Clinical trial results:
A Phase II, Single Centre, Open-label, Randomized Study to Investigate Meningococcal Serogroup A, C, W-135 and Y Saccharide Specific B Cell Response to a Primary and a Booster Course of the Novartis Meningococcal ACWY Conjugate Vaccine in Healthy Infants

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2006-003476-35
Trial protocol	GB
Global end of trial date	19 June 2009

Results information

Result version number	v2 (current)
This version publication date	03 June 2016
First version publication date	14 June 2015
Version creation reason	• Correction of full data set re-QC of the study needed because of EudraCT system glitch and updates are required.

Trial information

Trial identification

Sponsor protocol code	V59P16

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00488683
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Vaccines and Diagnostics S.r.l.
Sponsor organisation address	Via Fiorentina 1, Siena, Italy, 53100
Public contact	Posting Director, Novartis Vaccines and Diagnostics S.r.l. , RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting Director, Novartis Vaccines and Diagnostics S.r.l. , RegistryContactVaccinesUS@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000032-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 September 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 June 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess whether the frequency of meningococcal serogroup A, C, W-135 and Y specific memory B cells, measured 1 month after a 2, 4-month course of Novartis MenACWY vaccine, predicts the specific serum bactericidal activity using human complement (hSBA) of (respectively) serogroup A, C, W-135 and Y at 12 months of age.

Protection of trial subjects:

This clinical study was designed, implemented and reported in accordance with the International Conference on Harmonisation (ICH) Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations, including the European Directive 2001/20/EC, the US CFR Title 21, Novartis codes on the protection of human rights, and with the ethical principles laid down in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 July 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 216
Worldwide total number of subjects	216
EEA total number of subjects	216

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	216
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled from one study center in UK.

Pre-assignment

Screening details:

All enrolled subjects were included in study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MenACWY-CRM and Routine Vaccines (Group 1)

Arm description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 13 months), and 1 dose each of MMR and Hib (booster) at 13 months.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) of MenACWY conjugate vaccine supplied as an extemporaneous mixing just before injection of the lyophilized component (MenA) reconstituted with the liquid component (MenCWY) was administered at 2-, 4-, and 12-months as IM injections in the anterolateral area of the right thigh.

Investigational medicinal product name	DTaP-Hib-IPV
Investigational medicinal product code	
Other name	Combined diphtheria, tetanus toxoid, acellular pertussis, Haemophilus influenzae type B and inactivated polio vaccine, Pediacel
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses (0.5 mL each) were administered at 2-, 3-, and 4-months in the anterolateral area of the left thigh.

Investigational medicinal product name	PCV
Investigational medicinal product code	
Other name	Heptavalent Streptoccus pneumonia, Prevnar
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses (0.5 mL each) were administered at 2-, 4-, 13-months in the anterolateral area of the left thigh.

Investigational medicinal product name	Hib
Investigational medicinal product code	
Other name	Vaxem Hib
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) was administered at 13 months in the anterolateral area of the right thigh.

Investigational medicinal product name	MMR
Investigational medicinal product code	
Other name	Measles, mumps, and rubella vaccine, Priorix
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) was administered at 13 months in the anterolateral area of the left thigh.

Arm title	MenACWY-CRM and Routine Vaccines (Group 2)

Arm description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months. This group had an additional blood draw at the time of enrollment.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) of MenACWY conjugate vaccine supplied as an extemporaneous mixing just before injection of the lyophilized component (MenA) reconstituted with the liquid component (MenCWY) was administered at 2-, 4-, and 12-months as IM injections in the anterolateral area of the right thigh.

Investigational medicinal product name	DTaP-Hib-IPV
Investigational medicinal product code	
Other name	Combined diphtheria, tetanus toxoid, acellular pertussis, Haemophilus influenzae type B and inactivated polio vaccine, Pediacel
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses (0.5 mL each) were administered at 2-, 3-, and 4-months in the anterolateral area of the left thigh.

Investigational medicinal product name	PCV
Investigational medicinal product code	
Other name	Heptavalent Streptoccus pneumonia, Prevnar
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses (0.5 mL each) were administered at 2-, 4-, 12-months in the anterolateral area of the left thigh.

Investigational medicinal product name	MMR
Investigational medicinal product code	
Other name	Measles, mumps, and rubella vaccine, Priorix
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) was administered at 13 months in the anterolateral area of the left thigh.

Investigational medicinal product name	Hib
Investigational medicinal product code	
Other name	Vaxem Hib
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) was administered at 13 months in the anterolateral area of the right thigh.

Arm title	MenACWY-CRM and Routine Vaccines (Group 3)

Arm description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months of age. This group had an additional blood draw at 6-7 days after third dose of MenACWY-CRM.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM-197 conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) of MenACWY conjugate vaccine supplied as an extemporaneous mixing just before injection of the lyophilized component (MenA) reconstituted with the liquid component (MenCWY) was administered at 2-, 4-, and 12-months as IM injections in the anterolateral area of the right thigh.

Investigational medicinal product name	DTaP-Hib-IPV
Investigational medicinal product code	
Other name	Combined diphtheria, tetanus toxoid, acellular pertussis, Haemophilus influenzae type B and inactivated polio vaccine, Pediacel
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses (0.5 mL each) were administered at 2-, 3-, and 4-months in the anterolateral area of the left thigh.

Investigational medicinal product name	PCV
Investigational medicinal product code	
Other name	Heptavalent Streptoccus pneumonia, Prevnar
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses (0.5 mL each) were administered at 2-, 4-, 12-months in the anterolateral area of the left thigh

Investigational medicinal product name	MMR
Investigational medicinal product code	
Other name	Measles, mumps, and rubella vaccine, Priorix
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) was administered at 13 months in the anterolateral area of the left thigh.

Investigational medicinal product name	Hib
Investigational medicinal product code	
Other name	Vaxem Hib

Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose (0.5 mL) was administered at 13 months in the anterolateral area of the right thigh.

Number of subjects in period 1	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)
Started	108	54	54
Completed	96	48	52
Not completed	12	6	2
Consent withdrawn by subject	1	2	2
Unable to classify	1	-	-
Lost to follow-up	5	3	-
Protocol deviation	5	1	-

Baseline characteristics

Reporting groups	
Reporting group title	MenACWY-CRM and Routine Vaccines (Group 1)
Reporting group description:	
Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 13 months), and 1 dose each of MMR and Hib (booster) at 13 months.	
Reporting group title	MenACWY-CRM and Routine Vaccines (Group 2)
Reporting group description:	
Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months. This group had an additional blood draw at the time of enrollment.	
Reporting group title	MenACWY-CRM and Routine Vaccines (Group 3)
Reporting group description:	
Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months of age. This group had an additional blood draw at 6-7 days after third dose of MenACWY-CRM.	

Reporting group values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)
Number of subjects	108	54	54
Age categorical			
Units: Subjects			

Age continuous			
Analysis was done on all enrolled subjects.			
Units: days			
arithmetic mean	60.5	59.8	59.8
standard deviation	± 3.7	± 3.6	± 3.6
Gender categorical			
Analysis was done on all enrolled subjects.			
Units: Subjects			
Female	48	28	25
Male	60	26	29

Reporting group values	Total		
Number of subjects	216		
Age categorical			
Units: Subjects			

Age continuous			
Analysis was done on all enrolled subjects.			
Units: days			
arithmetic mean			
standard deviation	-		

Gender categorical			
Analysis was done on all enrolled subjects.			
Units: Subjects			
Female	101		
Male	115		

End points

End points reporting groups

Reporting group title	MenACWY-CRM and Routine Vaccines (Group 1)

Reporting group description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 13 months), and 1 dose each of MMR and Hib (booster) at 13 months.

Reporting group title	MenACWY-CRM and Routine Vaccines (Group 2)

Reporting group description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months. This group had an additional blood draw at the time of enrollment.

Reporting group title	MenACWY-CRM and Routine Vaccines (Group 3)

Reporting group description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months of age. This group had an additional blood draw at 6-7 days after third dose of MenACWY-CRM.

Subject analysis set title	All enrolled population
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects enrolled/randomized in the study, i.e., with a record in DEMOG. This population was used for the analysis of demographics.

Subject analysis set title	Modified Intention-to-treat (ITT) population, Immunogenicity
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All randomized subjects who received a dose of MenACWY, and provided at least one evaluable blood sample after vaccination.

Subject analysis set title	Per protocol (PP) population, Immunogenicity
Subject analysis set type	Per protocol

Subject analysis set description:

All subjects in the enrolled population who received all the relevant doses of vaccine correctly, and
- provided evaluable blood samples at the relevant time points, and
- had no major protocol violation as defined prior to analysis.

Subject analysis set title	Safety population
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects who received a dose of MenACWY and some post-baseline safety data.

Subject analysis set title	Plasma cells at 7 Days after booster vacc. (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Plasma cells per 2x10E5 PBMCs at 7 Days After Booster Vaccination of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific IgG GMC 7 Days after booster vacc. (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Serogroup Specific IgG Geometric Mean Concentration at 1 week after booster vaccination of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific Memory B cells at 7 days after booster vacc (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells per 2x10E5 Lymphocytes Obtained from Culture (LOC) at 7 Days After Booster Vaccination of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Human SBA GMTs at 7 days after booster vacc. (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 7 Days After Booster Vaccination of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Human SBA GMTs at 12 Months of Age (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Human SBA GMTs at 12 Months of Age (Group 2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Human SBA GMTs at 12 Months of Age (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific Memory B Cells at 12 Months of Age (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Specific Memory B Cells at 12 Months of Age (Group 2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells at 12 Months of Age f subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Specific Memory B Cells at 12 Months of Age (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells at 12 Months of Age f subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at 12 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Human SBA GMTs at 13 Months of Age (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Human SBA GMTs at 13 Months of Age (Group 2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Human SBA GMTs at 13 Months of Age (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Human SBA GMTs at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific Memory B Cells at 13 Months of Age (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Specific Memory B Cells at 13 Months of Age (Group 2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Specific Memory B Cells at 13 Months of Age (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of Memory B cells at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at 13 Months of Age of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Subject analysis set title	Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at Day 1 in mothers of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 1).

Subject analysis set title	Specific IgG Geometric Mean Conc at Day 1 in mothers (Group

	2)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at Day 1 in mothers of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 2).

Subject analysis set title	Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Subject analysis set type	Per protocol

Subject analysis set description:

Summary of IgG Geometric Mean Concentrations at Day 1 in mothers of subjects that belongs to MenACWY-CRM and Routine Vaccines (Group 3).

Primary: 1. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135, and Y Specific Memory B Cells at 5 Months of Age and hSBA Titers at 12 Months of Age by Serogroup A, C, W-135 and Y

End point title	1. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135, and Y Specific Memory B Cells at 5 Months of Age and hSBA Titers at 12 Months of Age by Serogroup A, C, W-135 and Y

End point description:

The memory B cell response at one month after primary vaccinations (5 months of age) was defined as the mean number of meningococcal serogroup A, C, W-135 and Y specific memory B cells, measured in vitro by ELISpot assay per 2x10^5 lymphocytes obtained from culture (LOC) of peripheral blood mononuclear cells (PBMC) circulating in blood incubated for 5.5 days in the presence of polyclonal B cell activators. Serogroup A, C, W-135 and Y geometric mean titers (GMTs) were measured by serum bactericidal assay using human complement (hSBA) at 12 months of age (before third dose). Correlation and linear regression coefficients were determined between memory B cells at 1 month after primary vaccinations with MenACWY-CRM (5 months of age) and hSBA titers at 12 months of age (before third dose) for the serogroups A, C, W-135 and Y.
Analysis was performed on per-protocol (PP) dataset of primary vaccination.
Note: hSBA GMTs dispersion was reported as confidence intervals (see table notes)

End point type	Primary

End point timeframe:

1 month after primary vaccination and 12 months of age

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Human SBA GMTs at 12 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[1]	31[2]	43[3]	85[4]
Units: B cells per 2x10^5 lymphocytes				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	2.2 (± 0)
Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	5.56 (± 0)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.72)	1.57 (± 1.47)	8.4 (± 0)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	8.71 (± 0)

Notes:

[1] - N= Serogroup A=50, C=71, W-135=62, Y=54

[2] - N= Serogroup A=25, C=31, W-135=26, Y=25

[3] - N= Serogroup A=30, C=43, W-135=40, Y=30

[4] - N= Serogroup A=85, C=83, W-135=67, Y=43; 95%CI= A=2.05-2.36, C=4.23-7.3,W-135=6.03-12,Y=5.82-13

End point values	Human SBA	Human SBA		

	GMTs at 12 Months of Age (Group 2)	GMTs at 12 Months of Age (Group 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[5]	42[6]		
Units: B cells per 2x10^5 lymphocytes				
arithmetic mean (standard deviation)				
Serogroup A	2 (± 0)	2.14 (± 0)		
Serogroup C	4.83 (± 0)	5.61 (± 0)		
Serogroup W-135	12 (± 0)	10 (± 0)		
Serogroup Y	9.9 (± 0)	9.15 (± 0)		

Notes:

[5] - N= Serogroup A=40, C=39, W-135=37, Y=25; 95%CI= A=2-2, C=3.28-7.09, W-135=8.05-17, Y=5.39-18

[6] - N= Serogroup A=42, C=40, W-135=34, Y=16; 95%CI= A=1.93-2.37, C=3.78-8.33, W-135=6.73-15, Y=4.95-17

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup A.

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[7]
P-value	= 0.69 [8]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[7] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[8] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[9]
P-value	= 0.3 [10]
Method	parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[9] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[10] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[11]
P-value	< 0.0001 [12]
Method	parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[11] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[12] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[13]
P-value	= 0.0012 [14]
Method	parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[13] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[14] - Values from Groups 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[15]
P-value	= 0.61 [16]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[15] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[16] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[17]
P-value	= 0.02 [18]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[17] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[18] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[19]
P-value	= 0.0018 [20]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[19] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[20] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[21]
P-value	= 0.08 [22]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[21] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[22] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[23]
Method	Regression, Linear
Parameter estimate	R-square
Point estimate	0.0041
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[23] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[24]
Method	Regression, Linear
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[24] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup W - 135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[25]
Method	Regression, Linear
Parameter estimate	R-square
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[25] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 1) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	other[26]
Method	Regression, Linear
Parameter estimate	R-square
Point estimate	0.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[26] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Secondary: 2. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135 and Y Specific Memory B Cells at 1 Month After MenACWY-CRM Primary Vaccination and Serogroup A, C, W-135 and Y Specific Memory B Cells and IgG Concentration at 12 Months Age

End point title	2. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135 and Y Specific Memory B Cells at 1 Month After MenACWY-CRM Primary Vaccination and Serogroup A, C, W-135 and Y Specific Memory B Cells and IgG Concentration at 12 Months Age

End point description:

Memory B cell response at 1 month after primary vaccination and immediately before third dose at 12 months of age was measured as mean number of meningococcal serogroup specific memory B cells by ELISpot assay per 2x10^5 LOC.
The meningococcal serogroup A, C, W-135 and Y specific IgG concentrations immediately before third dose at 12 months of age were measured by ELISA and reported as µg/mL.
Note: Specific IgG GMCs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

1 month after primary vaccination (B cells) and at 12 months of age (B cells and IgG concentration)

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Specific Memory B Cells at 12 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[27]	31[28]	43[29]	75[30]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	1.811 (± 1.935)
Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	2.076 (± 1.926)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.721)	1.57 (± 1.47)	1.783 (± 2.189)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	2.172 (± 2.934)

Notes:

[27] - N= Serogroup A=50, C=71, W-135=62, Y=54

[28] - N= Serogroup A=25, C=31, W-135=26, Y=25

[29] - N= Serogroup A=30, C=43, W-135=40, Y=30

[30] - N= Serogroup A=58, C=75, W-135=75, Y=67

End point values	Specific Memory B Cells at 12 Months of Age (Group	Specific Memory B Cells at 12 Months of Age (Group	Specific IgG Geometric Mean Conc at 12 Months of	Specific IgG Geometric Mean Conc at 12 Months of

	2)	3)	Age (Group 1)	Age (Group 2)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35[31]	38[32]	55[33]	25[34]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	1.988 (± 1.881)	1.692 (± 1.398)	0.37 (± 0)	0.33 (± 0)
Serogroup C	1.983 (± 1.482)	2.188 (± 2.004)	0.19 (± 0)	0.18 (± 0)
Serogroup W-135	1.793 (± 1.531)	2.067 (± 2.716)	0.31 (± 0)	0.35 (± 0)
Serogroup Y	1.556 (± 0.898)	1.749 (± 1.797)	0.43 (± 0)	0.47 (± 0)

Notes:

[31] - N= Serogroup A=29, C=35, W-135=34, Y=33

[32] - N= Serogroup A=31, C=38, W-135=38, Y=34

[33] - N= Serogroup A=49, C=55, W-135=55, Y=49; 95%CI= A=0.27-0.49, C=0.16-0.23,W-135=0.25-0.38,Y=0.34-0.55

[34] - N= Serogroup A=23, C=25, W-135=21, Y=21; 95%CI= A=0.23-0.46, C=0.14-0.22,W-135=0.25-0.48,Y=0.33-0.67

End point values	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)			
Subject group type	Subject analysis set			
Number of subjects analysed	26[35]			
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	0.31 (± 0)			
Serogroup C	0.2 (± 0)			
Serogroup W-135	0.29 (± 0)			
Serogroup Y	0.37 (± 0)			

Notes:

[35] - N= Serogroup A=24, C=26, W-135=26, Y=24; 95%CI= A=0.23-0.42, C=0.15-0.28,W-135=0.2-0.43,Y=0.25-0.55

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[36]
P-value	= 0.7 [37]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	-0.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[36] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[37] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[38]
P-value	= 0.37 [39]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[38] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[39] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[40]
P-value	< 0.0001 [41]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.66

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[40] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[41] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[42]
P-value	< 0.0001 [43]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[42] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[43] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[44]
P-value	= 0.94 [45]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	0.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[44] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[45] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[46]
P-value	= 0.7 [47]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[46] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[47] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[48]
P-value	= 0.04 [49]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	0.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[48] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[49] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[50]
P-value	= 0.0043 [51]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[50] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[51] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[52]
Parameter estimate	R-square
Point estimate	0.0053

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[52] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[53]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[53] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[54]
Parameter estimate	R-square
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[54] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccinations and memory B cells at 12 months of age for the serogroup Y	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	293
Analysis specification	Pre-specified
Analysis type	other[55]
Parameter estimate	R-square
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[55] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 13
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup A	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[56]
P-value	= 0.68 [57]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[56] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[57] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 14
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup C	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[58]
P-value	= 0.46 [59]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[58] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[59] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 15
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup W-135	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[60]
P-value	= 0.08 [61]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[60] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[61] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 16
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup Y	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[62]
P-value	= 0.000145 [63]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[62] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[63] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 17
Statistical analysis description:	
Spearman correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup A	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[64]
P-value	= 0.75 [65]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[64] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[65] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 18
Statistical analysis description:	
Spearman correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup C	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[66]
P-value	= 0.27 [67]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[66] - Confidence Intervals were not calculated for the purpose of this study.

[67] - Non-parametric correlation
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 19
Statistical analysis description:	
Spearman correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup W-135	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[68]
P-value	= 0.07 [69]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[68] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[69] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 20
Statistical analysis description:	
Spearman correlation coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup Y	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[70]
P-value	= 0.06 [71]
Method	Non-parametric correlation
Parameter estimate	spearman correlation coefficient
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[70] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[71] - Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 21
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup A	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[72]
Parameter estimate	R-square
Point estimate	0.0029
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[72] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 22

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[73]
Parameter estimate	R-square
Point estimate	0.0059
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[73] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 23

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and serogroup specific IgG concentration at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[74]
Parameter estimate	R-square
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[74] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 24

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccinations and

serogroup specific IgG concentration at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	other[75]
Parameter estimate	R-square
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[75] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Secondary: 3. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135 and Y Specific Memory B Cells 1 Month After MenACWY-CRM Primary Vaccination and Memory B Cells and hSBA Titers and IgG Conc. 1 Month Post MenACWY-CRM Booster Vaccination

End point title	3. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135 and Y Specific Memory B Cells 1 Month After MenACWY-CRM Primary Vaccination and Memory B Cells and hSBA Titers and IgG Conc. 1 Month Post MenACWY-CRM Booster Vaccination

End point description:

Memory B cell response at 1 month after MenACWY-CRM primary and booster vaccinations was measured as mean number of meningococcal serogroup specific memory B cells by ELISpot assay per 2x100000 LOC.
hSBA geometric mean titers (GMTs) for the serogroup A, C, W-135 and Y were measured one month after the third MenACWY-CRM vaccination.
The meningococcal serogroup A, C, W-135 and Y specific IgG concentrations one month after third MenACWY-CRM vaccination were measured by ELISA and reported as µg/mL.
Values from Group 1 were analyzed separately. Values from Group 2 and 3 were combined for the analysis. Groups 2 and 3 received PCV at 12 months while Group 1 received PCV at 13 months. Analysis was performed on PP booster population.
Note: Specific IgG GMCs and hSBA GMTs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

1 month after primary vaccination and 1 month after third vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Human SBA GMTs at 13 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[76]	31[77]	43[78]	85[79]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	65 (± 0)

Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	315 (± 0)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.72)	1.57 (± 1.47)	889 (± 0)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	492 (± 0)

Notes:

[76] - N= Serogroup A=50, C=71, W-135=62, Y=54

[77] - N= Serogroup A=25, C=31, W-135=26, Y=25

[78] - N= Serogroup A=30, C=43, W-135=40, Y=30

[79] - N= Serogroup A=85, C=78, W-135=59, Y=32; 95%CI= A=47-89, C=239-417,W-135=622-1271, Y=305-793

End point values	Human SBA GMTs at 13 Months of Age (Group 2)	Human SBA GMTs at 13 Months of Age (Group 3)	Specific Memory B Cells at 13 Months of Age (Group 1)	Specific Memory B Cells at 13 Months of Age (Group 2)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[80]	42[81]	73[82]	37[83]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	48 (± 0)	67 (± 0)	6.429 (± 6.365)	6.527 (± 5.957)
Serogroup C	217 (± 0)	308 (± 0)	9.437 (± 10.861)	8.907 (± 9.791)
Serogroup W-135	649 (± 0)	602 (± 0)	6.205 (± 6.776)	4.43 (± 5.939)
Serogroup Y	480 (± 0)	475 (± 0)	6.95 (± 9.122)	6.603 (± 8.198)

Notes:

[80] - N= Serogroup A=40, C=39, W-135=35, Y=20; 95%CI= A=32-72, C=138-341,W-135=419-1004, Y=269-857

[81] - N= Serogroup A=42, C=40, W-135=33, Y=15; 95%CI= A=44-102, C=214-445,W-135=343-1057,Y=220-1025

[82] - N= Serogroup A=54, C=73, W-135=73, Y=64

[83] - N= Serogroup A=26, C=37, W-135=37, Y=32

End point values	Specific Memory B Cells at 13 Months of Age (Group 3)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[84]	66[85]	34[86]	38[87]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	7.488 (± 12.512)	4.59 (± 0)	3.5 (± 0)	5.18 (± 0)
Serogroup C	8.915 (± 10.83)	1.83 (± 0)	1.67 (± 0)	2.63 (± 0)
Serogroup W-135	5.201 (± 6.648)	5.97 (± 0)	5.37 (± 0)	5.12 (± 0)
Serogroup Y	5.746 (± 12.624)	6.2 (± 0)	5.58 (± 0)	5.75 (± 0)

Notes:

[84] - N= Serogroup A=33, C=40, W-135=39, Y=34

[85] - N= Serogroup A=66, C=59, W-135=56, Y=56; 95%CI= A=3.63-5.81, C=1.43-2.35,W-135=4.67-7.64,Y=4.77-8.05

[86] - N= Serogroup A=34, C=33, W-135=32, Y=31; 95%CI= A=2.6-4.73, C=1.18-2.36,W-135=4.06-7.1,Y=4.06-7.67

[87] - N= Serogroup A=38, C=37, W-135=32, Y=33; 95%CI= A=3.48-6.99, C=1.87-3.7,W-135=3.5-7.5,Y=3.93-8.42

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[88]
P-value	= 0.46
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	-0.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[88] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[89]
P-value	= 0.59 [90]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[89] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[90] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[91]
P-value	= 0.98
Method	parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.006
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[91] - parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[92]
P-value	= 0.2 [93]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[92] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[93] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[94]
P-value	= 0.08
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[94] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[95]
P-value	= 0.68 [96]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[95] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[96] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[97]
P-value	= 0.006
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[97] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[98]
P-value	= 0.48 [99]
Method	Parametric correlation
Parameter estimate	pearson correlation coefficient
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[98] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[99] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[100]
P-value	= 0.46
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[100] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[101]
P-value	= 0.4 [102]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[101] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[102] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[103]
P-value	= 0.6
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[103] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v MenACWY-CRM and Routine Vaccines (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[104]
P-value	= 0.03 [105]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[104] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[105] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[106]
P-value	= 0.001
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[106] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[107]
P-value	= 1 [108]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[107] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[108] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[109]
P-value	= 0.24
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[109] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[110]
P-value	= 0.34 [111]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[110] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[111] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 17

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[112]
Parameter estimate	Regression, Linear
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[112] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells

	at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[113]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[113] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 19

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[114]
Parameter estimate	Regression, Linear
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[114] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 20

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[115]
Parameter estimate	Regression, Linear
Point estimate	0.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[115] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 21

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[116]
Parameter estimate	R-square
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[116] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 22

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[117]
Parameter estimate	R-square
Point estimate	0.0068
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[117] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 23

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[118]
Parameter estimate	R-square
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[118] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 24

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[119]
Parameter estimate	R-square
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[119] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 25

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[120]
P-value	= 0.0002
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[120] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 26

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[121]
P-value	= 0.9 [122]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[121] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[122] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 27

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[123]
P-value	= 0.02
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.47

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[123] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 28

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[124]
P-value	= 0.12 [125]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[124] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[125] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 29

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[126]
P-value	= 0.22
Method	Parametric correlation
Parameter estimate	[Pearson correlation coefficient
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[126] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 30

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[127]
P-value	< 0.0001 [128]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[127] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[128] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 31

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[129]
P-value	= 0.82
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[129] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 32

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA

titers one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[130]
P-value	= 0.66 [131]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[130] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[131] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 33

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[132]
P-value	= 0.03
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[132] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 34

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[133]
P-value	= 0.53 [134]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[133] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[134] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 35

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[135]
P-value	= 0.35
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[135] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 36

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[136]
P-value	= 0.09 [137]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.47

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[136] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[137] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 37

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[138]
P-value	= 0.04
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[138] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 38

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[139]
P-value	= 0.1 [140]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[139] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[140] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 39

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[141]
P-value	= 0.56
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[141] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 40

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[142]
P-value	= 0.84 [143]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[142] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[143] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 41

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[144]
Parameter estimate	R-square
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[144] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 42

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[145]
Parameter estimate	R-square
Point estimate	0.0007
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[145] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 43

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[146]
Parameter estimate	R-square
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[146] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 44

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[147]
Parameter estimate	R-square
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[147] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 45

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[148]
Parameter estimate	R-square
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[148] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 46

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[149]
Parameter estimate	R-square
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[149] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 47

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[150]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[150] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 48

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[151]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[151] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 49

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[152]
P-value	= 0.08
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[152] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 50

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[153]
P-value	= 0.74 [154]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[153] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[154] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 51

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[155]
P-value	= 0.94
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[155] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 52

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[156]
P-value	= 0.51 [157]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[156] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[157] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 53

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[158]
P-value	= 0.12
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[158] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 54

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[159]
P-value	= 0.09 [160]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[159] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[160] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 55

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[161]
P-value	= 0.81
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[161] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 56

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[162]
P-value	= 0.07 [163]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[162] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[163] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 57

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[164]
P-value	= 0.02
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[164] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 58

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[165]
P-value	= 0.59 [166]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[165] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[166] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 59

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[167]
P-value	= 0.51
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[167] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 60

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[168]
P-value	= 0.9 [169]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[168] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[169] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 61

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[170]
P-value	= 0.02
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[170] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 62

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[171]
P-value	= 0.2 [172]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[171] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[172] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 63

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[173]
P-value	= 0.34
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[173] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 64

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and

serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[174]
P-value	= 0.04 [175]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[174] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[175] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 65

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[176]
Parameter estimate	R-square
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[176] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 66

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[177]
Parameter estimate	R-square
Point estimate	0.0027
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[177] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 67

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[178]
Parameter estimate	R-square
Point estimate	0.0002
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[178] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 68

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[179]
Parameter estimate	R-square
Point estimate	0.0077
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[179] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 69

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[180]
Parameter estimate	R-square
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[180] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 70

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[181]
Parameter estimate	R-square
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[181] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 71

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[182]
Parameter estimate	R-square
Point estimate	0.0023
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[182] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 72

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[183]
Parameter estimate	R-square
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[183] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Secondary: 4. Correlation and Regression Coefficients Between Memory B Cells 1 Month After Primary Vaccination and Rise From Prebooster Levels in Serogroup Specific Memory B Cells and IgG Concentration and hSBA Titers 1 Month After MenACWY -CRM Booster Vaccination

End point title	4. Correlation and Regression Coefficients Between Memory B Cells 1 Month After Primary Vaccination and Rise From Prebooster Levels in Serogroup Specific Memory B Cells and IgG Concentration and hSBA Titers 1 Month After MenACWY -CRM Booster Vaccination

End point description:

Memory B cell response at 1 month after MenACWY-CRM primary and booster vaccination was measured as mean number of meningococcal serogroup specific memory B cells by ELISpot assay per 2x100000 LOC. The serogroup A, C, W-135 and Y specific IgG concentrations at 1 month after MenACWY-CRM booster were measured by ELISA and reported as µg/mL.. hSBA GMTs were measured by hSBA assay one month after MenACWY-CRM booster vaccination.The rise in serogroup specific IgG, memory B cells and hSBA was calculated by pre/post third dose geometric mean ratios, calculated by the difference in the log10 of the concentrations/titers measured at 13 months to the log10 of the concentrations at 12 months: (i.e. rise = log10(x) at 13 months minus log10(x) at 12 months) where x is the serogroup specific IgG or memory B cell concentrations or SBA titers. Analysis was performed on PP booster population.
Note: Specific IgG GMCs and hSBA GMTs dispersion was reported as confidence intervals (see table notes).

End point type	Secondary

End point timeframe:

1 month after primary and booster vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Human SBA GMTs at 13 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[184]	31[185]	43[186]	85[187]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	65 (± 0)
Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	315 (± 0)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.72)	1.57 (± 1.47)	889 (± 0)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	492 (± 0)

Notes:

[184] - N= Serogroup A=50, C=71, W-135=62, Y=54

[185] - N= Serogroup A=25, C=31, W-135=26, Y=25

[186] - N= Serogroup A=30, C=43, W-135=40, Y=30

[187] - N= Serogroup A=85, C=78, W-135=59, Y=32; 95%CI= A=47-89, C=239-417,W-135=622-1271,Y=305-793

End point values	Human SBA GMTs at 13 Months of Age (Group 2)	Human SBA GMTs at 13 Months of Age (Group 3)	Specific Memory B Cells at 13 Months of Age (Group 1)	Specific Memory B Cells at 13 Months of Age (Group 2)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[188]	42[189]	73[190]	37[191]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	48 (± 0)	67 (± 0)	6.429 (± 6.365)	6.527 (± 5.957)
Serogroup C	217 (± 0)	308 (± 0)	9.437 (± 10.861)	8.907 (± 9.791)
Serogroup W-135	649 (± 0)	602 (± 0)	6.205 (± 6.776)	4.43 (± 5.939)
Serogroup Y	480 (± 0)	475 (± 0)	6.95 (± 9.122)	6.603 (± 8.198)

Notes:

[188] - N= Serogroup A=40, C=39, W-135=35, Y=20; 95%CI= A=32-72, C=138-341,W-135=419-1004,Y=269-857

[189] - N= Serogroup A=42, C=40, W-135=33, Y=15; 95%CI= A=44-102, C=214-445,W-135=343-1057,Y=220-1025

[190] - N= Serogroup A=54, C=73, W-135=73, Y=64

[191] - N= Serogroup A=26, C=37, W-135=37, Y=32

End point values	Specific Memory B Cells at 13 Months of Age (Group 3)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[192]	66[193]	34[194]	38[195]

Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	7.488 (± 12.512)	4.59 (± 0)	3.5 (± 0)	5.18 (± 0)
Serogroup C	8.915 (± 10.83)	1.83 (± 0)	1.67 (± 0)	2.63 (± 0)
Serogroup W-135	5.201 (± 6.648)	5.97 (± 0)	5.37 (± 0)	5.12 (± 0)
Serogroup Y	5.746 (± 12.624)	6.2 (± 0)	5.58 (± 0)	5.75 (± 0)

Notes:

[192] - N= Serogroup A=33, C=40, W-135=39, Y=34

[193] - N= Serogroup A=66, C=59, W-135=56, Y=56; 95%CI= A=3.63-5.81, C=1.43-2.35,W-135=4.67-7.64,Y=4.77-8.05

[194] - N= Serogroup A=34, C=33, W-135=32, Y=31; 95%CI= A=2.6-4.73, C=1.18-2.36,W-135=4.06-7.1,Y=4.06-7.67

[195] - N= Serogroup A=38, C=37, W-135=32, Y=33; 95%CI= A=3.48-6.99, C=1.87-3.7,W-135=3.5-7.5,Y=3.93-8.42

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup A.

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[196]
P-value	= 0.59
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[196] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)

Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[197]
P-value	= 0.68 [198]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[197] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[198] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[199]
P-value	= 0.12
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[199] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[200]
P-value	= 0.26 [201]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.22

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[200] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[201] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[202]
P-value	= 0.08
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[202] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[203]
P-value	= 0.42 [204]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[203] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[204] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[205]
P-value	= 0.01
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[205] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[206]
P-value	= 0.65 [207]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[206] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[207] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[208]
P-value	= 0.58
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[208] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[209]
P-value	= 0.51 [210]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[209] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[210] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific

	Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[211]
P-value	= 0.24
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[211] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[212]
P-value	= 0.06 [213]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[212] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[213] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[214]
P-value	= 0.001
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[214] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[215]
P-value	= 0.12 [216]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[215] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[216] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[217]
P-value	= 0.18
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[217] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[218]
P-value	= 0.34 [219]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[218] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[219] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 17

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[220]
Parameter estimate	R-square
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[220] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[221]
Parameter estimate	R-square
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[221] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 19

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[222]
Parameter estimate	R-square
Point estimate	0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[222] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 20

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[223]
Parameter estimate	R-square
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[223] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 21

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[224]
Parameter estimate	R-square
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[224] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 22

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[225]
Parameter estimate	R-square
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[225] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 23

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[226]
Parameter estimate	R-square
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[226] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 24

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other[227]
Parameter estimate	R-square
Point estimate	0.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[227] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.
Specific number of subjects for serogroup Y is 121.

Statistical analysis title	Statistical Analysis 25

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[228]
P-value	= 0.0008
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[228] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 26

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[229]
P-value	= 0.57 [230]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[229] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[230] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 27

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[231]
P-value	= 0.001
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[231] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 28

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[232]
P-value	= 0.11 [233]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[232] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[233] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 29

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[234]
P-value	= 0.94
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[234] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 30

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[235]
P-value	= 1 [236]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.0003
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[235] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
[236] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 31

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[237]
P-value	= 1
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.004
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[237] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 32

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[238]
P-value	= 0.37 [239]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[238] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[239] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 33

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[240]
P-value	= 0.09
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[240] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 34

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[241]
P-value	= 0.4 [242]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[241] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[242] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 35

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[243]
P-value	= 0.2
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[243] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 36

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[244]
P-value	= 0.03 [245]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[244] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[245] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 37

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[246]
P-value	= 0.07
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[246] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 38

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[247]
P-value	= 0.3 [248]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[247] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[248] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 39

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[249]
P-value	= 0.74
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[249] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 40

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[250]
P-value	= 0.25 [251]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[250] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[251] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 41

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[252]
Parameter estimate	R-square
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[252] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 42

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[253]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[253] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 43

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[254]
Parameter estimate	R-square
Point estimate	0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[254] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 44

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[255]
Parameter estimate	R-square
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[255] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 45

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[256]
Parameter estimate	R-square
Point estimate	0.0004
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[256] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 46

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of

	Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[257]
Parameter estimate	R-square
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[257] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 47

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 13 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[258]
Parameter estimate	R-square
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[258] - Regression, Linea
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 48

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers rise from pre-booster to one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 13 Months of Age (Group 2) v Human SBA GMTs at 13 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[259]
Parameter estimate	R-square
Point estimate	0.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[259] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 49

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[260]
P-value	= 0.86
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[260] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 50

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[261]
P-value	= 0.7 [262]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[261] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[262] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 51

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[263]
P-value	= 0.58
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[263] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 52

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[264]
P-value	= 0.44 [265]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[264] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[265] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 53

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[266]
P-value	= 0.75
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[266] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 54

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[267]
P-value	= 0.84 [268]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[267] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[268] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 55

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[269]
P-value	= 0.67
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[269] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 56

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[270]
P-value	= 0.99 [271]
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.002
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[270] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[271] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 57

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[272]
P-value	= 0.62
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[272] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 58

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[273]
P-value	= 0.36 [274]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[273] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[274] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 59

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for

the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[275]
P-value	= 0.99
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.003
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[275] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 60

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[276]
P-value	= 0.24 [277]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[276] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[277] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 61

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[278]
P-value	= 0.62
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[278] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 62

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[279]
P-value	= 0.69 [280]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[279] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[280] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 63

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[281]
P-value	= 0.6
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[281] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 64

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[282]
P-value	= 0.95 [283]
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[282] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

[283] - Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 65

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[284]
Parameter estimate	R-square
Point estimate	0.0015
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[284] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 66

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[285]
Parameter estimate	R-square
Point estimate	0.0057
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[285] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 67

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[286]
Parameter estimate	R-square
Point estimate	0.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[286] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 68

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[287]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[287] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 69

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[288]
Parameter estimate	R-square
Point estimate	0.0048
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[288] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 70

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[289]
Parameter estimate	R-square
Point estimate	0.0018
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[289] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 71

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other[290]
Parameter estimate	R-square
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[290] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 72

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise from pre-booster levels in serogroup specific IgG concentration one month after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[291]
Parameter estimate	R-square
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[291] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Secondary: 5. Correlation and Linear Regression Coefficients Between Memory B Cells 1 Month After Primary Vaccination and Serogroup A, C, W-135 and Y Specific Plasma Cells and Memory B Cells and IgG Concentration and hSBA Titers 1 Week After MenACWY-CRM Booster

End point title	5. Correlation and Linear Regression Coefficients Between Memory B Cells 1 Month After Primary Vaccination and Serogroup A, C, W-135 and Y Specific Plasma Cells and Memory B Cells and IgG Concentration and hSBA Titers 1 Week After MenACWY-CRM Booster[292]

End point description:

Memory B cell response at 1 month after primary vaccination and at 1 week after booster vaccination was measured as mean number of meningococcal serogroup specific memory B cells by ELISpot assay per 2x100000 LOC. Plasma B cell response at 1 week after vaccination was measured as the mean number of cells secreting antibodies specific for meningococcal serogroup A, C, W-135 and Y, measured by ELISpot assay, per 2x100000 PBMC. Serogroup A, C, W-135 and Y specific IgG were measured by ELISA and reported as µg/mL and hSBA titers (GMTs) were measured at 1 week after booster vaccination.
This outcome was assessed in Group 3 subjects only as they provided a blood draw at 1 week following the MenACWY-CRM booster vaccination. Analysis was performed on PP booster population.
Note: Specific IgG GMCs and hSBA GMTs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

One month after primary and 1 week after booster

Notes:

[292] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: statistical analyses not applicable for this endpoint.

End point values	MenACWY-CRM and Routine Vaccines (Group 3)	Plasma cells at 7 Days after booster vacc. (Group 3)	Specific IgG GMC 7 Days after booster vacc. (Group 3)	Specific Memory B cells at 7 days after booster vacc (Group 3)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43[293]	41[294]	32[295]	7[296]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	1.72 (± 1.89)	15.511 (± 22.96)	9.28 (± 0)	19.85 (± 9.12)
Serogroup C	2.43 (± 2.32)	7.373 (± 9.002)	4.16 (± 0)	39.41 (± 43.16)

Serogroup W-135	1.57 (± 1.47)	10.894 (± 13.229)	7.3 (± 0)	71.88 (± 67.59)
Serogroup Y	1.78 (± 1.67)	13.626 (± 19.535)	11 (± 0)	85.46 (± 86.23)

Notes:

[293] - N= Serogroup A=30, C=43, W-135=40, Y=30

[294] - N= Serogroup A=40, C=41, W-135=41, Y=41

[295] - N= Serogroup A=32, C=31, W-135=31, Y=31; 95%CI= A=6.49-13, C=2.9-5.96,W-135=4.86-11,Y=7.27-16

[296] - N= Serogroup A=2, C=7, W-135=5, Y=5

End point values	Human SBA GMTs at 7 days after booster vacc. (Group 3)			
Subject group type	Subject analysis set			
Number of subjects analysed	43[297]			
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	97 (± 0)			
Serogroup C	657 (± 0)			
Serogroup W-135	1063 (± 0)			
Serogroup Y	435 (± 0)			

Notes:

[297] - N= Serogroup A=43, C=41, W-135=31, Y=16; 95%CI= A=67-139, C=466-927,W-135=628-1802,Y=199-954

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[298]
P-value	= 0.68
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[298] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and

serogroup specific plasma cells one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[299]
P-value	= 0.09
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[299] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[300]
P-value	= 0.69
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[300] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)

Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[301]
P-value	= 0.2
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[301] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[302]
P-value	= 0.88
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[302] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[303]
P-value	= 0.12
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[303] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[304]
P-value	= 0.37
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[304] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[305]
P-value	= 0.36
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[305] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[306]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[306] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[307]
Parameter estimate	R-square
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[307] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)

Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[308]
Parameter estimate	R-square
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[308] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific plasma cells one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Plasma cells at 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other[309]
Parameter estimate	R-square
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[309] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and memory B cells one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B cells at 7 days after booster vacc (Group 3)
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other[310]
Parameter estimate	Pearson correlation coefficient
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[310] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and memory B cells one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B cells at 7 days after booster vacc (Group 3)
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other[311]
Parameter estimate	Spearman correlation coefficient
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[311] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B cells at 7 days after booster vacc (Group 3)
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other[312]
Parameter estimate	R-square
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[312] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B cells at 7 days after booster vacc (Group 3)

Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other[313]
Parameter estimate	R-square
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[313] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 17

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and memory B cells one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B cells at 7 days after booster vacc (Group 3)
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other[314]
Parameter estimate	R-square
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[314] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[315]
P-value	= 0.79
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[315] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 19
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup C	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[316]
P-value	= 0.16
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[316] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 20
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup W-135	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[317]
P-value	= 0.1
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[317] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 21
Statistical analysis description:	
Pearson correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup Y	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA

	GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[318]
P-value	= 0.0033
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[318] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 22

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[319]
P-value	= 0.91
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[319] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 23

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[320]
P-value	= 0.01
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[320] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 24

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[321]
P-value	= 0.19
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[321] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 25

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[322]
P-value	= 0.04
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[322] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 26

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[323]
Parameter estimate	R-square
Point estimate	0.006
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[323] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 27

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[324]
Parameter estimate	R-square
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[324] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 28

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[325]
Parameter estimate	R-square
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[325] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 29

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 7 days after booster vacc. (Group 3)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other[326]
Parameter estimate	R-square
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[326] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 30

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[327]
P-value	= 0.46
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[327] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 31

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[328]
P-value	= 0.9
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[328] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 32

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[329]
P-value	= 0.00844
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[329] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 33

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG

	GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[330]
P-value	= 0.08
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[330] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 34

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[331]
P-value	= 0.52
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[331] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 35

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[332]
P-value	= 0.18
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.27

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[332] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 36

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[333]
P-value	= 0.07
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[333] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 37

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[334]
P-value	= 0.55
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[334] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 38
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup A	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[335]
Parameter estimate	R-square
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[335] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 39
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup C	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[336]
Parameter estimate	R-square
Point estimate	0.0007
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[336] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 40
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup W-135	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)

Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[337]
Parameter estimate	R-square
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[337] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 41

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration one week after booster vaccination for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG GMC 7 Days after booster vacc. (Group 3)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other[338]
Parameter estimate	R-square
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[338] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Secondary: 6. Correlation and Linear Regression Coefficients Between CRM197 Specific Memory B Cells 1 Month After Primary Vaccination and CRM197 Specific Memory B Cells and IgG Concentration at 12 Months of Age and One Month After MenACWYCRM Booster Vaccination

End point title	6. Correlation and Linear Regression Coefficients Between CRM197 Specific Memory B Cells 1 Month After Primary Vaccination and CRM197 Specific Memory B Cells and IgG Concentration at 12 Months of Age and One Month After MenACWYCRM Booster Vaccination

End point description:

CRM197 specific memory B cell response at each time point was measured as mean number of CRM197 specific memory B cells by ELISpot assay per 2x100000 LOC.
CRM197 specific IgG concentration was measured by ELISA reported as µg/mL at 12 months of age and one month after MenACWY-CRM booster vaccination.
Analysis was done on the PP primary population and PP booster population.
Specific IgG GMCs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

5 months (memory B cells), 12 months, and 13 months (memory B cells and IgG) of age

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Specific Memory B Cells at 12 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71	30	43	75
Units: Mean of CRM197 Specific B cells				
arithmetic mean (standard deviation)				
CRM197	6.942 (± 8.379)	4.317 (± 4.589)	6.063 (± 7.244)	11.252 (± 10.883)

End point values	Specific Memory B Cells at 12 Months of Age (Group 2)	Specific Memory B Cells at 12 Months of Age (Group 3)	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	38	85[339]	37[340]
Units: Mean of CRM197 Specific B cells				
arithmetic mean (standard deviation)				
CRM197	8.143 (± 8.81)	10.112 (± 9.997)	0.26 (± 0)	0.23 (± 0)

Notes:

[339] - 95%CI = 0.22-0.3

[340] - 95%CI =0.18-0.29

End point values	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)	Specific Memory B Cells at 13 Months of Age (Group 1)	Specific Memory B Cells at 13 Months of Age (Group 2)	Specific Memory B Cells at 13 Months of Age (Group 3)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[341]	73	37	40
Units: Mean of CRM197 Specific B cells				
arithmetic mean (standard deviation)				
CRM197	0.28 (± 0)	25.64 (± 17.527)	19.978 (± 12.454)	22.953 (± 13.325)

Notes:

[341] - 95%CI = 0.22-0.35

End point values	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2)	Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	81[342]	39[343]	46[344]	
Units: Mean of CRM197 Specific B cells				
arithmetic mean (standard deviation)				

CRM197	2.84 (± 0)	2.81 (± 0)	3.34 (± 0)	

Notes:

[342] - 95%CI = 2.43-3.32

[343] - 95%CI = 2.24-3.52

[344] - 95%CI = 2.71-4.11

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells at 12 months of age

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	other[345]
P-value	= 0.0006
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[345] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Spearman correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells at 12 months of age

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	other[346]
P-value	= 0.0021
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[346] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Linear regression coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells at 12 months of age

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 12 Months of Age (Group 1) v Specific Memory B Cells at 12 Months of Age (Group 2) v Specific Memory B Cells at 12 Months of Age (Group 3)
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	other[347]
Parameter estimate	R-square
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[347] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells 1 month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[348]
P-value	= 0.53
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[348] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 5
Statistical analysis description:	
Pearson correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells one month after booster vaccination	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	other[349]
P-value	= 0.26
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[349] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 6
Statistical analysis description:	
Spearman correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells one month after booster vaccination	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[350]
P-value	= 0.84
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[350] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Spearman correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	other[351]
P-value	= 0.26
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[351] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Linear regression coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific Memory B Cells at 13 Months of Age (Group 1)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[352]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[352] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific memory B cells one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific Memory B Cells at 13 Months of Age (Group 2) v Specific Memory B Cells at 13 Months of Age (Group 3)

Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	other[353]
Parameter estimate	R-square
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[353] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Pearson correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration at 12 months of age

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other[354]
P-value	= 0.00012
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[354] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Spearman correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration at 12 months of age

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)

Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other[355]
P-value	< 0.001
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[355] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Linear regression coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration at 12 months of age

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other[356]
P-value	< 0.001
Method	Regression, Linear
Parameter estimate	R-square
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[356] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 1, 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Pearson correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	other[357]
P-value	= 0.06
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[357] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Pearson correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other[358]
P-value	< 0.001
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[358] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

Spearman correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	other[359]
P-value	= 0.01
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[359] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

Spearman correlation coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other[360]
P-value	= 0.1
Method	Non-parametric correlation
Parameter estimate	Spearman correlation coefficient
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[360] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 17

Statistical analysis description:

Linear regression coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 1)

Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	other[361]
Parameter estimate	R-square
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[361] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Linear regression coefficient between CRM197 specific memory B cells one month after primary vaccination and CRM197 specific IgG concentration one month after booster vaccination

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 13 Months of Age (Group 3)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other[362]
Parameter estimate	R-square
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[362] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Secondary: 7. Increase in Serogroup A, C, W-135 and Y Specific Memory B Cells Before and 1 Month After MenACWY-CRM Booster Vaccination at 12 Months of Age Administered Concomitantly With Pneumococcal Conjugate Vaccine or Alone

End point title	7. Increase in Serogroup A, C, W-135 and Y Specific Memory B Cells Before and 1 Month After MenACWY-CRM Booster Vaccination at 12 Months of Age Administered Concomitantly With Pneumococcal Conjugate Vaccine or Alone

End point description:

Memory B cell response before and one month after MenACWY-CRM booster vaccination at 12 months of age was measured as mean number of meningococcal serogroup A, C, W-135 and Y specific memory B cells by ELISpot assay per 2x10^5 LOC.

End point type	Secondary

End point timeframe:

Before and one month after booster vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	37	40	
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A specific B cells (N=58,29,31) month 12	1.811 (± 1.935)	1.988 (± 1.881)	1.692 (± 1.398)	
Serogroup A specific B cells (N=54,26,33) month 13	6.429 (± 6.365)	6.527 (± 5.957)	7.488 (± 12.512)	
Serogroup C specific B cells (N=75,35,38) month 12	2.076 (± 1.926)	1.983 (± 1.482)	2.188 (± 2.004)	
Serogroup C specific B cells (N=73,37,40)month 13	9.437 (± 10.861)	8.907 (± 9.791)	8.915 (± 10.83)	
Serogroup W specific B cells (N=75,34,38) month 12	1.783 (± 2.189)	1.793 (± 1.531)	2.067 (± 2.716)	
Serogroup W specific B cells(N=73,37,39) month 13	6.205 (± 6.776)	4.43 (± 5.939)	5.201 (± 6.648)	
Serogroup Y specific B cells (N=67,33,34) month 12	2.172 (± 2.934)	1.556 (± 0.898)	1.749 (± 1.797)	
Serogroup Y specific B cells (N=64,32,34) month 13	6.95 (± 9.122)	6.603 (± 8.198)	5.746 (± 12.624)	

Statistical analyses

No statistical analyses for this end point

Secondary: 8. Increase in Serogroup A, C, W-135 and Y Specific IgG Concentrations Before and 1 Month After MenACWY-CRM Booster Vaccination at 12 Months of Age Administered Concomitantly With Pneumococcal Conjugate Vaccine or Alone

End point title	8. Increase in Serogroup A, C, W-135 and Y Specific IgG Concentrations Before and 1 Month After MenACWY-CRM Booster Vaccination at 12 Months of Age Administered Concomitantly With Pneumococcal Conjugate Vaccine or Alone

End point description:

Serogroup A, C, W-135 and Y specific IgG concentrations were measured before and one month after MenACWY-CRM booster vaccination by ELISA.

End point type	Secondary

End point timeframe:

Before and one month after booster vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	34	38	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serogroup A specific IgG (N=49,23,47) before	0.37 (0.27 to 0.49)	0.33 (0.23 to 0.46)	0.31 (0.23 to 0.42)	
Serogroup A specific IgG (N=66,34,38) after	4.59 (3.63 to 5.81)	3.5 (2.6 to 4.73)	5.18 (3.84 to 6.99)	
Serogroup C specific IgG (N=55,25,26) before	0.19 (0.16 to 0.23)	0.18 (0.14 to 0.22)	0.2 (0.15 to 0.28)	
Serogroup C specific IgG (N=59,33,37) after	1.83 (1.43 to 2.35)	1.67 (1.18 to 2.36)	2.63 (1.87 to 3.7)	
Serogroup W specific IgG (N=55,21,26) before	0.31 (0.25 to 0.38)	0.35 (0.25 to 0.48)	0.29 (0.2 to 0.43)	
Serogroup W specific IgG (N=56,32,32) after	5.97 (4.67 to 7.64)	5.37 (4.06 to 7.1)	5.12 (3.5 to 7.5)	
Serogroup Y specific IgG (N=49,21,24) before	0.43 (0.34 to 0.55)	0.47 (0.33 to 0.67)	0.37 (0.25 to 0.55)	
Serogroup Y specific IgG (N=56,31,33) after	6.2 (4.77 to 8.05)	5.58 (4.06 to 7.67)	5.75 (3.93 to 8.42)	

Statistical analyses

No statistical analyses for this end point

Secondary: 9. Increase in Serogroup A, C, W-135 and Y hSBA Titers Before and 1 Month After MenACWY-CRM Booster Vaccination at 12 Months of Age Administered Concomitantly With Pneumococcal Conjugate Vaccine or Alone

End point title	9. Increase in Serogroup A, C, W-135 and Y hSBA Titers Before and 1 Month After MenACWY-CRM Booster Vaccination at 12 Months of Age Administered Concomitantly With Pneumococcal Conjugate Vaccine or Alone

End point description:

hSBA GMTs were measured before and one month after MenACWY-CRM booster vaccination at 12 months of age.

End point type	Secondary

End point timeframe:

Before and one month after booster vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	85	40	42	
Units: Geometric mean of titers				
geometric mean (confidence interval 95%)				

Serogroup A - hSBA GMT - before	2.2 (2.05 to 2.36)	2 (2 to 2)	2.14 (1.93 to 2.37)	
Serogroup A - hSBA GMT - after	65 (47 to 89)	48 (32 to 72)	67 (44 to 102)	
Serogroup C - hSBA GMT (N=83,39,40) - before	5.56 (4.23 to 7.3)	4.83 (3.28 to 7.09)	5.61 (3.78 to 8.33)	
Serogroup C - hSBA GMT (N=78,39,40)- after	315 (239 to 417)	217 (138 to 341)	308 (214 to 445)	
Serogroup W - hSBA GMT (N=67,37,34)- before	8.4 (6.03 to 12)	12 (8.05 to 17)	10 (6.73 to 15)	
Serogroup W - hSBA GMT (N=59,35,33)	889 (622 to 1271)	649 (419 to 1004)	602 (343 to 1057)	
Serogroup Y - hSBA GMT (N=43,25,16)- before	8.71 (5.82 to 13)	9.9 (5.39 to 18)	9.15 (4.95 to 17)	
Serogroup Y - hSBA GMT (N=32,20,15)- after	492 (305 to 793)	480 (269 to 857)	475 (220 to 1025)	

Statistical analyses

No statistical analyses for this end point

Secondary: 10. Serogroups A, C, W-135 and Y Specific Memory B Cell Response in Children Lacking a hSBA Titer of ≥1:8 One Month After MenACWY-CRM Primary Vaccination

End point title	10. Serogroups A, C, W-135 and Y Specific Memory B Cell Response in Children Lacking a hSBA Titer of ≥1:8 One Month After MenACWY-CRM Primary Vaccination

End point description:

The memory B cell response in children lacking a hSBA titer ≥1:8 one month after MenACWY-CRM primary vaccination was calculated as the mean number of meningococcal serogroup specific memory B cells, measured by ELISpot assay per 2x100000 LOC.
- Serogroup C specific memory B cells (N=6,2,1)/ Group 3: Analysis was done on one subject only
- Serogroup W-135 specific memory B cells (N=3,0,1)/ Group 2: None of the subject had hSBA titer <1:8
- Serogroup W-135 specific memory B cells (N=3,0,1)/ Group 3: Analysis was done on one subject only
- Serogroup Y specific memory B cells (N=0,1,1)/ Group 1: None of the subject had hSBA titer <1:8

End point type	Secondary

End point timeframe:

One month after primary vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	11	8	
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A specific memory B cells (N=24,11,8)	1.533 (± 1.028)	1.391 (± 0.467)	1.25 (± 0)	
Serogroup C specific memory B cells (N=6,2,1)	2.667 (± 2.444)	1.25 (± 0)	1.25 (± 0)	
Serogroup W-135 specific memory B cells (N=3,0,1)	1.25 (± 0)	0 (± 0)	1.25 (± 0)	

Serogroup Y specific memory B cells (N=0,1,1)	0 (± 0)	1.25 (± 0)	1.25 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: 11. Kinetics of Serogroup A, C, W-135 and Y Specific Memory B Cells and Plasma B Cells After MenACWY-CRM Primary Vaccination

End point title	11. Kinetics of Serogroup A, C, W-135 and Y Specific Memory B Cells and Plasma B Cells After MenACWY-CRM Primary Vaccination[363]

End point description:

To assess the kinetics of serogroup A, C, W-135 and Y specific memory B cells and plasma B cells were measured on days 0, 7, 14, 49, 90, and 120 following vaccination with MenACWY-CRM vaccination at month 4 of the study

End point type	Secondary

End point timeframe:

Day 0, 7, 14, 49, 90, and 120 after MenACWY-CRM vaccination at month 4

Notes:

[363] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: statistical analyses not applicable for this endpoint.

End point values	MenACWY-CRM and Routine Vaccines (Group 1)			
Subject group type	Reporting group			
Number of subjects analysed	88			
Units: Mean				
arithmetic mean (standard deviation)				
Serogroup A sp. memory B cell (N=4)-Day 0	1.25 (± 0)			
Serogroup A sp. memory B cell (N=14)-Day 7	3.889 (± 5.07)			
Serogroup A sp. memory B cell (N=7)-Day 14	2.343 (± 2.891)			
Serogroup A sp. memory B cell (N=10)-Day 49	1.97 (± 1.533)			
Serogroup A sp. memory B cell (N=9)-Day 90	1.25 (± 0)			
Serogroup A sp. memory B cell (N=11)-Day 120	1.845 (± 1.14)			
Serogroup C sp. memory B cell (N=6)-Day 0	1.558 (± 0.775)			
Serogroup C sp. memory B cell (N=16)-Day 7	2.856 (± 2.974)			
Serogroup C sp. memory B cell (N=12)-Day 14	5.183 (± 5.723)			
Serogroup C sp. memory B cell (N=13)-Day 49	2.323 (± 2.044)			
Serogroup C sp. memory B cell (N=16)-Day 90	2.469 (± 1.865)			

Serogroup C sp. memory B cell (N=14)- Day 120	1.561 (± 1.163)			
Serogroup W-135 sp. memory B cell (N=4)- Day 0	1.25 (± 0)			
Serogroup W-135 sp. memory B cell (N=15)- Day 7	3.737 (± 6.68)			
Serogroup W-135 sp. memory B cell (N=12)- Day 14	2.754 (± 2.245)			
Serogroup W-135 sp. memory B cell (N=13)- Day 49	2.735 (± 2.4)			
Serogroup W-135 sp. memory B cell (N=14)- Day 90	1.404 (± 0.575)			
Serogroup W-135 sp. memory B cell (N=14)- Day 120	1.25 (± 0)			
Serogroup Y sp. memory B cell (N=3)- Day 0	1.25 (± 0)			
Serogroup Y sp. memory B cell (N=15)- Day 7	4.847 (± 9.043)			
Serogroup Y sp. memory B cell (N=7)- Day 14	1.471 (± 0.586)			
Serogroup Y sp. memory B cell (N=11)- Day 49	1.482 (± 0.769)			
Serogroup Y sp. memory B cell (N=12)- Day 90	1.567 (± 0.74)			
Serogroup Y sp. memory B cell (N=13)- Day 120	1.527 (± 0.684)			
Serogroup A sp. plasma B cell (N=3)- Day 0	1.25 (± 0)			
Serogroup A sp. plasma B cell (N=1)- Day 7	1.25 (± 0)			
Serogroup A sp. plasma B cell (N=1)- Day 14	1.25 (± 0)			
Serogroup A sp. plasma B cell (N=2)- Day 49	1.25 (± 0)			
Serogroup A sp. plasma B cell (N=2)- Day 90	1.25 (± 0)			
Serogroup A sp. plasma B cell (N=2)- Day 120	1.25 (± 0)			
Serogroup C sp. plasma B cell (N=3)- Day 0	1.25 (± 0)			
Serogroup C sp. plasma B cell (N=2)- Day 7	2.025 (± 1.096)			
Serogroup C sp. plasma B cell (N=1)- Day 14	1.25 (± 0)			
Serogroup C sp. plasma B cell (N=2)- Day 49	1.25 (± 0)			
Serogroup C sp. plasma B cell (N=2)- Day 90	1.25 (± 0)			
Serogroup C sp. plasma B cell (N=3)- Day 120	1.25 (± 0)			
Serogroup W-135 sp. plasma B cell (N=3)- Day 0	1.25 (± 0)			
Serogroup W-135 sp. plasma B cell (N=1)- Day 7	1.25 (± 0)			
Serogroup W-135 sp. plasma B cell (N=1)- Day 14	1.25 (± 0)			
Serogroup W-135 sp. plasma B cell (N=2)- Day 49	1.25 (± 0)			
Serogroup W-135 sp. plasma B cell (N=2)- Day 90	1.25 (± 0)			
Serogroup W-135 sp. plasma B cell (N=3)- Day 120	1.25 (± 0)			

Serogroup Y sp. plasma B cell (N=3)- Day 0	1.25 (± 0)			
Serogroup Y sp. plasma B cell (N=1)- Day 7	1.25 (± 0)			
Serogroup Y sp. plasma B cell (N=1)- Day 14	1.25 (± 0)			
Serogroup Y sp. plasma B cell (N=2)- Day 49	1.25 (± 0)			
Serogroup Y sp. plasma B cell (N=2)- Day 90	1.25 (± 0)			
Serogroup Y sp. plasma B cell (N=2)- Day 120	1.25 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: 12. Kinetics of Serogroup A, C, W-135 and Y Specific IgG Concentrations After MenACWY-CRM Primary Vaccination

End point title	12. Kinetics of Serogroup A, C, W-135 and Y Specific IgG Concentrations After MenACWY-CRM Primary Vaccination[364]

End point description:

To assess the kinetics of serogroup A, C, W-135 and Y specific IgG concentrations, the geometric means was measured on day 0, 7, 14, 30, 49, 90, and 120 following vaccination with MenACWY-CRM vaccination at month 4 of the study.

Note: Confidence Interval was not calculated for Serogroup A specific IgG (N=1)- Day 120 because only one subject was analyzed.

End point type	Secondary

End point timeframe:

Day 0, 7, 14, 30, 49, 90,120 after MenACWY-CRM vaccination at month 4

Notes:

[364] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: statistical analyses not applicable for this endpoint.

End point values	MenACWY-CRM and Routine Vaccines (Group 1)			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Geometric mean of Concentrations				
geometric mean (confidence interval 95%)				
Serogroup A specific IgG (N=3)- Day 0	0.98 (0.0094 to 101)			
Serogroup A specific IgG (N=9)- Day 7	2.23 (1.02 to 4.87)			
Serogroup A specific IgG (N=7)- Day 14	2.27 (0.75 to 6.9)			
Serogroup A specific IgG (N=45)- Day 30	1.29 (1.01 to 1.65)			

Serogroup A specific IgG (N=5)- Day 49	1.39 (0.47 to 4.14)			
Serogroup A specific IgG (N=5)- Day 90	0.94 (0.62 to 1.43)			
Serogroup A specific IgG (N=1)- Day 120	1.03 (-9999 to 9999)			
Serogroup C specific IgG (N=4)- Day 0	0.92 (0.19 to 4.35)			
Serogroup C specific IgG (N=14)- Day 7	1.4 (0.85 to 2.28)			
Serogroup C specific IgG (N=8)- Day 14	1.43 (0.76 to 2.7)			
Serogroup C specific IgG (N=60)- Day 30	0.94 (0.77 to 1.14)			
Serogroup C specific IgG (N=5)- Day 49	1.02 (0.28 to 3.69)			
Serogroup C specific IgG (N=7)- Day 90	0.75 (0.46 to 1.23)			
Serogroup C specific IgG (N=5)- Day 120	0.85 (0.26 to 2.75)			
Serogroup W-135 specific IgG (N=3)- Day 0	0.43 (0.0096 to 19)			
Serogroup W-135 specific IgG (N=10)- Day 7	3.75 (1.76 to 8)			
Serogroup W-135 specific IgG (N=8)- Day 14	3.77 (1.82 to 7.84)			
Serogroup W-135 specific IgG (N=39)- Day 30	1.53 (1.14 to 2.05)			
Serogroup W-135 specific IgG (N=6)- Day 49	2.58 (0.83 to 8.05)			
Serogroup W-135 specific IgG (N=9)- Day 90	0.81 (0.59 to 1.13)			
Serogroup W-135 specific IgG (N=2)- Day 120	0.57 (0.0011 to 305)			
Serogroup Y specific IgG (N=3)- Day 0	0.82 (0.039 to 18)			
Serogroup Y specific IgG (N=4)- Day 7	1.46 (0.24 to 8.99)			
Serogroup Y specific IgG (N=3)- Day 14	5.04 (0.58 to 44)			
Serogroup Y specific IgG (N=33)- Day 30	1.34 (1.01 to 1.79)			
Serogroup Y specific IgG (N=3)- Day 49	2.47 (0.24 to 26)			
Serogroup Y specific IgG (N=2)- Day 90	0.57 (0.039 to 8.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: 13. Kinetics of Serogroup A, C, W-135 and Y hSBA Titers After MenACWY-CRM Primary Vaccination

End point title	13. Kinetics of Serogroup A, C, W-135 and Y hSBA Titers After MenACWY-CRM Primary Vaccination[365]

End point description:

To assess the kinetics of serogroup A, C, W-135 and Y hSBA titers, the geometric means was measured on day 0, 7, 14, 30, 49, 90, and 120 following vaccination with MenACWY-CRM vaccination at month 4

of the study.

Note: Confidence Interval was not calculated for Serogroup Y - hSBA GMTs (N=1)- Day 0 because only one subject was analyzed.

End point type	Secondary

End point timeframe:

Day 0, 7, 14, 30, 49, 90,120 after MenACWY-CRM vaccination at month 4

Notes:

[365] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: statistical analyses not applicable for this endpoint.

End point values	MenACWY-CRM and Routine Vaccines (Group 1)			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Geometric mean of titers				
geometric mean (confidence interval 95%)				
Serogroup A - hSBA GMTs (N=7)- Day 0	2 (2 to 2)			
Serogroup A - hSBA GMTs (N=18)- Day 7	13 (7.15 to 25)			
Serogroup A - hSBA GMTs (N=16)- Day 14	26 (10 to 63)			
Serogroup A - hSBA GMTs - Day 30	9.79 (7.22 to 13)			
Serogroup A - hSBA GMTs (N=16)- Day 49	9.53 (4.49 to 20)			
Serogroup A - hSBA GMTs (N=18)- Day 90	2.63 (1.77 to 3.91)			
Serogroup A - hSBA GMTs (N=16) Day 120	4.45 (2.25 to 8.83)			
Serogroup C - hSBA GMTs (N=5)- Day 0	7.19 (1.33 to 39)			
Serogroup C - hSBA GMTs (N=16)- Day 7	138 (43 to 439)			
Serogroup C - hSBA GMTs (N=12)- Day 14	180 (55 to 596)			
Serogroup C - hSBA GMTs (N=31)- Day 30	105 (73 to 151)			
Serogroup C - hSBA GMTs (N=16)- Day 49	104 (50 to 219)			
Serogroup C - hSBA GMTs (N=18)- Day 90	31 (18 to 53)			
Serogroup C - hSBA GMTs (N=16)- Day 120	15 (6.5 to 36)			
Serogroup W-135 - hSBA GMTs (N=5)- Day 0	4.43 (1.48 to 13)			
Serogroup W-135 - hSBA GMTs (N=12)- Day 7	99 (42 to 232)			
Serogroup W-135 - hSBA GMTs (N=9)- Day 14	144 (42 to 497)			
Serogroup W-135 - hSBA GMTs (N=61)- Day 30	60 (44 to 83)			
Serogroup W-135 - hSBA GMTs (N=11)- Day 49	35 (18 to 69)			
Serogroup W-135 - hSBA GMTs (N=15)- Day 90	20 (11 to 35)			

Serogroup W-135 - hSBA GMTs (N=4)- Day 120	12 (7.58 to 20)			
Serogroup Y - hSBA GMTs (N=1)- Day 0	2 (-9999 to 9999)			
Serogroup Y - hSBA GMTs (N=8)- Day 7	32 (8.06 to 123)			
Serogroup Y - hSBA GMTs (N=4)- Day 14	95 (8 to 1131)			
Serogroup Y - hSBA GMTs (N=20)- Day 30	24 (16 to 38)			
Serogroup Y - hSBA GMTs (N=8)- Day 49	33 (11 to 101)			
Serogroup Y - hSBA GMTs (N=9)- Day 90	12 (4.62 to 29)			
Serogroup Y - hSBA GMTs (N=8)- Day 120	8.15 (3.77 to 18)			

Statistical analyses

No statistical analyses for this end point

Secondary: 14. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135 and Y Specific Memory B Cells 1 Month After MenACWY-CRM Primary Vaccination and IgG Concentration at Day 1 in the Serum of Mothers of Infants

End point title	14. Correlation and Linear Regression Coefficients Between Serogroup A, C, W-135 and Y Specific Memory B Cells 1 Month After MenACWY-CRM Primary Vaccination and IgG Concentration at Day 1 in the Serum of Mothers of Infants

End point description:

The serogroup A, C, W-135 and Y specific IgG concentrations were measured in the serum of mothers at the time of their enrollment into the study (Day 1) by ELISA and reported as µg/mL.
Analysis was done on the PP primary population and PP booster population.
Specific IgG GMCs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

Day 1 (IgG) and one month after primary vaccination (B cells)

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[366]	31[367]	43[368]	101[369]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	4.14 (± 0)
Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	0.54 (± 0)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.72)	1.57 (± 1.47)	0.48 (± 0)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	0.64 (± 0)

Notes:

[366] - N= Serogroup A=50, C=71, W-135=62, Y=54

[367] - N= Serogroup A=25, C=31, W-135=26, Y=25

[368] - N= Serogroup A=30, C=43, W-135=40, Y=30

[369] - N= Serogroup A,C,Y =101, W-135=98; 95%CI= A=3.18-5.4, C=0.38-0.75,W-135=0.37-0.61, Y=0.48-0.84

End point values	Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2)	Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41[370]	52[371]		
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	6.11 (± 0)	3.28 (± 0)		
Serogroup C	1.59 (± 0)	0.61 (± 0)		
Serogroup W-135	0.75 (± 0)	0.62 (± 0)		
Serogroup Y	0.96 (± 0)	0.69 (± 0)		

Notes:

[370] - 95%CI= A=4.03-9.27, C=0.94-2.7,W-135=0.5-1.11,Y=0.62-1.49

[371] - N= Serogroup A,C,Y=52, W-135=51; 95%CI= A=2.27-4.75, C=0.38-0.98, W-135=0.43-0.88, Y=0.47-1.02

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[372]
P-value	= 0.7
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[372] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[373]
P-value	= 0.63
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[373] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[374]
P-value	= 0.74
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[374] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Pearson correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[375]
P-value	= 0.74
Method	Parametric correlation
Parameter estimate	Pearson correlation coefficient
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[375] - Parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[376]
P-value	= 0.05
Method	Non-parametric correlation]
Parameter estimate	Spearman correlation coefficient
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[376] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric

	Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[377]
P-value	= 0.36
Method	Non-parametric correlation]
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[377] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[378]
P-value	= 0.18
Method	Non-parametric correlation]
Parameter estimate	Spearman correlation coefficient
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[378] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Spearman correlation coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)

Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[379]
P-value	= 0.82
Method	Non-parametric correlation]
Parameter estimate	Spearman correlation coefficient
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[379] - Non-parametric correlation
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[380]
Parameter estimate	R-square
Point estimate	0.0013
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[380] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)

Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[381]
Parameter estimate	R-square
Point estimate	0.0014
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[381] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[382]
Parameter estimate	R-square
Point estimate	0.0008
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[382] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at day 1 in the serum of mother for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 1) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 2) v Specific IgG Geometric Mean Conc at Day 1 in mothers (Group 3)
Number of subjects included in analysis	339
Analysis specification	Pre-specified
Analysis type	other[383]
Parameter estimate	R-square
Point estimate	0.0009

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[383] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Secondary: 15. Linear Regression Coefficients (1) Between Serogroup A, C, W-135 and Y Memory B at 5 Months and hSBA Titers at 12 Months, (2) Between Serogroup A, C, W-135 and Y Memory B at 5 Months and IgG at 12 Months, After a 2-Dose Primary Course of MenACWY-CRM

End point title	15. Linear Regression Coefficients (1) Between Serogroup A, C, W-135 and Y Memory B at 5 Months and hSBA Titers at 12 Months, (2) Between Serogroup A, C, W-135 and Y Memory B at 5 Months and IgG at 12 Months, After a 2-Dose Primary Course of MenACWY-CRM

End point description:

Linear regression analysis between memory B cells at 5 months of age and hSBA titers and IgG at 12 months of age was performed with and without inclusion of demographic factors (subject's household smoking status, number of older children living in subject's household, attendance at daycare and total duration of breast feeding) in the model.
Analysis was performed on the PP dataset of persistence population.
Note: Specific IgG GMCs and hSBA GMTs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

1 month post primary vaccination (B cells) and 12 months (hSBA titers and IgG)

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Human SBA GMTs at 12 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[384]	31[385]	43[386]	85[387]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	2.2 (± 0)
Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	5.56 (± 0)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.721)	1.57 (± 1.47)	8.4 (± 0)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	8.71 (± 0)

Notes:

[384] - N= Serogroup A=50, C=71, W-135=62, Y=54

[385] - N= Serogroup A=25, C=31, W-135=26, Y=25

[386] - N= Serogroup A=30, C=43, W-135=40, Y=30

[387] - N= Serogroup A=85, C=83, W-135=67, Y=43; 95%CI= A=2.05-2.36, C=4.23-7.3,W-135=6.03-12,Y=5.82-13

End point values	Human SBA GMTs at 12 Months of Age (Group 2)	Human SBA GMTs at 12 Months of Age (Group 3)	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2)

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[388]	42[389]	55[390]	25[391]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2 (± 0)	2.14 (± 0)	0.37 (± 0)	0.33 (± 0)
Serogroup C	4.83 (± 0)	5.61 (± 0)	0.19 (± 0)	0.18 (± 0)
Serogroup W-135	12 (± 0)	10 (± 0)	0.31 (± 0)	0.35 (± 0)
Serogroup Y	9.9 (± 0)	9.15 (± 0)	0.43 (± 0)	0.47 (± 0)

Notes:

[388] - N= Serogroup A=40, C=39, W-135=37, Y=25; 95%CI= A=2-2, C=3.28-7.09, W-135=8.05-17, Y=5.39-18
[389] - N= Serogroup A=42, C=40, W-135=34, Y=16; 95%CI= A=1.93-2.37, C=3.78-8.33, W-135=6.73-15, Y=4.95-17
[390] - N= Serogroup A=49, C=55, W-135=55, Y=49; 95%CI= A=0.27-0.49, C=0.16-0.23,W-135=0.25-0.38,Y=0.34-0.55
[391] - N= Serogroup A=23, C=25, W-135=21, Y=21; 95%CI= A=0.23-0.46, C=0.14-0.22,W-135=0.25-0.48,Y=0.33-0.67

End point values	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)			
Subject group type	Subject analysis set			
Number of subjects analysed	26[392]			
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	0.31 (± 0)			
Serogroup C	0.2 (± 0)			
Serogroup W-135	0.29 (± 0)			
Serogroup Y	0.37 (± 0)			

Notes:

[392] - N= Serogroup A=24, C=26, W-135=26, Y=24; 95%CI= A=0.23-0.42, C=0.15-0.28,W-135=0.2-0.43,Y=0.25-0.55

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[393]
Parameter estimate	R-square
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[393] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[394]
Parameter estimate	R-square
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[394] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells at 5 months of age and hSBA titers at 12 months of age after a 2, 4-month course of MenACWY-CRM vaccination for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[395]
Parameter estimate	R-square
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[395] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[396]
Parameter estimate	R-square
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[396] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[397]
Parameter estimate	R-square
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[397] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[398]
Parameter estimate	R-square
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[398] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[399]
Parameter estimate	R-square
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[399] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[400]
Parameter estimate	R-square
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[400] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[401]
Parameter estimate	R-square
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[401] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[402]
Parameter estimate	R-square
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[402] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[403]
Parameter estimate	R-square
Point estimate	0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[403] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[404]
Parameter estimate	R-square
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[404] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[405]
Parameter estimate	R-square
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[405] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[406]
Parameter estimate	R-square
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[406] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[407]
Parameter estimate	R-square
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[407] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and hSBA titers at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[408]
Parameter estimate	R-square
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[408] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 17

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[409]
Parameter estimate	R-square
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[409] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[410]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[410] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 19

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[411]
Parameter estimate	R-square
Point estimate	0.007
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[411] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 20

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[412]
Parameter estimate	R-square
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[412] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 21

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[413]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[413] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 22
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup W-135	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[414]
Parameter estimate	R-square
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[414] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 23
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup Y	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[415]
Parameter estimate	R-square
Point estimate	0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[415] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 24
Statistical analysis description:	
Linear regression coefficient between memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup Y	
Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)

Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[416]
Parameter estimate	R-square
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[416] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 25

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[417]
Parameter estimate	R-square
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[417] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 26

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[418]
Parameter estimate	R-square
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[418] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 27

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[419]
Parameter estimate	R-square
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[419] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 28

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[420]
Parameter estimate	R-square
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[420] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 29

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[421]
Parameter estimate	R-square
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[421] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 30

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[422]
Parameter estimate	R-square
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[422] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 31

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[423]
Parameter estimate	R-square
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[423] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 32

Statistical analysis description:

Linear regression coefficient between demographic factors memory B cells one month after primary vaccination and serogroup specific IgG concentration at 12 months of age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other[424]
Parameter estimate	R-square
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[424] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Secondary: 16. Linear Regression Coefficients (1) Between Serogroup A, C, W-135 and Y Memory B Cells at 5 Months and Rise in hSBA Titers, (2) Between Serogroup A, C, W-135 and Y Memory B Cells at 5 Months and Rise in IgG, After Third Dose of MenACWY-CRM at 12 Months

End point title	16. Linear Regression Coefficients (1) Between Serogroup A, C, W-135 and Y Memory B Cells at 5 Months and Rise in hSBA Titers, (2) Between Serogroup A, C, W-135 and Y Memory B Cells at 5 Months and Rise in IgG, After Third Dose of MenACWY-CRM at 12 Months

End point description:

The rise in serogroup-specific hSBA and IgG was calculated by pre/post third dose geometric mean ratios, calculated by the difference in the log10 of the concentrations/titers measured at 13 months to the log10 of the concentrations at 12 months: i.e. rise = log10(x) at 13 months minus log10(x) at 12 months where x is the serogroup specific IgG or SBA titers.
Linear regression analysis between memory B cells at 5 months of age and rise in hSBA titers or IgG at 12 months of age was performed with and without inclusion of demographic factors (subject's household smoking status, number of older children living in subject's household, attendance at daycare and total duration of breast feeding) in the model.
Analysis was performed on the PP dataset after booster vaccination.
Note: Specific IgG GMCs and hSBA GMTs dispersion was reported as confidence intervals (see table notes)

End point type	Secondary

End point timeframe:

1 month post primary vaccination (B cells) and 12 months (hSBA titers and IgG)

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	Human SBA GMTs at 12 Months of Age (Group 1)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	71[425]	31[426]	43[427]	85[428]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2.1 (± 2.03)	1.8 (± 1.27)	1.72 (± 1.89)	2.2 (± 0)
Serogroup C	2.57 (± 2.73)	1.71 (± 1.12)	2.43 (± 2.32)	5.56 (± 0)
Serogroup W-135	2.39 (± 4.69)	1.5 (± 0.721)	1.57 (± 1.47)	8.4 (± 0)
Serogroup Y	2.91 (± 8.36)	1.43 (± 0.71)	1.78 (± 1.67)	8.71 (± 0)

Notes:

[425] - N= Serogroup A=50, C=71, W-135=62, Y=54

[426] - N= Serogroup A=25, C=31, W-135=26, Y=25

[427] - N= Serogroup A=30, C=43, W-135=40, Y=30

[428] - N= Serogroup A=85, C=83, W-135=67, Y=43; 95%CI= A=2.05-2.36, C=4.23-7.3,W-135=6.03-12,Y=5.82-13

End point values	Human SBA GMTs at 12 Months of Age (Group 2)	Human SBA GMTs at 12 Months of Age (Group 3)	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40[429]	42[430]	55[431]	25[432]
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	2 (± 0)	2.14 (± 0)	0.37 (± 0)	0.33 (± 0)
Serogroup C	4.83 (± 0)	5.61 (± 0)	0.19 (± 0)	0.18 (± 0)
Serogroup W-135	12 (± 0)	10 (± 0)	0.31 (± 0)	0.35 (± 0)
Serogroup Y	9.9 (± 0)	9.15 (± 0)	0.43 (± 0)	0.47 (± 0)

Notes:

[429] - N= Serogroup A=40, C=39, W-135=37, Y=25; 95%CI= A=2-2, C=3.28-7.09, W-135=8.05-17, Y=5.39-18

[430] - N= Serogroup A=42, C=40, W-135=34, Y=16; 95%CI= A=1.93-2.37, C=3.78-8.33, W-135=6.73-15, Y=4.95-17

[431] - N= Serogroup A=49, C=55, W-135=55, Y=49; 95%CI= A=0.27-0.49, C=0.16-0.23,W-135=0.25-0.38,Y=0.34-0.55

[432] - N= Serogroup A=23, C=25, W-135=21, Y=21; 95%CI= A=0.23-0.46, C=0.14-0.22,W-135=0.25-0.48,Y=0.33-0.67

End point values	Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)			
Subject group type	Subject analysis set			
Number of subjects analysed	47[433]			
Units: Mean of memory B cells				
arithmetic mean (standard deviation)				
Serogroup A	0.31 (± 0)			
Serogroup C	0.2 (± 0)			
Serogroup W-135	0.29 (± 0)			
Serogroup Y	0.37 (± 0)			

Notes:

[433] - N= Serogroup A=47, C=26, W-135=26, Y=24; 95%CI= A=0.23-0.42, C=0.15-0.28,W-135=0.2-0.43,Y=0.25-0.55

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[434]
Parameter estimate	R-square
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[434] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[435]
Parameter estimate	R-square
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[435] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[436]
Parameter estimate	R-square
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[436] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[437]
Parameter estimate	R-square
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[437] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[438]
Parameter estimate	R-square
Point estimate	0.52

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[438] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[439]
Parameter estimate	R-square
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[439] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[440]
Parameter estimate	R-square
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[440] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[441]
Parameter estimate	R-square
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[441] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[442]
Parameter estimate	R-square
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[442] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[443]
Parameter estimate	R-square
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[443] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[444]
Parameter estimate	R-square
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[444] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[445]
Parameter estimate	R-square
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[445] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[446]
Parameter estimate	R-square
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[446] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[447]
Parameter estimate	R-square
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[447] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Human SBA GMTs at 12 Months of Age (Group 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[448]
Parameter estimate	R-square
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[448] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in hSBA after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Human SBA GMTs at 12 Months of Age (Group 2) v Human SBA GMTs at 12 Months of Age (Group 3)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	other[449]
Parameter estimate	R-square
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[449] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 17

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[450]
Parameter estimate	R-square
Point estimate	0.0015
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[450] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 18

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[451]
Parameter estimate	R-square
Point estimate	0.0057
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[451] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 19

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[452]
Parameter estimate	R-square
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[452] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 20

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric

	Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[453]
Parameter estimate	R-square
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[453] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 21

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[454]
Parameter estimate	R-square
Point estimate	0.0048
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[454] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 22

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[455]
Parameter estimate	R-square
Point estimate	0.0018

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[455] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 23

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[456]
Parameter estimate	R-square
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[456] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 24

Statistical analysis description:

Linear regression coefficient between memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[457]
Parameter estimate	R-square
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[457] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 25

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[458]
Parameter estimate	R-square
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[458] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 26

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup A

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[459]
Parameter estimate	R-square
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[459] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 27

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[460]
Parameter estimate	R-square
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[460] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 28

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup C

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[461]
Parameter estimate	R-square
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[461] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 29

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[462]
Parameter estimate	R-square
Point estimate	0.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[462] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 30

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup W-135

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[463]
Parameter estimate	R-square
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[463] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Statistical analysis title	Statistical Analysis 31

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 1) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other[464]
Parameter estimate	R-square
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[464] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.

Statistical analysis title	Statistical Analysis 32

Statistical analysis description:

Linear regression coefficient between demographic factors, memory B cells one month after primary vaccination and rise in serogroup specific IgG concentration after booster vaccination age for the serogroup Y

Comparison groups	MenACWY-CRM and Routine Vaccines (Group 2) v MenACWY-CRM and Routine Vaccines (Group 3) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 2) v Specific IgG Geometric Mean Conc at 12 Months of Age (Group 3)
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	other[465]
Parameter estimate	R-square
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9999
upper limit	9999

Notes:

[465] - Regression, Linear
Confidence Intervals were not calculated for the purpose of this study.
Values from Group 2 and 3 were combined for this analysis.

Secondary: 17. Percentage of Subjects Who Reported Injection Site Local Reactions After Each MenACWY-CRM and Routine Infant Vaccinations.

End point title	17. Percentage of Subjects Who Reported Injection Site Local Reactions After Each MenACWY-CRM and Routine Infant Vaccinations.

End point description:

Safety was assessed as the percentage of subjects who reported injection site local reactions during 7-day follow-up period after each MenACWY-CRM and routine infant vaccination administered as a primary course of vaccination.

End point type	Secondary

End point timeframe:

7 days post primary MenACWY-CRM and routine infant vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	54	54	
Units: Percentage of subjects				
Tenderness - MenACWY-CRM (Vaccination 1)	35	19	12	
Tenderness - MenACWY-CRM (Vaccination 2)	21	15	9	
Erythema - MenACWY-CRM (Vaccination 1)	101	52	51	

Erythema - MenACWY-CRM (Vaccination 2)	104	52	54	
Induration - MenACWY-CRM (Vaccination 1)	38	20	21	
Induration - MenACWY-CRM (Vaccination 2)	48	27	29	
Tenderness - DTaP-IPV-Hib (Vaccination 1)	43	23	15	
Tenderness - DTaP-IPV-Hib (Vaccination 2)	33	19	17	
Tenderness - DTaP-IPV-Hib (Vaccination 3)	29	18	13	
Erythema - DTaP-IPV-Hib (Vaccination 1)	105	53	49	
Erythema - DTaP-IPV-Hib (Vaccination 2)	102	50	54	
Erythema - DTaP-IPV-Hib (Vaccination 3)	105	53	53	
Induration - DTaP-IPV-Hib (Vaccination 1)	53	27	29	
Induration - DTaP-IPV-Hib (Vaccination 2)	57	35	29	
Induration - DTaP-IPV-Hib (Vaccination 3)	71	39	38	
Tenderness - PCV (Vaccination 1)	43	21	18	
Tenderness - PCV (Vaccination 2)	29	21	14	
Erythema - PCV (Vaccination 1)	103	53	50	
Erythema - PCV (Vaccination 2)	105	52	54	
Induration - PCV (Vaccination 1)	41	24	27	
Induration - PCV (Vaccination 2)	57	33	35	

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Percentage of Subjects Who Reported Solicited Systemic Reactions After MenACWY-CRM and Routine Infants Primary Vaccinations

End point title	18. Percentage of Subjects Who Reported Solicited Systemic Reactions After MenACWY-CRM and Routine Infants Primary Vaccinations

End point description:

Safety was assessed as the percentage of subjects who reported systemic reactions during 7-day follow-up period after MenACWY-CRM (2 and 4 months) and routine infant primary vaccinations (2, 3 and 4 months).

End point type	Secondary

End point timeframe:

7 days post vaccination at 2, 3, and 4 months of age

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	54	54	
Units: Percentage of subjects				
Change in eat. habits (N=106,54,54)-Vaccination 1	20	11	16	
Change in eat. habits (N=107,53,54)-Vaccination 2	19	8	9	
Change in eat. habits (N=106,54,53)-Vaccination 3	20	14	16	
Sleepiness (Vaccination 1)	63	29	32	
Sleepiness (Vaccination 2)	42	18	28	
Sleepiness (Vaccination 3)	38	18	20	
Vomiting (Vaccination 1)	26	6	9	
Vomiting (Vaccination 2)	15	7	3	
Vomiting (Vaccination 3)	16	6	8	
Diarrhea (Vaccination 1)	22	11	8	
Diarrhea (Vaccination 2)	18	5	7	
Diarrhea (Vaccination 3)	10	9	7	
Irritability (Vaccination 1)	71	37	33	
Irritability (Vaccination 2)	51	41	27	
Irritability (Vaccination 3)	55	30	31	
Unusual crying (Vaccination 1)	29	11	8	
Unusual crying (Vaccination 2)	18	15	10	
Unusual crying (Vaccination 3)	23	8	14	
Fever (≥38 °C) - Vaccination 1	4	2	0	
Fever (≥38 °C) - Vaccination 2	6	3	0	
Fever (≥38 °C) - Vaccination 3	6	5	2	
Analg. Antipyr. Med. Used (Vaccination 1)	43	14	15	
Analg. Antipyr. Med. Used (Vaccination 2)	28	24	21	
Analg. Antipyr. Med. Used (Vaccination 3)	44	18	30	

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Percentage of Subjects Who Reported Injection Site Local Reactions After MenACWY-CRM and PCV Vaccinations at 12 Months of Age

End point title	19. Percentage of Subjects Who Reported Injection Site Local Reactions After MenACWY-CRM and PCV Vaccinations at 12 Months of Age

End point description:

Safety was assessed as the percentage of subjects who reported injection site local reactions during 7-day follow-up period after MenACWY-CRM and PCV vaccinations at 12 months of age.

End point type	Secondary

End point timeframe:

7 days post 12 month vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	103	50	52	
Units: Percentage of subjects				
Tenderness - MenACWY-CRM	29	14	10	
Erythema - MenACWY-CRM	102	46	49	
Induration - MenACWY-CRM	54	25	29	
Tenderness - PCV	15	15	11	
Erythema - PCV	43	43	49	
Induration - PCV	24	24	33	

Statistical analyses

No statistical analyses for this end point

Secondary: 20. Percentage of Subjects Who Reported Solicited Systemic Reactions After MenACWY-CRM and PCV Vaccination at 12 Months of Age

End point title	20. Percentage of Subjects Who Reported Solicited Systemic Reactions After MenACWY-CRM and PCV Vaccination at 12 Months of Age

End point description:

Safety was assessed as the percentage of subjects who reported systemic reactions during 7-day follow-up period after MenACWY-CRM and PCV vaccination at 12 months of age.

End point type	Secondary

End point timeframe:

7 days post 12 months vaccination

End point values	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	103	50	52	
Units: Percentage of subjects				
Change in eating habits (N=97,48,52)	22	11	16	
Sleepiness	21	12	13	
Vomiting	3	5	6	
Diarrhea	14	8	8	
Irritability	26	23	21	
Unusual crying	12	10	8	
Fever (≥38 °C)	8	3	3	
Analgesics Antipyretics Medicine Used	33	22	24	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All the serious adverse events were collected throughout the study (day 1 to 18 months).

Adverse event reporting additional description:

Other adverse events included solicited local and systemic reactions and non-serious unsolicited adverse events.
Solicited local and systemic reactions were collected from day 1 to day 7 after each vaccination.
Non-serious unsolicited adverse events were collected from 7 days after each vaccination to the next visit.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.1

Reporting groups

Reporting group title	MenACWY-CRM and Routine Vaccines (Group 1)

Reporting group description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 13 months), and 1 dose each of MMR and Hib (booster) at 13 months.

Reporting group title	MenACWY-CRM and Routine Vaccines (Group 2)

Reporting group description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months. This group had an additional blood draw at the time of enrollment.

Reporting group title	MenACWY-CRM and Routine Vaccines (Group 3)

Reporting group description:

Infants received 2 doses of MenACWY-CRM (at 2 and 4 months) as a primary course of vaccination and third dose (at 12 months) as a booster. Infants also received routine vaccines - 3 doses of DTaP-Hib-IPV (at 2, 3, and 4 months), 3 doses of PCV (at 2, 4, and 12 months), and 1 dose each of MMR and Hib (booster) at 13 months of age. This group had an additional blood draw at 6-7 days after third dose of MenACWY-CRM.

Serious adverse events	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 108 (6.48%)	4 / 54 (7.41%)	6 / 54 (11.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 108 (0.00%)	0 / 54 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 108 (0.00%)	1 / 54 (1.85%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 108 (0.00%)	0 / 54 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Eosinophilic colitis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 54 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 108 (0.93%)	0 / 54 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Wheezing			
subjects affected / exposed	1 / 108 (0.93%)	0 / 54 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 108 (1.85%)	1 / 54 (1.85%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 108 (0.00%)	1 / 54 (1.85%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 108 (0.00%)	0 / 54 (0.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 108 (0.93%)	1 / 54 (1.85%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	3 / 108 (2.78%)	0 / 54 (0.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 108 (0.00%)	1 / 54 (1.85%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	MenACWY-CRM and Routine Vaccines (Group 1)	MenACWY-CRM and Routine Vaccines (Group 2)	MenACWY-CRM and Routine Vaccines (Group 3)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	108 / 108 (100.00%)	54 / 54 (100.00%)	54 / 54 (100.00%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	81 / 108 (75.00%)	40 / 54 (74.07%)	42 / 54 (77.78%)
occurrences (all)	184	82	108
General disorders and administration site conditions			
Injection site erythema			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	108 / 108 (100.00%)	53 / 54 (98.15%)	54 / 54 (100.00%)
occurrences (all)	859	475	486
Injection site induration			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	91 / 108 (84.26%)	50 / 54 (92.59%)	50 / 54 (92.59%)
occurrences (all)	437	271	283
Injection site pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	74 / 108 (68.52%)	42 / 54 (77.78%)	38 / 54 (70.37%)
occurrences (all)	265	172	121
Pyrexia			
subjects affected / exposed	25 / 108 (23.15%)	12 / 54 (22.22%)	9 / 54 (16.67%)
occurrences (all)	36	19	10
Crying			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	49 / 108 (45.37%)	29 / 54 (53.70%)	29 / 54 (53.70%)
occurrences (all)	98	57	47
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	45 / 108 (41.67%)	23 / 54 (42.59%)	19 / 54 (35.19%)
occurrences (all)	77	43	40
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 108 (2.78%)	4 / 54 (7.41%)	2 / 54 (3.70%)
occurrences (all)	3	4	2
Teething			
subjects affected / exposed	14 / 108 (12.96%)	8 / 54 (14.81%)	5 / 54 (9.26%)
occurrences (all)	15	10	7
Vomiting			
subjects affected / exposed	43 / 108 (39.81%)	20 / 54 (37.04%)	19 / 54 (35.19%)
occurrences (all)	75	31	34
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	14 / 108 (12.96%)	6 / 54 (11.11%)	3 / 54 (5.56%)
occurrences (all)	15	9	3
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	7 / 108 (6.48%)	4 / 54 (7.41%)	4 / 54 (7.41%)
occurrences (all)	8	4	4
Rash			

subjects affected / exposed	10 / 108 (9.26%)	4 / 54 (7.41%)	1 / 54 (1.85%)
occurrences (all)	10	4	2
Psychiatric disorders			
Irritability			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	93 / 108 (86.11%)	53 / 54 (98.15%)	47 / 54 (87.04%)
occurrences (all)	248	163	145
Eating disorder			
subjects affected / exposed	55 / 108 (50.93%)	30 / 54 (55.56%)	31 / 54 (57.41%)
occurrences (all)	100	52	80
Infections and infestations			
Conjunctivitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	7 / 108 (6.48%)	3 / 54 (5.56%)	5 / 54 (9.26%)
occurrences (all)	9	3	6
Ear infection			
subjects affected / exposed	7 / 108 (6.48%)	5 / 54 (9.26%)	1 / 54 (1.85%)
occurrences (all)	7	5	1
Lower respiratory tract infection			
subjects affected / exposed	10 / 108 (9.26%)	11 / 54 (20.37%)	5 / 54 (9.26%)
occurrences (all)	12	13	5
Nasopharyngitis			
subjects affected / exposed	1 / 108 (0.93%)	3 / 54 (5.56%)	0 / 54 (0.00%)
occurrences (all)	1	4	0
Rhinitis			
subjects affected / exposed	21 / 108 (19.44%)	15 / 54 (27.78%)	13 / 54 (24.07%)
occurrences (all)	26	20	15
Upper respiratory tract infection			
subjects affected / exposed	7 / 108 (6.48%)	2 / 54 (3.70%)	6 / 54 (11.11%)
occurrences (all)	7	2	6

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 June 2008	Amendment No. 1: The main reason for this amendment was to insert a new secondary objective due to the addition of an optional genetic analysis. Moreover also the Sponsor Study personnel have been updated. Finally some changes have been implemented throughout the protocol for consistency and to better clarify the text.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/23538521

http://www.ncbi.nlm.nih.gov/pubmed/23566945