
4	1.203695	0.993599	1.413790

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	663
Number of Observations Used	663

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	172.7036988	86.3518494	210.57	<.0001
Error	660	270.6514594	0.4100780		
Corrected Total	662	443.3551582			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.389538	21.30798	0.640373	3.005322

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	172.7036988	86.3518494	210.57	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	172.7036988	86.3518494	210.57	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.14446390	0.03760402	<.0001
2	3.27507236	0.03820147	<.0001
4	1.74281016	0.06676353	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.144464	3.070626	3.218302
2	3.275072	3.200061	3.350083
4	1.742810	1.611716	1.873905

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.5247404	3.2623702	6.19	0.0023
Error	326	171.9233683	0.5273723		
Corrected Total	328	178.4481086			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.036564	72.47442	0.726204	1.002014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.52474037	3.26237019	6.19	0.0023

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.52474037	3.26237019	6.19	0.0023

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.03635294	0.06072823	<.0001
2	1.08352013	0.06181859	<.0001
4	0.66538389	0.10481852	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.036353	0.916884	1.155822
2	1.083520	0.961906	1.205134
4	0.665384	0.459178	0.871590

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	37.0921105	18.5460553	32.92	<.0001
Error	326	183.6416298	0.5633179		
Corrected Total	328	220.7337404			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.168040	45.11742	0.750545	1.663537

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	37.09211054	18.54605527	32.92	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	37.09211054	18.54605527	32.92	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.80140927	0.06232937	<.0001
2	1.78927705	0.06343263	<.0001
4	0.80910521	0.11314892	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.801409	1.678791	1.924028
2	1.789277	1.664488	1.914066
4	0.809105	0.586511	1.031699

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	166.6014869	83.3007434	205.21	<.0001
Error	661	268.3150092	0.4059229		
Corrected Total	663	434.9164961			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.383065	22.64306	0.637121	2.813758

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	166.6014869	83.3007434	205.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	166.6014869	83.3007434	205.21	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.02802685	0.03741302	<.0001
2	3.00329786	0.03800744	<.0001
4	1.57291095	0.06606634	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.028027	2.954564	3.101490
2	3.003298	2.928668	3.077928
4	1.572911	1.443186	1.702636

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.84860646	0.84860646	6.01	0.0145
Error	662	93.51695282	0.14126428		
Corrected Total	663	94.36555928			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.008993	84.46854	0.375851	0.444960

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.84860646	0.84860646	6.01	0.0145

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.84860646	0.84860646	6.01	0.0145

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.45938780	0.01572889	<.0001
4	0.35637820	0.03897398	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.459388	0.428503	0.490272
4	0.356378	0.279851	0.432906

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	662
Number of Observations Used	662

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	13.8229586	13.8229586	26.05	<.0001
Error	660	350.1958411	0.5305998		
Corrected Total	661	364.0187996			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.037973	68.63504	0.728423	1.061299

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	13.82295855	13.82295855	26.05	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	13.82295855	13.82295855	26.05	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.11971811	0.03053707	<.0001
4	0.70387272	0.07553392	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.119718	1.059757	1.179680
4	0.703873	0.555557	0.852188

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	5.8363731	5.8363731	13.54	0.0003
Error	662	285.2548745	0.4308986		
Corrected Total	663	291.0912476			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.020050	49.76203	0.656429	1.319136

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	5.83637314	5.83637314	13.54	0.0003

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	5.83637314	5.83637314	13.54	0.0003

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.35697201	0.02747068	<.0001
4	1.08682756	0.06806848	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.356972	1.303032	1.410912
4	1.086828	0.953171	1.220484

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	661
Number of Observations Used	661

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	6.3526018	6.3526018	15.95	<.0001
Error	659	262.3895135	0.3981631		
Corrected Total	660	268.7421153			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.023638	70.03533	0.631002	0.900976

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.35260179	6.35260179	15.95	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.35260179	6.35260179	15.95	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.94064449	0.02647624	<.0001
4	0.65870176	0.06543183	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.940644	0.888657	0.992632
4	0.658702	0.530222	0.787182

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.51647756	0.51647756	3.17	0.0757
Error	328	53.36974903	0.16271265		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.009585	90.07373	0.403377	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.51647756	0.51647756	3.17	0.0757

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.51647756	0.51647756	3.17	0.0757

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.46415100	0.02402072	<.0001
4	0.35193946	0.05822239	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.464151	0.416897	0.511405
4	0.351939	0.237403	0.466476

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	16.8598483	16.8598483	28.25	<.0001
Error	328	195.7334324	0.5967483		
Corrected Total	329	212.5932807			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.079306	79.57556	0.772495	0.970769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.85984827	16.85984827	28.25	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.85984827	16.85984827	28.25	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.05942602	0.04567858	<.0001
4	0.39449829	0.11645798	0.0008

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.059426	0.969566	1.149286
4	0.394498	0.165399	0.623597

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	665
Number of Observations Used	665

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	56.6093427	56.6093427	180.44	<.0001
Error	663	208.0062929	0.3137350		
Corrected Total	664	264.6156357			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.213930	25.11422	0.560121	2.230293

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.60934274	56.60934274	180.44	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.60934274	56.60934274	180.44	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	2.34793837	0.02341981	<.0001
4	1.50670714	0.05808179	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	2.347938	2.301952	2.393924
4	1.506707	1.392661	1.620754

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.7631412	7.7631412	13.71	0.0003
Error	328	185.7938895	0.5664448		
Corrected Total	329	193.5570307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.040108	62.87748	0.752625	1.196971

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.76314116	7.76314116	13.71	0.0003

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.76314116	7.76314116	13.71	0.0003

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.26024983	0.04481818	<.0001
4	0.82520848	0.10863210	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.260250	1.172082	1.348417
4	0.825208	0.611505	1.038912

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	328
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	48.9268557	48.9268557	81.48	<.0001
Error	326	195.7672197	0.6005129		
Corrected Total	327	244.6940754			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.199951	42.86355	0.774928	1.807894

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	48.92685565	48.92685565	81.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	48.92685565	48.92685565	81.48	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.95991529	0.04598350	<.0001
4	0.82666701	0.11682475	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.959915	1.869453	2.050377
4	0.826667	0.596841	1.056493

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	128.7378949	128.7378949	309.51	<.0001
Error	662	275.3501661	0.4159368		
Corrected Total	663	404.0880610			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.318589	22.49498	0.644932	2.867002

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.7378949	128.7378949	309.51	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.7378949	128.7378949	309.51	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.04470405	0.02698955	<.0001
4	1.77594920	0.06687629	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.044704	2.991709	3.097699
4	1.775949	1.644634	1.907264

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	4.4812985	4.4812985	10.01	0.0017
Error	328	146.7815913	0.4475049		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.029626	47.03603	0.668958	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.48129846	4.48129846	10.01	0.0017

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.48129846	4.48129846	10.01	0.0017

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.47030220	0.03983587	<.0001
4	1.13977003	0.09655578	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.470302	1.391936	1.548668
4	1.139770	0.949823	1.329717

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	30.8578385	30.8578385	61.37	<.0001
Error	328	164.9138922	0.5027863		
Corrected Total	329	195.7717307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.157622	35.75199	0.709074	1.983314

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	30.85783846	30.85783846	61.37	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	30.85783846	30.85783846	61.37	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	2.10325518	0.04192844	<.0001
4	1.20369471	0.10689696	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	2.103255	2.020773	2.185738
4	1.203695	0.993405	1.413985

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	663
Number of Observations Used	663

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	170.2691932	170.2691932	412.13	<.0001
Error	661	273.0859651	0.4131406		
Corrected Total	662	443.3551582			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.384047	21.38740	0.642760	3.005322

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	170.2691932	170.2691932	412.13	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	170.2691932	170.2691932	412.13	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.20873882	0.02689868	<.0001
4	1.74281016	0.06701238	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.208739	3.155922	3.261556
4	1.742810	1.611227	1.874393

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	6.3685016	6.3685016	12.10	0.0006
Error	327	172.0796070	0.5262373		
Corrected Total	328	178.4481086			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.035688	72.39640	0.725422	1.002014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.36850158	6.36850158	12.10	0.0006

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.36850158	6.36850158	12.10	0.0006

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.05951690	0.04327506	<.0001
4	0.66538389	0.10470567	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.059517	0.974384	1.144650
4	0.665384	0.459402	0.871366

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	37.0816264	37.0816264	66.03	<.0001
Error	327	183.6521140	0.5616273		
Corrected Total	328	220.7337404			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.167993	45.04966	0.749418	1.663537

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	37.08162642	37.08162642	66.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	37.08162642	37.08162642	66.03	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.79544958	0.04439169	<.0001
4	0.80910521	0.11297901	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.795450	1.708120	1.882779
4	0.809105	0.586848	1.031363

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	166.5142136	166.5142136	410.70	<.0001
Error	662	268.4022825	0.4054415		
Corrected Total	663	434.9164961			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.382865	22.62963	0.636743	2.813758

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	166.5142136	166.5142136	410.70	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	166.5142136	166.5142136	410.70	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.01585724	0.02664686	<.0001
4	1.57291095	0.06602716	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.015857	2.963535	3.068180
4	1.572911	1.443263	1.702559

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.04774399	0.02387199	0.40	0.6708
Error	327	19.52953007	0.05972333		
Corrected Total	329	19.57727406			

R-Square	Coeff Var	Root MSE	CHG Mean
0.002439	1661.256	0.244384	0.014711

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.04774399	0.02387199	0.40	0.6708

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.04774399	0.02387199	0.40	0.6708

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.00825629	0.02036530	0.6854
2	0.02803720	0.02080331	0.1787
4	-0.00423926	0.03527373	0.9044

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.008256	-0.031807	0.048320
2	0.028037	-0.012888	0.068962
4	-0.004239	-0.073631	0.065153

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	13.1453984	6.5726992	12.63	<.0001
Error	326	169.6392031	0.5203657		
Corrected Total	328	182.7846015			

R-Square	Coeff Var	Root MSE	CHG Mean
0.071917	140.4034	0.721364	0.513779

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.14539841	6.57269921	12.63	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.14539841	6.57269921	12.63	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.66065039	0.05990600	<.0001
2	0.51161952	0.06096636	<.0001
4	0.03664454	0.10874968	0.7364

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.660650	0.542799	0.778502
2	0.511620	0.391682	0.631557
4	0.036645	-0.177295	0.250584

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 665
Number of Observations Used 664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	43.7904367	21.8952184	59.82	<.0001
Error	661	241.9245224	0.3659978		
Corrected Total	663	285.7149591			

R-Square	Coeff Var	Root MSE	CHG Mean
0.153266	33.87695	0.604977	1.785809

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	43.79043670	21.89521835	59.82	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	43.79043670	21.89521835	59.82	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	1.87517840	0.03558691	<.0001
2	1.90379413	0.03602589	<.0001
4	1.15032893	0.06273324	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	1.875178	1.805301	1.945055
2	1.903794	1.833055	1.974533
4	1.150329	1.027148	1.273509

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.45821664	0.22910832	1.99	0.1390
Error	325	37.50089404	0.11538737		
Corrected Total	327	37.95911068			

R-Square	Coeff Var	Root MSE	CHG Mean
0.012071	381.1100	0.339687	0.089131

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.45821664	0.22910832	1.99	0.1390

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.45821664	0.22910832	1.99	0.1390

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.05055199	0.02840607	0.0761
2	0.13132720	0.02902143	<.0001
4	0.08362934	0.04902962	0.0890

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.050552	-0.005331	0.106435
2	0.131327	0.074234	0.188421
4	0.083629	-0.012826	0.180085

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	328
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	19.7482003	9.8741001	16.02	<.0001
Error	324	199.7065556	0.6163783		
Corrected Total	326	219.4547559			

R-Square	Coeff Var	Root MSE	CHG Mean
0.089988	100.2512	0.785098	0.783130

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.74820028	9.87410014	16.02	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.74820028	9.87410014	16.02	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.86045677	0.06542480	<.0001
2	0.89976086	0.06659111	<.0001
4	0.16161464	0.11835792	0.1731

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.860457	0.731746	0.989168
2	0.899761	0.768755	1.030766
4	0.161615	-0.071232	0.394462

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	661

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	59.9978154	29.9989077	54.67	<.0001
Error	658	361.0624808	0.5487272		
Corrected Total	660	421.0602962			

R-Square	Coeff Var	Root MSE	CHG Mean
0.142492	41.12604	0.740761	1.801197

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.99781538	29.99890769	54.67	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.99781538	29.99890769	54.67	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	1.85565629	0.04364977	<.0001
2	1.98735462	0.04426895	<.0001
4	1.07207648	0.07681336	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	1.855656	1.769947	1.941366
2	1.987355	1.900429	2.074280
4	1.072076	0.921248	1.222905

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.08662315	0.54331157	3.37	0.0357
Error	327	52.78435103	0.16142003		
Corrected Total	329	53.87097417			

R-Square	Coeff Var	Root MSE	CHG Mean
0.020171	506.7999	0.401771	0.079276

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.08662315	0.54331157	3.37	0.0357

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.08662315	0.54331157	3.37	0.0357

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.02300832	0.03348093	0.4924
2	0.14562843	0.03420103	<.0001
4	0.05731639	0.05799067	0.3237

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.023008	-0.042857	0.088874
2	0.145628	0.078347	0.212910
4	0.057316	-0.056765	0.171398

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	16.4932990	8.2466495	16.41	<.0001
Error	326	163.8062916	0.5024733		
Corrected Total	328	180.2995907			

R-Square	Coeff Var	Root MSE	CHG Mean
0.091477	102.8730	0.708854	0.689057

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	16.49329904	8.24664952	16.41	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	16.49329904	8.24664952	16.41	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.75657654	0.05886708	<.0001
2	0.79756723	0.05990906	<.0001
4	0.12128955	0.10686369	0.2572

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.756577	0.640769	0.872384
2	0.797567	0.679710	0.915424
4	0.121290	-0.088940	0.331519

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 663
Number of Observations Used 662

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	114.4157068	57.2078534	88.39	<.0001
Error	659	426.4967012	0.6471877		
Corrected Total	661	540.9124080			

R-Square	Coeff Var	Root MSE	CHG Mean
0.211524	47.64857	0.804480	1.688361

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	114.4157068	57.2078534	88.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	114.4157068	57.2078534	88.39	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	1.80363983	0.04732234	<.0001
2	1.90636338	0.04799124	<.0001
4	0.66037970	0.08387281	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	1.803640	1.710719	1.896561
2	1.906363	1.812129	2.000598
4	0.660380	0.495690	0.825070

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.67591861	0.33795931	1.88	0.1548
Error	324	58.35058643	0.18009440		
Corrected Total	326	59.02650505			

R-Square	Coeff Var	Root MSE	CHG Mean
0.011451	402.9233	0.424375	0.105324

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.67591861	0.33795931	1.88	0.1548

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.67591861	0.33795931	1.88	0.1548

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.13149800	0.03561278	0.0003
2	0.11612803	0.03625683	0.0015
4	-0.00294321	0.06125330	0.9617

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.131498	0.061437	0.201559
2	0.116128	0.044800	0.187457
4	-0.002943	-0.123448	0.117561

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	19.6581420	9.8290710	16.10	<.0001
Error	324	197.7659521	0.6103887		
Corrected Total	326	217.4240941			

R-Square	Coeff Var	Root MSE	CHG Mean
0.090414	102.0002	0.781274	0.765953

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.65814202	9.82907101	16.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.65814202	9.82907101	16.10	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.78480476	0.06533340	<.0001
2	0.93412317	0.06602969	<.0001
4	0.16960136	0.11778146	0.1508

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.784805	0.656274	0.913336
2	0.934123	0.804222	1.064024
4	0.169601	-0.062112	0.401314

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 664
Number of Observations Used 660

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	108.4538354	54.2269177	86.88	<.0001
Error	657	410.0932578	0.6241907		
Corrected Total	659	518.5470933			

R-Square	Coeff Var	Root MSE	CHG Mean
0.209149	41.26202	0.790057	1.914733

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	108.4538354	54.2269177	86.88	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	108.4538354	54.2269177	86.88	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	2.06664075	0.04663561	<.0001
2	2.09134375	0.04721496	<.0001
4	0.91420919	0.08192513	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	2.066641	1.975068	2.158214
2	2.091344	1.998633	2.184054
4	0.914209	0.753343	1.075076

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02017093	0.02017093	0.34	0.5612
Error	328	19.55710313	0.05962531		
Corrected Total	329	19.57727406			

R-Square	Coeff Var	Root MSE	CHG Mean
0.001030	1659.892	0.244183	0.014711

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02017093	0.02017093	0.34	0.5612

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02017093	0.02017093	0.34	0.5612

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.01793631	0.01454088	0.2183
4	-0.00423926	0.03524477	0.9043

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.017936	-0.010669	0.046541
4	-0.004239	-0.073574	0.065095

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	11.5634087	11.5634087	22.08	<.0001
Error	327	171.2211928	0.5236122		
Corrected Total	328	182.7846015			

R-Square	Coeff Var	Root MSE	CHG Mean
0.063262	140.8407	0.723611	0.513779

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	11.56340872	11.56340872	22.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	11.56340872	11.56340872	22.08	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.58744225	0.04286299	<.0001
4	0.03664454	0.10908839	0.7371

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.587442	0.503120	0.671764
4	0.036645	-0.177959	0.251248

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	665
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	43.6735620	43.6735620	119.45	<.0001
Error	662	242.0413970	0.3656214		
Corrected Total	663	285.7149591			

R-Square	Coeff Var	Root MSE	CHG Mean
0.152857	33.85952	0.604666	1.785809

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	43.67356203	43.67356203	119.45	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	43.67356203	43.67356203	119.45	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	1.88931086	0.02530450	<.0001
4	1.15032893	0.06270098	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	1.889311	1.839624	1.938998
4	1.150329	1.027212	1.273446

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.00170194	0.00170194	0.01	0.9038
Error	326	37.95740874	0.11643377		
Corrected Total	327	37.95911068			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000045	382.8342	0.341224	0.089131

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00170194	0.00170194	0.01	0.9038

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00170194	0.00170194	0.01	0.9038

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.09007414	0.02039203	<.0001
4	0.08362934	0.04925143	0.0905

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.090074	0.049958	0.130191
4	0.083629	-0.013261	0.180520

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	328
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	19.6389390	19.6389390	31.94	<.0001
Error	325	199.8158169	0.6148179		
Corrected Total	326	219.4547559			

R-Square	Coeff Var	Root MSE	CHG Mean
0.089490	100.1242	0.784103	0.783130

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.63893898	19.63893898	31.94	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.63893898	19.63893898	31.94	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.87976160	0.04661010	<.0001
4	0.16161464	0.11820801	0.1725

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.879762	0.788066	0.971457
4	0.161615	-0.070935	0.394164

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	661

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	57.5353921	57.5353921	104.30	<.0001
Error	659	363.5249041	0.5516311		
Corrected Total	660	421.0602962			

R-Square	Coeff Var	Root MSE	CHG Mean
0.136644	41.23472	0.742719	1.801197

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	57.53539214	57.53539214	104.30	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	57.53539214	57.53539214	104.30	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	1.92057800	0.03116379	<.0001
4	1.07207648	0.07701634	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	1.920578	1.859386	1.981770
4	1.072076	0.920849	1.223303

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02708687	0.02708687	0.17	0.6849
Error	328	53.84388731	0.16415819		
Corrected Total	329	53.87097417			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000503	511.0802	0.405164	0.079276

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02708687	0.02708687	0.17	0.6849

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02708687	0.02708687	0.17	0.6849

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.08301391	0.02412719	0.0007
4	0.05731639	0.05848044	0.3278

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.083014	0.035550	0.130477
4	0.057316	-0.057728	0.172360

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	16.3736190	16.3736190	32.66	<.0001
Error	327	163.9259716	0.5013027		
Corrected Total	328	180.2995907			

R-Square	Coeff Var	Root MSE	CHG Mean
0.090813	102.7531	0.708027	0.689057

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.37361904	16.37361904	32.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.37361904	16.37361904	32.66	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.77671232	0.04193992	<.0001
4	0.12128955	0.10673913	0.2567

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.776712	0.694206	0.859218
4	0.121290	-0.088692	0.331272

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	663
Number of Observations Used	662

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	112.9123247	112.9123247	174.12	<.0001
Error	660	428.0000833	0.6484850		
Corrected Total	661	540.9124080			

R-Square	Coeff Var	Root MSE	CHG Mean
0.208744	47.69630	0.805286	1.688361

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	112.9123247	112.9123247	174.12	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	112.9123247	112.9123247	174.12	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	1.85428074	0.03372970	<.0001
4	0.66037970	0.08395683	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	1.854281	1.788050	1.920511
4	0.660380	0.495525	0.825234

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.65944645	0.65944645	3.67	0.0562
Error	325	58.36705859	0.17959095		
Corrected Total	326	59.02650505			

R-Square	Coeff Var	Root MSE	CHG Mean
0.011172	402.3597	0.423782	0.105324

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.65944645	0.65944645	3.67	0.0562

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.65944645	0.65944645	3.67	0.0562

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.12395074	0.02537115	<.0001
4	-0.00294321	0.06116762	0.9617

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.123951	0.074038	0.173863
4	-0.002943	-0.123278	0.117391

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	18.0808781	18.0808781	29.48	<.0001
Error	325	199.3432160	0.6133637		
Corrected Total	326	217.4240941			

R-Square	Coeff Var	Root MSE	CHG Mean
0.083159	102.2484	0.783175	0.765953

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.08087808	18.08087808	29.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.08087808	18.08087808	29.48	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.85867253	0.04655495	<.0001
4	0.16960136	0.11806814	0.1518

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.858673	0.767085	0.950260
4	0.169601	-0.062673	0.401876

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	660

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	108.3673474	108.3673474	173.84	<.0001
Error	658	410.1797459	0.6233735		
Corrected Total	659	518.5470933			

R-Square	Coeff Var	Root MSE	CHG Mean
0.208983	41.23500	0.789540	1.914733

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	108.3673474	108.3673474	173.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	108.3673474	108.3673474	173.84	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	2.07883976	0.03315756	<.0001
4	0.91420919	0.08187149	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	2.078840	2.013732	2.143947
4	0.914209	0.753448	1.074970

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men A Human Complement SBA	Menveo-Menveo	1.968	2.810	2.542	3.105
Day 1	Men A Human Complement SBA	Menactra-Menveo	1.968	2.954	2.669	3.268
Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	2.880	2.682	3.092
Day 1	Men A Human Complement SBA	Naive	1.986	2.272	1.905	2.710
Day 4	Men A Human Complement SBA	Menveo-Menveo	1.977	2.826	2.426	3.291
Day 4	Men A Human Complement SBA	Menactra-Menveo	1.977	3.004	2.571	3.510
Day 4	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	2.912	2.612	3.246
Day 4	Men A Human Complement SBA	Naive	2.012	2.249	1.727	2.928
Day 6	Men A Human Complement SBA	Menveo-Menveo	1.976	12.867	9.633	17.187
Day 6	Men A Human Complement SBA	Menactra-Menveo	1.977	10.168	7.565	13.665
Day 6	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	11.466	9.323	14.102
Day 6	Men A Human Complement SBA	Naive	2.017	2.480	1.464	4.203
Day 29	Men A Human Complement SBA	Menveo-Menveo	1.968	210.102	181.074	243.782
Day 29	Men A Human Complement SBA	Menactra-Menveo	1.968	236.685	203.558	275.204
Day 29	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	222.812	200.425	247.699
Day 29	Men A Human Complement SBA	Naive	1.986	32.115	24.699	41.758
Day 4/Day 1	Men A Human Complement SBA	Menveo-Menveo	1.977	1.019	0.929	1.118
Day 4/Day 1	Men A Human Complement SBA	Menactra-Menveo	1.977	1.067	0.971	1.172
Day 4/Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	1.042	0.976	1.113
Day 4/Day 1	Men A Human Complement SBA	Naive	2.012	0.990	0.844	1.162
Day 6/Day 1	Men A Human Complement SBA	Menveo-Menveo	1.977	4.578	3.490	6.005
Day 6/Day 1	Men A Human Complement SBA	Menactra-Menveo	1.977	3.248	2.464	4.281
Day 6/Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	3.868	3.185	4.696
Day 6/Day 1	Men A Human Complement SBA	Naive	2.017	1.088	0.665	1.781
Day 29/Day 1	Men A Human Complement SBA	Menveo-Menveo	1.968	75.020	63.871	88.116
Day 29/Day 1	Men A Human Complement SBA	Menactra-Menveo	1.968	80.130	68.086	94.305
Day 29/Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	77.502	69.123	86.896
Day 29/Day 1	Men A Human Complement SBA	Naive	1.986	14.136	10.645	18.772

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men C Human Complement SBA	Menveo-Menveo	1.968	16.112	13.284	19.541
Day 1	Men C Human Complement SBA	Menactra-Menveo	1.968	10.718	8.816	13.031
Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	13.174	11.475	15.124
Day 1	Men C Human Complement SBA	Naive	1.986	5.057	3.601	7.102
Day 4	Men C Human Complement SBA	Menveo-Menveo	1.977	22.959	17.313	30.445
Day 4	Men C Human Complement SBA	Menactra-Menveo	1.977	14.295	10.714	19.072
Day 4	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	18.207	14.862	22.306
Day 4	Men C Human Complement SBA	Naive	2.012	6.687	4.101	10.902
Day 6	Men C Human Complement SBA	Menveo-Menveo	1.977	92.272	68.909	123.556
Day 6	Men C Human Complement SBA	Menactra-Menveo	1.977	90.061	66.840	121.351
Day 6	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	91.183	74.038	112.299
Day 6	Men C Human Complement SBA	Naive	2.017	6.709	3.949	11.398
Day 29	Men C Human Complement SBA	Menveo-Menveo	1.968	1159.926	977.331	1376.635
Day 29	Men C Human Complement SBA	Menactra-Menveo	1.968	1057.660	888.742	1258.684
Day 29	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1108.419	981.089	1252.274
Day 29	Men C Human Complement SBA	Naive	1.986	59.697	44.115	80.781
Day 4/Day 1	Men C Human Complement SBA	Menveo-Menveo	1.977	1.123	0.988	1.278
Day 4/Day 1	Men C Human Complement SBA	Menactra-Menveo	1.978	1.353	1.186	1.543
Day 4/Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.969	1.230	1.122	1.350
Day 4/Day 1	Men C Human Complement SBA	Naive	2.012	1.212	0.971	1.514
Day 6/Day 1	Men C Human Complement SBA	Menveo-Menveo	1.977	7.252	5.392	9.754
Day 6/Day 1	Men C Human Complement SBA	Menactra-Menveo	1.977	7.939	5.872	10.734
Day 6/Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	7.582	6.139	9.364
Day 6/Day 1	Men C Human Complement SBA	Naive	2.017	1.451	0.849	2.480
Day 29/Day 1	Men C Human Complement SBA	Menveo-Menveo	1.968	71.723	58.877	87.371
Day 29/Day 1	Men C Human Complement SBA	Menactra-Menveo	1.969	97.130	79.511	118.653
Day 29/Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	83.287	72.341	95.889
Day 29/Day 1	Men C Human Complement SBA	Naive	1.986	11.805	8.342	16.707

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men W Human Complement SBA	Menveo-Menveo	1.968	22.075	18.537	26.288
Day 1	Men W Human Complement SBA	Menactra-Menveo	1.968	23.463	19.660	28.001
Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	22.750	20.092	25.758
Day 1	Men W Human Complement SBA	Naive	1.986	12.213	8.976	16.617
Day 4	Men W Human Complement SBA	Menveo-Menveo	1.977	25.896	20.126	33.320
Day 4	Men W Human Complement SBA	Menactra-Menveo	1.977	33.873	26.183	43.821
Day 4	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	29.533	24.657	35.373
Day 4	Men W Human Complement SBA	Naive	2.012	13.797	8.916	21.349
Day 6	Men W Human Complement SBA	Menveo-Menveo	1.976	112.493	86.256	146.711
Day 6	Men W Human Complement SBA	Menactra-Menveo	1.977	143.754	109.607	188.539
Day 6	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	126.840	104.899	153.369
Day 6	Men W Human Complement SBA	Naive	2.017	15.984	9.854	25.929
Day 29	Men W Human Complement SBA	Menveo-Menveo	1.968	1394.646	1176.592	1653.110
Day 29	Men W Human Complement SBA	Menactra-Menveo	1.968	1883.963	1585.117	2239.151
Day 29	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1617.107	1431.930	1826.232
Day 29	Men W Human Complement SBA	Naive	1.986	55.311	40.899	74.801
Day 4/Day 1	Men W Human Complement SBA	Menveo-Menveo	1.977	1.054	0.906	1.227
Day 4/Day 1	Men W Human Complement SBA	Menactra-Menveo	1.977	1.398	1.198	1.633
Day 4/Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	1.211	1.085	1.350
Day 4/Day 1	Men W Human Complement SBA	Naive	2.012	1.141	0.877	1.484
Day 6/Day 1	Men W Human Complement SBA	Menveo-Menveo	1.977	5.709	4.373	7.454
Day 6/Day 1	Men W Human Complement SBA	Menactra-Menveo	1.977	6.274	4.783	8.230
Day 6/Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	5.980	4.945	7.231
Day 6/Day 1	Men W Human Complement SBA	Naive	2.017	1.322	0.815	2.145
Day 29/Day 1	Men W Human Complement SBA	Menveo-Menveo	1.968	63.627	51.371	78.806
Day 29/Day 1	Men W Human Complement SBA	Menactra-Menveo	1.968	80.605	64.883	100.138
Day 29/Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	71.496	61.383	83.274
Day 29/Day 1	Men W Human Complement SBA	Naive	1.986	4.575	3.131	6.685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.968	9.244	7.812	10.940
Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.968	8.220	6.934	9.745
Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	8.723	7.738	9.832
Day 1	Men Y Human Complement SBA	Naive	1.986	4.557	3.390	6.126
Day 4	Men Y Human Complement SBA	Menveo-Menveo	1.977	10.873	8.258	14.316
Day 4	Men Y Human Complement SBA	Menactra-Menveo	1.977	12.120	9.160	16.037
Day 4	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	11.469	9.427	13.952
Day 4	Men Y Human Complement SBA	Naive	2.012	4.628	2.879	7.440
Day 6	Men Y Human Complement SBA	Menveo-Menveo	1.977	63.301	47.730	83.951
Day 6	Men Y Human Complement SBA	Menactra-Menveo	1.977	61.557	46.184	82.048
Day 6	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	62.438	51.065	76.345
Day 6	Men Y Human Complement SBA	Naive	2.017	6.443	3.859	10.757
Day 29	Men Y Human Complement SBA	Menveo-Menveo	1.968	1066.662	900.667	1263.251
Day 29	Men Y Human Complement SBA	Menactra-Menveo	1.968	1007.622	848.532	1196.541
Day 29	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1037.187	919.464	1169.984
Day 29	Men Y Human Complement SBA	Naive	1.986	37.403	27.745	50.424
Day 4/Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.977	1.354	1.152	1.591
Day 4/Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.978	1.307	1.109	1.540
Day 4/Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.969	1.330	1.186	1.492
Day 4/Day 1	Men Y Human Complement SBA	Naive	2.012	0.993	0.753	1.311
Day 6/Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.977	6.093	4.532	8.191
Day 6/Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.977	8.593	6.371	11.588
Day 6/Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	7.222	5.849	8.918
Day 6/Day 1	Men Y Human Complement SBA	Naive	2.017	1.478	0.867	2.519
Day 29/Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.968	116.584	94.421	143.951
Day 29/Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.969	123.408	99.686	152.776
Day 29/Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	119.906	103.213	139.299
Day 29/Day 1	Men Y Human Complement SBA	Naive	1.986	8.207	5.667	11.887

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.56634457	0.28317228	1.74	0.1777
Error	327	53.31988202	0.16305774		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.010510	90.16919	0.403804	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.56634457	0.28317228	1.74	0.1777

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.56634457	0.28317228	1.74	0.1777

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.09919366	0.06730068	1.47	0.1415
2 vs 4	0.12579542	0.06766546	1.86	0.0639
1 vs 2	-0.02660176	0.04810326	-0.55	0.5806

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	17.6073235	8.8036617	14.76	<.0001
Error	327	194.9859572	0.5962873		
Corrected Total	329	212.5932807			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.082822	79.54482	0.772196	0.970769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60732348	8.80366174	14.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60732348	8.80366174	14.76	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.71498913	0.13280115	5.38	<.0001
2 vs 4	0.61272085	0.13345853	4.59	<.0001
1 vs 2	0.10226828	0.09134197	1.12	0.2637

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 665
Number of Observations Used 665

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	56.9921134	28.4960567	90.86	<.0001
Error	662	207.6235223	0.3136307		
Corrected Total	664	264.6156357			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.215377	25.11004	0.560027	2.230293

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	56.99211336	28.49605668	90.86	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	56.99211336	28.49605668	90.86	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.81572204	0.06673723	12.22	<.0001
2 vs 4	0.86746410	0.06696670	12.95	<.0001
1 vs 2	-0.05174207	0.04683643	-1.10	0.2697

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 330
Number of Observations Used 330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	10.7469338	5.3734669	9.61	<.0001
Error	327	182.8100969	0.5590523		
Corrected Total	329	193.5570307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.055523	62.46584	0.747698	1.196971

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.74693381	5.37346690	9.61	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.74693381	5.37346690	9.61	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.53573871	0.12461633	4.30	<.0001
2 vs 4	0.32996585	0.12529176	2.63	0.0089
1 vs 2	0.20577286	0.08906970	2.31	0.0215

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	328
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	48.9347252	24.4673626	40.62	<.0001
Error	325	195.7593502	0.6023365		
Corrected Total	327	244.6940754			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.199983	42.92858	0.776103	1.807894

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	48.93472516	24.46736258	40.62	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	48.93472516	24.46736258	40.62	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.13840220	0.13357960	8.52	<.0001
2 vs 4	1.12787188	0.13424910	8.40	<.0001
1 vs 2	0.01053032	0.09212709	0.11	0.9091

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 664
Number of Observations Used 664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	128.9671983	64.4835991	154.93	<.0001
Error	661	275.1208628	0.4162192		
Corrected Total	663	404.0880610			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.319156	22.50262	0.645150	2.867002

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.9671983	64.4835991	154.93	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.9671983	64.4835991	154.93	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.28848095	0.07688116	16.76	<.0001
2 vs 4	1.24839694	0.07717954	16.18	<.0001
1 vs 2	0.04008401	0.05400412	0.74	0.4582

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	5.4396506	2.7198253	6.10	0.0025
Error	327	145.8232391	0.4459426		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.035962	46.95385	0.667789	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.43965064	2.71982532	6.10	0.0025

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.43965064	2.71982532	6.10	0.0025

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.27346369	0.11129823	2.46	0.0145
2 vs 4	0.39008189	0.11190147	3.49	0.0006
1 vs 2	-0.11661820	0.07955056	-1.47	0.1436

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	31.6683612	15.8341806	31.55	<.0001
Error	327	164.1033695	0.5018452		
Corrected Total	329	195.7717307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.161762	35.71852	0.708410	1.983314

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.66836119	15.83418059	31.55	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.66836119	15.83418059	31.55	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.84743054	0.12183131	6.96	<.0001
2 vs 4	0.95392455	0.12243439	7.79	<.0001
1 vs 2	-0.10649401	0.08379680	-1.27	0.2047

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 663
Number of Observations Used 663

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	172.7036988	86.3518494	210.57	<.0001
Error	660	270.6514594	0.4100780		
Corrected Total	662	443.3551582			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.389538	21.30798	0.640373	3.005322

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	172.7036988	86.3518494	210.57	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	172.7036988	86.3518494	210.57	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.40165375	0.07662526	18.29	<.0001
2 vs 4	1.53226220	0.07692023	19.92	<.0001
1 vs 2	-0.13060845	0.05360424	-2.44	0.0151

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 329
Number of Observations Used 329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.5247404	3.2623702	6.19	0.0023
Error	326	171.9233683	0.5273723		
Corrected Total	328	178.4481086			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.036564	72.47442	0.726204	1.002014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.52474037	3.26237019	6.19	0.0023

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.52474037	3.26237019	6.19	0.0023

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.37096904	0.12113976	3.06	0.0024
2 vs 4	0.41813623	0.12169002	3.44	0.0007
1 vs 2	-0.04716719	0.08665712	-0.54	0.5866

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 329
Number of Observations Used 329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	37.0921105	18.5460553	32.92	<.0001
Error	326	183.6416298	0.5633179		
Corrected Total	328	220.7337404			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.168040	45.11742	0.750545	1.663537

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	37.09211054	18.54605527	32.92	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	37.09211054	18.54605527	32.92	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.99230405	0.12918061	7.68	<.0001
2 vs 4	0.98017183	0.12971653	7.56	<.0001
1 vs 2	0.01213222	0.08893059	0.14	0.8916

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	166.6014869	83.3007434	205.21	<.0001
Error	661	268.3150092	0.4059229		
Corrected Total	663	434.9164961			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.383065	22.64306	0.637121	2.813758

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	166.6014869	83.3007434	205.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	166.6014869	83.3007434	205.21	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.45511590	0.07592428	19.17	<.0001
2 vs 4	1.43038691	0.07621894	18.77	<.0001
1 vs 2	0.02472900	0.05333197	0.46	0.6430

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.51647756	0.51647756	3.17	0.0757
Error	328	53.36974903	0.16271265		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.009585	90.07373	0.403377	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.51647756	0.51647756	3.17	0.0757

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.51647756	0.51647756	3.17	0.0757

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.11221154	0.06298287	1.78	0.0757

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	16.8598483	16.8598483	28.25	<.0001
Error	328	195.7334324	0.5967483		
Corrected Total	329	212.5932807			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.079306	79.57556	0.772495	0.970769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.85984827	16.85984827	28.25	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.85984827	16.85984827	28.25	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.66492773	0.12509594	5.32	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	665
Number of Observations Used	665

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	56.6093427	56.6093427	180.44	<.0001
Error	663	208.0062929	0.3137350		
Corrected Total	664	264.6156357			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.213930	25.11422	0.560121	2.230293

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.60934274	56.60934274	180.44	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.60934274	56.60934274	180.44	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.84123124	0.06262573	13.43	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.7631412	7.7631412	13.71	0.0003
Error	328	185.7938895	0.5664448		
Corrected Total	329	193.5570307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.040108	62.87748	0.752625	1.196971

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.76314116	7.76314116	13.71	0.0003

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.76314116	7.76314116	13.71	0.0003

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.43504135	0.11751426	3.70	0.0003

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	328
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	48.9268557	48.9268557	81.48	<.0001
Error	326	195.7672197	0.6005129		
Corrected Total	327	244.6940754			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.199951	42.86355	0.774928	1.807894

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	48.92685565	48.92685565	81.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	48.92685565	48.92685565	81.48	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.13324828	0.12554881	9.03	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	128.7378949	128.7378949	309.51	<.0001
Error	662	275.3501661	0.4159368		
Corrected Total	663	404.0880610			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.318589	22.49498	0.644932	2.867002

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.7378949	128.7378949	309.51	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.7378949	128.7378949	309.51	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.26875484	0.07211709	17.59	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	4.4812985	4.4812985	10.01	0.0017
Error	328	146.7815913	0.4475049		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.029626	47.03603	0.668958	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.48129846	4.48129846	10.01	0.0017

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.48129846	4.48129846	10.01	0.0017

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.33053217	0.10445054	3.16	0.0017

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	30.8578385	30.8578385	61.37	<.0001
Error	328	164.9138922	0.5027863		
Corrected Total	329	195.7717307			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.157622	35.75199	0.709074	1.983314

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	30.85783846	30.85783846	61.37	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	30.85783846	30.85783846	61.37	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.89956048	0.11482576	7.83	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read 663
Number of Observations Used 663

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	170.2691932	170.2691932	412.13	<.0001
Error	661	273.0859651	0.4131406		
Corrected Total	662	443.3551582			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.384047	21.38740	0.642760	3.005322

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	170.2691932	170.2691932	412.13	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	170.2691932	170.2691932	412.13	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.46592866	0.07220940	20.30	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	6.3685016	6.3685016	12.10	0.0006
Error	327	172.0796070	0.5262373		
Corrected Total	328	178.4481086			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.035688	72.39640	0.725422	1.002014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.36850158	6.36850158	12.10	0.0006

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.36850158	6.36850158	12.10	0.0006

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.39413300	0.11329611	3.48	0.0006

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	37.0816264	37.0816264	66.03	<.0001
Error	327	183.6521140	0.5616273		
Corrected Total	328	220.7337404			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.167993	45.04966	0.749418	1.663537

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	37.08162642	37.08162642	66.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	37.08162642	37.08162642	66.03	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.98634437	0.12138731	8.13	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	166.5142136	166.5142136	410.70	<.0001
Error	662	268.4022825	0.4054415		
Corrected Total	663	434.9164961			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.382865	22.62963	0.636743	2.813758

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	166.5142136	166.5142136	410.70	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	166.5142136	166.5142136	410.70	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.44294629	0.07120141	20.27	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.04774399	0.02387199	0.40	0.6708
Error	327	19.52953007	0.05972333		
Corrected Total	329	19.57727406			

R-Square	Coeff Var	Root MSE	CHG Mean
0.002439	1661.256	0.244384	0.014711

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.04774399	0.02387199	0.40	0.6708

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.04774399	0.02387199	0.40	0.6708

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.01249555	0.04073060	0.31	0.7592
2 vs 4	0.03227646	0.04095136	0.79	0.4312
1 vs 2	-0.01978091	0.02911225	-0.68	0.4973

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	13.1453984	6.5726992	12.63	<.0001
Error	326	169.6392031	0.5203657		
Corrected Total	328	182.7846015			

R-Square	Coeff Var	Root MSE	CHG Mean
0.071917	140.4034	0.721364	0.513779

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.14539841	6.57269921	12.63	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.14539841	6.57269921	12.63	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.62400585	0.12415805	5.03	<.0001
2 vs 4	0.47497498	0.12467313	3.81	0.0002
1 vs 2	0.14903087	0.08547296	1.74	0.0822

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	43.7904367	21.8952184	59.82	<.0001
Error	661	241.9245224	0.3659978		
Corrected Total	663	285.7149591			

R-Square	Coeff Var	Root MSE	CHG Mean
0.153266	33.87695	0.604977	1.785809

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	43.79043670	21.89521835	59.82	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	43.79043670	21.89521835	59.82	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.72484947	0.07212412	10.05	<.0001
2 vs 4	0.75346520	0.07234172	10.42	<.0001
1 vs 2	-0.02861573	0.05063885	-0.57	0.5722

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	328
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.45821664	0.22910832	1.99	0.1390
Error	325	37.50089404	0.11538737		
Corrected Total	327	37.95911068			

R-Square	Coeff Var	Root MSE	CHG Mean
0.012071	381.1100	0.339687	0.089131

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.45821664	0.22910832	1.99	0.1390

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.45821664	0.22910832	1.99	0.1390

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	-0.03307735	0.05666399	-0.58	0.5598
2 vs 4	0.04769786	0.05697497	0.84	0.4031
1 vs 2	-0.08077521	0.04060971	-1.99	0.0475

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	327
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	19.7482003	9.8741001	16.02	<.0001
Error	324	199.7065556	0.6163783		
Corrected Total	326	219.4547559			

R-Square	Coeff Var	Root MSE	CHG Mean
0.089988	100.2512	0.785098	0.783130

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.74820028	9.87410014	16.02	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.74820028	9.87410014	16.02	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.69884213	0.13523683	5.17	<.0001
2 vs 4	0.73814622	0.13580491	5.44	<.0001
1 vs 2	-0.03930409	0.09335299	-0.42	0.6740

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	661
Number of Observations Used	661

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	59.9978154	29.9989077	54.67	<.0001
Error	658	361.0624808	0.5487272		
Corrected Total	660	421.0602962			

R-Square	Coeff Var	Root MSE	CHG Mean
0.142492	41.12604	0.740761	1.801197

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.99781538	29.99890769	54.67	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.99781538	29.99890769	54.67	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.78357981	0.08834928	8.87	<.0001
2 vs 4	0.91527814	0.08865682	10.32	<.0001
1 vs 2	-0.13169833	0.06216947	-2.12	0.0345

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.08662315	0.54331157	3.37	0.0357
Error	327	52.78435103	0.16142003		
Corrected Total	329	53.87097417			

R-Square	Coeff Var	Root MSE	CHG Mean
0.020171	506.7999	0.401771	0.079276

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.08662315	0.54331157	3.37	0.0357

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.08662315	0.54331157	3.37	0.0357

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	-0.03430806	0.06696185	-0.51	0.6088
2 vs 4	0.08831204	0.06732479	1.31	0.1905
1 vs 2	-0.12262010	0.04786108	-2.56	0.0109

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 329
Number of Observations Used 329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	16.4932990	8.2466495	16.41	<.0001
Error	326	163.8062916	0.5024733		
Corrected Total	328	180.2995907			

R-Square	Coeff Var	Root MSE	CHG Mean
0.091477	102.8730	0.708854	0.689057

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	16.49329904	8.24664952	16.41	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	16.49329904	8.24664952	16.41	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.63528699	0.12200484	5.21	<.0001
2 vs 4	0.67627768	0.12251099	5.52	<.0001
1 vs 2	-0.04099069	0.08399064	-0.49	0.6259

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	662
Number of Observations Used	662

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	114.4157068	57.2078534	88.39	<.0001
Error	659	426.4967012	0.6471877		
Corrected Total	661	540.9124080			

R-Square	Coeff Var	Root MSE	CHG Mean
0.211524	47.64857	0.804480	1.688361

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	114.4157068	57.2078534	88.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	114.4157068	57.2078534	88.39	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.14326012	0.09630188	11.87	<.0001
2 vs 4	1.24598368	0.09663233	12.89	<.0001
1 vs 2	-0.10272355	0.06739854	-1.52	0.1280

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	327
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.67591861	0.33795931	1.88	0.1548
Error	324	58.35058643	0.18009440		
Corrected Total	326	59.02650505			

R-Square	Coeff Var	Root MSE	CHG Mean
0.011451	402.9233	0.424375	0.105324

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.67591861	0.33795931	1.88	0.1548

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.67591861	0.33795931	1.88	0.1548

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.13444121	0.07085363	1.90	0.0587
2 vs 4	0.11907124	0.07117952	1.67	0.0953
1 vs 2	0.01536997	0.05082153	0.30	0.7625

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	327
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	19.6581420	9.8290710	16.10	<.0001
Error	324	197.7659521	0.6103887		
Corrected Total	326	217.4240941			

R-Square	Coeff Var	Root MSE	CHG Mean
0.090414	102.0002	0.781274	0.765953

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.65814202	9.82907101	16.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	19.65814202	9.82907101	16.10	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.61520340	0.13468825	4.57	<.0001
2 vs 4	0.76452182	0.13502737	5.66	<.0001
1 vs 2	-0.14931841	0.09288903	-1.61	0.1089

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	660
Number of Observations Used	660

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	108.4538354	54.2269177	86.88	<.0001
Error	657	410.0932578	0.6241907		
Corrected Total	659	518.5470933			

R-Square	Coeff Var	Root MSE	CHG Mean
0.209149	41.26202	0.790057	1.914733

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	108.4538354	54.2269177	86.88	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	108.4538354	54.2269177	86.88	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.15243156	0.09426881	12.22	<.0001
2 vs 4	1.17713456	0.09455675	12.45	<.0001
1 vs 2	-0.02470300	0.06636364	-0.37	0.7098

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02017093	0.02017093	0.34	0.5612
Error	328	19.55710313	0.05962531		
Corrected Total	329	19.57727406			

R-Square	Coeff Var	Root MSE	CHG Mean
0.001030	1659.892	0.244183	0.014711

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02017093	0.02017093	0.34	0.5612

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02017093	0.02017093	0.34	0.5612

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.02217557	0.03812652	0.58	0.5612

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	11.5634087	11.5634087	22.08	<.0001
Error	327	171.2211928	0.5236122		
Corrected Total	328	182.7846015			

R-Square	Coeff Var	Root MSE	CHG Mean
0.063262	140.8407	0.723611	0.513779

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	11.56340872	11.56340872	22.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	11.56340872	11.56340872	22.08	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.55079770	0.11720714	4.70	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	43.6735620	43.6735620	119.45	<.0001
Error	662	242.0413970	0.3656214		
Corrected Total	663	285.7149591			

R-Square	Coeff Var	Root MSE	CHG Mean
0.152857	33.85952	0.604666	1.785809

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	43.67356203	43.67356203	119.45	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	43.67356203	43.67356203	119.45	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.73898193	0.06761458	10.93	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	328
Number of Observations Used	328

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.00170194	0.00170194	0.01	0.9038
Error	326	37.95740874	0.11643377		
Corrected Total	327	37.95911068			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000045	382.8342	0.341224	0.089131

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00170194	0.00170194	0.01	0.9038

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00170194	0.00170194	0.01	0.9038

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.00644480	0.05330608	0.12	0.9038

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	327
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	19.6389390	19.6389390	31.94	<.0001
Error	325	199.8158169	0.6148179		
Corrected Total	326	219.4547559			

R-Square	Coeff Var	Root MSE	CHG Mean
0.089490	100.1242	0.784103	0.783130

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.63893898	19.63893898	31.94	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.63893898	19.63893898	31.94	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.71814697	0.12706548	5.65	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	661
Number of Observations Used	661

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	57.5353921	57.5353921	104.30	<.0001
Error	659	363.5249041	0.5516311		
Corrected Total	660	421.0602962			

R-Square	Coeff Var	Root MSE	CHG Mean
0.136644	41.23472	0.742719	1.801197

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	57.53539214	57.53539214	104.30	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	57.53539214	57.53539214	104.30	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.84850152	0.08308248	10.21	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02708687	0.02708687	0.17	0.6849
Error	328	53.84388731	0.16415819		
Corrected Total	329	53.87097417			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000503	511.0802	0.405164	0.079276

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02708687	0.02708687	0.17	0.6849

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02708687	0.02708687	0.17	0.6849

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.02569752	0.06326202	0.41	0.6849

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	16.3736190	16.3736190	32.66	<.0001
Error	327	163.9259716	0.5013027		
Corrected Total	328	180.2995907			

R-Square	Coeff Var	Root MSE	CHG Mean
0.090813	102.7531	0.708027	0.689057

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.37361904	16.37361904	32.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.37361904	16.37361904	32.66	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.65542276	0.11468304	5.72	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	662
Number of Observations Used	662

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	112.9123247	112.9123247	174.12	<.0001
Error	660	428.0000833	0.6484850		
Corrected Total	661	540.9124080			

R-Square	Coeff Var	Root MSE	CHG Mean
0.208744	47.69630	0.805286	1.688361

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	112.9123247	112.9123247	174.12	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	112.9123247	112.9123247	174.12	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.19390103	0.09047896	13.20	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	327
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.65944645	0.65944645	3.67	0.0562
Error	325	58.36705859	0.17959095		
Corrected Total	326	59.02650505			

R-Square	Coeff Var	Root MSE	CHG Mean
0.011172	402.3597	0.423782	0.105324

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.65944645	0.65944645	3.67	0.0562

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.65944645	0.65944645	3.67	0.0562

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.12689395	0.06622064	1.92	0.0562

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	327
Number of Observations Used	327

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	18.0808781	18.0808781	29.48	<.0001
Error	325	199.3432160	0.6133637		
Corrected Total	326	217.4240941			

R-Square	Coeff Var	Root MSE	CHG Mean
0.083159	102.2484	0.783175	0.765953

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.08087808	18.08087808	29.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.08087808	18.08087808	29.48	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.68907117	0.12691512	5.43	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	660
Number of Observations Used	660

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	108.3673474	108.3673474	173.84	<.0001
Error	658	410.1797459	0.6233735		
Corrected Total	659	518.5470933			

R-Square	Coeff Var	Root MSE	CHG Mean
0.208983	41.23500	0.789540	1.914733

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	108.3673474	108.3673474	173.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	108.3673474	108.3673474	173.84	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.16463057	0.08833100	13.18	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4

Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	1.0292	0.8558	1.2377
Day 4	2	vs 4	gmr	1.0772	0.8948	1.2967
Day 4	1	vs 2	gmr	0.9555	0.8374	1.0902
Day 4	3	vs 4	gmr	1.0524	0.8855	1.2508
Day 4	1	vs 4	gmt	1.2566	0.9264	1.7045
Day 4	2	vs 4	gmt	1.3360	0.9833	1.8151
Day 4	1	vs 2	gmt	0.9406	0.7564	1.1696
Day 4	3	vs 4	gmt	1.2948	0.9734	1.7223
Day 6	1	vs 4	gmr	4.2073	2.3975	7.3834
Day 6	2	vs 4	gmr	2.9852	1.6971	5.2510
Day 6	1	vs 2	gmr	1.4094	0.9569	2.0758
Day 6	3	vs 4	gmr	3.5547	2.0904	6.0447
Day 6	1	vs 4	gmt	5.1879	2.8427	9.4676
Day 6	2	vs 4	gmt	4.0994	2.2396	7.5035
Day 6	1	vs 2	gmt	1.2655	0.8367	1.9141
Day 6	3	vs 4	gmt	4.6230	2.6232	8.1474
Day 29	1	vs 4	gmr	5.3070	3.8303	7.3531
Day 29	2	vs 4	gmr	5.6685	4.0871	7.8616
Day 29	1	vs 2	gmr	0.9362	0.7446	1.1771
Day 29	3	vs 4	gmr	5.4825	4.0385	7.4430
Day 29	1	vs 4	gmt	6.5422	4.8382	8.8464
Day 29	2	vs 4	gmt	7.3699	5.4447	9.9760
Day 29	1	vs 2	gmt	0.8877	0.7183	1.0970
Day 29	3	vs 4	gmt	6.9380	5.2271	9.2087

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4

Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	0.9267	0.7169	1.1978
Day 4	2	vs 4	gmr	1.1161	0.8622	1.4447
Day 4	1	vs 2	gmr	0.8303	0.6908	0.9980
Day 4	3	vs 4	gmr	1.0150	0.7972	1.2921
Day 4	1	vs 4	gmt	3.4335	1.9525	6.0380
Day 4	2	vs 4	gmt	2.1378	1.2120	3.7709
Day 4	1	vs 2	gmt	1.6061	1.0729	2.4043
Day 4	3	vs 4	gmt	2.7230	1.5991	4.6368
Day 6	1	vs 4	gmr	4.9985	2.7089	9.2235
Day 6	2	vs 4	gmr	5.4720	2.9578	10.1232
Day 6	1	vs 2	gmr	0.9135	0.5985	1.3943
Day 6	3	vs 4	gmr	5.2257	2.9388	9.2923
Day 6	1	vs 4	gmt	13.7532	7.5095	25.1879
Day 6	2	vs 4	gmt	13.4237	7.3074	24.6592
Day 6	1	vs 2	gmt	1.0245	0.6750	1.5551
Day 6	3	vs 4	gmt	13.5909	7.6959	24.0014
Day 29	1	vs 4	gmr	6.0755	4.0747	9.0586
Day 29	2	vs 4	gmr	8.2277	5.5105	12.2846
Day 29	1	vs 2	gmr	0.7384	0.5575	0.9781
Day 29	3	vs 4	gmr	7.0551	4.8458	10.2716
Day 29	1	vs 4	gmt	19.4304	13.7252	27.5069
Day 29	2	vs 4	gmt	17.7173	12.4983	25.1156
Day 29	1	vs 2	gmt	1.0967	0.8591	1.4000
Day 29	3	vs 4	gmt	18.5676	13.4014	25.7253

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4

Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	0.9240	0.6823	1.2515
Day 4	2	vs 4	gmr	1.2255	0.9034	1.6625
Day 4	1	vs 2	gmr	0.7540	0.6071	0.9366
Day 4	3	vs 4	gmr	1.0610	0.7966	1.4130
Day 4	1	vs 4	gmt	1.8770	1.1337	3.1075
Day 4	2	vs 4	gmt	2.4552	1.4789	4.0759
Day 4	1	vs 2	gmt	0.7645	0.5332	1.0962
Day 4	3	vs 4	gmt	2.1406	1.3337	3.4357
Day 6	1	vs 4	gmr	4.3180	2.4847	7.5042
Day 6	2	vs 4	gmr	4.7455	2.7244	8.2659
Day 6	1	vs 2	gmr	0.9099	0.6220	1.3312
Day 6	3	vs 4	gmr	4.5230	2.6904	7.6038
Day 6	1	vs 4	gmt	7.0377	4.0528	12.2209
Day 6	2	vs 4	gmt	8.9934	5.1649	15.6597
Day 6	1	vs 2	gmt	0.7825	0.5354	1.1438
Day 6	3	vs 4	gmt	7.9352	4.7171	13.3490
Day 29	1	vs 4	gmr	13.9079	8.9984	21.4959
Day 29	2	vs 4	gmr	17.6191	11.3825	27.2727
Day 29	1	vs 2	gmr	0.7894	0.5820	1.0706
Day 29	3	vs 4	gmr	15.6279	10.3810	23.5268
Day 29	1	vs 4	gmt	25.2147	17.8318	35.6543
Day 29	2	vs 4	gmt	34.0614	24.0561	48.2281
Day 29	1	vs 2	gmt	0.7403	0.5809	0.9433
Day 29	3	vs 4	gmt	29.2367	21.0931	40.5244

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4

Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	1.3628	0.9887	1.8786
Day 4	2	vs 4	gmr	1.3154	0.9529	1.8159
Day 4	1	vs 2	gmr	1.0360	0.8230	1.3042
Day 4	3	vs 4	gmr	1.3393	0.9922	1.8079
Day 4	1	vs 4	gmt	2.3495	1.3572	4.0671
Day 4	2	vs 4	gmt	2.6190	1.5092	4.5450
Day 4	1	vs 2	gmt	0.8971	0.6058	1.3283
Day 4	3	vs 4	gmt	2.4782	1.4834	4.1401
Day 6	1	vs 4	gmr	4.1229	2.2399	7.5889
Day 6	2	vs 4	gmr	5.8146	3.1541	10.7192
Day 6	1	vs 2	gmr	0.7091	0.4655	1.0800
Day 6	3	vs 4	gmr	4.8873	2.7504	8.6846
Day 6	1	vs 4	gmt	9.8244	5.4723	17.6375
Day 6	2	vs 4	gmt	9.5537	5.3087	17.1933
Day 6	1	vs 2	gmt	1.0283	0.6874	1.5384
Day 6	3	vs 4	gmt	9.6905	5.5917	16.7936
Day 29	1	vs 4	gmr	14.2047	9.2753	21.7538
Day 29	2	vs 4	gmr	15.0361	9.8054	23.0571
Day 29	1	vs 2	gmr	0.9447	0.6998	1.2753
Day 29	3	vs 4	gmr	14.6093	9.7991	21.7809
Day 29	1	vs 4	gmt	28.5178	20.2318	40.1974
Day 29	2	vs 4	gmt	26.9393	19.0865	38.0231
Day 29	1	vs 2	gmt	1.0586	0.8318	1.3473
Day 29	3	vs 4	gmt	27.7298	20.0973	38.2608

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0016AB	Menveo-Menveo	289	.	0.45	0.386	0.023	0.149	.	.	.	1.968	2.810	2.535	3.114
Day 1	M0016AB	Menactra-Menveo	282	.	0.47	0.407	0.024	0.165	.	.	.	1.968	2.954	2.647	3.296
Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	571	.	0.46	0.396	0.017	0.157	.	.	.	1.964	2.880	2.672	3.104
Day 1	M0016AB	Naive	93	.	0.36	0.211	0.022	0.044	.	.	.	1.986	2.272	2.056	2.511
Day 4	M0016AB	Menveo-Menveo	144	0	0.45	0.417	0.035	0.174	2.00	2.0	244.0	1.977	2.826	2.412	3.310
Day 4	M0016AB	Menactra-Menveo	138	0	0.48	0.428	0.036	0.183	2.00	2.0	453.0	1.977	3.004	2.545	3.547
Day 4	M0016AB	Pooled Menveo/ Menactra-Menveo	282	0	0.46	0.422	0.025	0.178	2.00	2.0	453.0	1.968	2.912	2.598	3.263
Day 4	M0016AB	Naive	48	0	0.35	0.266	0.038	0.071	2.00	2.0	101.0	2.012	2.249	1.882	2.686
Day 6	M0016AB	Menveo-Menveo	146	0	1.11	0.823	0.068	0.677	11.00	2.0	817.0	1.976	12.867	9.439	17.542
Day 6	M0016AB	Menactra-Menveo	140	0	1.01	0.819	0.069	0.670	2.00	2.0	1688.0	1.977	10.168	7.421	13.931
Day 6	M0016AB	Pooled Menveo/ Menactra-Menveo	286	0	1.06	0.821	0.049	0.674	8.00	2.0	1688.0	1.968	11.466	9.202	14.288
Day 6	M0016AB	Naive	44	0	0.39	0.294	0.044	0.086	2.00	2.0	36.0	2.017	2.480	2.019	3.046

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0016AB	Menveo-Menveo	290	0	2.32	0.476	0.028	0.226	215.00	2.0	7250.0	1.968	210.102	185.114	238.462
Day 29	M0016AB	Menactra-Menveo	282	0	2.37	0.497	0.030	0.247	215.00	2.0	3861.0	1.968	236.685	206.948	270.695
Day 29	M0016AB	Pooled Menveo/ Menactra-Menveo	572	0	2.35	0.487	0.020	0.237	215.00	2.0	7250.0	1.964	222.812	203.216	244.298
Day 29	M0016AB	Naive	93	0	1.51	0.889	0.092	0.790	37.00	2.0	1999.0	1.986	32.115	21.070	48.949

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0019AB	Menveo-Menveo	288	.	1.21	0.789	0.046	0.622	.	.	.	1.968	16.112	13.052	19.889
Day 1	M0019AB	Menactra-Menveo	281	.	1.03	0.724	0.043	0.525	.	.	.	1.968	10.718	8.812	13.037
Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	569	.	1.12	0.762	0.032	0.581	.	.	.	1.964	13.174	11.402	15.222
Day 1	M0019AB	Naive	93	.	0.70	0.470	0.049	0.221	.	.	.	1.986	5.057	4.046	6.320
Day 4	M0019AB	Menveo-Menveo	144	0	1.36	0.787	0.066	0.620	20.50	2.0	1457.0	1.977	22.959	17.033	30.946
Day 4	M0019AB	Menactra-Menveo	138	0	1.16	0.771	0.066	0.594	12.50	2.0	3385.0	1.977	14.295	10.603	19.272
Day 4	M0019AB	Pooled Menveo/ Menactra-Menveo	282	0	1.26	0.785	0.047	0.616	15.00	2.0	3385.0	1.968	18.207	14.733	22.502
Day 4	M0019AB	Naive	48	0	0.83	0.522	0.075	0.273	6.00	2.0	232.0	2.012	6.687	4.716	9.480
Day 6	M0019AB	Menveo-Menveo	145	0	1.97	0.827	0.069	0.683	115.00	2.0	3663.0	1.977	92.272	67.514	126.109
Day 6	M0019AB	Menactra-Menveo	139	0	1.95	0.773	0.066	0.597	99.00	2.0	3859.0	1.977	90.061	66.820	121.388
Day 6	M0019AB	Pooled Menveo/ Menactra-Menveo	284	0	1.96	0.799	0.047	0.639	104.50	2.0	3859.0	1.968	91.183	73.544	113.054
Day 6	M0019AB	Naive	44	0	0.83	0.589	0.089	0.347	5.00	2.0	351.0	2.017	6.709	4.442	10.134

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0019AB	Menveo-Menveo	290	0	3.06	0.569	0.033	0.323	1425.00	13.0	19263	1.968	1159.926	997.061	1349.394
Day 29	M0019AB	Menactra-Menveo	281	0	3.02	0.593	0.035	0.352	1122.00	2.0	33272	1.968	1057.660	900.961	1241.613
Day 29	M0019AB	Pooled Menveo/ Menactra-Menveo	571	0	3.04	0.581	0.024	0.337	1234.00	2.0	33272	1.964	1108.419	993.081	1237.154
Day 29	M0019AB	Naive	93	0	1.78	0.951	0.099	0.905	50.00	2.0	41043	1.986	59.697	38.024	93.722

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0021AB	Menveo-Menveo	289	.	1.34	0.634	0.037	0.402	.	.	.	1.968	22.075	18.641	26.141
Day 1	M0021AB	Menactra-Menveo	282	.	1.37	0.678	0.040	0.459	.	.	.	1.968	23.463	19.540	28.173
Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	571	.	1.36	0.656	0.027	0.430	.	.	.	1.964	22.750	20.094	25.755
Day 1	M0021AB	Naive	93	.	1.09	0.661	0.069	0.437	.	.	.	1.986	12.213	8.927	16.709
Day 4	M0021AB	Menveo-Menveo	144	0	1.41	0.622	0.052	0.387	33.00	2.0	763.0	1.977	25.896	20.456	32.783
Day 4	M0021AB	Menactra-Menveo	138	0	1.53	0.706	0.060	0.498	42.00	2.0	7353.0	1.977	33.873	25.769	44.526
Day 4	M0021AB	Pooled Menveo/ Menactra-Menveo	282	0	1.47	0.665	0.040	0.443	36.00	2.0	7353.0	1.968	29.533	24.677	35.343
Day 4	M0021AB	Naive	48	0	1.14	0.690	0.100	0.476	23.00	2.0	186.0	2.012	13.797	8.700	21.878
Day 6	M0021AB	Menveo-Menveo	146	0	2.05	0.714	0.059	0.510	146.50	2.0	6974.0	1.976	112.493	85.960	147.216
Day 6	M0021AB	Menactra-Menveo	140	0	2.16	0.700	0.059	0.490	164.50	2.0	22491	1.977	143.754	109.819	188.174
Day 6	M0021AB	Pooled Menveo/ Menactra-Menveo	286	0	2.10	0.708	0.042	0.501	150.50	2.0	22491	1.968	126.840	104.919	153.340
Day 6	M0021AB	Naive	44	0	1.20	0.716	0.108	0.513	20.00	2.0	577.0	2.017	15.984	9.681	26.391

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0021AB	Menveo-Menveo	290	0	3.14	0.535	0.031	0.286	1521.00	20.0	87078	1.968	1394.646	1209.519	1608.108
Day 29	M0021AB	Menactra-Menveo	281	0	3.28	0.653	0.039	0.427	2057.00	18.0	78040	1.968	1883.963	1578.934	2247.920
Day 29	M0021AB	Pooled Menveo/ Menactra-Menveo	571	0	3.21	0.599	0.025	0.359	1680.00	18.0	87078	1.964	1617.107	1443.722	1811.316
Day 29	M0021AB	Naive	92	0	1.74	0.867	0.090	0.752	57.50	2.0	29145	1.986	55.311	36.581	83.630

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0023AB	Menveo-Menveo	287	.	0.97	0.645	0.038	0.416	.	.	.	1.968	9.244	7.779	10.985
Day 1	M0023AB	Menactra-Menveo	281	.	0.91	0.663	0.040	0.439	.	.	.	1.968	8.220	6.871	9.834
Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	568	.	0.94	0.654	0.027	0.427	.	.	.	1.964	8.723	7.705	9.875
Day 1	M0023AB	Naive	93	.	0.66	0.466	0.048	0.217	.	.	.	1.986	4.557	3.653	5.685
Day 4	M0023AB	Menveo-Menveo	143	0	1.04	0.730	0.061	0.532	10.00	2.0	381.0	1.977	10.873	8.237	14.353
Day 4	M0023AB	Menactra-Menveo	138	0	1.08	0.787	0.067	0.619	11.00	2.0	12288	1.977	12.120	8.935	16.442
Day 4	M0023AB	Pooled Menveo/ Menactra-Menveo	281	0	1.06	0.757	0.045	0.573	10.00	2.0	12288	1.968	11.469	9.345	14.074
Day 4	M0023AB	Naive	48	0	0.67	0.496	0.072	0.246	2.00	2.0	84.0	2.012	4.628	3.322	6.446
Day 6	M0023AB	Menveo-Menveo	145	0	1.80	0.760	0.063	0.578	80.00	2.0	2563.0	1.977	63.301	47.496	84.365
Day 6	M0023AB	Menactra-Menveo	140	0	1.79	0.777	0.066	0.604	61.50	2.0	23434	1.977	61.557	45.642	83.022
Day 6	M0023AB	Pooled Menveo/ Menactra-Menveo	285	0	1.80	0.767	0.045	0.589	72.00	2.0	23434	1.968	62.438	50.814	76.721
Day 6	M0023AB	Naive	44	0	0.81	0.618	0.093	0.382	2.00	2.0	184.0	2.017	6.443	4.179	9.934

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0023AB	Menveo-Menveo	290	0	3.03	0.537	0.032	0.289	879.00	45.0	26324	1.968	1066.662	924.562	1230.602
Day 29	M0023AB	Menactra-Menveo	281	0	3.00	0.615	0.037	0.378	965.00	2.0	22572	1.968	1007.622	853.324	1189.822
Day 29	M0023AB	Pooled Menveo/ Menactra-Menveo	571	0	3.02	0.576	0.024	0.332	912.00	2.0	26324	1.964	1037.187	930.013	1156.712
Day 29	M0023AB	Naive	93	0	1.57	0.927	0.096	0.860	30.00	2.0	6607.0	1.986	37.403	24.096	58.061

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	34.80305956	11.60101985	198.18	<.0001
Error	326	19.08316703	0.05853732		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.645862	54.02614	0.241945	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.56634457	0.28317228	4.84	0.0085
BASE	1	34.23671499	34.23671499	584.87	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.06963544	0.03481772	0.59	0.5523
BASE	1	34.23671499	34.23671499	584.87	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.44237487	0.02016533	<.0001
2	0.46285478	0.02060490	<.0001
4	0.42099444	0.03503828	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.442375	0.402704	0.482045
2	0.462855	0.422319	0.503390
4	0.420994	0.352065	0.489924

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	45.8351811	15.2783937	29.86	<.0001
Error	325	166.3081858	0.5117175		
Corrected Total	328	212.1433670			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.216058	73.53422	0.715344	0.972805

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.81552080	8.90776040	17.41	<.0001
BASE	1	28.01966034	28.01966034	54.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	14.12808723	7.06404361	13.80	<.0001
BASE	1	28.01966034	28.01966034	54.76	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.11849307	0.05940792	<.0001
2	0.98002216	0.06056925	<.0001
4	0.46973045	0.10832040	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.118493	1.001620	1.235366
2	0.980022	0.860865	1.099179
4	0.469730	0.256633	0.682828

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	665
Number of Observations Used	664

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	66.3658894	22.1219631	73.68	<.0001
Error	660	198.1494367	0.3002264		
Corrected Total	663	264.5153261			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.250896	24.56235	0.547929	2.230769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	57.05934800	28.52967400	95.03	<.0001
BASE	1	9.30654141	9.30654141	31.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	52.18366865	26.09183432	86.91	<.0001
BASE	1	9.30654141	9.30654141	31.00	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	2.32267404	0.03223181	<.0001
2	2.36615026	0.03266050	<.0001
4	1.53466159	0.05703903	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	2.322674	2.259385	2.385963
2	2.366150	2.302019	2.430281
4	1.534662	1.422662	1.646661

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	328

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	156.2438136	52.0812712	465.97	<.0001
Error	324	36.2130537	0.1117687		
Corrected Total	327	192.4568673			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.811838	27.94949	0.334318	1.196152

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	11.0526655	5.5263328	49.44	<.0001
BASE	1	145.1911481	145.1911481	1299.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.2882906	0.1441453	1.29	0.2768
BASE	1	145.1911481	145.1911481	1299.03	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.17553457	0.02845347	<.0001
2	1.23061974	0.02865332	<.0001
4	1.15919487	0.04913638	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.175535	1.119558	1.231511
2	1.230620	1.174250	1.286990
4	1.159195	1.062528	1.255861

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	328
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	88.1896699	29.3965566	61.02	<.0001
Error	323	155.6146261	0.4817790		
Corrected Total	326	243.8042960			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.361723	38.45417	0.694103	1.805014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	48.66492398	24.33246199	50.51	<.0001
BASE	1	39.52474595	39.52474595	82.04	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.73132130	15.86566065	32.93	<.0001
BASE	1	39.52474595	39.52474595	82.04	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.92203636	0.05799056	<.0001
2	1.93854125	0.05889954	<.0001
4	1.00020647	0.10637958	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.922036	1.807949	2.036123
2	1.938541	1.822666	2.054416
4	1.000206	0.790922	1.209491

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	661

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	176.2976353	58.7658784	171.37	<.0001
Error	657	225.2993674	0.3429214		
Corrected Total	660	401.5970028			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.438991	20.44928	0.585595	2.863646

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.3008636	64.1504318	187.07	<.0001
BASE	1	47.9967717	47.9967717	139.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	94.90872354	47.45436177	138.38	<.0001
BASE	1	47.99677170	47.99677170	139.96	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.00884209	0.03480654	<.0001
2	3.03116348	0.03500853	<.0001
4	1.90965446	0.06176612	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.008842	2.940497	3.077188
2	3.031163	2.962421	3.099906
4	1.909654	1.788372	2.030937

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	102.6609676	34.2203225	229.53	<.0001
Error	326	48.6019221	0.1490857		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.678692	27.14874	0.386116	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.43965064	2.71982532	18.24	<.0001
BASE	1	97.22131700	97.22131700	652.12	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.28587511	0.64293756	4.31	0.0142
BASE	1	97.22131700	97.22131700	652.12	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.37407832	0.03221286	<.0001
2	1.49566741	0.03289563	<.0001
4	1.35551668	0.05636780	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.374078	1.310707	1.437450
2	1.495667	1.430953	1.560382
4	1.355517	1.244626	1.466407

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	67.3132513	22.4377504	56.84	<.0001
Error	325	128.2856376	0.3947250		
Corrected Total	328	195.5988889			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.344139	31.65773	0.628271	1.984576

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.73034291	15.86517146	40.19	<.0001
BASE	1	35.58290838	35.58290838	90.15	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	23.06212164	11.53106082	29.21	<.0001
BASE	1	35.58290838	35.58290838	90.15	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	2.05327490	0.05217525	<.0001
2	2.12533838	0.05320737	<.0001
4	1.31029804	0.09537866	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	2.053275	1.950631	2.155919
2	2.125338	2.020664	2.230013
4	1.310298	1.122661	1.497936

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	663
Number of Observations Used	662

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	187.3468749	62.4489583	160.86	<.0001
Error	658	255.4484685	0.3882196		
Corrected Total	661	442.7953434			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.423100	20.72452	0.623073	3.006451

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	172.9329932	86.4664966	222.73	<.0001
BASE	1	14.4138817	14.4138817	37.13	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	155.4311832	77.7155916	200.18	<.0001
BASE	1	14.4138817	14.4138817	37.13	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.14172737	0.03666371	<.0001
2	3.26368416	0.03721636	<.0001
4	1.79582892	0.06553997	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.141727	3.069735	3.213719
2	3.263684	3.190607	3.336761
4	1.795829	1.667136	1.924522

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	120.7299134	40.2433045	229.13	<.0001
Error	323	56.7294267	0.1756329		
Corrected Total	326	177.4593401			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.680324	41.64614	0.419086	1.006302

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.6972395	3.3486198	19.07	<.0001
BASE	1	114.0326739	114.0326739	649.27	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.9812931	0.4906465	2.79	0.0627
BASE	1	114.0326739	114.0326739	649.27	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.03344020	0.03517033	<.0001
2	1.02478921	0.03589412	<.0001
4	0.87324969	0.06103743	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.033440	0.964248	1.102632
2	1.024789	0.954173	1.095405
4	0.873250	0.753169	0.993331

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	59.1599331	19.7199777	39.56	<.0001
Error	323	161.0229006	0.4985229		
Corrected Total	326	220.1828337			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.268685	42.41754	0.706062	1.664551

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	37.22376251	18.61188125	37.33	<.0001
BASE	1	21.93617059	21.93617059	44.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	27.56112891	13.78056445	27.64	<.0001
BASE	1	21.93617059	21.93617059	44.00	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.75236777	0.05958780	<.0001
2	1.80821313	0.05974133	<.0001
4	0.92203851	0.10779570	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.752368	1.635139	1.869597
2	1.808213	1.690682	1.925744
4	0.922039	0.709968	1.134109

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	660

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	180.7082324	60.2360775	155.60	<.0001
Error	656	253.9578307	0.3871308		
Corrected Total	659	434.6660631			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.415740	22.10288	0.622198	2.815011

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	167.1258343	83.5629172	215.85	<.0001
BASE	1	13.5823981	13.5823981	35.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	148.9658561	74.4829280	192.40	<.0001
BASE	1	13.5823981	13.5823981	35.08	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.01757570	0.03681373	<.0001
2	3.00166126	0.03718683	<.0001
4	1.62793360	0.06518426	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.017576	2.945289	3.089863
2	3.001661	2.928642	3.074681
4	1.627934	1.499939	1.755929

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	34.77350563	17.38675282	297.47	<.0001
Error	327	19.11272096	0.05844869		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.645313	53.98522	0.241762	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.51647756	0.51647756	8.84	0.0032
BASE	1	34.25702807	34.25702807	586.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.04008151	0.04008151	0.69	0.4082
BASE	1	34.25702807	34.25702807	586.10	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.45239392	0.01440488	<.0001
4	0.42101226	0.03501173	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.452394	0.424056	0.480732
4	0.421012	0.352136	0.489889

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	44.4726893	22.2363446	43.23	<.0001
Error	326	167.6706777	0.5143272		
Corrected Total	328	212.1433670			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.209635	73.72149	0.717166	0.972805

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.98711723	16.98711723	33.03	<.0001
BASE	1	27.48557204	27.48557204	53.44	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	12.76559535	12.76559535	24.82	<.0001
BASE	1	27.48557204	27.48557204	53.44	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.05059719	0.04251032	<.0001
4	0.46892131	0.10859512	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.050597	0.966968	1.134226
4	0.468921	0.255286	0.682557

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	665
Number of Observations Used	664

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	66.0963006	33.0481503	110.09	<.0001
Error	661	198.4190255	0.3001801		
Corrected Total	663	264.5153261			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.249877	24.56045	0.547887	2.230769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.69782732	56.69782732	188.88	<.0001
BASE	1	9.39847326	9.39847326	31.31	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	51.91407982	51.91407982	172.94	<.0001
BASE	1	9.39847326	9.39847326	31.31	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	2.34412487	0.02294292	<.0001
4	1.53478921	0.05703446	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	2.344125	2.299075	2.389175
4	1.534789	1.422799	1.646780

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	328

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	156.0388540	78.0194270	696.26	<.0001
Error	325	36.4180133	0.1120554		
Corrected Total	327	192.4568673			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.810773	27.98532	0.334747	1.196152

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.7369809	7.7369809	69.05	<.0001
BASE	1	148.3018731	148.3018731	1323.47	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.0833310	0.0833310	0.74	0.3891
BASE	1	148.3018731	148.3018731	1323.47	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.20288719	0.02006590	<.0001
4	1.15686019	0.04916907	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.202887	1.163412	1.242363
4	1.156860	1.060130	1.253590

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	328
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	88.1704189	44.0852095	91.78	<.0001
Error	324	155.6338771	0.4803515		
Corrected Total	326	243.8042960			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.361644	38.39715	0.693074	1.805014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	48.66309785	48.66309785	101.31	<.0001
BASE	1	39.50732105	39.50732105	82.25	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	31.71207027	31.71207027	66.02	<.0001
BASE	1	39.50732105	39.50732105	82.25	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.93016019	0.04130611	<.0001
4	1.00009592	0.10622042	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.930160	1.848898	2.011422
4	1.000096	0.791127	1.209065

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	661

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	176.2277727	88.1138863	257.26	<.0001
Error	658	225.3692301	0.3425064		
Corrected Total	660	401.5970028			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.438817	20.43690	0.585240	2.863646

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.0418542	128.0418542	373.84	<.0001
BASE	1	48.1859185	48.1859185	140.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	94.83886087	94.83886087	276.90	<.0001
BASE	1	48.18591851	48.18591851	140.69	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.01993843	0.02462482	<.0001
4	1.90908743	0.06171596	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.019938	2.971586	3.068291
4	1.909087	1.787903	2.030271

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	101.6191928	50.8095964	334.68	<.0001
Error	327	49.6436970	0.1518156		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.671805	27.39618	0.389635	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.48129846	4.48129846	29.52	<.0001
BASE	1	97.13789434	97.13789434	639.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.24410027	0.24410027	1.61	0.2057
BASE	1	97.13789434	97.13789434	639.84	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.43359545	0.02324777	<.0001
4	1.35542217	0.05688153	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.433595	1.387861	1.479330
4	1.355422	1.243522	1.467322

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	66.9440683	33.4720342	84.82	<.0001
Error	326	128.6548206	0.3946467		
Corrected Total	328	195.5988889			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.342252	31.65458	0.628209	1.984576

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	30.97228338	30.97228338	78.48	<.0001
BASE	1	35.97178493	35.97178493	91.15	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	22.69293866	22.69293866	57.50	<.0001
BASE	1	35.97178493	35.97178493	91.15	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	2.08860081	0.03725216	<.0001
4	1.31077537	0.09536792	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	2.088601	2.015316	2.161886
4	1.310775	1.123161	1.498390

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	663
Number of Observations Used	662

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	185.2284773	92.6142387	236.96	<.0001
Error	659	257.5668661	0.3908450		
Corrected Total	661	442.7953434			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.418316	20.79448	0.625176	3.006451

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	170.6154807	170.6154807	436.53	<.0001
BASE	1	14.6129966	14.6129966	37.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	153.3127856	153.3127856	392.26	<.0001
BASE	1	14.6129966	14.6129966	37.39	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.20179235	0.02622362	<.0001
4	1.79618565	0.06576104	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.201792	3.150300	3.253284
4	1.796186	1.667059	1.925312

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	120.7247052	60.3623526	344.72	<.0001
Error	324	56.7346350	0.1751069		
Corrected Total	326	177.4593401			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.680295	41.58373	0.418458	1.006302

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.5385859	6.5385859	37.34	<.0001
BASE	1	114.1861193	114.1861193	652.09	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.9760848	0.9760848	5.57	0.0188
BASE	1	114.1861193	114.1861193	652.09	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.02920286	0.02509150	<.0001
4	0.87318785	0.06094491	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.029203	0.979840	1.078566
4	0.873188	0.753290	0.993086

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	58.9429595	29.4714797	59.22	<.0001
Error	324	161.2398742	0.4976539		
Corrected Total	326	220.1828337			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.267700	42.38056	0.705446	1.664551

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	37.20478614	37.20478614	74.76	<.0001
BASE	1	21.73817334	21.73817334	43.68	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	27.34415529	27.34415529	54.95	<.0001
BASE	1	21.73817334	21.73817334	43.68	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.78021906	0.04201634	<.0001
4	0.92059386	0.10767948	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.780219	1.697560	1.862878
4	0.920594	0.708755	1.132433

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	660

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	180.6723907	90.3361953	233.67	<.0001
Error	657	253.9936725	0.3865962		
Corrected Total	659	434.6660631			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.415658	22.08761	0.621769	2.815011

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	167.0155570	167.0155570	432.02	<.0001
BASE	1	13.6568337	13.6568337	35.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	148.9300143	148.9300143	385.23	<.0001
BASE	1	13.6568337	13.6568337	35.33	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Adjusted GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.00969879	0.02615611	<.0001
4	1.62804290	0.06513824	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.009699	2.958339	3.061058
4	1.628043	1.500139	1.755947

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.ugmt: Unadjusted GMTs and Summary Statistics

Work.gmt: Adjusted GMTs and Summary Statistics

Visit	Test	Trt	T	Adjusted GMTs and GMRs	Adjusted Lower lcl	Adjusted Upper lcl
Day 4	Men A Human Complement SBA	Menveo-Menveo	1.977	2.769	2.528	3.034
Day 4	Men A Human Complement SBA	Menactra-Menveo	1.977	2.903	2.644	3.187
Day 4	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	2.834	2.655	3.025
Day 4	Men A Human Complement SBA	Naive	2.012	2.636	2.249	3.090
Day 6	Men A Human Complement SBA	Menveo-Menveo	1.976	13.137	10.037	17.194
Day 6	Men A Human Complement SBA	Menactra-Menveo	1.977	9.550	7.259	12.565
Day 6	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	11.236	9.268	13.622
Day 6	Men A Human Complement SBA	Naive	2.017	2.949	1.806	4.818
Day 29	Men A Human Complement SBA	Menveo-Menveo	1.968	210.220	181.712	243.200
Day 29	Men A Human Complement SBA	Menactra-Menveo	1.968	232.354	200.456	269.328
Day 29	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	220.864	199.102	245.005
Day 29	Men A Human Complement SBA	Naive	1.986	34.250	26.464	44.326

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.ugmt: Unadjusted GMTs and Summary Statistics

Work.gmt: Adjusted GMTs and Summary Statistics

Visit	Test	Trt	T	Adjusted GMTs and GMRs	Adjusted Lower lcl	Adjusted Upper lcl
Day 4	Men C Human Complement SBA	Menveo-Menveo	1.977	14.981	13.169	17.042
Day 4	Men C Human Complement SBA	Menactra-Menveo	1.977	17.007	14.937	19.364
Day 4	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	15.955	14.568	17.473
Day 4	Men C Human Complement SBA	Naive	2.012	14.428	11.549	18.024
Day 6	Men C Human Complement SBA	Menveo-Menveo	1.977	83.567	64.261	108.673
Day 6	Men C Human Complement SBA	Menactra-Menveo	1.977	86.804	66.476	113.349
Day 6	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	85.145	70.615	102.665
Day 6	Men C Human Complement SBA	Naive	2.017	10.005	6.179	16.199
Day 29	Men C Human Complement SBA	Menveo-Menveo	1.968	1020.568	871.960	1194.504
Day 29	Men C Human Complement SBA	Menactra-Menveo	1.968	1074.394	917.110	1258.652
Day 29	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1046.980	936.668	1170.284
Day 29	Men C Human Complement SBA	Naive	1.986	81.218	61.429	107.383

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.ugmt: Unadjusted GMTs and Summary Statistics

Work.gmt: Adjusted GMTs and Summary Statistics

Visit	Test	Trt	T	Adjusted GMTs and GMRs	Adjusted Lower lcl	Adjusted Upper lcl
Day 4	Men W Human Complement SBA	Menveo-Menveo	1.977	23.663	20.451	27.381
Day 4	Men W Human Complement SBA	Menactra-Menveo	1.977	31.309	26.974	36.340
Day 4	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	27.139	24.427	30.153
Day 4	Men W Human Complement SBA	Naive	2.012	22.673	17.564	29.269
Day 6	Men W Human Complement SBA	Menveo-Menveo	1.976	113.051	89.255	143.192
Day 6	Men W Human Complement SBA	Menactra-Menveo	1.977	133.456	104.873	169.829
Day 6	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	122.631	103.590	145.173
Day 6	Men W Human Complement SBA	Naive	2.017	20.431	13.264	31.473
Day 29	Men W Human Complement SBA	Menveo-Menveo	1.968	1385.886	1174.182	1635.759
Day 29	Men W Human Complement SBA	Menactra-Menveo	1.968	1835.203	1550.983	2171.507
Day 29	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1591.448	1413.515	1791.778
Day 29	Men W Human Complement SBA	Naive	1.986	62.493	46.466	84.047

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.ugmt: Unadjusted GMTs and Summary Statistics

Work.gmt: Adjusted GMTs and Summary Statistics

Visit	Test	Trt	T	Adjusted GMTs and GMRs	Adjusted Lower lcl	Adjusted Upper lcl
Day 4	Men Y Human Complement SBA	Menveo-Menveo	1.977	10.800	9.210	12.666
Day 4	Men Y Human Complement SBA	Menactra-Menveo	1.977	10.587	8.999	12.457
Day 4	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	10.696	9.546	11.983
Day 4	Men Y Human Complement SBA	Naive	2.012	7.469	5.665	9.848
Day 6	Men Y Human Complement SBA	Menveo-Menveo	1.977	56.542	43.166	74.062
Day 6	Men Y Human Complement SBA	Menactra-Menveo	1.977	64.300	49.055	84.284
Day 6	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	60.286	49.838	72.925
Day 6	Men Y Human Complement SBA	Naive	2.017	8.357	5.128	13.618
Day 29	Men Y Human Complement SBA	Menveo-Menveo	1.968	1041.300	881.635	1229.880
Day 29	Men Y Human Complement SBA	Menactra-Menveo	1.968	1003.833	848.480	1187.629
Day 29	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1022.584	908.530	1150.955
Day 29	Men Y Human Complement SBA	Naive	1.986	42.455	31.618	57.007

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	34.80305956	11.60101985	198.18	<.0001
Error	326	19.08316703	0.05853732		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.645862	54.02614	0.241945	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.56634457	0.28317228	4.84	0.0085
BASE	1	34.23671499	34.23671499	584.87	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.06963544	0.03481772	0.59	0.5523
BASE	1	34.23671499	34.23671499	584.87	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.02138043	0.04045231	0.53	0.5975
2 vs 4	0.04186034	0.04069099	1.03	0.3044
1 vs 2	-0.02047991	0.02882285	-0.71	0.4779

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	45.8351811	15.2783937	29.86	<.0001
Error	325	166.3081858	0.5117175		
Corrected Total	328	212.1433670			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.216058	73.53422	0.715344	0.972805

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.81552080	8.90776040	17.41	<.0001
BASE	1	28.01966034	28.01966034	54.76	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	14.12808723	7.06404361	13.80	<.0001
BASE	1	28.01966034	28.01966034	54.76	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.64876262	0.12350378	5.25	<.0001
2 vs 4	0.51029171	0.12440529	4.10	<.0001
1 vs 2	0.13847091	0.08486072	1.63	0.1037

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 665
Number of Observations Used 664

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	66.3658894	22.1219631	73.68	<.0001
Error	660	198.1494367	0.3002264		
Corrected Total	663	264.5153261			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.250896	24.56235	0.547929	2.230769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	57.05934800	28.52967400	95.03	<.0001
BASE	1	9.30654141	9.30654141	31.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	52.18366865	26.09183432	86.91	<.0001
BASE	1	9.30654141	9.30654141	31.00	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.78801245	0.06553204	12.02	<.0001
2 vs 4	0.83148867	0.06583787	12.63	<.0001
1 vs 2	-0.04347622	0.04588020	-0.95	0.3437

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 330
Number of Observations Used 328

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	156.2438136	52.0812712	465.97	<.0001
Error	324	36.2130537	0.1117687		
Corrected Total	327	192.4568673			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.811838	27.94949	0.334318	1.196152

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	11.0526655	5.5263328	49.44	<.0001
BASE	1	145.1911481	145.1911481	1299.03	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.2882906	0.1441453	1.29	0.2768
BASE	1	145.1911481	145.1911481	1299.03	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.01633971	0.05763725	0.28	0.7770
2 vs 4	0.07142487	0.05650843	1.26	0.2071
1 vs 2	-0.05508517	0.04067809	-1.35	0.1766

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 328
Number of Observations Used 327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	88.1896699	29.3965566	61.02	<.0001
Error	323	155.6146261	0.4817790		
Corrected Total	326	243.8042960			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.361723	38.45417	0.694103	1.805014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	48.66492398	24.33246199	50.51	<.0001
BASE	1	39.52474595	39.52474595	82.04	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.73132130	15.86566065	32.93	<.0001
BASE	1	39.52474595	39.52474595	82.04	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.92182989	0.12181348	7.57	<.0001
2 vs 4	0.93833478	0.12187474	7.70	<.0001
1 vs 2	-0.01650489	0.08256757	-0.20	0.8417

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 664
Number of Observations Used 661

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	176.2976353	58.7658784	171.37	<.0001
Error	657	225.2993674	0.3429214		
Corrected Total	660	401.5970028			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.438991	20.44928	0.585595	2.863646

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.3008636	64.1504318	187.07	<.0001
BASE	1	47.9967717	47.9967717	139.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	94.90872354	47.45436177	138.38	<.0001
BASE	1	47.99677170	47.99677170	139.96	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.09918763	0.07162140	15.35	<.0001
2 vs 4	1.12150902	0.07084825	15.83	<.0001
1 vs 2	-0.02232139	0.04945338	-0.45	0.6519

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	102.6609676	34.2203225	229.53	<.0001
Error	326	48.6019221	0.1490857		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.678692	27.14874	0.386116	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.43965064	2.71982532	18.24	<.0001
BASE	1	97.22131700	97.22131700	652.12	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.28587511	0.64293756	4.31	0.0142
BASE	1	97.22131700	97.22131700	652.12	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.01856164	0.06512223	0.29	0.7758
2 vs 4	0.14015072	0.06543753	2.14	0.0330
1 vs 2	-0.12158908	0.04599658	-2.64	0.0086

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.ugmt: Unadjusted GMTs and Summary Statistics

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	67.3132513	22.4377504	56.84	<.0001
Error	325	128.2856376	0.3947250		
Corrected Total	328	195.5988889			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.344139	31.65773	0.628271	1.984576

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	31.73034291	15.86517146	40.19	<.0001
BASE	1	35.58290838	35.58290838	90.15	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	23.06212164	11.53106082	29.21	<.0001
BASE	1	35.58290838	35.58290838	90.15	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.74297685	0.10872966	6.83	<.0001
2 vs 4	0.81504034	0.10956487	7.44	<.0001
1 vs 2	-0.07206349	0.07451467	-0.97	0.3342

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 663
Number of Observations Used 662

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	187.3468749	62.4489583	160.86	<.0001
Error	658	255.4484685	0.3882196		
Corrected Total	661	442.7953434			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.423100	20.72452	0.623073	3.006451

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	172.9329932	86.4664966	222.73	<.0001
BASE	1	14.4138817	14.4138817	37.13	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	155.4311832	77.7155916	200.18	<.0001
BASE	1	14.4138817	14.4138817	37.13	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.34589845	0.07520834	17.90	<.0001
2 vs 4	1.46785524	0.07558485	19.42	<.0001
1 vs 2	-0.12195679	0.05220847	-2.34	0.0198

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 329
Number of Observations Used 327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	120.7299134	40.2433045	229.13	<.0001
Error	323	56.7294267	0.1756329		
Corrected Total	326	177.4593401			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.680324	41.64614	0.419086	1.006302

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	6.6972395	3.3486198	19.07	<.0001
BASE	1	114.0326739	114.0326739	649.27	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.9812931	0.4906465	2.79	0.0627
BASE	1	114.0326739	114.0326739	649.27	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.16019050	0.07048192	2.27	0.0237
2 vs 4	0.15153952	0.07110006	2.13	0.0338
1 vs 2	0.00865099	0.05023678	0.17	0.8634

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read 329
Number of Observations Used 327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	59.1599331	19.7199777	39.56	<.0001
Error	323	161.0229006	0.4985229		
Corrected Total	326	220.1828337			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.268685	42.41754	0.706062	1.664551

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	37.22376251	18.61188125	37.33	<.0001
BASE	1	21.93617059	21.93617059	44.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	27.56112891	13.78056445	27.64	<.0001
BASE	1	21.93617059	21.93617059	44.00	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.83032927	0.12427448	6.68	<.0001
2 vs 4	0.88617463	0.12284844	7.21	<.0001
1 vs 2	-0.05584536	0.08464985	-0.66	0.5099

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	664
Number of Observations Used	660

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	180.7082324	60.2360775	155.60	<.0001
Error	656	253.9578307	0.3871308		
Corrected Total	659	434.6660631			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.415740	22.10288	0.622198	2.815011

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	167.1258343	83.5629172	215.85	<.0001
BASE	1	13.5823981	13.5823981	35.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	148.9658561	74.4829280	192.40	<.0001
BASE	1	13.5823981	13.5823981	35.08	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.38964210	0.07517381	18.49	<.0001
2 vs 4	1.37372766	0.07510749	18.29	<.0001
1 vs 2	0.01591444	0.05230285	0.30	0.7610

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	34.77350563	17.38675282	297.47	<.0001
Error	327	19.11272096	0.05844869		
Corrected Total	329	53.88622659			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.645313	53.98522	0.241762	0.447829

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.51647756	0.51647756	8.84	0.0032
BASE	1	34.25702807	34.25702807	586.10	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.04008151	0.04008151	0.69	0.4082
BASE	1	34.25702807	34.25702807	586.10	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.03138166	0.03789582	0.83	0.4082

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	44.4726893	22.2363446	43.23	<.0001
Error	326	167.6706777	0.5143272		
Corrected Total	328	212.1433670			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.209635	73.72149	0.717166	0.972805

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	16.98711723	16.98711723	33.03	<.0001
BASE	1	27.48557204	27.48557204	53.44	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	12.76559535	12.76559535	24.82	<.0001
BASE	1	27.48557204	27.48557204	53.44	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.58167588	0.11675629	4.98	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	665
Number of Observations Used	664

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	66.0963006	33.0481503	110.09	<.0001
Error	661	198.4190255	0.3001801		
Corrected Total	663	264.5153261			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.249877	24.56045	0.547887	2.230769

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.69782732	56.69782732	188.88	<.0001
BASE	1	9.39847326	9.39847326	31.31	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	51.91407982	51.91407982	172.94	<.0001
BASE	1	9.39847326	9.39847326	31.31	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.80933566	0.06154277	13.15	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	328

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	156.0388540	78.0194270	696.26	<.0001
Error	325	36.4180133	0.1120554		
Corrected Total	327	192.4568673			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.810773	27.98532	0.334747	1.196152

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.7369809	7.7369809	69.05	<.0001
BASE	1	148.3018731	148.3018731	1323.47	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.0833310	0.0833310	0.74	0.3891
BASE	1	148.3018731	148.3018731	1323.47	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.04602699	0.05337352	0.86	0.3891

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	328
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	88.1704189	44.0852095	91.78	<.0001
Error	324	155.6338771	0.4803515		
Corrected Total	326	243.8042960			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.361644	38.39715	0.693074	1.805014

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	48.66309785	48.66309785	101.31	<.0001
BASE	1	39.50732105	39.50732105	82.25	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	31.71207027	31.71207027	66.02	<.0001
BASE	1	39.50732105	39.50732105	82.25	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.93006427	0.11446698	8.13	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	661

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	176.2277727	88.1138863	257.26	<.0001
Error	658	225.3692301	0.3425064		
Corrected Total	660	401.5970028			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.438817	20.43690	0.585240	2.863646

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.0418542	128.0418542	373.84	<.0001
BASE	1	48.1859185	48.1859185	140.69	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	94.83886087	94.83886087	276.90	<.0001
BASE	1	48.18591851	48.18591851	140.69	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.11085099	0.06675703	16.64	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	330

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	101.6191928	50.8095964	334.68	<.0001
Error	327	49.6436970	0.1518156		
Corrected Total	329	151.2628898			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.671805	27.39618	0.389635	1.422225

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.48129846	4.48129846	29.52	<.0001
BASE	1	97.13789434	97.13789434	639.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.24410027	0.24410027	1.61	0.2057
BASE	1	97.13789434	97.13789434	639.84	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.07817328	0.06164990	1.27	0.2057

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	330
Number of Observations Used	329

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	66.9440683	33.4720342	84.82	<.0001
Error	326	128.6548206	0.3946467		
Corrected Total	328	195.5988889			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.342252	31.65458	0.628209	1.984576

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	30.97228338	30.97228338	78.48	<.0001
BASE	1	35.97178493	35.97178493	91.15	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	22.69293866	22.69293866	57.50	<.0001
BASE	1	35.97178493	35.97178493	91.15	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.77782544	0.10257488	7.58	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	663
Number of Observations Used	662

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	185.2284773	92.6142387	236.96	<.0001
Error	659	257.5668661	0.3908450		
Corrected Total	661	442.7953434			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.418316	20.79448	0.625176	3.006451

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	170.6154807	170.6154807	436.53	<.0001
BASE	1	14.6129966	14.6129966	37.39	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	153.3127856	153.3127856	392.26	<.0001
BASE	1	14.6129966	14.6129966	37.39	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.40560670	0.07097035	19.81	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	120.7247052	60.3623526	344.72	<.0001
Error	324	56.7346350	0.1751069		
Corrected Total	326	177.4593401			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.680295	41.58373	0.418458	1.006302

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.5385859	6.5385859	37.34	<.0001
BASE	1	114.1861193	114.1861193	652.09	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.9760848	0.9760848	5.57	0.0188
BASE	1	114.1861193	114.1861193	652.09	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.15601501	0.06608064	2.36	0.0188

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	329
Number of Observations Used	327

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	58.9429595	29.4714797	59.22	<.0001
Error	324	161.2398742	0.4976539		
Corrected Total	326	220.1828337			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.267700	42.38056	0.705446	1.664551

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	37.20478614	37.20478614	74.76	<.0001
BASE	1	21.73817334	21.73817334	43.68	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	27.34415529	27.34415529	54.95	<.0001
BASE	1	21.73817334	21.73817334	43.68	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.85962520	0.11596865	7.41	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	664
Number of Observations Used	660

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	180.6723907	90.3361953	233.67	<.0001
Error	657	253.9936725	0.3865962		
Corrected Total	659	434.6660631			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.415658	22.08761	0.621769	2.815011

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	167.0155570	167.0155570	432.02	<.0001
BASE	1	13.6568337	13.6568337	35.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	148.9300143	148.9300143	385.23	<.0001
BASE	1	13.6568337	13.6568337	35.33	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.38165589	0.07039431	19.63	<.0001

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.vgr_: Ratio of GMTs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4		1 vs 4	gmt	1.0505	0.8746	1.2617
Day 4		2 vs 4	gmt	1.1012	0.9158	1.3241
Day 4		1 vs 2	gmt	0.9539	0.8372	1.0870
Day 4		3 vs 4	gmt	1.0749	0.9054	1.2762
Day 6		1 vs 4	gmt	4.4541	2.5456	7.7935
Day 6		2 vs 4	gmt	3.2381	1.8431	5.6890
Day 6		1 vs 2	gmt	1.3755	0.9365	2.0203
Day 6		3 vs 4	gmt	3.8166	2.2490	6.4769
Day 29		1 vs 4	gmt	6.1378	4.5639	8.2545
Day 29		2 vs 4	gmt	6.7840	5.0375	9.1362
Day 29		1 vs 2	gmt	0.9047	0.7352	1.1133
Day 29		3 vs 4	gmt	6.4467	4.8808	8.5149

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.vgr_: Ratio of GMTs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4		1 vs 4	gmt	1.0383	0.7997	1.3481
Day 4		2 vs 4	gmt	1.1788	0.9125	1.5226
Day 4		1 vs 2	gmt	0.8809	0.7326	1.0591
Day 4		3 vs 4	gmt	1.1118	0.8730	1.4159
Day 6		1 vs 4	gmt	8.3528	4.8104	14.5037
Day 6		2 vs 4	gmt	8.6763	4.9954	15.0697
Day 6		1 vs 2	gmt	0.9627	0.6623	1.3994
Day 6		3 vs 4	gmt	8.5126	5.0684	14.2974
Day 29		1 vs 4	gmt	12.5657	9.0898	17.3709
Day 29		2 vs 4	gmt	13.2285	9.6027	18.2232
Day 29		1 vs 2	gmt	0.9499	0.7596	1.1879
Day 29		3 vs 4	gmt	12.9078	9.5448	17.4555

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.vgr_: Ratio of GMTs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmt	1.0437	0.7770	1.4018
Day 4	2	vs 4	gmt	1.3809	1.0266	1.8573
Day 4	1	vs 2	gmt	0.7558	0.6137	0.9309
Day 4	3	vs 4	gmt	1.1972	0.9055	1.5829
Day 6	1	vs 4	gmt	5.5332	3.3812	9.0548
Day 6	2	vs 4	gmt	6.5319	3.9764	10.7297
Day 6	1	vs 2	gmt	0.8471	0.6044	1.1872
Day 6	3	vs 4	gmt	5.9955	3.7673	9.5415
Day 29	1	vs 4	gmt	22.1768	15.7841	31.1584
Day 29	2	vs 4	gmt	29.3667	20.8660	41.3306
Day 29	1	vs 2	gmt	0.7552	0.5964	0.9562
Day 29	3	vs 4	gmt	25.4452	18.4608	35.0721

PPD

ANCOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Days 4, 6 and 29 after Booster Vaccination

Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.1

Work.vgr_: Ratio of GMTs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmt	1.4461	1.0508	1.9900
Day 4	2	vs 4	gmt	1.4176	1.0272	1.9562
Day 4	1	vs 2	gmt	1.0201	0.8125	1.2808
Day 4	3	vs 4	gmt	1.4322	1.0617	1.9320
Day 6	1	vs 4	gmt	6.7660	3.8534	11.8801
Day 6	2	vs 4	gmt	7.6944	4.4105	13.4233
Day 6	1	vs 2	gmt	0.8793	0.5993	1.2903
Day 6	3	vs 4	gmt	7.2381	4.2803	12.2397
Day 29	1	vs 4	gmt	24.5269	17.4595	34.4550
Day 29	2	vs 4	gmt	23.6444	16.8363	33.2053
Day 29	1	vs 2	gmt	1.0373	0.8189	1.3141
Day 29	3	vs 4	gmt	24.0800	17.5158	33.1040

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0016AB	Menveo-Menveo	296	0	0.45	0.392	0.023	0.154	2.00	2.0	140.0	1.968	2.824	2.547	3.132
Day 1	M0016AB	Menactra-Menveo	296	0	0.49	0.432	0.025	0.187	2.00	2.0	173.0	1.968	3.087	2.755	3.459
Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	592	0	0.47	0.413	0.017	0.170	2.00	2.0	173.0	1.964	2.953	2.735	3.188
Day 1	M0016AB	Naive	96	0	0.35	0.208	0.021	0.043	2.00	2.0	71.0	1.985	2.263	2.054	2.493
Day 4	M0016AB	Menveo-Menveo	149	0	0.46	0.435	0.036	0.189	2.00	2.0	244.0	1.976	2.915	2.478	3.428
Day 4	M0016AB	Menactra-Menveo	144	0	0.50	0.449	0.037	0.202	2.00	2.0	453.0	1.977	3.139	2.648	3.722
Day 4	M0016AB	Pooled Menveo/ Menactra-Menveo	293	0	0.48	0.442	0.026	0.195	2.00	2.0	453.0	1.968	3.023	2.690	3.398
Day 4	M0016AB	Naive	49	0	0.35	0.263	0.038	0.069	2.00	2.0	101.0	2.011	2.243	1.885	2.670
Day 6	M0016AB	Menveo-Menveo	148	0	1.11	0.822	0.068	0.675	11.00	2.0	817.0	1.976	12.841	9.443	17.461
Day 6	M0016AB	Menactra-Menveo	148	0	1.03	0.838	0.069	0.702	2.00	2.0	1688.0	1.976	10.600	7.748	14.501
Day 6	M0016AB	Pooled Menveo/ Menactra-Menveo	296	0	1.07	0.829	0.048	0.688	8.00	2.0	1688.0	1.968	11.667	9.377	14.516
Day 6	M0016AB	Naive	46	0	0.39	0.288	0.042	0.083	2.00	2.0	36.0	2.014	2.457	2.018	2.991

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0016AB	Menveo-Menveo	297	0	2.32	0.474	0.028	0.225	214.00	2.0	7250.0	1.968	207.227	182.930	234.750
Day 29	M0016AB	Menactra-Menveo	296	0	2.37	0.507	0.029	0.257	215.50	2.0	3861.0	1.968	235.030	205.635	268.626
Day 29	M0016AB	Pooled Menveo/ Menactra-Menveo	593	0	2.34	0.491	0.020	0.241	215.00	2.0	7250.0	1.964	220.667	201.423	241.750
Day 29	M0016AB	Naive	96	0	1.49	0.894	0.091	0.799	36.00	2.0	1999.0	1.985	30.776	20.279	46.707
Day 4/Day 1	M0016AB	Menveo-Menveo	149	0	0.02	0.273	0.022	0.074	1.00	0.1	122.0	1.976	1.035	0.935	1.146
Day 4/Day 1	M0016AB	Menactra-Menveo	144	0	0.03	0.261	0.022	0.068	1.00	0.1	226.5	1.977	1.063	0.963	1.174
Day 4/Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	293	0	0.02	0.267	0.016	0.071	1.00	0.1	226.5	1.968	1.049	0.977	1.126
Day 4/Day 1	M0016AB	Naive	49	0	-0.00	0.062	0.009	0.004	1.00	0.4	1.4	2.011	0.990	0.951	1.032
Day 6/Day 1	M0016AB	Menveo-Menveo	147	0	0.66	0.789	0.065	0.623	1.67	0.1	408.5	1.976	4.589	3.413	6.172
Day 6/Day 1	M0016AB	Menactra-Menveo	148	0	0.51	0.754	0.062	0.569	1.00	0.1	373.0	1.976	3.250	2.451	4.310
Day 6/Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	295	0	0.59	0.774	0.045	0.599	1.00	0.1	408.5	1.968	3.860	3.147	4.735
Day 6/Day 1	M0016AB	Naive	46	0	0.04	0.232	0.034	0.054	1.00	0.4	18.0	2.014	1.084	0.925	1.271

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0016AB	Menveo-Menveo	296	0	1.87	0.542	0.032	0.294	92.00	1.0	862.5	1.968	73.602	63.808	84.901
Day 29/Day 1	M0016AB	Menactra-Menveo	296	0	1.88	0.576	0.033	0.332	88.50	1.0	1930.5	1.968	76.136	65.422	88.605
Day 29/Day 1	M0016AB	Pooled Menveo/ Menactra-Menveo	592	0	1.87	0.559	0.023	0.312	89.25	1.0	1930.5	1.964	74.859	67.474	83.052
Day 29/Day 1	M0016AB	Naive	96	0	1.13	0.873	0.089	0.761	17.00	1.0	999.5	1.985	13.601	9.053	20.435

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0019AB	Menveo-Menveo	295	0	1.21	0.783	0.046	0.612	13.00	2.0	1590.0	1.968	16.118	13.111	19.814
Day 1	M0019AB	Menactra-Menveo	294	0	1.03	0.724	0.042	0.524	10.00	2.0	1848.0	1.968	10.657	8.802	12.903
Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	589	0	1.12	0.758	0.031	0.575	11.00	2.0	1848.0	1.964	13.111	11.383	15.101
Day 1	M0019AB	Naive	96	0	0.71	0.467	0.048	0.218	4.50	2.0	208.0	1.985	5.090	4.093	6.329
Day 4	M0019AB	Menveo-Menveo	149	0	1.36	0.783	0.064	0.613	19.00	2.0	1457.0	1.976	22.790	17.020	30.515
Day 4	M0019AB	Menactra-Menveo	144	0	1.16	0.765	0.064	0.585	13.00	2.0	3385.0	1.977	14.415	10.786	19.264
Day 4	M0019AB	Pooled Menveo/ Menactra-Menveo	293	0	1.26	0.779	0.046	0.607	15.00	2.0	3385.0	1.968	18.196	14.804	22.364
Day 4	M0019AB	Naive	49	0	0.83	0.518	0.074	0.268	6.00	2.0	232.0	2.011	6.755	4.797	9.512
Day 6	M0019AB	Menveo-Menveo	147	0	1.96	0.821	0.068	0.674	115.00	2.0	3663.0	1.976	92.129	67.692	125.389
Day 6	M0019AB	Menactra-Menveo	147	0	1.97	0.783	0.065	0.614	103.00	2.0	3859.0	1.976	93.028	69.331	124.827
Day 6	M0019AB	Pooled Menveo/ Menactra-Menveo	294	0	1.97	0.801	0.047	0.642	106.50	2.0	3859.0	1.968	92.578	74.912	114.410
Day 6	M0019AB	Naive	46	0	0.82	0.582	0.086	0.339	5.00	2.0	351.0	2.014	6.618	4.444	9.856

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0019AB	Menveo-Menveo	297	0	3.06	0.570	0.033	0.325	1373.00	13.0	19263	1.968	1138.035	979.687	1321.976
Day 29	M0019AB	Menactra-Menveo	294	0	3.02	0.596	0.035	0.355	1121.00	2.0	33272	1.968	1043.823	891.664	1221.947
Day 29	M0019AB	Pooled Menveo/ Menactra-Menveo	591	0	3.04	0.583	0.024	0.340	1197.00	2.0	33272	1.964	1090.150	978.135	1214.994
Day 29	M0019AB	Naive	96	0	1.79	0.944	0.096	0.891	51.50	2.0	41043	1.985	61.865	39.826	96.100
Day 4/Day 1	M0019AB	Menveo-Menveo	148	0	0.05	0.245	0.020	0.060	1.00	0.3	30.3	1.976	1.119	1.021	1.226
Day 4/Day 1	M0019AB	Menactra-Menveo	143	0	0.13	0.433	0.036	0.188	1.00	0.1	178.2	1.977	1.354	1.149	1.597
Day 4/Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	291	0	0.09	0.352	0.021	0.124	1.00	0.1	178.2	1.968	1.229	1.119	1.349
Day 4/Day 1	M0019AB	Naive	49	0	0.08	0.250	0.036	0.063	1.00	0.4	10.5	2.011	1.208	1.023	1.425
Day 6/Day 1	M0019AB	Menveo-Menveo	146	0	0.86	0.833	0.069	0.693	5.92	0.0	923.0	1.976	7.247	5.296	9.916
Day 6/Day 1	M0019AB	Menactra-Menveo	146	0	0.92	0.826	0.068	0.683	6.00	0.7	1929.5	1.976	8.296	6.077	11.325
Day 6/Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	292	0	0.89	0.829	0.048	0.687	6.00	0.0	1929.5	1.968	7.753	6.224	9.659
Day 6/Day 1	M0019AB	Naive	46	0	0.16	0.387	0.057	0.150	1.00	0.4	59.0	2.014	1.430	1.098	1.864

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0019AB	Menveo-Menveo	295	0	1.85	0.710	0.041	0.503	68.85	0.5	3265.0	1.968	70.340	58.331	84.821
Day 29/Day 1	M0019AB	Menactra-Menveo	293	0	1.98	0.743	0.043	0.552	97.45	0.3	8361.5	1.968	96.471	79.245	117.442
Day 29/Day 1	M0019AB	Pooled Menveo/ Menactra-Menveo	588	0	1.92	0.729	0.030	0.531	83.21	0.3	8361.5	1.964	82.332	71.866	94.322
Day 29/Day 1	M0019AB	Naive	96	0	1.08	0.828	0.084	0.685	9.00	0.8	4178.5	1.985	12.154	8.261	17.883

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0021AB	Menveo-Menveo	296	0	1.35	0.633	0.037	0.401	28.00	2.0	761.0	1.968	22.470	19.018	26.548
Day 1	M0021AB	Menactra-Menveo	296	0	1.38	0.690	0.040	0.476	31.00	2.0	6726.0	1.968	23.857	19.893	28.611
Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	592	0	1.36	0.662	0.027	0.438	30.00	2.0	6726.0	1.964	23.153	20.473	26.183
Day 1	M0021AB	Naive	96	0	1.07	0.661	0.067	0.437	14.00	2.0	200.0	1.985	11.854	8.708	16.137
Day 4	M0021AB	Menveo-Menveo	149	0	1.42	0.619	0.051	0.383	33.00	2.0	763.0	1.976	26.371	20.940	33.211
Day 4	M0021AB	Menactra-Menveo	144	0	1.53	0.723	0.060	0.523	42.00	2.0	7353.0	1.977	33.994	25.841	44.719
Day 4	M0021AB	Pooled Menveo/ Menactra-Menveo	293	0	1.48	0.673	0.039	0.453	36.00	2.0	7353.0	1.968	29.876	25.000	35.703
Day 4	M0021AB	Naive	49	0	1.14	0.683	0.098	0.466	23.00	2.0	186.0	2.011	13.901	8.850	21.836
Day 6	M0021AB	Menveo-Menveo	148	0	2.04	0.714	0.059	0.510	143.00	2.0	6974.0	1.976	110.310	84.449	144.090
Day 6	M0021AB	Menactra-Menveo	148	0	2.17	0.731	0.060	0.535	166.00	2.0	22491	1.976	149.096	113.410	196.009
Day 6	M0021AB	Pooled Menveo/ Menactra-Menveo	296	0	2.11	0.725	0.042	0.525	150.50	2.0	22491	1.968	128.245	105.963	155.212
Day 6	M0021AB	Naive	46	0	1.16	0.724	0.107	0.525	14.00	2.0	577.0	2.014	14.603	8.898	23.966

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0021AB	Menveo-Menveo	297	0	3.13	0.540	0.031	0.292	1497.00	20.0	87078	1.968	1345.635	1167.496	1550.956
Day 29	M0021AB	Menactra-Menveo	294	0	3.26	0.650	0.038	0.423	1899.50	18.0	78040	1.968	1838.295	1548.113	2182.868
Day 29	M0021AB	Pooled Menveo/ Menactra-Menveo	591	0	3.20	0.601	0.025	0.361	1642.00	18.0	87078	1.964	1571.547	1405.410	1757.323
Day 29	M0021AB	Naive	95	0	1.72	0.870	0.089	0.756	55.00	2.0	29145	1.986	52.043	34.612	78.253
Day 4/Day 1	M0021AB	Menveo-Menveo	149	0	0.02	0.350	0.029	0.122	1.00	0.0	64.0	1.976	1.051	0.923	1.197
Day 4/Day 1	M0021AB	Menactra-Menveo	144	0	0.14	0.415	0.035	0.172	1.02	0.2	68.7	1.977	1.375	1.175	1.609
Day 4/Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	293	0	0.08	0.387	0.023	0.150	1.00	0.0	68.7	1.968	1.199	1.083	1.329
Day 4/Day 1	M0021AB	Naive	49	0	0.05	0.467	0.067	0.218	1.00	0.1	51.0	2.011	1.132	0.831	1.541
Day 6/Day 1	M0021AB	Menveo-Menveo	147	0	0.74	0.715	0.059	0.511	4.33	0.2	646.5	1.976	5.532	4.230	7.233
Day 6/Day 1	M0021AB	Menactra-Menveo	148	0	0.81	0.749	0.062	0.562	5.04	0.5	346.0	1.976	6.421	4.851	8.498
Day 6/Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	295	0	0.78	0.732	0.043	0.535	4.40	0.2	646.5	1.968	5.961	4.915	7.231
Day 6/Day 1	M0021AB	Naive	46	0	0.12	0.588	0.087	0.346	1.00	0.1	288.5	2.014	1.306	0.874	1.953

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0021AB	Menveo-Menveo	296	0	1.78	0.705	0.041	0.497	71.56	1.7	6382.5	1.968	60.294	50.077	72.597
Day 29/Day 1	M0021AB	Menactra-Menveo	294	0	1.89	0.884	0.052	0.781	73.91	0.4	6902.0	1.968	77.375	61.256	97.735
Day 29/Day 1	M0021AB	Pooled Menveo/ Menactra-Menveo	590	0	1.83	0.800	0.033	0.640	72.30	0.4	6902.0	1.964	68.274	58.823	79.244
Day 29/Day 1	M0021AB	Naive	95	0	0.65	0.873	0.090	0.762	2.09	0.3	14573	1.986	4.435	2.945	6.679

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0023AB	Menveo-Menveo	294	0	0.97	0.653	0.038	0.427	10.00	2.0	1370.0	1.968	9.289	7.815	11.040
Day 1	M0023AB	Menactra-Menveo	295	0	0.93	0.689	0.040	0.475	6.00	2.0	5173.0	1.968	8.596	7.167	10.309
Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	589	0	0.95	0.671	0.028	0.450	8.00	2.0	5173.0	1.964	8.935	7.884	10.125
Day 1	M0023AB	Naive	96	0	0.65	0.463	0.047	0.214	2.00	2.0	72.0	1.985	4.441	3.578	5.513
Day 4	M0023AB	Menveo-Menveo	148	0	1.05	0.740	0.061	0.548	11.00	2.0	1225.0	1.976	11.222	8.508	14.802
Day 4	M0023AB	Menactra-Menveo	144	0	1.09	0.799	0.067	0.638	11.00	2.0	12288	1.977	12.231	9.033	16.560
Day 4	M0023AB	Pooled Menveo/ Menactra-Menveo	292	0	1.07	0.769	0.045	0.591	11.00	2.0	12288	1.968	11.709	9.550	14.356
Day 4	M0023AB	Naive	49	0	0.66	0.493	0.070	0.243	2.00	2.0	84.0	2.011	4.549	3.283	6.304
Day 6	M0023AB	Menveo-Menveo	147	0	1.79	0.759	0.063	0.577	79.00	2.0	2563.0	1.976	62.058	46.669	82.521
Day 6	M0023AB	Menactra-Menveo	148	0	1.83	0.815	0.067	0.664	66.50	2.0	23434	1.976	67.001	49.401	90.870
Day 6	M0023AB	Pooled Menveo/ Menactra-Menveo	295	0	1.81	0.786	0.046	0.618	74.00	2.0	23434	1.968	64.490	52.406	79.360
Day 6	M0023AB	Naive	46	0	0.79	0.614	0.090	0.376	2.00	2.0	184.0	2.014	6.124	4.025	9.316

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29	M0023AB	Menveo-Menveo	297	0	3.02	0.549	0.032	0.301	869.00	44.0	26324	1.968	1037.409	898.043	1198.404
Day 29	M0023AB	Menactra-Menveo	294	0	2.98	0.644	0.038	0.414	950.00	2.0	22572	1.968	964.386	813.491	1143.271
Day 29	M0023AB	Pooled Menveo/ Menactra-Menveo	591	0	3.00	0.598	0.025	0.357	908.00	2.0	26324	1.964	1000.417	895.165	1118.044
Day 29	M0023AB	Naive	96	0	1.55	0.931	0.095	0.866	29.00	2.0	6607.0	1.985	35.241	22.828	54.402
Day 4/Day 1	M0023AB	Menveo-Menveo	147	0	0.13	0.448	0.037	0.201	1.00	0.1	177.0	1.976	1.349	1.140	1.596
Day 4/Day 1	M0023AB	Menactra-Menveo	143	0	0.11	0.440	0.037	0.194	1.00	0.0	77.5	1.977	1.295	1.095	1.531
Day 4/Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	290	0	0.12	0.443	0.026	0.197	1.00	0.0	177.0	1.968	1.322	1.175	1.488
Day 4/Day 1	M0023AB	Naive	49	0	-0.00	0.192	0.027	0.037	1.00	0.2	2.3	2.011	0.993	0.875	1.128
Day 6/Day 1	M0023AB	Menveo-Menveo	145	0	0.79	0.789	0.066	0.623	4.78	0.0	621.0	1.977	6.109	4.533	8.231
Day 6/Day 1	M0023AB	Menactra-Menveo	148	0	0.94	0.854	0.070	0.729	9.00	0.1	958.2	1.976	8.687	6.312	11.955
Day 6/Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	293	0	0.86	0.825	0.048	0.680	6.00	0.0	958.2	1.968	7.298	5.866	9.078
Day 6/Day 1	M0023AB	Naive	46	0	0.16	0.451	0.067	0.204	1.00	0.3	88.0	2.014	1.453	1.067	1.978

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 29/Day 1	M0023AB	Menveo-Menveo	294	0	2.05	0.727	0.042	0.529	134.24	1.2	5831.0	1.968	112.787	93.071	136.679
Day 29/Day 1	M0023AB	Menactra-Menveo	293	0	2.05	0.838	0.049	0.703	125.41	0.8	7755.5	1.968	112.981	90.489	141.063
Day 29/Day 1	M0023AB	Pooled Menveo/ Menactra-Menveo	587	0	2.05	0.784	0.032	0.615	129.80	0.8	7755.5	1.964	112.884	97.517	130.672
Day 29/Day 1	M0023AB	Naive	96	0	0.90	0.920	0.094	0.847	5.52	0.1	3303.5	1.985	7.935	5.165	12.190

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	688
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.3240982	0.6620491	4.33	0.0135
Error	685	104.6386401	0.1527571		
Corrected Total	687	105.9627383			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.012496	86.07031	0.390842	0.454096

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.32409817	0.66204909	4.33	0.0135

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.32409817	0.66204909	4.33	0.0135

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.45091307	0.02271721	<.0001
2	0.48953149	0.02271721	<.0001
4	0.35464857	0.03989010	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.450913	0.406309	0.495517
2	0.489531	0.444928	0.534135
4	0.354649	0.276327	0.432970

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	685
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	18.6905527	9.3452763	18.00	<.0001
Error	682	354.1729237	0.5193151		
Corrected Total	684	372.8634764			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.050127	67.98192	0.720635	1.060040

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.69055270	9.34527635	18.00	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.69055270	9.34527635	18.00	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.20729956	0.04195701	<.0001
2	1.02765220	0.04202830	<.0001
4	0.70670811	0.07354953	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.207300	1.124919	1.289680
2	1.027652	0.945132	1.110173
4	0.706708	0.562297	0.851119

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	688
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7.0824185	3.5412093	8.08	0.0003
Error	685	300.2152985	0.4382705		
Corrected Total	687	307.2977170			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.023047	50.00001	0.662020	1.324040

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.08241850	3.54120925	8.08	0.0003

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.08241850	3.54120925	8.08	0.0003

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.35159449	0.03847913	<.0001
2	1.37761983	0.03847913	<.0001
4	1.07387497	0.06756714	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.351594	1.276043	1.427146
2	1.377620	1.302069	1.453171
4	1.073875	0.941211	1.206539

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	685
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7.7734423	3.8867212	9.30	0.0001
Error	682	285.0753434	0.4179990		
Corrected Total	684	292.8487858			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.026544	71.16122	0.646528	0.908540

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.77344235	3.88672117	9.30	0.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.77344235	3.88672117	9.30	0.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.96795099	0.03770630	<.0001
2	0.93427192	0.03764234	<.0001
4	0.64752452	0.06598603	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.967951	0.893917	1.041985
2	0.934272	0.860363	1.008181
4	0.647525	0.517964	0.777085

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.78065469	0.39032734	2.20	0.1126
Error	339	60.20770842	0.17760386		
Corrected Total	341	60.98836311			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.012800	91.23781	0.421431	0.461904

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.78065469	0.39032734	2.20	0.1126

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.78065469	0.39032734	2.20	0.1126

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.46464259	0.03452495	<.0001
2	0.49684144	0.03511923	<.0001
4	0.35090049	0.06020439	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	0.464643	0.396732	0.532553
2	0.496841	0.427762	0.565920
4	0.350900	0.232479	0.469322

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	18.7346042	9.3673021	15.40	<.0001
Error	339	206.1709271	0.6081738		
Corrected Total	341	224.9055312			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.083300	79.90659	0.779855	0.975958

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.73460415	9.36730208	15.40	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.73460415	9.36730208	15.40	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.10859137	0.06410369	<.0001
2	1.02531232	0.06410369	<.0001
4	0.39043445	0.11498335	0.0008

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.108591	0.982500	1.234682
2	1.025312	0.899221	1.151403
4	0.390434	0.164264	0.616605

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	689
Number of Observations Used	689

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	60.9171163	30.4585581	95.65	<.0001
Error	686	218.4412281	0.3184274		
Corrected Total	688	279.3583444			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.218061	25.36680	0.564294	2.224536

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	60.91711629	30.45855814	95.65	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	60.91711629	30.45855814	95.65	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	2.31644538	0.03274364	<.0001
2	2.37112288	0.03279891	<.0001
4	1.48821707	0.05759299	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	2.316445	2.252156	2.380735
2	2.371123	2.306725	2.435521
4	1.488217	1.375137	1.601297

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	10.6728809	5.3364405	9.66	<.0001
Error	339	187.2043477	0.5522252		
Corrected Total	341	197.8772287			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.053937	62.01375	0.743119	1.198313

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.67288093	5.33644047	9.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.67288093	5.33644047	9.66	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.35774392	0.06087865	<.0001
2	1.15880305	0.06192655	<.0001
4	0.82962040	0.10615980	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.357744	1.237996	1.477491
2	1.158803	1.036994	1.280612
4	0.829620	0.620806	1.038435

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	340
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	52.2200957	26.1100478	43.28	<.0001
Error	337	203.3159902	0.6033115		
Corrected Total	339	255.5360859			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.204355	42.87803	0.776731	1.811490

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	52.22009567	26.11004783	43.28	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	52.22009567	26.11004783	43.28	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.96439810	0.06406372	<.0001
2	1.96861592	0.06406372	<.0001
4	0.82072956	0.11452279	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.964398	1.838383	2.090413
2	1.968616	1.842601	2.094631
4	0.820730	0.595460	1.045999

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	128.4317621	64.2158811	154.18	<.0001
Error	684	284.8918455	0.4165085		
Corrected Total	686	413.3236077			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.310729	22.53902	0.645375	2.863367

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.4317621	64.2158811	154.18	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.4317621	64.2158811	154.18	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.05615546	0.03744844	<.0001
2	3.01862678	0.03763902	<.0001
4	1.79144310	0.06586828	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.056155	2.982628	3.129683
2	3.018627	2.944725	3.092529
4	1.791443	1.662115	1.920771

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	5.5248828	2.7624414	6.09	0.0025
Error	339	153.7625121	0.4535767		
Corrected Total	341	159.2873948			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.034685	47.17187	0.673481	1.427718

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.52488275	2.76244138	6.09	0.0025

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.52488275	2.76244138	6.09	0.0025

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.42112728	0.05517372	<.0001
2	1.53139891	0.05612342	<.0001
4	1.14306105	0.09621158	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.421127	1.312601	1.529653
2	1.531399	1.421005	1.641793
4	1.143061	0.953814	1.332308

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	36.7149576	18.3574788	35.11	<.0001
Error	339	177.2406947	0.5228339		
Corrected Total	341	213.9556523			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.171601	36.49810	0.723073	1.981124

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	36.71495759	18.35747879	35.11	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	36.71495759	18.35747879	35.11	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	2.04261416	0.05943620	<.0001
2	2.17346465	0.05943620	<.0001
4	1.16444842	0.10661123	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	2.042614	1.925704	2.159524
2	2.173465	2.056554	2.290375
4	1.164448	0.954746	1.374151

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	686
Number of Observations Used	686

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	181.9745463	90.9872731	220.98	<.0001
Error	683	281.2166294	0.4117374		
Corrected Total	685	463.1911757			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.392871	21.45058	0.641668	2.991376

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	181.9745463	90.9872731	220.98	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	181.9745463	90.9872731	220.98	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.12892740	0.03723333	<.0001
2	3.26441509	0.03742282	<.0001
4	1.71636356	0.06583371	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.128927	3.055822	3.202033
2	3.264415	3.190938	3.337893
4	1.716364	1.587103	1.845624

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7.1746809	3.5873405	6.61	0.0015
Error	338	183.4870250	0.5428610		
Corrected Total	340	190.6617059			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.037630	72.98458	0.736791	1.009516

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.17468094	3.58734047	6.61	0.0015

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.17468094	3.58734047	6.61	0.0015

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.05007903	0.06056385	<.0001
2	1.08745687	0.06139925	<.0001
4	0.65794810	0.10525586	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.050079	0.930949	1.169209
2	1.087457	0.966684	1.208230
4	0.657948	0.450909	0.864987

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	41.6855481	20.8427740	35.46	<.0001
Error	338	198.6800890	0.5878109		
Corrected Total	340	240.3656371			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.173426	45.86654	0.766688	1.671563

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	41.68554810	20.84277405	35.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	41.68554810	20.84277405	35.46	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.79279458	0.06323538	<.0001
2	1.82607873	0.06302139	<.0001
4	0.78701499	0.11304202	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	1.792795	1.668410	1.917179
2	1.826079	1.702115	1.950042
4	0.787015	0.564661	1.009369

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	174.5358136	87.2679068	203.84	<.0001
Error	684	292.8295630	0.4281134		
Corrected Total	686	467.3653766			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.373446	23.39203	0.654304	2.797123

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	174.5358136	87.2679068	203.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	174.5358136	87.2679068	203.84	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
1	3.01595012	0.03796655	<.0001
2	2.98425107	0.03815977	<.0001
4	1.54704424	0.06677960	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
1	3.015950	2.941405	3.090495
2	2.984251	2.909327	3.059175
4	1.547044	1.415927	1.678162

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	688
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	1.1033736	1.1033736	7.22	0.0074
Error	686	104.8593647	0.1528562		
Corrected Total	687	105.9627383			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.010413	86.09822	0.390968	0.454096

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	1.10337358	1.10337358	7.22	0.0074

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	1.10337358	1.10337358	7.22	0.0074

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.47022228	0.01606870	<.0001
4	0.35464857	0.03990304	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.470222	0.438673	0.501772
4	0.354649	0.276302	0.432995

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	685
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	13.9383411	13.9383411	26.52	<.0001
Error	683	358.9251353	0.5255126		
Corrected Total	684	372.8634764			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.037382	68.38636	0.724923	1.060040

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	13.93834111	13.93834111	26.52	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	13.93834111	13.93834111	26.52	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.11762838	0.02986991	<.0001
4	0.70670811	0.07398709	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.117628	1.058981	1.176276
4	0.706708	0.561439	0.851978

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	688
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	6.9821754	6.9821754	15.95	<.0001
Error	686	300.3155416	0.4377778		
Corrected Total	687	307.2977170			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.022721	49.97189	0.661648	1.324040

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.98217539	6.98217539	15.95	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	6.98217539	6.98217539	15.95	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.36460716	0.02719356	<.0001
4	1.07387497	0.06752914	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.364607	1.311215	1.418000
4	1.073875	0.941286	1.206464

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	685
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.6064202	7.6064202	18.21	<.0001
Error	683	285.2423656	0.4176316		
Corrected Total	684	292.8487858			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.025974	71.12994	0.646244	0.908540

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.60642016	7.60642016	18.21	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.60642016	7.60642016	18.21	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.95108286	0.02662803	<.0001
4	0.64752452	0.06595702	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.951083	0.898800	1.003365
4	0.647525	0.518022	0.777027

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.70473369	0.70473369	3.97	0.0470
Error	340	60.28362942	0.17730479		
Corrected Total	341	60.98836311			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.011555	91.16096	0.421076	0.461904

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.70473369	0.70473369	3.97	0.0470

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.70473369	0.70473369	3.97	0.0470

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	0.48046728	0.02459951	<.0001
4	0.35090049	0.06015368	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	0.480467	0.432081	0.528854
4	0.350900	0.232580	0.469221

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	18.2213845	18.2213845	29.97	<.0001
Error	340	206.6841467	0.6078945		
Corrected Total	341	224.9055312			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.081018	79.88824	0.779676	0.975958

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.22138454	18.22138454	29.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.22138454	18.22138454	29.97	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.06695185	0.04531774	<.0001
4	0.39043445	0.11495694	0.0008

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.066952	0.977813	1.156090
4	0.390434	0.164318	0.616551

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	689
Number of Observations Used	689

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	60.4739051	60.4739051	189.81	<.0001
Error	687	218.8844393	0.3186091		
Corrected Total	688	279.3583444			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.216474	25.37404	0.564455	2.224536

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	60.47390514	60.47390514	189.81	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	60.47390514	60.47390514	189.81	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	2.34373803	0.02317938	<.0001
4	1.48821707	0.05760941	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	2.343738	2.298227	2.389249
4	1.488217	1.375105	1.601329

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.7746755	7.7746755	13.91	0.0002
Error	340	190.1025531	0.5591252		
Corrected Total	341	197.8772287			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.039290	62.39998	0.747747	1.198313

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.77467553	7.77467553	13.91	0.0002

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.77467553	7.77467553	13.91	0.0002

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.25997093	0.04368383	<.0001
4	0.82962040	0.10682096	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.259971	1.174046	1.345896
4	0.829620	0.619507	1.039734

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	340
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	52.2187881	52.2187881	86.81	<.0001
Error	338	203.3172978	0.6015305		
Corrected Total	339	255.5360859			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.204350	42.81470	0.775584	1.811490

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	52.21878810	52.21878810	86.81	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	52.21878810	52.21878810	86.81	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.96650701	0.04523297	<.0001
4	0.82072956	0.11435362	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.966507	1.877533	2.055481
4	0.820730	0.595795	1.045664

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	128.2236761	128.2236761	308.08	<.0001
Error	685	285.0999316	0.4162043		
Corrected Total	686	413.3236077			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.310226	22.53078	0.645139	2.863367

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.2236761	128.2236761	308.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.2236761	128.2236761	308.08	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.03748637	0.02653747	<.0001
4	1.79144310	0.06584422	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.037486	2.985382	3.089591
4	1.791443	1.662162	1.920724

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	4.6344345	4.6344345	10.19	0.0015
Error	340	154.6529603	0.4548616		
Corrected Total	341	159.2873948			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.029095	47.23864	0.674434	1.427718

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.63443447	4.63443447	10.19	0.0015

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.63443447	4.63443447	10.19	0.0015

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.47532221	0.03940087	<.0001
4	1.14306105	0.09634776	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.475322	1.397822	1.552822
4	1.143061	0.953548	1.332574

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	35.4479406	35.4479406	67.52	<.0001
Error	340	178.5077118	0.5250227		
Corrected Total	341	213.9556523			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.165679	36.57442	0.724584	1.981124

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	35.44794057	35.44794057	67.52	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	35.44794057	35.44794057	67.52	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	2.10803941	0.04211562	<.0001
4	1.16444842	0.10683415	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	2.108039	2.025199	2.190879
4	1.164448	0.954309	1.374588

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	686
Number of Observations Used	686

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	179.2623820	179.2623820	431.85	<.0001
Error	684	283.9287937	0.4151006		
Corrected Total	685	463.1911757			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.387016	21.53801	0.644283	2.991376

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	179.2623820	179.2623820	431.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	179.2623820	179.2623820	431.85	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.19632737	0.02650226	<.0001
4	1.71636356	0.06610204	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.196327	3.144292	3.248363
4	1.716364	1.586576	1.846151

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.0727115	7.0727115	13.06	0.0003
Error	339	183.5889944	0.5415605		
Corrected Total	340	190.6617059			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.037096	72.89711	0.735908	1.009516

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.07271155	7.07271155	13.06	0.0003

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.07271155	7.07271155	13.06	0.0003

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.06851194	0.04306575	<.0001
4	0.65794810	0.10512970	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.068512	0.983802	1.153222
4	0.657948	0.451159	0.864737

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	41.6038462	41.6038462	70.96	<.0001
Error	339	198.7617908	0.5863180		
Corrected Total	340	240.3656371			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.173086	45.80825	0.765714	1.671563

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	41.60384624	41.60384624	70.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	41.60384624	41.60384624	70.96	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	1.80949307	0.04458159	<.0001
4	0.78701499	0.11289837	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	1.809493	1.721802	1.897184
4	0.787015	0.564945	1.009085

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	174.3873538	174.3873538	407.73	<.0001
Error	685	292.9780228	0.4277051		
Corrected Total	686	467.3653766			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.373129	23.38087	0.653992	2.797123

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	174.3873538	174.3873538	407.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	174.3873538	174.3873538	407.73	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	AVAL LSMEAN	Standard Error	Pr > |t|
3	3.00018105	0.02690162	<.0001
4	1.54704424	0.06674775	<.0001

NEWTRTN	AVAL LSMEAN	95% Confidence Limits	
3	3.000181	2.947362	3.053001
4	1.547044	1.415989	1.678099

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.03563235	0.01781618	0.29	0.7495
Error	339	20.93059427	0.06174217		
Corrected Total	341	20.96622662			

R-Square	Coeff Var	Root MSE	CHG Mean
0.001700	1446.153	0.248480	0.017182

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.03563235	0.01781618	0.29	0.7495

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.03563235	0.01781618	0.29	0.7495

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.01512325	0.02035625	0.4580
2	0.02657224	0.02070664	0.2003
4	-0.00415274	0.03549710	0.9069

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.015123	-0.024917	0.055164
2	0.026572	-0.014157	0.067302
4	-0.004153	-0.073975	0.065670

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	13.7609606	6.8804803	13.14	<.0001
Error	338	176.9610381	0.5235534		
Corrected Total	340	190.7219987			

R-Square	Coeff Var	Root MSE	CHG Mean
0.072152	141.2682	0.723570	0.512196

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.76096064	6.88048032	13.14	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.76096064	6.88048032	13.14	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.66175923	0.05967904	<.0001
2	0.51194451	0.05947708	<.0001
4	0.03505130	0.10668456	0.7427

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.661759	0.544370	0.779148
2	0.511945	0.394953	0.628936
4	0.035051	-0.174798	0.244901

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	689
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	45.3486568	22.6743284	60.47	<.0001
Error	685	256.8584645	0.3749759		
Corrected Total	687	302.2071213			

R-Square	Coeff Var	Root MSE	CHG Mean
0.150058	34.57877	0.612353	1.770892

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	45.34865677	22.67432838	60.47	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	45.34865677	22.67432838	60.47	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	1.86689256	0.03559228	<.0001
2	1.88159139	0.03559228	<.0001
4	1.13356849	0.06249799	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	1.866893	1.797009	1.936776
2	1.881591	1.811708	1.951474
4	1.133568	1.010858	1.256279

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.50303635	0.25151818	2.20	0.1120
Error	337	38.46426507	0.11413729		
Corrected Total	339	38.96730143			

R-Square	Coeff Var	Root MSE	CHG Mean
0.012909	382.0226	0.337842	0.088435

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.50303635	0.25151818	2.20	0.1120

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.50303635	0.25151818	2.20	0.1120

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.04876181	0.02777045	0.0800
2	0.13172714	0.02825178	<.0001
4	0.08192262	0.04826316	0.0905

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.048762	-0.005863	0.103387
2	0.131727	0.076155	0.187299
4	0.081923	-0.013012	0.176858

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	340
Number of Observations Used	338

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	21.6662984	10.8331492	17.59	<.0001
Error	335	206.2783160	0.6157562		
Corrected Total	337	227.9446144			

R-Square	Coeff Var	Root MSE	CHG Mean
0.095051	99.38155	0.784701	0.789584

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.66629837	10.83314918	17.59	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.66629837	10.83314918	17.59	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.86012944	0.06494234	<.0001
2	0.91884812	0.06494234	<.0001
4	0.15540940	0.11569790	0.1801

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.860129	0.732383	0.987876
2	0.918848	0.791102	1.046594
4	0.155409	-0.072177	0.382995

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	687
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	59.7333317	29.8666658	54.34	<.0001
Error	681	374.2681266	0.5495861		
Corrected Total	683	434.0014583			

R-Square	Coeff Var	Root MSE	CHG Mean
0.137634	41.20943	0.741341	1.798959

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.73333168	29.86666584	54.34	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.73333168	29.86666584	54.34	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	1.84720151	0.04316253	<.0001
2	1.98439858	0.04330959	<.0001
4	1.08473499	0.07566277	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	1.847202	1.762454	1.931949
2	1.984399	1.899362	2.069435
4	1.084735	0.936175	1.233295

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.02342169	0.51171084	3.26	0.0395
Error	339	53.15793705	0.15680807		
Corrected Total	341	54.18135874			

R-Square	Coeff Var	Root MSE	CHG Mean
0.018889	525.6643	0.395990	0.075331

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.02342169	0.51171084	3.26	0.0395

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.02342169	0.51171084	3.26	0.0395

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.02158394	0.03244076	0.5063
2	0.13826437	0.03299917	<.0001
4	0.05382129	0.05657000	0.3421

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.021584	-0.042227	0.085394
2	0.138264	0.073355	0.203173
4	0.053821	-0.057451	0.165094

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	17.6079321	8.8039661	17.23	<.0001
Error	338	172.6763342	0.5108767		
Corrected Total	340	190.2842664			

R-Square	Coeff Var	Root MSE	CHG Mean
0.092535	104.1322	0.714756	0.686393

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60793214	8.80396607	17.23	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60793214	8.80396607	17.23	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.74284818	0.05895212	<.0001
2	0.80759877	0.05875262	<.0001
4	0.11601609	0.10538508	0.2717

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.742848	0.626889	0.858807
2	0.807599	0.692032	0.923166
4	0.116016	-0.091277	0.323309

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	686
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	117.0916069	58.5458034	89.30	<.0001
Error	682	447.1425759	0.6556343		
Corrected Total	684	564.2341828			

R-Square	Coeff Var	Root MSE	CHG Mean
0.207523	48.49789	0.809712	1.669583

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	117.0916069	58.5458034	89.30	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	117.0916069	58.5458034	89.30	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	1.78027632	0.04706358	<.0001
2	1.88860059	0.04722339	<.0001
4	0.64688319	0.08307475	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	1.780276	1.687869	1.872683
2	1.888601	1.795880	1.981321
4	0.646883	0.483770	0.809996

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.66879987	0.33439994	1.92	0.1484
Error	336	58.55378296	0.17426721		
Corrected Total	338	59.22258283			

R-Square	Coeff Var	Root MSE	CHG Mean
0.011293	404.1999	0.417453	0.103279

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.66879987	0.33439994	1.92	0.1484

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.66879987	0.33439994	1.92	0.1484

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.13004602	0.03443096	0.0002
2	0.11214025	0.03490919	0.0014
4	-0.00288315	0.05963618	0.9615

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.130046	0.062319	0.197773
2	0.112140	0.043472	0.180808
4	-0.002883	-0.120190	0.114424

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	21.2466965	10.6233483	17.33	<.0001
Error	336	205.9838132	0.6130471		
Corrected Total	338	227.2305097			

R-Square	Coeff Var	Root MSE	CHG Mean
0.093503	101.9414	0.782973	0.768062

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.24669652	10.62334826	17.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.24669652	10.62334826	17.33	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	0.78594124	0.06502239	<.0001
2	0.93884533	0.06436000	<.0001
4	0.16222739	0.11544310	0.1609

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	0.785941	0.658039	0.913843
2	0.938845	0.812246	1.065445
4	0.162227	-0.064855	0.389310

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	687
Number of Observations Used	683

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	109.7062304	54.8531152	84.66	<.0001
Error	680	440.6121447	0.6479590		
Corrected Total	682	550.3183750			

R-Square	Coeff Var	Root MSE	CHG Mean
0.199350	42.57795	0.804959	1.890554

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	109.7062304	54.8531152	84.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	109.7062304	54.8531152	84.66	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
1	2.05225869	0.04694616	<.0001
2	2.05300431	0.04702621	<.0001
4	0.89951972	0.08215579	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
1	2.052259	1.960082	2.144436
2	2.053004	1.960670	2.145338
4	0.899520	0.738210	1.060829

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02603358	0.02603358	0.42	0.5160
Error	340	20.94019304	0.06158880		
Corrected Total	341	20.96622662			

R-Square	Coeff Var	Root MSE	CHG Mean
0.001242	1444.356	0.248171	0.017182

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02603358	0.02603358	0.42	0.5160

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02603358	0.02603358	0.42	0.5160

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 4, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.02075006	0.01449830	0.1533
4	-0.00415274	0.03545299	0.9068

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.020750	-0.007768	0.049268
4	-0.004153	-0.073888	0.065582

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	12.1057016	12.1057016	22.98	<.0001
Error	339	178.6162972	0.5268917		
Corrected Total	340	190.7219987			

R-Square	Coeff Var	Root MSE	CHG Mean
0.063473	141.7179	0.725873	0.512196

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	12.10570156	12.10570156	22.98	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	12.10570156	12.10570156	22.98	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 6, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.58659795	0.04226196	<.0001
4	0.03505130	0.10702415	0.7435

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.586598	0.503469	0.669727
4	0.035051	-0.175464	0.245566

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	689
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	45.3166805	45.3166805	121.01	<.0001
Error	686	256.8904407	0.3744759		
Corrected Total	687	302.2071213			

R-Square	Coeff Var	Root MSE	CHG Mean
0.149952	34.55571	0.611944	1.770892

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	45.31668053	45.31668053	121.01	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	45.31668053	45.31668053	121.01	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0016ABL, Visit: Day 29, M0016ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	1.87424197	0.02515076	<.0001
4	1.13356849	0.06245631	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	1.874242	1.824860	1.923624
4	1.133568	1.010940	1.256197

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.00242815	0.00242815	0.02	0.8847
Error	338	38.96487327	0.11528069		
Corrected Total	339	38.96730143			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000062	383.9313	0.339530	0.088435

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00242815	0.00242815	0.02	0.8847

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00242815	0.00242815	0.02	0.8847

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 4, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.08953171	0.01990361	<.0001
4	0.08192262	0.04850430	0.0921

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.089532	0.050381	0.128682
4	0.081923	-0.013486	0.177331

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	340
Number of Observations Used	338

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	21.4146029	21.4146029	34.84	<.0001
Error	336	206.5300115	0.6146727		
Corrected Total	337	227.9446144			

R-Square	Coeff Var	Root MSE	CHG Mean
0.093947	99.29408	0.784011	0.789584

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	21.41460288	21.41460288	34.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	21.41460288	21.41460288	34.84	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 6, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.88948878	0.04588075	<.0001
4	0.15540940	0.11559606	0.1797

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.889489	0.799239	0.979738
4	0.155409	-0.071974	0.382793

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	687
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	56.9663772	56.9663772	103.04	<.0001
Error	682	377.0350811	0.5528374		
Corrected Total	683	434.0014583			

R-Square	Coeff Var	Root MSE	CHG Mean
0.131258	41.33115	0.743530	1.798959

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.96637716	56.96637716	103.04	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.96637716	56.96637716	103.04	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0019ABL, Visit: Day 29, M0019ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	1.91556672	0.03066267	<.0001
4	1.08473499	0.07588625	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	1.915567	1.855362	1.975771
4	1.084735	0.935736	1.233734

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02646291	0.02646291	0.17	0.6838
Error	340	54.15489582	0.15927911		
Corrected Total	341	54.18135874			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000488	529.7899	0.399098	0.075331

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02646291	0.02646291	0.17	0.6838

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02646291	0.02646291	0.17	0.6838

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 4, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.07892859	0.02331555	0.0008
4	0.05382129	0.05701398	0.3458

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.078929	0.033068	0.124789
4	0.053821	-0.058323	0.165966

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	17.2987286	17.2987286	33.90	<.0001
Error	339	172.9855378	0.5102818		
Corrected Total	340	190.2842664			

R-Square	Coeff Var	Root MSE	CHG Mean
0.090910	104.0716	0.714340	0.686393

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	17.29872857	17.29872857	33.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	17.29872857	17.29872857	33.90	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 6, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.77533322	0.04159049	<.0001
4	0.11601609	0.10532371	0.2715

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.775333	0.693525	0.857141
4	0.116016	-0.091154	0.323186

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	686
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	115.3608398	115.3608398	175.53	<.0001
Error	683	448.8733430	0.6572084		
Corrected Total	684	564.2341828			

R-Square	Coeff Var	Root MSE	CHG Mean
0.204456	48.55608	0.810684	1.669583

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	115.3608398	115.3608398	175.53	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	115.3608398	115.3608398	175.53	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0021ABL, Visit: Day 29, M0021ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	1.83425485	0.03337533	<.0001
4	0.64688319	0.08317441	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	1.834255	1.768724	1.899785
4	0.646883	0.483575	0.810191

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.64555960	0.64555960	3.71	0.0548
Error	337	58.57702323	0.17381906		
Corrected Total	338	59.22258283			

R-Square	Coeff Var	Root MSE	CHG Mean
0.010901	403.6799	0.416916	0.103279

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.64555960	0.64555960	3.71	0.0548

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.64555960	0.64555960	3.71	0.0548

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 4, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.12121662	0.02448216	<.0001
4	-0.00288315	0.05955945	0.9614

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.121217	0.073060	0.169374
4	-0.002883	-0.120038	0.114272

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	19.5343160	19.5343160	31.70	<.0001
Error	337	207.6961938	0.6163092		
Corrected Total	338	227.2305097			

R-Square	Coeff Var	Root MSE	CHG Mean
0.085967	102.2123	0.785054	0.768062

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.53431597	19.53431597	31.70	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.53431597	19.53431597	31.70	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 6, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	0.86317607	0.04586332	<.0001
4	0.16222739	0.11574984	0.1620

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	0.863176	0.772962	0.953391
4	0.162227	-0.065456	0.389911

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	687
Number of Observations Used	683

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	109.7061488	109.7061488	169.56	<.0001
Error	681	440.6122263	0.6470077		
Corrected Total	682	550.3183750			

R-Square	Coeff Var	Root MSE	CHG Mean
0.199350	42.54668	0.804368	1.890554

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	109.7061488	109.7061488	169.56	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	109.7061488	109.7061488	169.56	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMRs
Serogroup: M0023ABL, Visit: Day 29, M0023ABL

The GLM Procedure
Least Squares Means

NEWTRTN	CHG LSMEAN	Standard Error	Pr > |t|
3	2.05263087	0.03319982	<.0001
4	0.89951972	0.08209545	<.0001

NEWTRTN	CHG LSMEAN	95% Confidence Limits	
3	2.052631	1.987445	2.117817
4	0.899520	0.738329	1.060710

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men A Human Complement SBA	Menveo-Menveo	1.968	2.824	2.549	3.130
Day 1	Men A Human Complement SBA	Menactra-Menveo	1.968	3.087	2.786	3.421
Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	2.953	2.746	3.175
Day 1	Men A Human Complement SBA	Naive	1.985	2.263	1.889	2.710
Day 4	Men A Human Complement SBA	Menveo-Menveo	1.976	2.915	2.493	3.408
Day 4	Men A Human Complement SBA	Menactra-Menveo	1.977	3.139	2.678	3.681
Day 4	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	3.023	2.704	3.380
Day 4	Men A Human Complement SBA	Naive	2.011	2.243	1.708	2.947
Day 6	Men A Human Complement SBA	Menveo-Menveo	1.976	12.841	9.605	17.167
Day 6	Men A Human Complement SBA	Menactra-Menveo	1.976	10.600	7.929	14.171
Day 6	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	11.667	9.502	14.325
Day 6	Men A Human Complement SBA	Naive	2.014	2.457	1.460	4.136
Day 29	Men A Human Complement SBA	Menveo-Menveo	1.968	207.227	178.713	240.290
Day 29	Men A Human Complement SBA	Menactra-Menveo	1.968	235.030	202.640	272.597
Day 29	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	220.667	198.713	245.047
Day 29	Men A Human Complement SBA	Naive	1.985	30.776	23.721	39.930
Day 4/Day 1	Men A Human Complement SBA	Menveo-Menveo	1.976	1.035	0.944	1.135
Day 4/Day 1	Men A Human Complement SBA	Menactra-Menveo	1.977	1.063	0.968	1.168
Day 4/Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	1.049	0.982	1.120
Day 4/Day 1	Men A Human Complement SBA	Naive	2.011	0.990	0.843	1.163
Day 6/Day 1	Men A Human Complement SBA	Menveo-Menveo	1.976	4.589	3.502	6.014
Day 6/Day 1	Men A Human Complement SBA	Menactra-Menveo	1.976	3.250	2.483	4.255
Day 6/Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	3.860	3.188	4.674
Day 6/Day 1	Men A Human Complement SBA	Naive	2.014	1.084	0.669	1.758
Day 29/Day 1	Men A Human Complement SBA	Menveo-Menveo	1.968	73.602	62.663	86.452
Day 29/Day 1	Men A Human Complement SBA	Menactra-Menveo	1.968	76.136	64.820	89.428
Day 29/Day 1	Men A Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	74.859	66.813	83.873
Day 29/Day 1	Men A Human Complement SBA	Naive	1.985	13.601	10.253	18.042

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men C Human Complement SBA	Menveo-Menveo	1.968	16.118	13.333	19.484
Day 1	Men C Human Complement SBA	Menactra-Menveo	1.968	10.657	8.813	12.888
Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	13.111	11.455	15.006
Day 1	Men C Human Complement SBA	Naive	1.985	5.090	3.650	7.098
Day 4	Men C Human Complement SBA	Menveo-Menveo	1.976	22.790	17.298	30.026
Day 4	Men C Human Complement SBA	Menactra-Menveo	1.977	14.415	10.889	19.081
Day 4	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	18.196	14.930	22.177
Day 4	Men C Human Complement SBA	Naive	2.011	6.755	4.176	10.925
Day 6	Men C Human Complement SBA	Menveo-Menveo	1.976	92.129	68.926	123.144
Day 6	Men C Human Complement SBA	Menactra-Menveo	1.976	93.028	69.599	124.346
Day 6	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	92.578	75.428	113.627
Day 6	Men C Human Complement SBA	Naive	2.014	6.618	3.940	11.117
Day 29	Men C Human Complement SBA	Menveo-Menveo	1.968	1138.035	960.788	1347.979
Day 29	Men C Human Complement SBA	Menactra-Menveo	1.968	1043.823	880.491	1237.453
Day 29	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1090.150	966.901	1229.110
Day 29	Men C Human Complement SBA	Naive	1.985	61.865	45.932	83.324
Day 4/Day 1	Men C Human Complement SBA	Menveo-Menveo	1.976	1.119	0.987	1.269
Day 4/Day 1	Men C Human Complement SBA	Menactra-Menveo	1.977	1.354	1.192	1.539
Day 4/Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	1.229	1.123	1.345
Day 4/Day 1	Men C Human Complement SBA	Naive	2.011	1.208	0.970	1.503
Day 6/Day 1	Men C Human Complement SBA	Menveo-Menveo	1.976	7.247	5.400	9.725
Day 6/Day 1	Men C Human Complement SBA	Menactra-Menveo	1.976	8.296	6.182	11.133
Day 6/Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	7.753	6.299	9.544
Day 6/Day 1	Men C Human Complement SBA	Naive	2.014	1.430	0.847	2.415
Day 29/Day 1	Men C Human Complement SBA	Menveo-Menveo	1.968	70.340	57.870	85.497
Day 29/Day 1	Men C Human Complement SBA	Menactra-Menveo	1.968	96.471	79.316	117.337
Day 29/Day 1	Men C Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	82.332	71.674	94.574
Day 29/Day 1	Men C Human Complement SBA	Naive	1.985	12.154	8.633	17.112

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men W Human Complement SBA	Menveo-Menveo	1.968	22.470	18.882	26.739
Day 1	Men W Human Complement SBA	Menactra-Menveo	1.968	23.857	20.048	28.390
Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	23.153	20.475	26.182
Day 1	Men W Human Complement SBA	Naive	1.985	11.854	8.734	16.089
Day 4	Men W Human Complement SBA	Menveo-Menveo	1.976	26.371	20.540	33.857
Day 4	Men W Human Complement SBA	Menactra-Menveo	1.977	33.994	26.364	43.832
Day 4	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	29.876	24.993	35.713
Day 4	Men W Human Complement SBA	Naive	2.011	13.901	8.991	21.494
Day 6	Men W Human Complement SBA	Menveo-Menveo	1.976	110.310	84.276	144.386
Day 6	Men W Human Complement SBA	Menactra-Menveo	1.976	149.096	113.908	195.153
Day 6	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	128.245	105.974	155.196
Day 6	Men W Human Complement SBA	Naive	2.014	14.603	9.010	23.667
Day 29	Men W Human Complement SBA	Menveo-Menveo	1.968	1345.635	1137.161	1592.330
Day 29	Men W Human Complement SBA	Menactra-Menveo	1.968	1838.295	1552.164	2177.172
Day 29	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1571.547	1394.093	1771.589
Day 29	Men W Human Complement SBA	Naive	1.986	52.043	38.646	70.085
Day 4/Day 1	Men W Human Complement SBA	Menveo-Menveo	1.976	1.051	0.907	1.217
Day 4/Day 1	Men W Human Complement SBA	Menactra-Menveo	1.977	1.375	1.184	1.597
Day 4/Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	1.199	1.079	1.333
Day 4/Day 1	Men W Human Complement SBA	Naive	2.011	1.132	0.876	1.462
Day 6/Day 1	Men W Human Complement SBA	Menveo-Menveo	1.976	5.532	4.235	7.224
Day 6/Day 1	Men W Human Complement SBA	Menactra-Menveo	1.976	6.421	4.921	8.378
Day 6/Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	5.961	4.938	7.197
Day 6/Day 1	Men W Human Complement SBA	Naive	2.014	1.306	0.810	2.105
Day 29/Day 1	Men W Human Complement SBA	Menveo-Menveo	1.968	60.294	48.738	74.590
Day 29/Day 1	Men W Human Complement SBA	Menactra-Menveo	1.968	77.375	62.500	95.790
Day 29/Day 1	Men W Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	68.274	58.712	79.394
Day 29/Day 1	Men W Human Complement SBA	Naive	1.986	4.435	3.046	6.456

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.968	9.289	7.833	11.015
Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.968	8.596	7.250	10.190
Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	8.935	7.921	10.078
Day 1	Men Y Human Complement SBA	Naive	1.985	4.441	3.296	5.985
Day 4	Men Y Human Complement SBA	Menveo-Menveo	1.976	11.222	8.530	14.764
Day 4	Men Y Human Complement SBA	Menactra-Menveo	1.977	12.231	9.262	16.152
Day 4	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	11.709	9.634	14.231
Day 4	Men Y Human Complement SBA	Naive	2.011	4.549	2.824	7.328
Day 6	Men Y Human Complement SBA	Menveo-Menveo	1.976	62.058	46.603	82.638
Day 6	Men Y Human Complement SBA	Menactra-Menveo	1.976	67.001	50.363	89.134
Day 6	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	64.490	52.699	78.920
Day 6	Men Y Human Complement SBA	Naive	2.014	6.124	3.670	10.218
Day 29	Men Y Human Complement SBA	Menveo-Menveo	1.968	1037.409	873.786	1231.672
Day 29	Men Y Human Complement SBA	Menactra-Menveo	1.968	964.386	811.571	1145.976
Day 29	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	1000.417	885.853	1129.797
Day 29	Men Y Human Complement SBA	Naive	1.985	35.241	26.057	47.661
Day 4/Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.976	1.349	1.154	1.577
Day 4/Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.977	1.295	1.105	1.516
Day 4/Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	1.322	1.183	1.477
Day 4/Day 1	Men Y Human Complement SBA	Naive	2.011	0.993	0.758	1.301
Day 6/Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.977	6.109	4.550	8.201
Day 6/Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.976	8.687	6.490	11.626
Day 6/Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.968	7.298	5.929	8.982
Day 6/Day 1	Men Y Human Complement SBA	Naive	2.014	1.453	0.861	2.451
Day 29/Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.968	112.787	91.218	139.455
Day 29/Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.968	112.981	91.342	139.746
Day 29/Day 1	Men Y Human Complement SBA	Pooled Menveo/ Menactra-Menveo	1.964	112.884	97.150	131.165
Day 29/Day 1	Men Y Human Complement SBA	Naive	1.985	7.935	5.473	11.503

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.78065469	0.39032734	2.20	0.1126
Error	339	60.20770842	0.17760386		
Corrected Total	341	60.98836311			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.012800	91.23781	0.421431	0.461904

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.78065469	0.39032734	2.20	0.1126

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.78065469	0.39032734	2.20	0.1126

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.11374210	0.06940130	1.64	0.1022
2 vs 4	0.14594096	0.06969884	2.09	0.0370
1 vs 2	-0.03219885	0.04924766	-0.65	0.5137

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	18.7346042	9.3673021	15.40	<.0001
Error	339	206.1709271	0.6081738		
Corrected Total	341	224.9055312			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.083300	79.90659	0.779855	0.975958

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.73460415	9.36730208	15.40	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	18.73460415	9.36730208	15.40	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.71815692	0.13164518	5.46	<.0001
2 vs 4	0.63487787	0.13164518	4.82	<.0001
1 vs 2	0.08327905	0.09065630	0.92	0.3589

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	689
Number of Observations Used	689

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	60.9171163	30.4585581	95.65	<.0001
Error	686	218.4412281	0.3184274		
Corrected Total	688	279.3583444			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.218061	25.36680	0.564294	2.224536

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	60.91711629	30.45855814	95.65	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	60.91711629	30.45855814	95.65	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.82822832	0.06625027	12.50	<.0001
2 vs 4	0.88290581	0.06627761	13.32	<.0001
1 vs 2	-0.05467749	0.04634560	-1.18	0.2385

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	10.6728809	5.3364405	9.66	<.0001
Error	339	187.2043477	0.5522252		
Corrected Total	341	197.8772287			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.053937	62.01375	0.743119	1.198313

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.67288093	5.33644047	9.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	10.67288093	5.33644047	9.66	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.52812351	0.12237693	4.32	<.0001
2 vs 4	0.32918264	0.12290159	2.68	0.0078
1 vs 2	0.19894087	0.08683955	2.29	0.0226

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	340
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	52.2200957	26.1100478	43.28	<.0001
Error	337	203.3159902	0.6033115		
Corrected Total	339	255.5360859			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.204355	42.87803	0.776731	1.811490

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	52.22009567	26.11004783	43.28	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	52.22009567	26.11004783	43.28	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.14366854	0.13122358	8.72	<.0001
2 vs 4	1.14788636	0.13122358	8.75	<.0001
1 vs 2	-0.00421782	0.09059978	-0.05	0.9629

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	128.4317621	64.2158811	154.18	<.0001
Error	684	284.8918455	0.4165085		
Corrected Total	686	413.3236077			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.310729	22.53902	0.645375	2.863367

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.4317621	64.2158811	154.18	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	128.4317621	64.2158811	154.18	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.26471236	0.07576949	16.69	<.0001
2 vs 4	1.22718367	0.07586387	16.18	<.0001
1 vs 2	0.03752869	0.05309502	0.71	0.4799

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	5.5248828	2.7624414	6.09	0.0025
Error	339	153.7625121	0.4535767		
Corrected Total	341	159.2873948			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.034685	47.17187	0.673481	1.427718

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.52488275	2.76244138	6.09	0.0025

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	5.52488275	2.76244138	6.09	0.0025

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.27806623	0.11090900	2.51	0.0126
2 vs 4	0.38833786	0.11138450	3.49	0.0006
1 vs 2	-0.11027163	0.07870183	-1.40	0.1621

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	36.7149576	18.3574788	35.11	<.0001
Error	339	177.2406947	0.5228339		
Corrected Total	341	213.9556523			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.171601	36.49810	0.723073	1.981124

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	36.71495759	18.35747879	35.11	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	36.71495759	18.35747879	35.11	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.87816575	0.12205989	7.19	<.0001
2 vs 4	1.00901624	0.12205989	8.27	<.0001
1 vs 2	-0.13085049	0.08405548	-1.56	0.1205

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	686
Number of Observations Used	686

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	181.9745463	90.9872731	220.98	<.0001
Error	683	281.2166294	0.4117374		
Corrected Total	685	463.1911757			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.392871	21.45058	0.641668	2.991376

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	181.9745463	90.9872731	220.98	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	181.9745463	90.9872731	220.98	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.41256384	0.07563332	18.68	<.0001
2 vs 4	1.54805154	0.07572678	20.44	<.0001
1 vs 2	-0.13548769	0.05279004	-2.57	0.0105

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7.1746809	3.5873405	6.61	0.0015
Error	338	183.4870250	0.5428610		
Corrected Total	340	190.6617059			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.037630	72.98458	0.736791	1.009516

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.17468094	3.58734047	6.61	0.0015

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	7.17468094	3.58734047	6.61	0.0015

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.39213093	0.12143631	3.23	0.0014
2 vs 4	0.42950877	0.12185510	3.52	0.0005
1 vs 2	-0.03737784	0.08624296	-0.43	0.6650

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	41.6855481	20.8427740	35.46	<.0001
Error	338	198.6800890	0.5878109		
Corrected Total	340	240.3656371			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.173426	45.86654	0.766688	1.671563

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	41.68554810	20.84277405	35.46	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	41.68554810	20.84277405	35.46	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.00577959	0.12952688	7.77	<.0001
2 vs 4	1.03906374	0.12942254	8.03	<.0001
1 vs 2	-0.03328415	0.08927715	-0.37	0.7095

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	174.5358136	87.2679068	203.84	<.0001
Error	684	292.8295630	0.4281134		
Corrected Total	686	467.3653766			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.373446	23.39203	0.654304	2.797123

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	174.5358136	87.2679068	203.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	174.5358136	87.2679068	203.84	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.46890589	0.07681780	19.12	<.0001
2 vs 4	1.43720683	0.07691347	18.69	<.0001
1 vs 2	0.03169905	0.05382961	0.59	0.5561

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.70473369	0.70473369	3.97	0.0470
Error	340	60.28362942	0.17730479		
Corrected Total	341	60.98836311			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.011555	91.16096	0.421076	0.461904

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.70473369	0.70473369	3.97	0.0470

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.70473369	0.70473369	3.97	0.0470

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.12956680	0.06498924	1.99	0.0470

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	18.2213845	18.2213845	29.97	<.0001
Error	340	206.6841467	0.6078945		
Corrected Total	341	224.9055312			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.081018	79.88824	0.779676	0.975958

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.22138454	18.22138454	29.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	18.22138454	18.22138454	29.97	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.67651740	0.12356697	5.47	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	689
Number of Observations Used	689

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	60.4739051	60.4739051	189.81	<.0001
Error	687	218.8844393	0.3186091		
Corrected Total	688	279.3583444			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.216474	25.37404	0.564455	2.224536

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	60.47390514	60.47390514	189.81	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	60.47390514	60.47390514	189.81	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.85552096	0.06209773	13.78	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.7746755	7.7746755	13.91	0.0002
Error	340	190.1025531	0.5591252		
Corrected Total	341	197.8772287			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.039290	62.39998	0.747747	1.198313

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.77467553	7.77467553	13.91	0.0002

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.77467553	7.77467553	13.91	0.0002

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.43035053	0.11540795	3.73	0.0002

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	340
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	52.2187881	52.2187881	86.81	<.0001
Error	338	203.3172978	0.6015305		
Corrected Total	339	255.5360859			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.204350	42.81470	0.775584	1.811490

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	52.21878810	52.21878810	86.81	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	52.21878810	52.21878810	86.81	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.14577745	0.12297468	9.32	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	128.2236761	128.2236761	308.08	<.0001
Error	685	285.0999316	0.4162043		
Corrected Total	686	413.3236077			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.310226	22.53078	0.645139	2.863367

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.2236761	128.2236761	308.08	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	128.2236761	128.2236761	308.08	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.24604327	0.07099083	17.55	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	4.6344345	4.6344345	10.19	0.0015
Error	340	154.6529603	0.4548616		
Corrected Total	341	159.2873948			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.029095	47.23864	0.674434	1.427718

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.63443447	4.63443447	10.19	0.0015

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	4.63443447	4.63443447	10.19	0.0015

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.33226116	0.10409284	3.19	0.0015

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	35.4479406	35.4479406	67.52	<.0001
Error	340	178.5077118	0.5250227		
Corrected Total	341	213.9556523			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.165679	36.57442	0.724584	1.981124

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	35.44794057	35.44794057	67.52	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	35.44794057	35.44794057	67.52	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.94359099	0.11483580	8.22	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	686
Number of Observations Used	686

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	179.2623820	179.2623820	431.85	<.0001
Error	684	283.9287937	0.4151006		
Corrected Total	685	463.1911757			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.387016	21.53801	0.644283	2.991376

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	179.2623820	179.2623820	431.85	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	179.2623820	179.2623820	431.85	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.47996381	0.07121692	20.78	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.0727115	7.0727115	13.06	0.0003
Error	339	183.5889944	0.5415605		
Corrected Total	340	190.6617059			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.037096	72.89711	0.735908	1.009516

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.07271155	7.07271155	13.06	0.0003

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	7.07271155	7.07271155	13.06	0.0003

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.41056384	0.11360860	3.61	0.0003

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	41.6038462	41.6038462	70.96	<.0001
Error	339	198.7617908	0.5863180		
Corrected Total	340	240.3656371			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.173086	45.80825	0.765714	1.671563

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	41.60384624	41.60384624	70.96	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	41.60384624	41.60384624	70.96	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.02247808	0.12138188	8.42	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	687
Number of Observations Used	687

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	174.3873538	174.3873538	407.73	<.0001
Error	685	292.9780228	0.4277051		
Corrected Total	686	467.3653766			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.373129	23.38087	0.653992	2.797123

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	174.3873538	174.3873538	407.73	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	174.3873538	174.3873538	407.73	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.45313681	0.07196499	20.19	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.03563235	0.01781618	0.29	0.7495
Error	339	20.93059427	0.06174217		
Corrected Total	341	20.96622662			

R-Square	Coeff Var	Root MSE	CHG Mean
0.001700	1446.153	0.248480	0.017182

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.03563235	0.01781618	0.29	0.7495

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.03563235	0.01781618	0.29	0.7495

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.01927599	0.04091969	0.47	0.6379
2 vs 4	0.03072498	0.04109512	0.75	0.4552
1 vs 2	-0.01144899	0.02903691	-0.39	0.6936

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	13.7609606	6.8804803	13.14	<.0001
Error	338	176.9610381	0.5235534		
Corrected Total	340	190.7219987			

R-Square	Coeff Var	Root MSE	CHG Mean
0.072152	141.2682	0.723570	0.512196

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.76096064	6.88048032	13.14	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	13.76096064	6.88048032	13.14	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.62670793	0.12224231	5.13	<.0001
2 vs 4	0.47689321	0.12214384	3.90	0.0001
1 vs 2	0.14981472	0.08425622	1.78	0.0763

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	688
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	45.3486568	22.6743284	60.47	<.0001
Error	685	256.8584645	0.3749759		
Corrected Total	687	302.2071213			

R-Square	Coeff Var	Root MSE	CHG Mean
0.150058	34.57877	0.612353	1.770892

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	45.34865677	22.67432838	60.47	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	45.34865677	22.67432838	60.47	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.73332406	0.07192224	10.20	<.0001
2 vs 4	0.74802290	0.07192224	10.40	<.0001
1 vs 2	-0.01469883	0.05033508	-0.29	0.7704

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	340
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.50303635	0.25151818	2.20	0.1120
Error	337	38.46426507	0.11413729		
Corrected Total	339	38.96730143			

R-Square	Coeff Var	Root MSE	CHG Mean
0.012909	382.0226	0.337842	0.088435

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.50303635	0.25151818	2.20	0.1120

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.50303635	0.25151818	2.20	0.1120

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	-0.03316080	0.05568240	-0.60	0.5519
2 vs 4	0.04980452	0.05592401	0.89	0.3738
1 vs 2	-0.08296532	0.03961516	-2.09	0.0370

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	338
Number of Observations Used	338

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	21.6662984	10.8331492	17.59	<.0001
Error	335	206.2783160	0.6157562		
Corrected Total	337	227.9446144			

R-Square	Coeff Var	Root MSE	CHG Mean
0.095051	99.38155	0.784701	0.789584

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.66629837	10.83314918	17.59	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.66629837	10.83314918	17.59	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.70472003	0.13267823	5.31	<.0001
2 vs 4	0.76343871	0.13267823	5.75	<.0001
1 vs 2	-0.05871868	0.09184234	-0.64	0.5230

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	684
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	59.7333317	29.8666658	54.34	<.0001
Error	681	374.2681266	0.5495861		
Corrected Total	683	434.0014583			

R-Square	Coeff Var	Root MSE	CHG Mean
0.137634	41.20943	0.741341	1.798959

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.73333168	29.86666584	54.34	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	59.73333168	29.86666584	54.34	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.76246652	0.08710832	8.75	<.0001
2 vs 4	0.89966359	0.08718128	10.32	<.0001
1 vs 2	-0.13719708	0.06114511	-2.24	0.0252

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.02342169	0.51171084	3.26	0.0395
Error	339	53.15793705	0.15680807		
Corrected Total	341	54.18135874			

R-Square	Coeff Var	Root MSE	CHG Mean
0.018889	525.6643	0.395990	0.075331

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.02342169	0.51171084	3.26	0.0395

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	1.02342169	0.51171084	3.26	0.0395

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	-0.03223735	0.06521172	-0.49	0.6214
2 vs 4	0.08444308	0.06549130	1.29	0.1981
1 vs 2	-0.11668043	0.04627470	-2.52	0.0121

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	17.6079321	8.8039661	17.23	<.0001
Error	338	172.6763342	0.5108767		
Corrected Total	340	190.2842664			

R-Square	Coeff Var	Root MSE	CHG Mean
0.092535	104.1322	0.714756	0.686393

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60793214	8.80396607	17.23	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	17.60793214	8.80396607	17.23	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.62683209	0.12075333	5.19	<.0001
2 vs 4	0.69158268	0.12065606	5.73	<.0001
1 vs 2	-0.06475059	0.08322993	-0.78	0.4371

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	685
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	117.0916069	58.5458034	89.30	<.0001
Error	682	447.1425759	0.6556343		
Corrected Total	684	564.2341828			

R-Square	Coeff Var	Root MSE	CHG Mean
0.207523	48.49789	0.809712	1.669583

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	117.0916069	58.5458034	89.30	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	117.0916069	58.5458034	89.30	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.13339313	0.09547981	11.87	<.0001
2 vs 4	1.24171741	0.09555868	12.99	<.0001
1 vs 2	-0.10832428	0.06667105	-1.62	0.1047

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	339
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	0.66879987	0.33439994	1.92	0.1484
Error	336	58.55378296	0.17426721		
Corrected Total	338	59.22258283			

R-Square	Coeff Var	Root MSE	CHG Mean
0.011293	404.1999	0.417453	0.103279

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.66879987	0.33439994	1.92	0.1484

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	0.66879987	0.33439994	1.92	0.1484

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.13292917	0.06886193	1.93	0.0544
2 vs 4	0.11502340	0.06910228	1.66	0.0969
1 vs 2	0.01790577	0.04903206	0.37	0.7152

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	339
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	21.2466965	10.6233483	17.33	<.0001
Error	336	205.9838132	0.6130471		
Corrected Total	338	227.2305097			

R-Square	Coeff Var	Root MSE	CHG Mean
0.093503	101.9414	0.782973	0.768062

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.24669652	10.62334826	17.33	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	21.24669652	10.62334826	17.33	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	0.62371386	0.13249536	4.71	<.0001
2 vs 4	0.77661795	0.13217156	5.88	<.0001
1 vs 2	-0.15290409	0.09148836	-1.67	0.0956

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	3	1 2 4

Number of Observations Read	683
Number of Observations Used	683

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	109.7062304	54.8531152	84.66	<.0001
Error	680	440.6121447	0.6479590		
Corrected Total	682	550.3183750			

R-Square	Coeff Var	Root MSE	CHG Mean
0.199350	42.57795	0.804959	1.890554

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	2	109.7062304	54.8531152	84.66	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	2	109.7062304	54.8531152	84.66	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 4	1.15273897	0.09462302	12.18	<.0001
2 vs 4	1.15348459	0.09466276	12.19	<.0001
1 vs 2	-0.00074561	0.06644853	-0.01	0.9911

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02603358	0.02603358	0.42	0.5160
Error	340	20.94019304	0.06158880		
Corrected Total	341	20.96622662			

R-Square	Coeff Var	Root MSE	CHG Mean
0.001242	1444.356	0.248171	0.017182

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02603358	0.02603358	0.42	0.5160

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02603358	0.02603358	0.42	0.5160

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.02490280	0.03830294	0.65	0.5160

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	12.1057016	12.1057016	22.98	<.0001
Error	339	178.6162972	0.5268917		
Corrected Total	340	190.7219987			

R-Square	Coeff Var	Root MSE	CHG Mean
0.063473	141.7179	0.725873	0.512196

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	12.10570156	12.10570156	22.98	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	12.10570156	12.10570156	22.98	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.55154664	0.11506625	4.79	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	688
Number of Observations Used	688

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	45.3166805	45.3166805	121.01	<.0001
Error	686	256.8904407	0.3744759		
Corrected Total	687	302.2071213			

R-Square	Coeff Var	Root MSE	CHG Mean
0.149952	34.55571	0.611944	1.770892

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	45.31668053	45.31668053	121.01	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	45.31668053	45.31668053	121.01	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.74067348	0.06733016	11.00	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	340
Number of Observations Used	340

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.00242815	0.00242815	0.02	0.8847
Error	338	38.96487327	0.11528069		
Corrected Total	339	38.96730143			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000062	383.9313	0.339530	0.088435

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00242815	0.00242815	0.02	0.8847

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.00242815	0.00242815	0.02	0.8847

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.00760910	0.05242920	0.15	0.8847

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	338
Number of Observations Used	338

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	21.4146029	21.4146029	34.84	<.0001
Error	336	206.5300115	0.6146727		
Corrected Total	337	227.9446144			

R-Square	Coeff Var	Root MSE	CHG Mean
0.093947	99.29408	0.784011	0.789584

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	21.41460288	21.41460288	34.84	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	21.41460288	21.41460288	34.84	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.73407937	0.12436837	5.90	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	684
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	56.9663772	56.9663772	103.04	<.0001
Error	682	377.0350811	0.5528374		
Corrected Total	683	434.0014583			

R-Square	Coeff Var	Root MSE	CHG Mean
0.131258	41.33115	0.743530	1.798959

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.96637716	56.96637716	103.04	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	56.96637716	56.96637716	103.04	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.83083173	0.08184694	10.15	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	342
Number of Observations Used	342

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.02646291	0.02646291	0.17	0.6838
Error	340	54.15489582	0.15927911		
Corrected Total	341	54.18135874			

R-Square	Coeff Var	Root MSE	CHG Mean
0.000488	529.7899	0.399098	0.075331

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02646291	0.02646291	0.17	0.6838

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.02646291	0.02646291	0.17	0.6838

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.02510730	0.06159715	0.41	0.6838

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	341
Number of Observations Used	341

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	17.2987286	17.2987286	33.90	<.0001
Error	339	172.9855378	0.5102818		
Corrected Total	340	190.2842664			

R-Square	Coeff Var	Root MSE	CHG Mean
0.090910	104.0716	0.714340	0.686393

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	17.29872857	17.29872857	33.90	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	17.29872857	17.29872857	33.90	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.65931713	0.11323803	5.82	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	685
Number of Observations Used	685

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	115.3608398	115.3608398	175.53	<.0001
Error	683	448.8733430	0.6572084		
Corrected Total	684	564.2341828			

R-Square	Coeff Var	Root MSE	CHG Mean
0.204456	48.55608	0.810684	1.669583

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	115.3608398	115.3608398	175.53	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	115.3608398	115.3608398	175.53	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.18737167	0.08962084	13.25	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	339
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.64555960	0.64555960	3.71	0.0548
Error	337	58.57702323	0.17381906		
Corrected Total	338	59.22258283			

R-Square	Coeff Var	Root MSE	CHG Mean
0.010901	403.6799	0.416916	0.103279

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.64555960	0.64555960	3.71	0.0548

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	0.64555960	0.64555960	3.71	0.0548

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.12409977	0.06439491	1.93	0.0548

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	339
Number of Observations Used	339

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	19.5343160	19.5343160	31.70	<.0001
Error	337	207.6961938	0.6163092		
Corrected Total	338	227.2305097			

R-Square	Coeff Var	Root MSE	CHG Mean
0.085967	102.2123	0.785054	0.768062

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.53431597	19.53431597	31.70	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	19.53431597	19.53431597	31.70	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	0.70094869	0.12450490	5.63	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Class Level Information

Class	Levels	Values
NEWTRTN	2	3 4

Number of Observations Read	683
Number of Observations Used	683

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmrs

The GLM Procedure

Dependent Variable: CHG Change from Baseline

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	109.7061488	109.7061488	169.56	<.0001
Error	681	440.6122263	0.6470077		
Corrected Total	682	550.3183750			

R-Square	Coeff Var	Root MSE	CHG Mean
0.199350	42.54668	0.804368	1.890554

Source	DF	Type I SS	Mean Square	F Value	Pr > F
NEWTRTN	1	109.7061488	109.7061488	169.56	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
NEWTRTN	1	109.7061488	109.7061488	169.56	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
3 vs 4	1.15311114	0.08855445	13.02	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	1.0454	0.8685	1.2582
Day 4	2	vs 4	gmr	1.0733	0.8910	1.2929
Day 4	1	vs 2	gmr	0.9740	0.8540	1.1109
Day 4	3	vs 4	gmr	1.0590	0.8904	1.2596
Day 4	1	vs 4	gmt	1.2994	0.9489	1.7793
Day 4	2	vs 4	gmt	1.3994	1.0206	1.9188
Day 4	1	vs 2	gmt	0.9285	0.7429	1.1606
Day 4	3	vs 4	gmt	1.3476	1.0040	1.8088
Day 6	1	vs 4	gmr	4.2336	2.4336	7.3648
Day 6	2	vs 4	gmr	2.9984	1.7244	5.2138
Day 6	1	vs 2	gmr	1.4119	0.9640	2.0680
Day 6	3	vs 4	gmr	3.5608	2.1145	5.9963
Day 6	1	vs 4	gmt	5.2258	2.8788	9.4864
Day 6	2	vs 4	gmt	4.3140	2.3765	7.8311
Day 6	1	vs 2	gmt	1.2114	0.8035	1.8264
Day 6	3	vs 4	gmt	4.7481	2.7131	8.3094
Day 29	1	vs 4	gmr	5.4116	3.9094	7.4910
Day 29	2	vs 4	gmr	5.5979	4.0440	7.7489
Day 29	1	vs 2	gmr	0.9667	0.7700	1.2138
Day 29	3	vs 4	gmr	5.5039	4.0595	7.4623
Day 29	1	vs 4	gmt	6.7333	4.9906	9.0846
Day 29	2	vs 4	gmt	7.6367	5.6595	10.3047
Day 29	1	vs 2	gmt	0.8817	0.7150	1.0872
Day 29	3	vs 4	gmt	7.1700	5.4150	9.4939

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	0.9265	0.7200	1.1923
Day 4	2	vs 4	gmr	1.1215	0.8706	1.4448
Day 4	1	vs 2	gmr	0.8261	0.6904	0.9885
Day 4	3	vs 4	gmr	1.0177	0.8026	1.2904
Day 4	1	vs 4	gmt	3.3738	1.9382	5.8727
Day 4	2	vs 4	gmt	2.1339	1.2230	3.7233
Day 4	1	vs 2	gmt	1.5810	1.0669	2.3429
Day 4	3	vs 4	gmt	2.6937	1.5972	4.5431
Day 6	1	vs 4	gmr	5.0666	2.7780	9.2408
Day 6	2	vs 4	gmr	5.8001	3.1802	10.5786
Day 6	1	vs 2	gmr	0.8735	0.5763	1.3242
Day 6	3	vs 4	gmr	5.4210	3.0863	9.5218
Day 6	1	vs 4	gmt	13.9209	7.6833	25.2226
Day 6	2	vs 4	gmt	14.0568	7.7583	25.4687
Day 6	1	vs 2	gmt	0.9903	0.6570	1.4928
Day 6	3	vs 4	gmt	13.9887	8.0147	24.4157
Day 29	1	vs 4	gmr	5.7872	3.9033	8.5802
Day 29	2	vs 4	gmr	7.9371	5.3516	11.7717
Day 29	1	vs 2	gmr	0.7291	0.5530	0.9613
Day 29	3	vs 4	gmr	6.7738	4.6787	9.8070
Day 29	1	vs 4	gmt	18.3955	13.0600	25.9108
Day 29	2	vs 4	gmt	16.8727	11.9737	23.7759
Day 29	1	vs 2	gmt	1.0903	0.8576	1.3860
Day 29	3	vs 4	gmt	17.6215	12.7837	24.2901

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	0.9285	0.6910	1.2475
Day 4	2	vs 4	gmr	1.2146	0.9029	1.6340
Day 4	1	vs 2	gmr	0.7644	0.6199	0.9426
Day 4	3	vs 4	gmr	1.0595	0.8016	1.4004
Day 4	1	vs 4	gmt	1.8970	1.1479	3.1349
Day 4	2	vs 4	gmt	2.4453	1.4765	4.0498
Day 4	1	vs 2	gmt	0.7758	0.5432	1.1080
Day 4	3	vs 4	gmt	2.1491	1.3413	3.4436
Day 6	1	vs 4	gmr	4.2348	2.4508	7.3174
Day 6	2	vs 4	gmr	4.9157	2.8461	8.4901
Day 6	1	vs 2	gmr	0.8615	0.5909	1.2559
Day 6	3	vs 4	gmr	4.5637	2.7326	7.6218
Day 6	1	vs 4	gmt	7.5538	4.3459	13.1297
Day 6	2	vs 4	gmt	10.2098	5.8739	17.7462
Day 6	1	vs 2	gmt	0.7399	0.5056	1.0826
Day 6	3	vs 4	gmt	8.7820	5.2205	14.7730
Day 29	1	vs 4	gmr	13.5954	8.8292	20.9345
Day 29	2	vs 4	gmr	17.4469	11.3264	26.8746
Day 29	1	vs 2	gmr	0.7792	0.5765	1.0534
Day 29	3	vs 4	gmr	15.3947	10.2661	23.0854
Day 29	1	vs 4	gmt	25.8561	18.3680	36.3970
Day 29	2	vs 4	gmt	35.3225	25.0822	49.7435
Day 29	1	vs 2	gmt	0.7320	0.5766	0.9293
Day 29	3	vs 4	gmt	30.1970	21.8844	41.6672

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y, Geometric Mean Ratios and Group Ratios at Days 1 (pre-vaccination), 4, 6 and 29 after Booster Vaccination
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.2
Work.vgr_: Ratio of GMTs and GMRs

Visit	Test	Adjuvants Comparision	Type of Ratio	Ratio of GMTs/GMRs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 4	1	vs 4	gmr	1.3581	0.9942	1.8552
Day 4	2	vs 4	gmr	1.3032	0.9530	1.7822
Day 4	1	vs 2	gmr	1.0421	0.8346	1.3012
Day 4	3	vs 4	gmr	1.3308	0.9941	1.7814
Day 4	1	vs 4	gmt	2.4668	1.4232	4.2756
Day 4	2	vs 4	gmt	2.6885	1.5482	4.6687
Day 4	1	vs 2	gmt	0.9175	0.6208	1.3560
Day 4	3	vs 4	gmt	2.5737	1.5385	4.3056
Day 6	1	vs 4	gmr	4.2045	2.3072	7.6619
Day 6	2	vs 4	gmr	5.9789	3.2857	10.8794
Day 6	1	vs 2	gmr	0.7032	0.4647	1.0643
Day 6	3	vs 4	gmr	5.0228	2.8579	8.8278
Day 6	1	vs 4	gmt	10.1340	5.6364	18.2205
Day 6	2	vs 4	gmt	10.9412	6.0882	19.6625
Day 6	1	vs 2	gmt	0.9262	0.6182	1.3878
Day 6	3	vs 4	gmt	10.5312	6.0775	18.2488
Day 29	1	vs 4	gmr	14.2147	9.2672	21.8036
Day 29	2	vs 4	gmr	14.2392	9.2815	21.8449
Day 29	1	vs 2	gmr	0.9983	0.7392	1.3481
Day 29	3	vs 4	gmr	14.2269	9.5332	21.2316
Day 29	1	vs 4	gmt	29.4378	20.8007	41.6613
Day 29	2	vs 4	gmt	27.3657	19.3282	38.7455
Day 29	1	vs 2	gmt	1.0757	0.8434	1.3721
Day 29	3	vs 4	gmt	28.3881	20.5040	39.3039

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0016AB	Menveo-Menveo	297	0	0.45	0.382	0.022	0.146	2.00	2.0	140.0	1.968	2.798	2.531	3.094
Day 1	M0016AB	Menactra-Menveo	291	0	0.48	0.419	0.025	0.176	2.00	2.0	173.0	1.968	3.013	2.695	3.367
Day 1	M0016AB	Pooled Menveo/M	96	0	0.35	0.208	0.021	0.043	2.00	2.0	71.0	1.985	2.263	2.054	2.493

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0019AB	Menveo-Menveo	296	0	1.20	0.781	0.045	0.610	13.00	2.0	1590.0	1.968	15.986	13.014	19.638
Day 1	M0019AB	Menactra-Menveo	289	0	1.03	0.722	0.042	0.521	10.00	2.0	1848.0	1.968	10.628	8.768	12.884
Day 1	M0019AB	Pooled Menveo/M	96	0	0.72	0.472	0.048	0.223	5.00	2.0	208.0	1.985	5.239	4.203	6.530

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0021AB	Menveo-Menveo	297	0	1.35	0.629	0.037	0.396	28.00	2.0	761.0	1.968	22.543	19.105	26.599
Day 1	M0021AB	Menactra-Menveo	291	0	1.37	0.678	0.040	0.460	31.00	2.0	6726.0	1.968	23.328	19.484	27.932
Day 1	M0021AB	Pooled Menveo/M	96	0	1.09	0.662	0.068	0.438	14.00	2.0	200.0	1.985	12.331	9.054	16.794

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0023AB	Menveo-Menveo	295	0	0.96	0.640	0.037	0.410	10.00	2.0	350.0	1.968	9.121	7.704	10.799
Day 1	M0023AB	Menactra-Menveo	290	0	0.92	0.672	0.039	0.452	6.00	2.0	5173.0	1.968	8.343	6.976	9.977
Day 1	M0023AB	Pooled Menveo/M	96	0	0.65	0.463	0.047	0.214	2.00	2.0	72.0	1.985	4.441	3.578	5.513

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	684
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.11541029	0.55770514	3.86	0.0215
Error	681	98.31470391	0.14436814		
Corrected Total	683	99.43011420			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.011218	84.89202	0.379958	0.447578

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.11541029	0.55770514	3.86	0.0215

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.11541029	0.55770514	3.86	0.0215

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.44688734	0.02204740	<.0001
2	0.47894022	0.02227354	<.0001
3	0.35464857	0.03877931	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	0.446887	0.403598	0.490176
2	0.478940	0.435207	0.522673
3	0.354649	0.278507	0.430790

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	681
Number of Observations Used	681

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	17.5878133	8.7939066	16.97	<.0001
Error	678	351.2388243	0.5180514		
Corrected Total	680	368.8266376			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.047686	67.88788	0.719758	1.060215

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	17.58781326	8.79390663	16.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	17.58781326	8.79390663	16.97	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.20374757	0.04183508	<.0001
2	1.02646838	0.04233870	<.0001
3	0.71925103	0.07345998	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	1.203748	1.121606	1.285889
2	1.026468	0.943338	1.109599
3	0.719251	0.575015	0.863487

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	684
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.0209840	3.0104920	7.02	0.0010
Error	681	292.1327281	0.4289761		
Corrected Total	683	298.1537121			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.020194	49.52218	0.654963	1.322564

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.02098396	3.01049198	7.02	0.0010

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.02098396	3.01049198	7.02	0.0010

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.35300955	0.03800479	<.0001
2	1.36788566	0.03839459	<.0001
3	1.09099427	0.06684685	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	1.353010	1.278389	1.427630
2	1.367886	1.292500	1.443272
3	1.090994	0.959744	1.222245

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	681
Number of Observations Used	681

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7.3141178	3.6570589	9.13	0.0001
Error	678	271.4561009	0.4003777		
Corrected Total	680	278.7702187			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.026237	70.34616	0.632754	0.899486

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	7.31411780	3.65705890	9.13	0.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	7.31411780	3.65705890	9.13	0.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.96003746	0.03684037	<.0001
2	0.92129913	0.03715660	<.0001
3	0.64752452	0.06458019	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	0.960037	0.887703	1.032372
2	0.921299	0.848343	0.994255
3	0.647525	0.520723	0.774326

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men A Human Complement SBA	Menveo-Menveo	1.968	2.798	2.533	3.092
Day 1	Men A Human Complement SBA	Menactra-Menveo	1.968	3.013	2.724	3.332
Day 1	Men A Human Complement SBA	Pooled Menveo/M	1.985	2.263	1.899	2.696

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men C Human Complement SBA	Menveo-Menveo	1.968	15.986	13.231	19.315
Day 1	Men C Human Complement SBA	Menactra-Menveo	1.968	10.628	8.777	12.871
Day 1	Men C Human Complement SBA	Pooled Menveo/M	1.985	5.239	3.759	7.303

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men W Human Complement SBA	Menveo-Menveo	1.968	22.543	18.984	26.769
Day 1	Men W Human Complement SBA	Menactra-Menveo	1.968	23.328	19.611	27.751
Day 1	Men W Human Complement SBA	Pooled Menveo/M	1.985	12.331	9.115	16.682

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs and GMRs	Lower lcl	Upper lcl
Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.968	9.121	7.722	10.774
Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.968	8.343	7.053	9.869
Day 1	Men Y Human Complement SBA	Pooled Menveo/M	1.985	4.441	3.317	5.947

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	684
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.11541029	0.55770514	3.86	0.0215
Error	681	98.31470391	0.14436814		
Corrected Total	683	99.43011420			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.011218	84.89202	0.379958	0.447578

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.11541029	0.55770514	3.86	0.0215

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.11541029	0.55770514	3.86	0.0215

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	-0.03205287	0.03134005	-1.02	0.3068
2 vs 3	0.12429164	0.04472075	2.78	0.0056
1 vs 3	0.09223877	0.04460855	2.07	0.0390

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	681
Number of Observations Used	681

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	17.5878133	8.7939066	16.97	<.0001
Error	678	351.2388243	0.5180514		
Corrected Total	680	368.8266376			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.047686	67.88788	0.719758	1.060215

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	17.58781326	8.79390663	16.97	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	17.58781326	8.79390663	16.97	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	0.17727919	0.05952091	2.98	0.0030
2 vs 3	0.30721735	0.08478758	3.62	0.0003
1 vs 3	0.48449654	0.08453722	5.73	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	684
Number of Observations Used	684

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.0209840	3.0104920	7.02	0.0010
Error	681	292.1327281	0.4289761		
Corrected Total	683	298.1537121			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.020194	49.52218	0.654963	1.322564

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.02098396	3.01049198	7.02	0.0010

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.02098396	3.01049198	7.02	0.0010

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	-0.01487611	0.05402322	-0.28	0.7831
2 vs 3	0.27689139	0.07708856	3.59	0.0004
1 vs 3	0.26201528	0.07689516	3.41	0.0007

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	681
Number of Observations Used	681

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.ugmt: Unadjusted GMTs and Summary Statistics
Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	7.3141178	3.6570589	9.13	0.0001
Error	678	271.4561009	0.4003777		
Corrected Total	680	278.7702187			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.026237	70.34616	0.632754	0.899486

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	7.31411780	3.65705890	9.13	0.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	7.31411780	3.65705890	9.13	0.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	0.03873833	0.05232423	0.74	0.4593
2 vs 3	0.27377462	0.07450647	3.67	0.0003
1 vs 3	0.31251295	0.07434927	4.20	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	0.9289	0.8061	1.0702
Day 1		2 vs 3	gmt	1.3313	1.0876	1.6297
Day 1		1 vs 3	gmt	1.2366	1.0108	1.5130

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	1.5041	1.1492	1.9686
Day 1		2 vs 3	gmt	2.0287	1.3827	2.9764
Day 1		1 vs 3	gmt	3.0514	2.0821	4.4718

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	0.9663	0.7569	1.2337
Day 1		2 vs 3	gmt	1.8919	1.3352	2.6807
Day 1		1 vs 3	gmt	1.8282	1.2913	2.5882

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo-Menveo, Menactra-Menveo, Pooled Menveo/Menactra-Menveo and Naive subjects - Statistical Appendix for table 14.2.1.4.5
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	1.0933	0.8630	1.3851
Day 1		2 vs 3	gmt	1.8783	1.3412	2.6307
Day 1		1 vs 3	gmt	2.0536	1.4673	2.8741

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0016AB	Menveo-Menveo	300	0	0.45	0.391	0.023	0.153	2.00	2.0	140.0	1.968	2.825	2.551	3.130
Day 1	M0016AB	Menactra-Menveo	298	0	0.49	0.431	0.025	0.186	2.00	2.0	173.0	1.968	3.078	2.749	3.447
Day 1	M0016AB	Pooled Menveo/M	97	0	0.35	0.207	0.021	0.043	2.00	2.0	71.0	1.985	2.260	2.053	2.488

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0019AB	Menveo-Menveo	299	0	1.21	0.780	0.045	0.609	13.00	2.0	1590.0	1.968	16.061	13.092	19.704
Day 1	M0019AB	Menactra-Menveo	296	0	1.03	0.724	0.042	0.525	10.00	2.0	1848.0	1.968	10.754	8.886	13.014
Day 1	M0019AB	Pooled Menveo/M	97	0	0.71	0.472	0.048	0.222	5.00	2.0	208.0	1.985	5.187	4.168	6.457

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0021AB	Menveo-Menveo	300	0	1.36	0.631	0.036	0.398	28.50	2.0	761.0	1.968	22.748	19.287	26.830
Day 1	M0021AB	Menactra-Menveo	298	0	1.38	0.689	0.040	0.474	31.50	2.0	6726.0	1.968	24.021	20.049	28.780
Day 1	M0021AB	Pooled Menveo/M	97	0	1.08	0.664	0.067	0.440	14.00	2.0	200.0	1.985	12.102	8.894	16.466

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.ugmt: Unadjusted GMTs and Summary Statistics

Visit	Test	Trt	# Obs	# Miss-ing	LogGMT Mean	Std Dev.	Std Error	Vari-ance	GMT Median	GMT Min	GMT Max	T Value	Unadj. GMT/ LSMEAN	Unadj. Lower CL	Unadj. Upper CL
Day 1	M0023AB	Menveo-Menveo	298	0	0.97	0.650	0.038	0.423	10.00	2.0	1370.0	1.968	9.234	7.785	10.953
Day 1	M0023AB	Menactra-Menveo	297	0	0.94	0.694	0.040	0.482	6.00	2.0	5173.0	1.968	8.662	7.217	10.397
Day 1	M0023AB	Pooled Menveo/M	97	0	0.64	0.462	0.047	0.213	2.00	2.0	72.0	1.985	4.405	3.555	5.458

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	695
Number of Observations Used	695

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.3204083	0.6602041	4.35	0.0133
Error	692	105.0327998	0.1517815		
Corrected Total	694	106.3532081			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.012415	85.90886	0.389591	0.453494

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.32040826	0.66020413	4.35	0.0133

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.32040826	0.66020413	4.35	0.0133

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0016ABL, Visit: Day 1, M0016ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.45109200	0.02249307	<.0001
2	0.48826638	0.02256843	<.0001
3	0.35409580	0.03955702	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	0.451092	0.406929	0.495255
2	0.488266	0.443956	0.532577
3	0.354096	0.276430	0.431762

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	692
Number of Observations Used	692

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	18.1390337	9.0695169	17.48	<.0001
Error	689	357.5026134	0.5188717		
Corrected Total	691	375.6416471			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.048288	67.79835	0.720328	1.062456

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	18.13903372	9.06951686	17.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	18.13903372	9.06951686	17.48	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0019ABL, Visit: Day 1, M0019ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.20578040	0.04165762	<.0001
2	1.03156059	0.04186819	<.0001
3	0.71493947	0.07313818	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	1.205780	1.123989	1.287572
2	1.031561	0.949356	1.113765
3	0.714939	0.571339	0.858540

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	695
Number of Observations Used	695

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.9044977	3.4522489	7.91	0.0004
Error	692	302.0868615	0.4365417		
Corrected Total	694	308.9913593			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.022345	49.72155	0.660713	1.328826

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.90449775	3.45224887	7.91	0.0004

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.90449775	3.45224887	7.91	0.0004

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0021ABL, Visit: Day 1, M0021ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	1.35693994	0.03814628	<.0001
2	1.38058977	0.03827408	<.0001
3	1.08285030	0.06708524	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	1.356940	1.282044	1.431836
2	1.380590	1.305443	1.455737
3	1.082850	0.951135	1.214565

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	692
Number of Observations Used	692

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	8.0055825	4.0027912	9.55	<.0001
Error	689	288.7452771	0.4190788		
Corrected Total	691	296.7508595			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.026977	71.26206	0.647363	0.908426

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	8.00558247	4.00279123	9.55	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	8.00558247	4.00279123	9.55	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

GMTs
Serogroup: M0023ABL, Visit: Day 1, M0023ABL

The GLM Procedure
Least Squares Means

TRT01AN	AVAL LSMEAN	Standard Error	Pr > |t|
1	0.96540334	0.03750073	<.0001
2	0.93763331	0.03756381	<.0001
3	0.64395241	0.06572975	<.0001

TRT01AN	AVAL LSMEAN	95% Confidence Limits	
1	0.965403	0.891774	1.039033
2	0.937633	0.863880	1.011387
3	0.643952	0.514898	0.773007

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs	Lower lcl	Upper lcl
Day 1	Men A Human Complement SBA	Menveo-Menveo	1.968	2.825	2.552	3.128
Day 1	Men A Human Complement SBA	Menactra-Menveo	1.968	3.078	2.779	3.409
Day 1	Men A Human Complement SBA	Pooled Menveo/M	1.985	2.260	1.890	2.702

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs	Lower lcl	Upper lcl
Day 1	Men C Human Complement SBA	Menveo-Menveo	1.968	16.061	13.304	19.390
Day 1	Men C Human Complement SBA	Menactra-Menveo	1.968	10.754	8.899	12.995
Day 1	Men C Human Complement SBA	Pooled Menveo/M	1.985	5.187	3.727	7.220

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs	Lower lcl	Upper lcl
Day 1	Men W Human Complement SBA	Menveo-Menveo	1.968	22.748	19.144	27.029
Day 1	Men W Human Complement SBA	Menactra-Menveo	1.968	24.021	20.204	28.559
Day 1	Men W Human Complement SBA	Pooled Menveo/M	1.985	12.102	8.936	16.389

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Work.gmt: GMTs and Summary Statistics

Visit	Test	Trt	T	GMTs	Lower lcl	Upper lcl
Day 1	Men Y Human Complement SBA	Menveo-Menveo	1.968	9.234	7.794	10.940
Day 1	Men Y Human Complement SBA	Menactra-Menveo	1.968	8.662	7.309	10.266
Day 1	Men Y Human Complement SBA	Pooled Menveo/M	1.985	4.405	3.273	5.929

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	695
Number of Observations Used	695

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	1.3204083	0.6602041	4.35	0.0133
Error	692	105.0327998	0.1517815		
Corrected Total	694	106.3532081			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.012415	85.90886	0.389591	0.453494

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.32040826	0.66020413	4.35	0.0133

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	1.32040826	0.66020413	4.35	0.0133

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	-0.03717438	0.03186334	-1.17	0.2437
2 vs 3	0.13417057	0.04554220	2.95	0.0033
1 vs 3	0.09699620	0.04550490	2.13	0.0334

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	692
Number of Observations Used	692

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	18.1390337	9.0695169	17.48	<.0001
Error	689	357.5026134	0.5188717		
Corrected Total	691	375.6416471			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.048288	67.79835	0.720328	1.062456

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	18.13903372	9.06951686	17.48	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	18.13903372	9.06951686	17.48	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	0.17421981	0.05906185	2.95	0.0033
2 vs 3	0.31662111	0.08427418	3.76	0.0002
1 vs 3	0.49084093	0.08416977	5.83	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	695
Number of Observations Used	695

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	6.9044977	3.4522489	7.91	0.0004
Error	692	302.0868615	0.4365417		
Corrected Total	694	308.9913593			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.022345	49.72155	0.660713	1.328826

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.90449775	3.45224887	7.91	0.0004

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	6.90449775	3.45224887	7.91	0.0004

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	-0.02364984	0.05403743	-0.44	0.6618
2 vs 3	0.29773947	0.07723558	3.85	0.0001
1 vs 3	0.27408963	0.07717233	3.55	0.0004

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Class Level Information

Class	Levels	Values
TRT01AN	3	1 2 3

Number of Observations Read	692
Number of Observations Used	692

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1

Vaccine Group comparisions---Ratio of gmts

The GLM Procedure

Dependent Variable: AVAL Analysis Value

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	8.0055825	4.0027912	9.55	<.0001
Error	689	288.7452771	0.4190788		
Corrected Total	691	296.7508595			

R-Square	Coeff Var	Root MSE	AVAL Mean
0.026977	71.26206	0.647363	0.908426

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TRT01AN	2	8.00558247	4.00279123	9.55	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT01AN	2	8.00558247	4.00279123	9.55	<.0001

Parameter	Estimate	Standard Error	t Value	Pr > |t|
1 vs 2	0.02777003	0.05307866	0.52	0.6010
2 vs 3	0.29368090	0.07570627	3.88	0.0001
1 vs 3	0.32145093	0.07567499	4.25	<.0001

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	0.9180	0.7948	1.0602
Day 1		2 vs 3	gmt	1.3620	1.1085	1.6734
Day 1		1 vs 3	gmt	1.2502	1.0178	1.5358

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	1.4936	1.1436	1.9507
Day 1		2 vs 3	gmt	2.0731	1.4163	3.0345
Day 1		1 vs 3	gmt	3.0963	2.1163	4.5300

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	0.9470	0.7417	1.2091
Day 1		2 vs 3	gmt	1.9849	1.3999	2.8144
Day 1		1 vs 3	gmt	1.8797	1.3261	2.6645

PPD

ANOVA of Geometric Mean hSBA Titers against N. Meningitidis serogroups A, C, W and Y and Group Ratios at Day 1 (Persistence)
Groups: Menveo, Menactra and Naive subjects - Statistical Appendix for table 14.2.1.5.1
Work.vgr_: Ratio of GMTs

Visit	Test	Vaccine Comparision	Type of Ratio	Ratio of GMTs	Vaccine group Ratio Lower lcl	Vaccine group Ratio Upper lcl
Day 1		1 vs 2	gmt	1.0660	0.8386	1.3551
Day 1		2 vs 3	gmt	1.9664	1.3965	2.7690
Day 1		1 vs 3	gmt	2.0963	1.4889	2.9514

PPD

16.1.10 Documentation of Inter-Laboratory Standardization Methods and Quality Assurance Procedures

Not Applicable

16.1.11 Publications Based on the Study

Not applicable

16.1.12 Important Publications Referenced in the Report

Available upon request

16.2 Patient Data Listings

Pages 2232 to 3995 have been removed - Out of Scope of Phase 1 of Policy 0070 - Individual Subject Data Listings

16.3 Case Report Forms

Available upon request

Page(s) removed - Out of Scope of phase 1 of Policy 0070 - CRF/eCRFs

16.4 Individual Subject Data Listing

Available upon request

Page(s) removed - Out of Scope of phase 1 of Policy 0070 - Individual Subject Data Listings