Clinical trial results:
Immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in Europe

Summary

EudraCT number	2017-004731-36
Trial protocol	CZ SE FI IT ES PL RO
Global end of trial date	24 May 2023

Results information

Result version number	v2 (current)
This version publication date	22 February 2025
First version publication date	12 January 2025
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	MET58

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03547271
WHO universal trial number (UTN)	U1111-1183-6653

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	Discovery Drive, Swiftwater, PA, United States, 18370-0187
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001930-PIP01-16
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	08 July 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 May 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of the antibody response against meningococcal serogroups A, C, W, and Y following the administration of a 3-dose series of MenACYW conjugate vaccine compared to a 3-dose series of Nimenrix® when each vaccine is administered concomitantly with routine pediatric vaccines [pneumococcal conjugate vaccine, 10-valent absorbed (PCV10), and hexavalent vaccine] to infants and toddlers from 6 weeks to 18 months old (Group 1 versus Group 2).

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 December 2018
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	Czechia: 140
Country: Number of subjects enrolled	Finland: 907
Country: Number of subjects enrolled	Italy: 60
Country: Number of subjects enrolled	Poland: 241
Country: Number of subjects enrolled	Romania: 132
Country: Number of subjects enrolled	Spain: 160
Country: Number of subjects enrolled	Sweden: 20
Worldwide total number of subjects	1660
EEA total number of subjects	1660

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)	1660
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:

This study was conducted at 33 investigational sites in 7 countries between 14 December 2018 to 24 May 2023.

Pre-assignment

Screening details:

A total of 1660 participants were enrolled in this study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenACYW

Arm description:

Participants received 3 doses of meningococcal polysaccharide (serogroups A, C, Y and W) tetanus toxoid [MenACYW conjugate vaccine] 0.5 milliliter (mL) as an intramuscular (IM) injection at dose 1: 2 months of age (MoA), dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and haemophilus influenzae type b conjugate vaccine [DTaP-IPV-HB-Hib], the pneumococcal vaccine (PCV10) were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the measles, mumps, rubella (MMR) vaccine was administered at 12 to 18 MoA.

Arm type	Experimental
Investigational medicinal product name	Hexavalent vaccine
Investigational medicinal product code	
Other name	DTaP-IPV-HB-Hib; Hexyon®; Hexacima®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

Investigational medicinal product name	MMR vaccine
Investigational medicinal product code	
Other name	M-M-RVAXPRO®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

Investigational medicinal product name	MenACYW conjugate vaccine
Investigational medicinal product code	
Other name	Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA.

Investigational medicinal product name	PCV10
Investigational medicinal product code	
Other name	Synflorix®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received PCV10 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

Arm title	Group 2: Nimenrix

Arm description:

Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Arm type	Experimental
Investigational medicinal product name	Nimenrix®
Investigational medicinal product code	
Other name	Meningococcal group A, C, W-135, and Y conjugate vaccine
Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received Nimenrix® 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA.

Investigational medicinal product name	MMR vaccine
Investigational medicinal product code	
Other name	M-M-RVAXPRO®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

Investigational medicinal product name	PCV10
Investigational medicinal product code	
Other name	Synflorix®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received PCV10 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

Investigational medicinal product name	Hexavalent vaccine
Investigational medicinal product code	
Other name	DTaP-IPV-HB-Hib; Hexyon®; Hexacima®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

Arm title	Group 3: MenACYW

Arm description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the pneumococcal conjugate vaccine (13-valent, adsorbed) [PCV13] were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Arm type	Experimental
Investigational medicinal product name	MenACYW conjugate vaccine
Investigational medicinal product code	
Other name	Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA.

Investigational medicinal product name	MMR vaccine
Investigational medicinal product code	
Other name	M-M-RVAXPRO®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

Investigational medicinal product name	Hexavalent vaccine
Investigational medicinal product code	
Other name	DTaP-IPV-HB-Hib; Hexyon®; Hexacima®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

Investigational medicinal product name	PCV13
Investigational medicinal product code	
Other name	Prevenar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received PCV13 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

Arm title	Group 4: MenACYW

Arm description:

Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.

Arm type	Experimental

Investigational medicinal product name	MenACYW conjugate vaccine
Investigational medicinal product code	
Other name	Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA.

Investigational medicinal product name	MMR vaccine
Investigational medicinal product code	
Other name	M-M-RVAXPRO®
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

Investigational medicinal product name	PCV13
Investigational medicinal product code	
Other name	Prevenar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received PCV13 0.5 mL IM injection in a 2+1 regimen (first between 6 and 12 weeks of age and second between 4 to 5 MoA in infancy and the toddler dose at 12 to 18 MoA).

Investigational medicinal product name	Hexavalent vaccine
Investigational medicinal product code	
Other name	DTaP-IPV-HB-Hib; Hexyon®; Hexacima®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (first between 6 and 12 weeks of age and second between 4 to 5 MoA in infancy and the toddler dose at 12 to 18 MoA).

Number of subjects in period 1	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW
Started	714	726	112
Safety analysis set (SafAS)	696	706	112
Completed	681	691	106
Not completed	33	35	6
Adverse event, non-fatal	1	1	-
Protocol deviation	5	7	3
Withdrawal by Parent/Guardian	24	24	2
Lost to follow-up	3	3	1

Number of subjects in period 1	Group 4: MenACYW
Started	108
Safety analysis set (SafAS)	108

Completed	104
Not completed	4
Adverse event, non-fatal	-
Protocol deviation	-
Withdrawal by Parent/Guardian	4
Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: MenACYW
Reporting group description:	
Participants received 3 doses of meningococcal polysaccharide (serogroups A, C, Y and W) tetanus toxoid [MenACYW conjugate vaccine] 0.5 milliliter (mL) as an intramuscular (IM) injection at dose 1: 2 months of age (MoA), dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and haemophilus influenzae type b conjugate vaccine [DTaP-IPV-HB-Hib], the pneumococcal vaccine (PCV10) were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the measles, mumps, rubella (MMR) vaccine was administered at 12 to 18 MoA.	
Reporting group title	Group 2: Nimenrix
Reporting group description:	
Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.	
Reporting group title	Group 3: MenACYW
Reporting group description:	
Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the pneumococcal conjugate vaccine (13-valent, adsorbed) [PCV13] were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.	
Reporting group title	Group 4: MenACYW
Reporting group description:	
Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.	

Reporting group values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW
Number of subjects	714	726	112
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	714	726	112
Age Continuous Units: Days			
arithmetic mean	72.6	72.4	62.5
standard deviation	± 12.2	± 12.1	± 7.12
Sex: Female, Male Units: Participants			
Female	355	378	45
Male	359	348	67

Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	2	1	4
Black or African American	0	0	1
Native Hawaiian or Other Pacific Islander	0	1	0
White	693	699	106
Not Reported	13	16	0
Unknown	2	3	0
Multiple origin	4	6	0

Reporting group values	Group 4: MenACYW	Total	
Number of subjects	108	1660	
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	108	1660	
Age Continuous Units: Days			
arithmetic mean	63.3		
standard deviation	± 7.93	-	
Sex: Female, Male Units: Participants			
Female	58	836	
Male	50	824	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	2	9	
Black or African American	3	4	
Native Hawaiian or Other Pacific Islander	0	1	
White	101	1599	
Not Reported	1	30	
Unknown	0	5	
Multiple origin	1	11	

End points

End points reporting groups

Reporting group title	Group 1: MenACYW

Reporting group description:

Participants received 3 doses of meningococcal polysaccharide (serogroups A, C, Y and W) tetanus toxoid [MenACYW conjugate vaccine] 0.5 milliliter (mL) as an intramuscular (IM) injection at dose 1: 2 months of age (MoA), dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and haemophilus influenzae type b conjugate vaccine [DTaP-IPV-HB-Hib], the pneumococcal vaccine (PCV10) were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the measles, mumps, rubella (MMR) vaccine was administered at 12 to 18 MoA.

Reporting group title	Group 2: Nimenrix

Reporting group description:

Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Reporting group title	Group 3: MenACYW

Reporting group description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the pneumococcal conjugate vaccine (13-valent, adsorbed) [PCV13] were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Reporting group title	Group 4: MenACYW

Reporting group description:

Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.

Primary: Groups 1 and 2: Geometric Mean Titers (GMTs) Against Meningococcal Serogroups A, C, W, and Y

End point title	Groups 1 and 2: Geometric Mean Titers (GMTs) Against Meningococcal Serogroups A, C, W, and Y[1]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the serum bactericidal assay using human complement (hSBA). Per-Protocol Analysis Set 2 (PPAS2) was a subset of Full Analysis Set 2 (FAS2). The FAS2 included the subset of randomized participants who received at least 1 dose of the study vaccine at booster vaccination and had a valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

At 30 days post Dose 3 [12 to 18 months of age (MoA)]

Notes:

[1] - 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: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

End point values	Group 1: MenACYW	Group 2: Nimenrix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	554	579		
Units: Titer				
geometric mean (confidence interval 95%)				
Serogroup A (n=543, 567)	131 (113 to 151)	189 (165 to 218)		
Serogroup C (n=550, 578)	565 (505 to 632)	120 (106 to 135)		
Serogroup W (n=547, 575)	423 (382 to 468)	275 (247 to 305)		
Serogroup Y (n=554, 579)	285 (260 to 313)	160 (145 to 177)		

Statistical analyses

Statistical analysis title	Statistical analysis for Serogroup A

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% confidence interval (CI) was >1/1.5 for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1133
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.565
upper limit	0.842

Statistical analysis title	Statistical analysis for Serogroup Y

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >1/1.5 for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1133
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT ratio
Point estimate	1.78

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.55
upper limit	2.04

Statistical analysis title	Statistical analysis for Serogroup W

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >1/1.5 for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1133
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Slope
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.33
upper limit	1.78

Statistical analysis title	Statistical analysis for Serogroup C

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >1/1.5 for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1133
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMT ratio
Point estimate	4.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	4
upper limit	5.58

Secondary: Groups 1 and 2: Percentage of Participants who Achieved Antibody Titers >=1:8 Against Meningococcal Serogroups A, C, W, and Y

End point title	Groups 1 and 2: Percentage of Participants who Achieved Antibody Titers >=1:8 Against Meningococcal Serogroups A, C, W, and Y[2]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. The FAS1 included the subset of randomized participants who received at least 1 dose of the study vaccine in the primary series and had a valid post-primary series vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

End point type	Secondary

End point timeframe:

At 30 days post Dose 2 (4 MoA)

Notes:

[2] - 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: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

End point values	Group 1: MenACYW	Group 2: Nimenrix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	518	523		
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=508, 508)	63.6 (59.2 to 67.8)	75.8 (71.8 to 79.5)		
Serogroup C (n=513, 521)	98.8 (97.5 to 99.6)	91.9 (89.3 to 94.1)		
Serogroup W (n=518, 523)	96.5 (94.6 to 97.9)	94.5 (92.1 to 96.3)		
Serogroup Y (n=516, 523)	96.5 (94.5 to 97.9)	93.5 (91.0 to 95.5)		

Statistical analyses

Statistical analysis title	Statistical analysis for Serogroup A

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1041
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	-12.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.74
upper limit	-6.56

Statistical analysis title	Statistical analysis for Serogroup Y

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1041
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	3.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	5.77

Statistical analysis title	Statistical analysis for Serogroup W

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1041
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	2.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	4.7

Statistical analysis title	Statistical analysis for Serogroup C

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

Comparison groups	Group 1: MenACYW v Group 2: Nimenrix
Number of subjects included in analysis	1041
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	6.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.44
upper limit	9.62

Secondary: Groups 3 and 4: Geometric Mean Titers Against Meningococcal Serogroups A, C, W, and Y

End point title	Groups 3 and 4: Geometric Mean Titers Against Meningococcal Serogroups A, C, W, and Y[3]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed.

End point type	Secondary

End point timeframe:

Group 3: Day 0 before Dose 1 (2 MoA) and Dose 3 (12 to 18 MoA) and Day 30 Post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: Day 0 before Dose 1 (2 MoA) and Dose 4 (12 to 18 MoA) and Day 30 Post Dose 3 (6 MoA) and Dose 4 (12 to 18 MoA)

Notes:

[3] - 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: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

End point values	Group 3: MenACYW	Group 4: MenACYW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	90		
Units: Titer				
geometric mean (confidence interval 95%)				
PPAS1: Serogroup A: Day 0 before dose 1 (n=94, 89)	3.00 (2.58 to 3.49)	2.86 (2.49 to 3.28)		
PPAS1: Serogroup A: Day 30 post dose 2 (n=91, 0)	14.8 (10.6 to 20.8)	9999 (9999 to 9999)		
PPAS1: Serogroup A: Day 30 post dose 3 (n=0, 88)	9999 (9999 to 9999)	23.0 (17.1 to 30.9)		
PPAS1: Serogroup C: Day 0 before dose 1 (n=94, 90)	3.91 (3.16 to 4.84)	3.88 (3.25 to 4.62)		
PPAS1: Serogroup C: Day 30 post dose 2 (n=95, 0)	309 (235 to 407)	9999 (9999 to 9999)		
PPAS1: Serogroup C: Day 30 post dose 3 (n=0, 90)	9999 (9999 to 9999)	481 (376 to 616)		
PPAS1: Serogroup W: Day 0 before dose 1 (n=94, 90)	2.67 (2.40 to 2.96)	3.08 (2.63 to 3.60)		
PPAS1: Serogroup W: Day 30 post dose 2 (n=96, 0)	102 (79.7 to 131)	9999 (9999 to 9999)		
PPAS1: Serogroup W: Day 30 post dose 3 (n=0, 90)	9999 (9999 to 9999)	196 (156 to 245)		
PPAS1: Serogroup Y: Day 0 before dose 1 (n=94, 90)	2.85 (2.45 to 3.32)	2.76 (2.36 to 3.23)		

PPAS1: Serogroup Y: Day 30 post dose 2 (n=96, 0)	73.4 (57.7 to 93.5)	9999 (9999 to 9999)		
PPAS1: Serogroup Y: Day 30 post dose 3 (n=0, 90)	9999 (9999 to 9999)	150 (116 to 195)		
PPAS2: Serogroup A: Day 0 before dose 3 (n=91, 0)	5.18 (4.22 to 6.37)	9999 (9999 to 9999)		
PPAS2: Serogroup A: Day 30 post dose 3 (n=92, 0)	104 (67.9 to 161)	9999 (9999 to 9999)		
PPAS2: Serogroup A: Day 0 before dose 4 (n=0, 89)	9999 (9999 to 9999)	8.13 (6.33 to 10.4)		
PPAS2: Serogroup A: Day 30 post dose 4 (n=0, 89)	9999 (9999 to 9999)	62.0 (39.9 to 96.4)		
PPAS2: Serogroup C: Day 0 before dose 3 (n=94, 0)	26.2 (18.7 to 36.8)	9999 (9999 to 9999)		
PPAS2: Serogroup C: Day 30 post dose 3 (n=93, 0)	819 (622 to 1078)	9999 (9999 to 9999)		
PPAS2: Serogroup C: Day 0 before dose 4 (n=0, 89)	9999 (9999 to 9999)	56.9 (42.4 to 76.4)		
PPAS2: Serogroup C: Day 30 post dose 4 (n=0, 86)	9999 (9999 to 9999)	791 (608 to 1029)		
PPAS2: Serogroup W: Day 0 before dose 3 (n=93, 0)	39.1 (29.6 to 51.8)	9999 (9999 to 9999)		
PPAS2: Serogroup W: Day 30 post dose 3 (n=87, 0)	1049 (782 to 1406)	9999 (9999 to 9999)		
PPAS2: Serogroup W: Day 0 before dose 4 (n=0, 90)	9999 (9999 to 9999)	92.6 (74.3 to 115)		
PPAS2: Serogroup W: Day 30 post dose 4 (n=0, 86)	9999 (9999 to 9999)	1024 (806 to 1301)		
PPAS2: Serogroup Y: Day 0 before dose 3 (n=94, 0)	33.0 (25.0 to 43.5)	9999 (9999 to 9999)		
PPAS2: Serogroup Y: Day 30 post dose 3 (n=94, 0)	589 (470 to 737)	9999 (9999 to 9999)		
PPAS2: Serogroup Y: Day 0 before dose 4 (n=0, 90)	9999 (9999 to 9999)	85.8 (68.2 to 108)		
PPAS2: Serogroup Y: Day 30 post dose 4 (n=0, 89)	9999 (9999 to 9999)	632 (512 to 780)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 and >=1:8

End point title	Groups 1 and 2: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 and >=1:8[4]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. Dose=D.

End point type	Secondary

End point timeframe:

Day 0 Before Dose 1 (2 MoA) and Day 30 Post Dose 2 (4 MoA); Day 0 Before Dose 3 (12 to 18 MoA) and Day 30 Post Dose 3 (12 to 18 MoA)

Notes:

[4] - 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: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

End point values	Group 1: MenACYW	Group 2: Nimenrix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	554	579		
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1:Serogroup A: >=1:4:Day0 before D1(n=521,519)	31.1 (27.1 to 35.3)	28.3 (24.5 to 32.4)		
PPAS1:Serogroup A:>=1:8: Day0 before D1(n=521,519)	5.6 (3.8 to 7.9)	6.4 (4.4 to 8.8)		
PPAS1:Serogroup A:>=1:4:Day30 post D2(n=508,508)	77.2 (73.3 to 80.7)	88.0 (84.8 to 90.7)		
PPAS1:Serogroup A:>=1:8:Day30 post D2(n=508,508)	63.6 (59.2 to 67.8)	75.8 (71.8 to 79.5)		
PPAS1:Serogroup C:>=1:4:Day0 before D1(n=517,517)	14.3 (11.4 to 17.6)	14.9 (11.9 to 18.3)		
PPAS1:Serogroup C:>=1:8:Day0 before D1(n=517,517)	5.2 (3.5 to 7.5)	5.2 (3.5 to 7.5)		
PPAS1:Serogroup C:>=1:4:Day30 post D2(n=513,521)	99.0 (97.7 to 99.7)	96.4 (94.4 to 97.8)		
PPAS1:Serogroup C:>=1:8:Day30 post D2(n=513,521)	98.8 (97.5 to 99.6)	91.9 (89.3 to 94.1)		
PPAS1:Serogroup W:>=1:4:Day0 before D1(n=520,520)	11.7 (9.1 to 14.8)	11.0 (8.4 to 14.0)		
PPAS1:Serogroup W:>=1:8:Day0 before D1(n=520,520)	3.7 (2.2 to 5.6)	3.5 (2.1 to 5.4)		
PPAS1:Serogroup W:>=1:4:Day30 post D2(n=518,523)	98.6 (97.2 to 99.5)	98.3 (96.8 to 99.2)		
PPAS1:Serogroup W:>=1:8:Day30 post D2(n=518,523)	96.5 (94.6 to 97.9)	94.5 (92.1 to 96.3)		
PPAS1:Serogroup Y:>=1:4:Day0 before D1(n=519,518)	10.0 (7.6 to 12.9)	9.8 (7.4 to 12.7)		
PPAS1:Serogroup Y:>=1:8:Day0 before D1(n=519,518)	6.4 (4.4 to 8.8)	5.6 (3.8 to 7.9)		
PPAS1:Serogroup Y:>=1:4:Day30 post D2(n=516,523)	98.3 (96.7 to 99.2)	97.3 (95.5 to 98.5)		
PPAS1:Serogroup Y:>=1:8:Day30 post D2(n=516,523)	96.5 (94.5 to 97.9)	93.5 (91.0 to 95.5)		
PPAS2:Serogroup A:>=1:4:Day0 before D3(n=540,567)	69.1 (65.0 to 73.0)	73.7 (69.9 to 77.3)		
PPAS2:Serogroup A:>=1:8:Day0 before D3(n=540,567)	33.7 (29.7 to 37.9)	46.2 (42.0 to 50.4)		
PPAS2:Serogroup A:>=1:4:Day30 post D3(n=543,567)	98.2 (96.6 to 99.1)	98.1 (96.6 to 99.0)		
PPAS2:Serogroup A:>=1:8:Day30 post D3(n=543,567)	94.7 (92.4 to 96.4)	96.5 (94.6 to 97.8)		
PPAS2:Serogroup C:>=1:4:Day0 before D3(n=545,572)	92.5 (89.9 to 94.5)	62.1 (57.9 to 66.1)		
PPAS2:Serogroup C:>=1:8:Day0 before D3(n=545,572)	88.1 (85.1 to 90.7)	41.6 (37.5 to 45.8)		
PPAS2:Serogroup C:>=1:4:Day30 post D3(n=550,578)	99.8 (99.0 to 100)	98.1 (96.6 to 99.0)		
PPAS2:Serogroup C:>=1:8:Day30 post D3(n=550,578)	99.6 (98.7 to 100)	95.5 (93.5 to 97.0)		
PPAS2:Serogroup W:>=1:4:Day0 before D3(n=541,567)	96.7 (94.8 to 98.0)	91.2 (88.5 to 93.4)		

PPAS2:Serogroup W:>=1:8:Day0 before D3(n=541,567)	89.1 (86.2 to 91.6)	77.6 (73.9 to 81.0)		
PPAS2:Serogroup W:>=1:4:Day30 post D3(n=547,575)	100 (99.3 to 100)	100 (99.4 to 100)		
PPAS2:Serogroup W:>=1:8:Day30 post D3(n=547,575)	99.8 (99.0 to 100)	99.5 (98.5 to 99.9)		
PPAS2:Serogroup Y:>=1:4:Day0 before D3(n=545,572)	95.8 (93.7 to 97.3)	85.7 (82.5 to 88.4)		
PPAS2:Serogroup Y:>=1:8:Day0 before D3(n=545,572)	87.9 (84.9 to 90.5)	69.6 (65.6 to 73.3)		
PPAS2:Serogroup Y:>=1:4:Day30 post D3(n=554,579)	100 (99.3 to 100)	100 (99.4 to 100)		
PPAS2:Serogroup Y:>=1:8:Day30 post D3(n=554,579)	100 (99.3 to 100)	99.8 (99.0 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 and >=1:8

End point title	Groups 3 and 4: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 and >=1:8[5]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Group 3: Day 0 before Dose 1 (2 MoA) and Dose 3 (12 to 18 MoA) and Day 30 Post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: Day 0 before Dose 1 (2 MoA) and Dose 4 (12 to 18 MoA) and Day 30 Post Dose 3 (6 MoA) and Dose 4 (12 to 18 MoA)

Notes:

[5] - 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: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

End point values	Group 3: MenACYW	Group 4: MenACYW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	90		
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1:Serogroup A:>=1:4:Day0 before D1(n=94,89)	33.0 (23.6 to 43.4)	32.6 (23.0 to 43.3)		
PPAS1:Serogroup A:>=1:8:Day0 before D1(n=94,89)	14.9 (8.4 to 23.7)	11.2 (5.5 to 19.7)		
PPAS1:Serogroup A:>=1:4:Day30 post D2(n=91,0)	79.1 (69.3 to 86.9)	9999 (9999 to 9999)		
PPAS1:Serogroup A:>=1:8:Day30 post D2(n=91,0)	63.7 (53.0 to 73.6)	9999 (9999 to 9999)		

PPAS1:Serogroup A:>=1:4:Day30 post D3(n=0,88)	9999 (9999 to 9999)	92.0 (84.3 to 96.7)		
PPAS1:Serogroup A:>=1:8:Day30 post D3(n=0,88)	9999 (9999 to 9999)	81.8 (72.2 to 89.2)		
PPAS1:Serogroup C:>=1:4:Day0 before D1(n=94,90)	43.6 (33.4 to 54.2)	48.9 (38.2 to 59.7)		
PPAS1:Serogroup C:>=1:8:Day0 before D1(n=94,90)	26.6 (18.0 to 36.7)	32.2 (22.8 to 42.9)		
PPAS1:Serogroup C:>=1:4:Day30 post D2(n=95,0)	98.9 (94.3 to 100)	9999 (9999 to 9999)		
PPAS1:Serogroup C:>=1:8:Day30 post D2(n=95,0)	98.9 (94.3 to 100)	9999 (9999 to 9999)		
PPAS1:Serogroup C:>=1:4:Day30 post D3(n=0,90)	9999 (9999 to 9999)	98.9 (94.0 to 100)		
PPAS1:Serogroup C:>=1:8:Day30 post D3(n=0,90)	9999 (9999 to 9999)	98.9 (94.0 to 100)		
PPAS1:Serogroup W:>=1:4:Day0 before D1(n=94,90)	28.7 (19.9 to 39.0)	35.6 (25.7 to 46.3)		
PPAS1:Serogroup W:>=1:8:Day0 before D1(n=94,90)	10.6 (5.2 to 18.7)	16.7 (9.6 to 26.0)		
PPAS1:Serogroup W:>=1:4:Day30 post D2(n=96,0)	99.0 (94.3 to 100)	9999 (9999 to 9999)		
PPAS1:Serogroup W:>=1:8:Day30 post D2(n=96,0)	96.9 (91.1 to 99.4)	9999 (9999 to 9999)		
PPAS1:Serogroup W:>=1:4:Day30 post D3(n=0,90)	9999 (9999 to 9999)	98.9 (94.0 to 100)		
PPAS1:Serogroup W:>=1:8:Day30 post D3(n=0,90)	9999 (9999 to 9999)	98.9 (94.0 to 100)		
PPAS1:Serogroup Y:>=1:4:Day0 before D1(n=94,90)	26.6 (18.0 to 36.7)	22.2 (14.1 to 32.2)		
PPAS1:Serogroup Y:>=1:8:Day0 before D1(n=94,90)	12.8 (6.8 to 21.2)	12.2 (6.3 to 20.8)		
PPAS1:Serogroup Y:>=1:4:Day30 post D2(n=96,0)	99.0 (94.3 to 100)	9999 (9999 to 9999)		
PPAS1:Serogroup Y:>=1:8:Day30 post D2(n=96,0)	95.8 (89.7 to 98.9)	9999 (9999 to 9999)		
PPAS1:Serogroup Y:>=1:4:Day30 post D3(n=0,90)	9999 (9999 to 9999)	98.9 (94.0 to 100)		
PPAS1:Serogroup Y:>=1:8:Day30 post D3(n=0,90)	9999 (9999 to 9999)	98.9 (94.0 to 100)		
PPAS2:Serogroup A:>=1:4:Day0 before D3(n=91,0)	65.9 (55.3 to 75.5)	9999 (9999 to 9999)		
PPAS2:Serogroup A:>=1:8:Day0 before D3(n=91,0)	37.4 (27.4 to 48.1)	9999 (9999 to 9999)		
PPAS2:Serogroup A:>=1:4:Day30 post D3(n=92,0)	92.4 (84.9 to 96.9)	9999 (9999 to 9999)		
PPAS2:Serogroup A:>=1:8:Day30 post D3(n=92,0)	89.1 (80.9 to 94.7)	9999 (9999 to 9999)		
PPAS2:Serogroup A:>=1:4:Day0 before D4(n=0,89)	9999 (9999 to 9999)	80.9 (71.2 to 88.5)		
PPAS2:Serogroup A:>=1:8:Day0 before D4(n=0,89)	9999 (9999 to 9999)	52.8 (41.9 to 63.5)		
PPAS2:Serogroup A:>=1:4:Day30 post D4(n=0,89)	9999 (9999 to 9999)	82.0 (72.5 to 89.4)		
PPAS2: Serogroup A: >=1:8: Day 30 post D4(n=0,89)	9999 (9999 to 9999)	82.0 (72.5 to 89.4)		
PPAS2:Serogroup C:>=1:4:Day0 before D3(n=94,0)	87.2 (78.8 to 93.2)	9999 (9999 to 9999)		
PPAS2:Serogroup C:>=1:8:Day0 before D3(n=94,0)	79.8 (70.2 to 87.4)	9999 (9999 to 9999)		
PPAS2:Serogroup C:>=1:4:Day30 post D3(n=93,0)	100 (96.1 to 100)	9999 (9999 to 9999)		

PPAS2:Serogroup C:>=1:8:Day30 post D3(n=93,0)	100 (96.1 to 100)	9999 (9999 to 9999)		
PPAS2:Serogroup C:>=1:4:Day0 before D4(n=0,89)	9999 (9999 to 9999)	97.8 (92.1 to 99.7)		
PPAS2:Serogroup C:>=1:8:Day0 before D4(n=0,89)	9999 (9999 to 9999)	92.1 (84.5 to 96.8)		
PPAS2:Serogroup C:>=1:4:Day30 post D4(n=0,86)	9999 (9999 to 9999)	100 (95.8 to 100)		
PPAS2:Serogroup C:>=1:8:Day30 post D4(n=0,86)	9999 (9999 to 9999)	100 (95.8 to 100)		
PPAS2:Serogroup W:>=1:4:Day0 before D3(n=93,0)	96.8 (90.9 to 99.3)	9999 (9999 to 9999)		
PPAS2:Serogroup W:>=1:8:Day0 before D3(n=93,0)	92.5 (85.1 to 96.9)	9999 (9999 to 9999)		
PPAS2:Serogroup W:>=1:4:Day30 post D3(n=87,0)	100 (95.8 to 100)	9999 (9999 to 9999)		
PPAS2:Serogroup W:>=1:8:Day30 post D3(n=87,0)	100 (95.8 to 100)	9999 (9999 to 9999)		
PPAS2:Serogroup W:>=1:4:Day0 before D4(n=0,90)	9999 (9999 to 9999)	100 (96.0 to 100)		
PPAS2:Serogroup W:>=1:8:Day0 before D4(n=0,90)	9999 (9999 to 9999)	100 (96.0 to 100)		
PPAS2:Serogroup W:>=1:4:Day30 post D4(n=0,86)	9999 (9999 to 9999)	100 (95.8 to 100)		
PPAS2:Serogroup W:>=1:8:Day30 post D4(n=0,86)	9999 (9999 to 9999)	100 (95.8 to 100)		
PPAS2:Serogroup Y:>=1:4:Day0 before D3(n=94,0)	94.7 (88.0 to 98.3)	9999 (9999 to 9999)		
PPAS2:Serogroup Y:>=1:8:Day0 before D3(n=94,0)	89.4 (81.3 to 94.8)	9999 (9999 to 9999)		
PPAS2:Serogroup Y:>=1:4:Day30 post D3(n=94,0)	100 (96.2 to 100)	9999 (9999 to 9999)		
PPAS2:Serogroup Y:>=1:8:Day30 post D3(n=94,0)	100 (96.2 to 100)	9999 (9999 to 9999)		
PPAS2:Serogroup Y:>=1:4:Day0 before D4(n=0,90)	9999 (9999 to 9999)	100 (96.0 to 100)		
PPAS2:Serogroup Y:>=1:8:Day0 before D4(n=0,90)	9999 (9999 to 9999)	100 (96.0 to 100)		
PPAS2:Serogroup Y:>=1:4:Day30 post D4(n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2:Serogroup Y:>=1:8:Day30 post D4(n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Percentage of Participants With Vaccine Seroresponse

End point title	Groups 1 and 2: Percentage of Participants With Vaccine Seroresponse[6]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. hSBA vaccine seroresponse was defined for a participant with a pre vaccination titer <1:8, post-vaccination titer must be >=1:16 and for a participant with a pre vaccination titer >=1:8, post-vaccination titer must be at least 4-fold greater than the pre vaccination titer. Percentages are rounded off to tenth decimal place. PPAS1 was subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was subset of FAS2. FAS2: subset of

randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

End point type	Secondary

End point timeframe:

Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA)

Notes:

[6] - 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: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

End point values	Group 1: MenACYW	Group 2: Nimenrix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	551	575		
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1: Serogroup A: Day 30 post dose 2 (n=507,504)	46.7 (42.3 to 51.2)	60.9 (56.5 to 65.2)		
PPAS1: Serogroup C: Day 30 post dose 2 (n=508,514)	97.4 (95.7 to 98.6)	86.8 (83.5 to 89.6)		
PPAS1: Serogroup W: Day 30 post dose 2 (n=516,519)	92.6 (90.0 to 94.7)	88.4 (85.4 to 91.1)		
PPAS1: Serogroup Y: Day 30 post dose 2 (n=513,517)	87.1 (83.9 to 89.9)	81.4 (77.8 to 84.7)		
PPAS2: Serogroup A: Day 30 post dose 3 (n=542,564)	90.6 (87.8 to 92.9)	91.7 (89.1 to 93.8)		
PPAS2: Serogroup C: Day 30 post dose 3 (n=545,573)	98.7 (97.4 to 99.5)	91.3 (88.7 to 93.5)		
PPAS2: Serogroup W: Day 30 post dose 3 (n=545,572)	99.4 (98.4 to 99.9)	98.4 (97.0 to 99.3)		
PPAS2: Serogroup Y: Day 30 post dose 3 (n=551,575)	98.7 (97.4 to 99.5)	96.9 (95.1 to 98.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Percentage of Participants With Vaccine Seroresponse

End point title	Groups 3 and 4: Percentage of Participants With Vaccine Seroresponse[7]

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing hSBA. hSBA vaccine seroresponse was defined for a participant with a pre vaccination titer <1:8, post-vaccination titer must be >=1:16 and for a participant with a pre vaccination titer >=1:8, post-vaccination titer must be at least 4-fold greater than pre vaccination titer. Percentages are rounded off to tenth decimal place. PPAS1 was a subset of FAS1. PPAS2 was a subset of FAS2. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed.

End point type	Secondary

End point timeframe:

Group 3: Day 30 Post Dose 2 (4 MoA), Day 30 Post Dose 3 (12 to 18 MoA); Group 4: D30 Post Dose 3 (6 MoA), Day 30 Post Dose 4 (12 to 18 MoA)

Notes:

[7] - 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: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

End point values	Group 3: MenACYW	Group 4: MenACYW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	90		
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1: Serogroup A: Day 30 post dose 2 (n=89,0)	51.7 (40.8 to 62.4)	9999 (9999 to 9999)		
PPAS1: Serogroup A: Day 30 post dose 3 (n=0,87)	9999 (9999 to 9999)	65.5 (54.6 to 75.4)		
PPAS1: Serogroup C: Day 30 post dose 2 (n=93,0)	92.5 (85.1 to 96.9)	9999 (9999 to 9999)		
PPAS1: Serogroup C: Day 30 post dose 3 (n=0,90)	9999 (9999 to 9999)	96.7 (90.6 to 99.3)		
PPAS1: Serogroup W: Day 30 post dose 2 (n=94,0)	94.7 (88.0 to 98.3)	9999 (9999 to 9999)		
PPAS1: Serogroup W: Day 30 post dose 3 (n=0,90)	9999 (9999 to 9999)	95.6 (89.0 to 98.8)		
PPAS1: Serogroup Y: Day 30 post dose 2 (n=94,0)	89.4 (81.3 to 94.8)	9999 (9999 to 9999)		
PPAS1: Serogroup Y: Day 30 post dose 3 (n=0,90)	9999 (9999 to 9999)	94.4 (87.5 to 98.2)		
PPAS2: Serogroup A: Day 30 post dose 3 (n=90,0)	77.8 (67.8 to 85.9)	9999 (9999 to 9999)		
PPAS2: Serogroup A: Day 30 post dose 4 (n=0,88)	9999 (9999 to 9999)	63.6 (52.7 to 73.6)		
PPAS2: Serogroup C: Day 30 post dose 3 (n=93,0)	97.8 (92.4 to 99.7)	9999 (9999 to 9999)		
PPAS2: Serogroup C: Day 30 post dose 4 (n=0,86)	9999 (9999 to 9999)	95.3 (88.5 to 98.7)		
PPAS2: Serogroup W: Day 30 post dose 3 (n=86,0)	97.7 (91.9 to 99.7)	9999 (9999 to 9999)		
PPAS2: Serogroup W: Day 30 post dose 4 (n=0,86)	9999 (9999 to 9999)	89.5 (81.1 to 95.1)		
PPAS2: Serogroup Y: Day 30 post dose 3 (n=94,0)	91.5 (83.9 to 96.3)	9999 (9999 to 9999)		
PPAS2: Serogroup Y: Day 30 post dose 4 (n=0,89)	9999 (9999 to 9999)	80.9 (71.2 to 88.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies

End point title	Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies

End point description:

GMCs of anti-pertussis antibodies (pertussis toxin [PT], filamentous hemagglutinin [FHA]) were measured by electrochemiluminescent (ECL) assay. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had

valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: Day 0 before Dose 1 (2 MoA); Group 4: Day 0 before Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	520	521	95	90
Units: Titer				
geometric mean (confidence interval 95%)				
PPAS1: Anti-PT: Day 0 before D1 (n=520,521,95,0)	2.97 (2.68 to 3.29)	2.61 (2.38 to 2.87)	11.0 (8.74 to 14.0)	9999 (9999 to 9999)
PPAS1: Anti-FHA: Day 0 before D1 (n=520,521,95,0)	10.8 (9.73 to 12.1)	10.1 (9.10 to 11.2)	55.6 (42.4 to 73.0)	9999 (9999 to 9999)
PPAS2: Anti-PT: Day 0 before D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	10.7 (8.82 to 13.1)
PPAS2: Anti-FHA: Day 0 before D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	30.3 (25.0 to 36.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations of Hexavalent Vaccines

End point title	Geometric Mean Concentrations of Hexavalent Vaccines

End point description:

GMCs of hexavalent vaccines were measured as:anti-diphtheria (AD),anti-tetanus (AT), anti-pertussis antibodies (PT, FHA) by ECL assay,anti-hepatitis antibodies (anti-Hepatitis B surface antigen [HBsAg]) by the commercially available VITROS ECi/ECiQ, anti-poliovirus(AP) types 1, 2, and 3 by neutralization assay and anti-Haemophilus influenzae type b (anti-polyribosylribitol phosphate [PRP]) by Farr-type radioimmunoassay (RIA). PPAS1: subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2: subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999':no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Day 0 Before Dose 3 (12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	555	583	96	90
Units: Titer				
geometric mean (confidence interval 95%)				
PPAS1: AD: Day 30 after D2 (n=514,520,93,0)	0.523 (0.474 to 0.578)	0.489 (0.443 to 0.541)	0.563 (0.458 to 0.691)	9999 (9999 to 9999)
PPAS1: AT: Day 30 after D2 (n=514,520,93,0)	1.10 (1.02 to 1.18)	1.13 (1.05 to 1.22)	0.931 (0.788 to 1.10)	9999 (9999 to 9999)
PPAS1: Anti-PT: Day 30 after D2 (n=514,520,93,0)	64.9 (61.4 to 68.7)	68.1 (64.5 to 72.0)	50.0 (43.2 to 58.0)	9999 (9999 to 9999)
PPAS1: Anti-FHA: Day 30 after D2 (n=514,520,93,0)	92.4 (87.3 to 97.8)	96.6 (90.8 to 103)	125 (109 to 144)	9999 (9999 to 9999)
PPAS1: Anti-HBsAg:Day30 after D2 (n=505,510,92,0)	369 (323 to 421)	345 (303 to 393)	218 (147 to 322)	9999 (9999 to 9999)
PPAS1: AP 1: Day 30 after D2 (n=486,489,83,0)	47.1 (40.1 to 55.3)	43.5 (37.0 to 51.2)	362 (260 to 504)	9999 (9999 to 9999)
PPAS1: AP 2: Day 30 after D2 (n=482,485,79,0)	139 (117 to 167)	143 (120 to 171)	618 (429 to 890)	9999 (9999 to 9999)
PPAS1: AP 3: Day 30 after D2 (n=488,492,82,0)	133 (112 to 157)	145 (123 to 172)	584 (419 to 814)	9999 (9999 to 9999)
PPAS1: Anti-PRP: Day 30 after D2 (n=517,521,96,0)	0.376 (0.326 to 0.435)	0.435 (0.379 to 0.499)	0.725 (0.492 to 1.07)	9999 (9999 to 9999)
PPAS2: AD: Day 0 before D3 (n=542,569,91,0)	0.086 (0.079 to 0.095)	0.080 (0.073 to 0.087)	0.094 (0.076 to 0.116)	9999 (9999 to 9999)
PPAS2: AD: Day 30 after D3 (n=551,577,92,0)	1.82 (1.69 to 1.96)	1.69 (1.57 to 1.81)	2.71 (2.36 to 3.11)	9999 (9999 to 9999)
PPAS2: AD: Day 30 after D4 (n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	3.26 (2.88 to 3.69)
PPAS2: AT: Day 0 before D3 (n=542,571,92,0)	0.362 (0.336 to 0.391)	0.424 (0.397 to 0.453)	0.218 (0.180 to 0.264)	9999 (9999 to 9999)
PPAS2: AT: Day 30 after D3 (n=551,577,92,0)	6.71 (6.33 to 7.12)	8.59 (8.13 to 9.08)	6.02 (5.06 to 7.16)	9999 (9999 to 9999)
PPAS2: AT: Day 30 after D4 (n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	7.00 (5.99 to 8.18)
PPAS2: Anti-PT: Day 0 before D3 (n=542,571,92,0)	14.8 (13.8 to 15.8)	14.6 (13.7 to 15.6)	10.4 (8.99 to 12.0)	9999 (9999 to 9999)
PPAS2: Anti-PT: Day 30 after D3 (n=551,577,92,0)	111 (105 to 118)	109 (104 to 115)	79.2 (66.2 to 94.6)	9999 (9999 to 9999)
PPAS2: Anti-PT: Day 30 after D4 (n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	80.9 (68.2 to 95.9)
PPAS2: Anti-FHA: Day 0 before D3 (n=542,571,92,0)	38.4 (35.8 to 41.2)	38.1 (35.5 to 40.8)	30.6 (26.0 to 36.0)	9999 (9999 to 9999)
PPAS2: Anti-FHA: Day 30 after D3 (n=551,577,92,0)	177 (167 to 187)	184 (173 to 195)	168 (142 to 200)	9999 (9999 to 9999)
PPAS2: Anti-FHA: Day 30 after D4 (n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	181 (151 to 217)
PPAS2: Anti-HBsAg:Day0 before D3 (n=535,565,91,0)	53.0 (45.5 to 61.8)	48.8 (42.1 to 56.5)	26.0 (17.6 to 38.2)	9999 (9999 to 9999)
PPAS2:Anti-HBsAg:Day30 after D3 (n=546,571,90,0)	2273 (1927 to 2681)	2158 (1852 to 2515)	1117 (666 to 1872)	9999 (9999 to 9999)
PPAS2:Anti-HBsAg:Day30 after D4 (n=0,0,0,86)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	1144 (648 to 2020)
PPAS2: AP 1: Day 0 before D3 (n=526,559,89,0)	14.5 (12.7 to 16.5)	13.6 (12.0 to 15.4)	55.2 (40.8 to 74.6)	9999 (9999 to 9999)
PPAS2: AP 1: Day 30 after D3 (n=533,553,86,0)	1099 (980 to 1233)	994 (883 to 1119)	1538 (1212 to 1952)	9999 (9999 to 9999)
PPAS2: AP 1: Day 30 after D4 (n=0,0,0,87)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	1625 (1291 to 2047)

PPAS2: AP 2: Day 0 before D3 (n=528,560,88,0)	33.2 (28.7 to 38.4)	33.1 (28.8 to 37.9)	85.3 (63.9 to 114)	9999 (9999 to 9999)
PPAS2: AP 2: Day 30 after D3 (n=530,554,87,0)	2214 (1982 to 2472)	2146 (1937 to 2379)	3549 (2846 to 4425)	9999 (9999 to 9999)
PPAS2: AP 2: Day 30 after D4 (n=0,0,0,87)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	3858 (3001 to 4960)
PPAS2: AP 3: Day 0 before D3 (n=529,560,89,0)	19.7 (17.1 to 22.6)	18.4 (16.0 to 21.1)	37.7 (27.6 to 51.5)	9999 (9999 to 9999)
PPAS2: AP 3: Day 30 after D3 (n=531,557,87,0)	1595 (1393 to 1827)	1533 (1361 to 1728)	2431 (1897 to 3115)	9999 (9999 to 9999)
PPAS2: AP 3: Day 30 after D4 (n=0,0,0,87)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	3397 (2567 to 4495)
PPAS2: Anti-PRP: Day 0 before D3 (n=545,571,93,0)	0.201 (0.176 to 0.230)	0.224 (0.197 to 0.255)	0.244 (0.174 to 0.343)	9999 (9999 to 9999)
PPAS2: Anti-PRP: Day 30 after D3 (n=555,583,91,0)	9.42 (8.31 to 10.7)	11.5 (10.3 to 12.9)	16.1 (11.9 to 21.6)	9999 (9999 to 9999)
PPAS2: Anti-PRP: Day 30 after D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	16.1 (12.1 to 21.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Response Rate for Anti-Diphtheria, Anti-Tetanus, Anti-Poliovirus Types 1, 2, and 3, Anti-Haemophilus Influenzae Type b (Anti-PRP)

End point title	Percentage of Participants With Response Rate for Anti-Diphtheria, Anti-Tetanus, Anti-Poliovirus Types 1, 2, and 3, Anti-Haemophilus Influenzae Type b (Anti-PRP)

End point description:

GMCs of AD, AT, AP types 1, 2, and 3, anti-haemophilus influenzae type b (anti-PRP) vaccines were measured as AD, AT by ECL assay, AP types 1, 2, and 3 by neutralization assay and anti-Haemophilus influenzae type b (anti-PRP) by Farr-type RIA. Response rate was defined as percentage of participants who achieved: AD and AT antibody concentrations >=0.01 international units (IU)/milliliter (mL), >=0.1 IU/mL and>=1.0 IU/mL; AP types 1, 2, and 3 antibody titers >=1:8; anti-PRP antibody concentrations >=0.15 microgram(mcg)/mL and >=1 mcg/mL. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. PPAS2 was a subset of FAS2. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Day 0 Before Dose 3 (12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	555	583	96	90
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1:AD:>=0.01IU/mL:Day30 post D2(n=514,520,93,0)	100 (99.3 to 100)	99.8 (98.9 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS1:AD:>=0.1IU/mL:Day30 post D2(n=514,520,93,0)	90.5 (87.6 to 92.9)	89.6 (86.7 to 92.1)	94.6 (87.9 to 98.2)	9999 (9999 to 9999)

PPAS1:AD:>=1.0IU/mL:Day30 post D2(n=514,520,93,0)	32.7 (28.6 to 36.9)	32.5 (28.5 to 36.7)	33.3 (23.9 to 43.9)	9999 (9999 to 9999)
PPAS1:AT:>=0.01IU/mL:Day30 post D2(n=514,520,93,0)	100 (99.3 to 100)	100 (99.3 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS1:AT:>=0.1IU/mL:Day30 post D2(n=514,520,93,0)	100 (99.3 to 100)	99.8 (98.9 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS1:AT:>=1.0IU/mL:Day30 post D2(n=514,520,93,0)	53.3 (48.9 to 57.7)	56.3 (52.0 to 60.7)	44.1 (33.8 to 54.8)	9999 (9999 to 9999)
PPAS1:AP 1:>=1:8:Day30 post D2(n=486,489,83,0)	87.0 (83.7 to 89.9)	83.2 (79.6 to 86.4)	98.8 (93.5 to 100)	9999 (9999 to 9999)
PPAS1:AP 2:>=1:8:Day30 post D2(n=482,485,79,0)	97.5 (95.7 to 98.7)	98.6 (97.0 to 99.4)	100 (95.4 to 100)	9999 (9999 to 9999)
PPAS1:AP 3:>=1:8:Day30 post D2(n=488,492,82,0)	95.9 (93.7 to 97.5)	96.1 (94.0 to 97.7)	98.8 (93.4 to 100)	9999 (9999 to 9999)
PPAS1:Anti-PRP:>=0.15:Day30 postD2(n=517,521,96,0)	71.8 (67.7 to 75.6)	74.9 (70.9 to 78.5)	78.1 (68.5 to 85.9)	9999 (9999 to 9999)
PPAS1:Anti-PRP:>=1:Day30 postD2(n=517,521,96,0)	24.2 (20.5 to 28.1)	27.3 (23.5 to 31.3)	39.6 (29.7 to 50.1)	9999 (9999 to 9999)
PPAS2:AD:>=0.01IU/mL:Day0 beforeD3(n=542,569,91,0)	98.2 (96.6 to 99.1)	98.6 (97.2 to 99.4)	97.8 (92.3 to 99.7)	9999 (9999 to 9999)
PPAS2:AD:>=0.01IU/mL:Day30 afterD3(n=551,577,92,0)	100 (99.3 to 100)	100 (99.4 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS2:AD:>=0.01IU/mL:Day30 afterD4(n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.9 to 100)
PPAS2:AD:>=0.1IU/mL:Day0 beforeD3(n=542,569,91,0)	48.2 (43.9 to 52.5)	41.3 (37.2 to 45.5)	47.3 (36.7 to 58.0)	9999 (9999 to 9999)
PPAS2:AD:>=0.1IU/mL:Day30 afterD3(n=551,577,92,0)	99.6 (98.7 to 100)	99.8 (99.0 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS2:AD:>=0.1IU/mL:Day30 afterD4(n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.9 to 100)
PPAS2:AD:>=1.0IU/mL:Day0 beforeD3(n=542,569,91,0)	1.1 (0.4 to 2.4)	0.7 (0.2 to 1.8)	0 (0 to 4.0)	9999 (9999 to 9999)
PPAS2:AD:>=1.0IU/mL:Day30 afterD3(n=551,577,92,0)	75.5 (71.7 to 79.0)	72.4 (68.6 to 76.1)	92.4 (84.9 to 96.9)	9999 (9999 to 9999)
PPAS2:AD:>=1.0IU/mL:Day30 afterD4(n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.9 to 100)
PPAS2:AT:>=0.01IU/mL:Day0 beforeD3(n=542,571,92,0)	100 (99.3 to 100)	100 (99.4 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS2:AT:>=0.01IU/mL:Day30 afterD3(n=551,577,92,0)	100 (99.3 to 100)	100 (99.4 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS2:AT:>=0.01IU/mL:Day30 afterD4(n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.9 to 100)
PPAS2:AT:>=0.1IU/mL:Day0 beforeD3(n=542,571,92,0)	94.1 (91.8 to 95.9)	97.4 (95.7 to 98.5)	83.7 (74.5 to 90.6)	9999 (9999 to 9999)
PPAS2:AT:>=0.1IU/mL:Day30 afterD3(n=551,577,92,0)	100 (99.3 to 100)	100 (99.4 to 100)	100 (96.1 to 100)	9999 (9999 to 9999)
PPAS2:AT:>=0.1IU/mL:Day30 afterD4(n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.9 to 100)
PPAS2:AT:>=1.0IU/mL:Day0 beforeD3(n=542,571,92,0)	10.7 (8.2 to 13.6)	14.7 (11.9 to 17.9)	6.5 (2.4 to 13.7)	9999 (9999 to 9999)
PPAS2:AT:>=1.0IU/mL:Day30 afterD3(n=551,577,92,0)	99.6 (98.7 to 100)	99.7 (98.8 to 100)	96.7 (90.8 to 99.3)	9999 (9999 to 9999)
PPAS2:AT:>=1.0IU/mL:Day30 afterD4(n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	98.9 (93.9 to 100)
PPAS2:AP 1:>=1:8:Day0 before D3(n=526,559,89,0)	64.4 (60.2 to 68.5)	63.7 (59.5 to 67.7)	93.3 (85.9 to 97.5)	9999 (9999 to 9999)
PPAS2:AP 1:>=1:8:Day30 after D3(n=533,553,86,0)	99.8 (99.0 to 100)	98.9 (97.7 to 99.6)	100 (95.8 to 100)	9999 (9999 to 9999)
PPAS2:AP 1:>=1:8:Day30 after D4(n=0,0,0,87)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.8 to 100)
PPAS2:AP 2:>=1:8:Day0 before D3(n=528,560,88,0)	79.5 (75.8 to 82.9)	80.9 (77.4 to 84.1)	95.5 (88.8 to 98.7)	9999 (9999 to 9999)

PPAS2:AP 2:>=1:8:Day30 after D3(n=530,554,87,0)	100 (99.3 to 100)	100 (99.3 to 100)	100 (95.8 to 100)	9999 (9999 to 9999)
PPAS2:AP 2:>=1:8:Day30 after D4(n=0,0,0,87)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.8 to 100)
PPAS2:AP 3:>=1:8:Day0 before D3(n=529,560,89,0)	68.6 (64.5 to 72.6)	65.7 (61.6 to 69.6)	84.3 (75.0 to 91.1)	9999 (9999 to 9999)
PPAS2:AP 3:>=1:8:Day30 after D3(n=531,557,87,0)	99.2 (98.1 to 99.8)	99.8 (99.0 to 100)	100 (95.8 to 100)	9999 (9999 to 9999)
PPAS2:AP 3:>=1:8:Day30 after D4(n=0,0,0,87)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (95.8 to 100)
PPAS2:Anti-PRP:>=0.15:Day0beforeD3(n=545,571,	56.5 (52.2 to 60.7)	60.4 (56.3 to 64.5)	60.2 (49.5 to 70.2)	9999 (9999 to 9999)
PPAS2:Anti-PRP:>=0.15:Day30afterD3(n=555,583,	98.2 (96.7 to 99.1)	98.8 (97.5 to 99.5)	100 (96.0 to 100)	9999 (9999 to 9999)
PPAS2:Anti-PRP:>=0.15:Day30afterD4(n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (96.0 to 100)
PPAS2:Anti-PRP:>=1:Day0beforeD3(n=545,571,93,	13.9 (11.1 to 17.1)	14.9 (12.1 to 18.1)	15.1 (8.5 to 24.0)	9999 (9999 to 9999)
PPAS2:Anti-PRP:>=1:Day30afterD3(n=555,583,91,	91.5 (88.9 to 93.7)	94.9 (92.7 to 96.5)	97.8 (92.3 to 99.7)	9999 (9999 to 9999)
PPAS2:Anti-PRP:>=1:Day30afterD4(n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	96.7 (90.6 to 99.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Vaccine Seroresponse for Anti-Pertussis Antibodies

End point title	Percentage of Participants who Achieved Vaccine Seroresponse for Anti-Pertussis Antibodies

End point description:

GMCs of anti-pertussis antibodies (PT, FHA) were measured by ECL assay. Pertussis vaccine seroresponse was defined as: For groups 1, 2, and 3, 30 days after dose 2 in infancy as if pre-primary vaccination concentration is <4 × lower limit of quantification (LLOQ), post-primary vaccination concentration >=4 × LLOQ, if pre-primary vaccination concentration is >=4 ×LLOQ, post-primary vaccination concentration >=pre-primary vaccination concentration; for Groups 1, 2, and 3, before and 30 days after dose 3 and for group 4, before and 30 days after dose 4 as if pre-booster vaccination concentration is <4 × LLOQ, post-booster vaccination concentration >=4 × pre-booster concentration, if pre-booster vaccination concentration is >=4 × LLOQ, post-booster vaccination concentration >=2 × pre-booster concentration. Percentages are rounded off to tenth decimal place. PPAS1 and PPAS2. n=number of participants with data collected for each specific serogroup. '9999': no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	533	565	92	89
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1: Anti-PT: Day 30 post D2 (n=512,518,92,0)	94.5 (92.2 to 96.3)	97.9 (96.2 to 98.9)	82.6 (73.3 to 89.7)	9999 (9999 to 9999)
PPAS1: Anti-FHA: Day 30 post D2 (n=512,518,92,0)	89.6 (86.7 to 92.1)	91.5 (88.8 to 93.8)	62.0 (51.2 to 71.9)	9999 (9999 to 9999)
PPAS2: Anti-PT: Day 30 post D3 (n=533,565,90,0)	97.0 (95.2 to 98.3)	97.0 (95.2 to 98.2)	93.3 (86.1 to 97.5)	9999 (9999 to 9999)
PPAS2: Anti-PT: Day 30 post D4 (n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	88.8 (80.3 to 94.5)
PPAS2: Anti-FHA: Day 30 post D3 (n=533,565,90,0)	89.1 (86.2 to 91.6)	90.1 (87.3 to 92.4)	92.2 (84.6 to 96.8)	9999 (9999 to 9999)
PPAS2: Anti-FHA: Day 30 post D4 (n=0,0,0,89)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.0 (83.1 to 96.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Anti-Hepatitis B Antibody Concentrations >=10 and >=100 Milli-International Units (mIU)/mL

End point title	Percentage of Participants who Achieved Anti-Hepatitis B Antibody Concentrations >=10 and >=100 Milli-International Units (mIU)/mL

End point description:

GMCs of anti-hepatitis antibodies (anti-HBsAg) was measured by the commercially available VITROS ECi/ECiQ. Response rate for anti-HBsAg was defined as percentage of participants who achieved anti-HBsAg antibody concentrations >=10 mIU/mL and >=100 mIU/mL. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and hadvalid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Day 0 Before Dose 3 (12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	546	571	92	90
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1:Anti-HBsAg:>=10:Day30postD2(n=505,510,	96.4 (94.4 to 97.9)	97.8 (96.2 to 98.9)	92.4 (84.9 to 96.9)	9999 (9999 to 9999)
PPAS1:Anti-HBsAg:>=100:Day30postD2(n=505,51	85.7 (82.4 to 88.7)	81.8 (78.1 to 85.0)	72.8 (62.6 to 81.6)	9999 (9999 to 9999)

PPAS2:Anti-HBsAg:>=10:Day0beforeD3(n=535,565	81.5 (77.9 to 84.7)	79.5 (75.9 to 82.7)	65.9 (55.3 to 75.5)	9999 (9999 to 9999)
PPAS2:Anti-HBsAg:>=10:Day30afterD3(n=546,571,	98.0 (96.4 to 99.0)	98.6 (97.3 to 99.4)	94.4 (87.5 to 98.2)	9999 (9999 to 9999)
PPAS2:Anti-HBsAg:>=10:Day0beforeD4(n=0,0,0,90	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	64.4 (53.7 to 74.3)
PPAS2:Anti-HBsAg:>=10:Day30afterD4(n=0,0,0,86	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.9 (83.9 to 96.7)
PPAS2:AntiHBsAg:>=100:Day0beforeD3 (n=535,565,91,0)	38.7 (34.5 to 43.0)	35.4 (31.5 to 39.5)	26.4 (17.7 to 36.7)	9999 (9999 to 9999)
PPAS2:AntiHBsAg:>=100:Day30afterD3 (n=546,571.90,1)	93.4 (91.0 to 95.3)	93.5 (91.2 to 95.4)	80.0 (70.2 to 87.7)	9999 (9999 to 9999)
PPAS2:AntiHBsAg:>=100: Day0beforeD 4(n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	27.8 (18.9 to 38.2)
PPAS2:AntiHBsAg:>=100:Day30afterD4 (n=0,0,0,86)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	83.7 (74.2 to 90.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine

End point title	Groups 1 and 2: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine[8]

End point description:

GMCs of anti-pneumococcal antibodies was assessed by pneumococcal capsular polysaccharide (PnPS) Immunoglobulin G (IgG) ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F) antibodies in human serum. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and hadvalid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

End point type	Secondary

End point timeframe:

At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA)

Notes:

[8] - 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: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

End point values	Group 1: MenACYW	Group 2: Nimenrix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	545	569		
Units: Titer				
geometric mean (confidence interval 95%)				
PPAS1: Serogroup 1 (n=505, 512)	1.68 (1.52 to 1.84)	1.71 (1.56 to 1.87)		
PPAS1: Serogroup 4 (n=505, 512)	1.97 (1.83 to 2.12)	2.06 (1.91 to 2.23)		
PPAS1: Serogroup 5 (n=505, 512)	1.08 (0.991 to 1.17)	1.10 (1.01 to 1.19)		

PPAS1: Serogroup 6B (n=505, 511)	0.600 (0.534 to 0.675)	0.660 (0.586 to 0.742)		
PPAS1: Serogroup 7F (n=505, 512)	2.03 (1.89 to 2.17)	2.20 (2.05 to 2.37)		
PPAS1: Serogroup 9V (n=504, 512)	1.67 (1.54 to 1.81)	1.81 (1.67 to 1.96)		
PPAS1: Serogroup 14 (n=505, 512)	5.92 (5.41 to 6.48)	5.97 (5.44 to 6.55)		
PPAS1: Serogroup 18C (n=505, 512)	0.680 (0.618 to 0.748)	0.796 (0.722 to 0.879)		
PPAS1: Serogroup 19F (n=505, 512)	1.59 (1.39 to 1.82)	1.45 (1.26 to 1.66)		
PPAS1: Serogroup 23F (n=505, 512)	0.830 (0.746 to 0.924)	0.869 (0.785 to 0.961)		
PPAS2: Serogroup 1 (n=545, 569)	4.71 (4.32 to 5.13)	4.54 (4.18 to 4.94)		
PPAS2: Serogroup 4 (n=545, 569)	3.61 (3.37 to 3.86)	3.19 (2.99 to 3.41)		
PPAS2: Serogroup 5 (n=544, 569)	2.21 (2.05 to 2.39)	2.05 (1.90 to 2.20)		
PPAS2: Serogroup 6B (n=545, 569)	4.21 (3.89 to 4.55)	4.36 (4.04 to 4.71)		
PPAS2: Serogroup 7F (n=545, 568)	2.91 (2.73 to 3.10)	2.89 (2.70 to 3.10)		
PPAS2: Serogroup 9V (n=545, 569)	4.08 (3.80 to 4.38)	4.17 (3.89 to 4.47)		
PPAS2: Serogroup 14 (n=544, 568)	9.07 (8.44 to 9.75)	7.89 (7.25 to 8.59)		
PPAS2: Serogroup 18C (n=545, 569)	2.12 (1.99 to 2.26)	2.17 (2.03 to 2.33)		
PPAS2: Serogroup 19F (n=545, 569)	9.03 (8.32 to 9.81)	8.41 (7.76 to 9.12)		
PPAS2: Serogroup 23F (n=545, 569)	2.24 (2.10 to 2.40)	2.04 (1.90 to 2.18)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine

End point title	Groups 3 and 4: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine[9]

End point description:

GMCs of anti-pneumococcal antibodies was assessed by PnPS IgG ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) antibodies in human serum. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and hadvalid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed.

End point type	Secondary

End point timeframe:

Group 3: At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA)

Notes:

[9] - 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: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

End point values	Group 3: MenACYW	Group 4: MenACYW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	89		
Units: Titer				
geometric mean (confidence interval 95%)				
PPAS1: Serogroup 1: 30 days post dose 2(n=89, 0)	1.47 (1.16 to 1.87)	9999 (9999 to 9999)		
PPAS1: Serogroup 3: 30 days post dose 2(n=89,0)	0.658 (0.554 to 0.781)	9999 (9999 to 9999)		
PPAS1: Serogroup 4: 30 days post dose 2(n=89,0)	1.73 (1.42 to 2.12)	9999 (9999 to 9999)		
PPAS1: Serogroup 5: 30 days post dose 2(n=89,0)	0.803 (0.617 to 1.04)	9999 (9999 to 9999)		
PPAS1: Serogroup 6A: 30 days post dose 2(n=89,0)	1.65 (1.24 to 2.19)	9999 (9999 to 9999)		
PPAS1: Serogroup 6B: 30 days post dose 2(n=89,0)	0.275 (0.205 to 0.368)	9999 (9999 to 9999)		
PPAS1: Serogroup 7F: 30 days post dose 2(n=89,0)	3.04 (2.59 to 3.57)	9999 (9999 to 9999)		
PPAS1: Serogroup 9V: 30 days post dose 2(n=89,0)	1.25 (0.987 to 1.59)	9999 (9999 to 9999)		
PPAS1: Serogroup 14: 30 days post dose 2(n=89,0)	5.88 (4.31 to 8.01)	9999 (9999 to 9999)		
PPAS1: Serogroup 18C: 30 days post dose 2(n=89,0)	1.65 (1.30 to 2.10)	9999 (9999 to 9999)		
PPAS1: Serogroup 19A: 30 days post dose 2(n=89,0)	2.17 (1.67 to 2.80)	9999 (9999 to 9999)		
PPAS1: Serogroup 19F: 30 days post dose 2(n=89,0)	5.73 (4.64 to 7.08)	9999 (9999 to 9999)		
PPAS1: Serogroup 23F: 30 days post dose 2(n=89,0)	0.722 (0.552 to 0.945)	9999 (9999 to 9999)		
PPAS2: Serogroup 1: 30 days post dose 3(n=91,0)	5.32 (4.41 to 6.42)	9999 (9999 to 9999)		
PPAS2: Serogroup 1: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	5.47 (4.66 to 6.42)		
PPAS2: Serogroup 3: 30 days post dose 3(n=91,0)	1.13 (0.945 to 1.35)	9999 (9999 to 9999)		
PPAS2: Serogroup 3: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	1.21 (0.982 to 1.50)		
PPAS2: Serogroup 4: 30 days post dose 3(n=91,0)	3.99 (3.43 to 4.64)	9999 (9999 to 9999)		
PPAS2: Serogroup 4: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	3.97 (3.35 to 4.70)		
PPAS2: Serogroup 5: 30 days post dose 3(n=91,0)	3.33 (2.75 to 4.03)	9999 (9999 to 9999)		
PPAS2: Serogroup 5: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	3.95 (3.36 to 4.65)		
PPAS2: Serogroup 6A: 30 days post dose 3(n=91,0)	12.9 (10.9 to 15.4)	9999 (9999 to 9999)		
PPAS2: Serogroup 6A: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	14.3 (12.2 to 16.8)		
PPAS2: Serogroup 6B: 30 days post dose 3(n=91,0)	7.01 (5.38 to 9.13)	9999 (9999 to 9999)		

PPAS2: Serogroup 6B: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	9.41 (7.86 to 11.3)		
PPAS2: Serogroup 7F: 30 days post dose 3(n=91,0)	5.36 (4.56 to 6.29)	9999 (9999 to 9999)		
PPAS2: Serogroup 7F: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	4.92 (4.20 to 5.76)		
PPAS2: Serogroup 9V: 30 days post dose 3(n=91,0)	5.12 (4.26 to 6.17)	9999 (9999 to 9999)		
PPAS2: Serogroup 9V: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	5.40 (4.65 to 6.26)		
PPAS2: Serogroup 14: 30 days post dose 3(n=91,0)	14.8 (12.2 to 18.1)	9999 (9999 to 9999)		
PPAS2: Serogroup 14: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	14.7 (12.1 to 17.9)		
PPAS2: Serogroup 18C: 30 days post dose 3(n=91,0)	3.18 (2.70 to 3.76)	9999 (9999 to 9999)		
PPAS2: Serogroup 18C: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	3.48 (3.00 to 4.03)		
PPAS2: Serogroup 19A: 30 days post dose 3(n=91,0)	8.82 (7.25 to 10.7)	9999 (9999 to 9999)		
PPAS2: Serogroup 19A: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	10.9 (9.26 to 12.9)		
PPAS2: Serogroup 19F: 30 days post dose 3(n=91,0)	12.1 (9.91 to 14.7)	9999 (9999 to 9999)		
PPAS2: Serogroup 19F: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	12.2 (10.5 to 14.2)		
PPAS2: Serogroup 23F: 30 days post dose 3(n=91,0)	3.70 (3.01 to 4.55)	9999 (9999 to 9999)		
PPAS2: Serogroup 23F: 30 days post dose 4(n=0,89)	9999 (9999 to 9999)	4.06 (3.45 to 4.76)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Percentage of Participants with Response Rate >=0.35 mcg/mL for Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine

End point title	Groups 1 and 2: Percentage of Participants with Response Rate >=0.35 mcg/mL for Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine[10]

End point description:

GMCs of anti-pneumococcal antibodies was assessed by PnPS IgG ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F) antibodies in human serum. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and hadvalid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

End point type	Secondary

End point timeframe:

At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA)

Notes:

[10] - 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: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

End point values	Group 1: MenACYW	Group 2: Nimenrix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	545	569		
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1: Serogroup 1 (n=505, 512)	92.7 (90.0 to 94.8)	93.6 (91.1 to 95.5)		
PPAS1: Serogroup 4 (n=505, 512)	96.8 (94.9 to 98.2)	96.7 (94.7 to 98.1)		
PPAS1: Serogroup 5 (n=505, 512)	88.5 (85.4 to 91.2)	90.6 (87.8 to 93.0)		
PPAS1: Serogroup 6B (n=505, 511)	67.1 (62.8 to 71.2)	69.9 (65.7 to 73.8)		
PPAS1: Serogroup 7F (n=505, 512)	98.8 (97.4 to 99.6)	98.2 (96.7 to 99.2)		
PPAS1: Serogroup 9V (n=504, 512)	94.6 (92.3 to 96.4)	95.1 (92.9 to 96.8)		
PPAS1: Serogroup 14 (n=505, 512)	97.8 (96.1 to 98.9)	98.2 (96.7 to 99.2)		
PPAS1: Serogroup 18C (n=505, 512)	72.5 (68.4 to 76.3)	77.3 (73.5 to 80.9)		
PPAS1: Serogroup 19F (n=505, 512)	82.2 (78.6 to 85.4)	79.3 (75.5 to 82.7)		
PPAS1: Serogroup 23F (n=505, 512)	77.8 (73.9 to 81.4)	80.3 (76.6 to 83.6)		
PPAS2: Serogroup 1 (n=545, 569)	99.8 (99.0 to 100)	99.8 (99.0 to 100)		
PPAS2: Serogroup 4 (n=545, 569)	99.8 (99.0 to 100)	99.6 (98.7 to 100)		
PPAS2: Serogroup 5 (n=544, 569)	98.2 (96.6 to 99.1)	97.7 (96.1 to 98.8)		
PPAS2: Serogroup 6B (n=545, 569)	98.9 (97.6 to 99.6)	99.5 (98.5 to 99.9)		
PPAS2: Serogroup 7F (n=545, 568)	99.6 (98.7 to 100)	99.3 (98.2 to 99.8)		
PPAS2: Serogroup 9V (n=545, 569)	99.8 (99.0 to 100)	99.8 (99.0 to 100)		
PPAS2: Serogroup 14 (n=544, 568)	100 (99.3 to 100)	99.3 (98.2 to 99.8)		
PPAS2: Serogroup 18C (n=545, 569)	99.1 (97.9 to 99.7)	98.6 (97.2 to 99.4)		
PPAS2: Serogroup 19F (n=545, 569)	99.3 (98.1 to 99.8)	99.3 (98.2 to 99.8)		
PPAS2: Serogroup 23F (n=545, 569)	98.5 (97.1 to 99.4)	97.2 (95.5 to 98.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Percentage of Participants with Response Rate >=0.35 mcg/mL for Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine

End point title	Groups 3 and 4: Percentage of Participants with Response Rate >=0.35 mcg/mL for Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine[11]

End point description:

GMCs of anti-pneumococcal antibodies was assessed by PnPS IgG ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) antibodies in human serum. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and hadvalid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Group 3: At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA)

Notes:

[11] - 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: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

End point values	Group 3: MenACYW	Group 4: MenACYW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	89		
Units: Percentage of participants				
number (confidence interval 95%)				
PPAS1: Serogroup 1: 30 days post D2 (n=89,0)	89.9 (81.7 to 95.3)	9999 (9999 to 9999)		
PPAS1: Serogroup 3: 30 days post D2 (n=89,0)	82.0 (72.5 to 89.4)	9999 (9999 to 9999)		
PPAS1: Serogroup 4: 30 days post D2 (n=89,0)	96.6 (90.5 to 99.3)	9999 (9999 to 9999)		
PPAS1: Serogroup 5: 30 days post D2 (n=89,0)	76.4 (66.2 to 84.8)	9999 (9999 to 9999)		
PPAS1: Serogroup 6A: 30 days post D2 (n=89,0)	88.8 (80.3 to 94.5)	9999 (9999 to 9999)		
PPAS1: Serogroup 6B: 30 days post D2 (n=89,0)	40.4 (30.2 to 51.4)	9999 (9999 to 9999)		
PPAS1: Serogroup 7F: 30 days post D2 (n=89,0)	97.8 (92.1 to 99.7)	9999 (9999 to 9999)		
PPAS1: Serogroup 9V: 30 days post D2 (n=89,0)	88.8 (80.3 to 94.5)	9999 (9999 to 9999)		
PPAS1: Serogroup 14: 30 days post D2 (n=89,0)	96.6 (90.5 to 99.3)	9999 (9999 to 9999)		
PPAS1: Serogroup 18C: 30 days post D2 (n=89,0)	91.0 (83.1 to 96.0)	9999 (9999 to 9999)		
PPAS1: Serogroup 19A: 30 days post D2 (n=89,0)	93.3 (85.9 to 97.5)	9999 (9999 to 9999)		
PPAS1: Serogroup 19F: 30 days post D2 (n=89,0)	98.9 (93.9 to 100)	9999 (9999 to 9999)		
PPAS1: Serogroup 23F: 30 days post D2 (n=89,0)	71.9 (61.4 to 80.9)	9999 (9999 to 9999)		
PPAS2: Serogroup 1: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 1: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 3: 30 days post D3 (n=91,0)	97.8 (92.3 to 99.7)	9999 (9999 to 9999)		
PPAS2: Serogroup 3: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	92.1 (84.5 to 96.8)		

PPAS2: Serogroup 4: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 4: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 5: 30 days post D3 (n=91,0)	98.9 (94.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 5: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 6A: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 6A: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 6B: 30 days post D3 (n=91,0)	98.9 (94.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 6B: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 7F: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 7F: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 9V: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 9V: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 14: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 14: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 18C: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 18C: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 19A: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 19A: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 19F: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 19F: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		
PPAS2: Serogroup 23F: 30 days post D3 (n=91,0)	100 (96.0 to 100)	9999 (9999 to 9999)		
PPAS2: Serogroup 23F: 30 days post D4 (n=0,89)	9999 (9999 to 9999)	100 (95.9 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations of Anti-Measles, Mumps and Rubella Antibodies

End point title	Geometric Mean Concentrations of Anti-Measles, Mumps and Rubella Antibodies

End point description:

GMCs of anti-measles and anti-rubella antibodies were measured by bulk IgG enzyme immunoassay (EIA) and anti-mumps antibodies were assessed by enzyme-linked immunosorbent assay (ELISA). PPAS2 was a subset of FAS2. FAS2 included subset of randomized participants who received at least 1 dose of the study vaccine at booster vaccination and had a valid post-booster vaccination blood sample

result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: At 30 days post Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	525	553	94	90
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-measles: 30 days post D3 (n=525,553,94,0)	2780 (2581 to 2995)	2919 (2739 to 3110)	3457 (2972 to 4021)	9999 (9999 to 9999)
Anti-measles: 30 days post D4(n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	3933 (3241 to 4773)
Anti-mumps: 30 days post D3(n=525,553,94,0)	83.3 (77.5 to 89.6)	86.1 (80.5 to 92.1)	105 (90.4 to 121)	9999 (9999 to 9999)
Anti-mumps: 30 days post D4(n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	121 (105 to 141)
Anti-rubella: 30 days post D3 (n=525,553,94,0)	56.8 (53.2 to 60.6)	56.0 (52.5 to 59.8)	72.8 (62.7 to 84.6)	9999 (9999 to 9999)
Anti-rubella: 30 days post D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	74.4 (63.7 to 86.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Vaccine Response for Measles, Mumps and Rubella Antibodies

End point title	Percentage of Participants who Achieved Vaccine Response for Measles, Mumps and Rubella Antibodies

End point description:

GMCs of anti-measles and anti-rubella antibodies were measured by bulk IgG EIA and anti-mumps antibodies were assessed by ELISA. Vaccine response against anti-measles, anti-mumps, anti-rubella antibodies were defined as percentage of participants with anti-measles, anti-mumps, anti-rubella antibody concentration that met the respective mentioned criterion: measles: >=255 mIU/mL; mumps: >=10 mumps antibody units/mL and rubella: >=10 IU/mL. Percentages are rounded off to the tenth decimal place. PPAS2 was a subset of FAS2. FAS2 included subset of randomized participants who received at least 1 dose of the study vaccine at booster vaccination and had a valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

End point type	Secondary

End point timeframe:

Groups 1, 2 and 3: At 30 days post Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA)

End point values	Group 1: MenACYW	Group 2: Nimenrix	Group 3: MenACYW	Group 4: MenACYW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	525	553	94	90
Units: Percentage of participants				
number (confidence interval 95%)				
Anti-measles: 30 days post D3 (n=525,553,94,0)	98.3 (96.8 to 99.2)	99.1 (97.9 to 99.7)	100 (96.2 to 100)	9999 (9999 to 9999)
Anti-measles: 30 days post D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	97.8 (92.2 to 99.7)
Anti-mumps: 30 days post D3 (n=525,553,94,0)	98.7 (97.3 to 99.5)	98.7 (97.4 to 99.5)	100 (96.2 to 100)	9999 (9999 to 9999)
Anti-mumps: 30 days post D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (96.0 to 100)
Anti-rubella: 30 days post D3 (n=525,553,94,0)	98.7 (97.3 to 99.5)	97.3 (95.6 to 98.5)	98.9 (94.2 to 100)	9999 (9999 to 9999)
Anti-rubella: 30 days post D4 (n=0,0,0,90)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	100 (96.0 to 100)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs), serious adverse events (SAEs) and deaths: From study vaccine administration (Day 0) until 30 days after last vaccination (Visit 5 [13 to 19 MoA] for Groups 1, 2, and 3 and Visit 6 [13 to 19 MoA] for Group 4), up to 14 to 20 MoA.

Adverse event reporting additional description:

Analysis was performed on the safety analysis set (SafAS)which included those participants who had received at least 1 dose of the study vaccine(s) and had any safety data available.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Group 1: MenACYW

Reporting group description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Reporting group title	Group 4: MenACYW

Reporting group description:

Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.

Reporting group title	Group 2: Nimenrix

Reporting group description:

Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), thePCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Reporting group title	Group 3: MenACYW

Reporting group description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

Serious adverse events	Group 1: MenACYW	Group 4: MenACYW	Group 2: Nimenrix
Total subjects affected by serious adverse events			
subjects affected / exposed	51 / 696 (7.33%)	3 / 108 (2.78%)	57 / 706 (8.07%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Testicular Yolk Sac Tumour Stage Iii			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
General disorders and administration site conditions			
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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			
Interstitial Lung Disease			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	3 / 706 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiration Abnormal			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral Injury			
subjects affected / exposed	0 / 696 (0.00%)	1 / 108 (0.93%)	0 / 706 (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
Concussion			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns Third Degree			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Burns Second Degree			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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

Exposure To Toxic Agent			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Road Traffic Accident			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fracture			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Congenital, familial and genetic disorders			
Laryngomalacia			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Hydronephrosis			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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

Lymphatic Malformation			
subjects affected / exposed	0 / 696 (0.00%)	1 / 108 (0.93%)	0 / 706 (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
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Petit Mal Epilepsy			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Convulsion			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	2 / 706 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clinically Isolated Syndrome			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Immune Thrombocytopenia			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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

Thrombocytopenia			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
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			
Anal Stenosis			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphthous Ulcer			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Diarrhoea			
subjects affected / exposed	2 / 696 (0.29%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Intussusception			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Gastrointestinal Inflammation			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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

Food Protein-Induced Enterocolitis Syndrome			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Enterocolitis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Gastrointestinal Pain			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Regurgitation			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	2 / 706 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urticaria			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Tubulointerstitial Nephritis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Musculoskeletal and connective tissue disorders			
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 696 (0.29%)	0 / 108 (0.00%)	2 / 706 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	6 / 696 (0.86%)	0 / 108 (0.00%)	5 / 706 (0.71%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis Viral			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Norovirus			

subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Adenovirus			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	3 / 696 (0.43%)	0 / 108 (0.00%)	5 / 706 (0.71%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema Subitum			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear Infection			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Cytomegalovirus Infection			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Covid-19			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Candidiasis			

subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Pneumonia			
subjects affected / exposed	1 / 696 (0.14%)	2 / 108 (1.85%)	5 / 706 (0.71%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Media			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	2 / 706 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Mastoiditis			

subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Laryngitis			
subjects affected / exposed	2 / 696 (0.29%)	0 / 108 (0.00%)	2 / 706 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	3 / 696 (0.43%)	0 / 108 (0.00%)	4 / 706 (0.57%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Respiratory Syncytial Viral			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	2 / 706 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 696 (0.00%)	2 / 108 (1.85%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			

subjects affected / exposed	2 / 696 (0.29%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 696 (0.29%)	0 / 108 (0.00%)	0 / 706 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	0 / 696 (0.00%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	1 / 706 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Rhinovirus Infection			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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
Metabolism and nutrition disorders			
Weight Gain Poor			
subjects affected / exposed	1 / 696 (0.14%)	0 / 108 (0.00%)	0 / 706 (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

Serious adverse events	Group 3: MenACYW		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 112 (7.14%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Testicular Yolk Sac Tumour Stage Iii			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Interstitial Lung Disease			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Apnoea				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiration Abnormal				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Insomnia				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Craniocerebral Injury				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns Third Degree				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns Second Degree				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exposure To Toxic Agent				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Road Traffic Accident				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull Fracture				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur Fracture				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Laryngomalacia				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital Hydronephrosis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocele				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Phimosis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphatic Malformation				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Petit Mal Epilepsy			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile Convulsion			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clinically Isolated Syndrome			
subjects affected / exposed	1 / 112 (0.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune Thrombocytopenia			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 112 (0.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anal Stenosis			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aphthous Ulcer			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal Hernia			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal Inflammation			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food Protein-Induced Enterocolitis Syndrome			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Enterocolitis			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspepsia			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal Pain			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Regurgitation			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			

Tubulointerstitial Nephritis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Musculoskeletal Stiffness				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchiolitis				
subjects affected / exposed	2 / 112 (1.79%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis Viral				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Rotavirus				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Norovirus				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Adenovirus				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Gastroenteritis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exanthema Subitum				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Infection				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear Infection				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus Infection				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Candidiasis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia Urinary Tract Infection				
subjects affected / exposed	1 / 112 (0.89%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia Pneumococcal				

subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 112 (1.79%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis Media				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orchitis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastoiditis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				

subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia Respiratory Syncytial Viral				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory Syncytial Virus Bronchiolitis				
subjects affected / exposed	1 / 112 (0.89%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory Syncytial Virus Infection				
subjects affected / exposed	1 / 112 (0.89%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral Upper Respiratory Tract Infection				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				
subjects affected / exposed	0 / 112 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper Respiratory Tract Infection				
subjects affected / exposed	1 / 112 (0.89%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tracheitis				

subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous Abscess			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhinovirus Infection			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Weight Gain Poor			
subjects affected / exposed	0 / 112 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Group 1: MenACYW	Group 4: MenACYW	Group 2: Nimenrix
Total subjects affected by non-serious adverse events			
subjects affected / exposed	678 / 696 (97.41%)	103 / 108 (95.37%)	680 / 706 (96.32%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	529 / 696 (76.01%)	75 / 108 (69.44%)	545 / 706 (77.20%)
occurrences (all)	1094	155	1060
General disorders and administration site conditions			
Injection Site Mass			
subjects affected / exposed	64 / 696 (9.20%)	1 / 108 (0.93%)	60 / 706 (8.50%)
occurrences (all)	139	1	134
Injection Site Pain			

subjects affected / exposed	562 / 696 (80.75%)	76 / 108 (70.37%)	566 / 706 (80.17%)
occurrences (all)	2842	450	2851
Injection Site Swelling			
subjects affected / exposed	422 / 696 (60.63%)	47 / 108 (43.52%)	417 / 706 (59.07%)
occurrences (all)	1445	164	1458
Pyrexia			
subjects affected / exposed	375 / 696 (53.88%)	42 / 108 (38.89%)	345 / 706 (48.87%)
occurrences (all)	570	70	537
Injection Site Induration			
subjects affected / exposed	68 / 696 (9.77%)	4 / 108 (3.70%)	52 / 706 (7.37%)
occurrences (all)	137	6	91
Injection Site Haematoma			
subjects affected / exposed	55 / 696 (7.90%)	16 / 108 (14.81%)	56 / 706 (7.93%)
occurrences (all)	97	21	92
Injection Site Erythema			
subjects affected / exposed	537 / 696 (77.16%)	58 / 108 (53.70%)	520 / 706 (73.65%)
occurrences (all)	2207	188	2169
Injection Site Bruising			
subjects affected / exposed	110 / 696 (15.80%)	4 / 108 (3.70%)	124 / 706 (17.56%)
occurrences (all)	194	7	188
Crying			
subjects affected / exposed	579 / 696 (83.19%)	75 / 108 (69.44%)	579 / 706 (82.01%)
occurrences (all)	1274	158	1279
Gastrointestinal disorders			
Toothache			
subjects affected / exposed	13 / 696 (1.87%)	5 / 108 (4.63%)	8 / 706 (1.13%)
occurrences (all)	16	5	13
Teething			
subjects affected / exposed	99 / 696 (14.22%)	15 / 108 (13.89%)	93 / 706 (13.17%)
occurrences (all)	142	28	135
Diarrhoea			
subjects affected / exposed	55 / 696 (7.90%)	2 / 108 (1.85%)	37 / 706 (5.24%)
occurrences (all)	63	2	44
Vomiting			
subjects affected / exposed	196 / 696 (28.16%)	27 / 108 (25.00%)	197 / 706 (27.90%)
occurrences (all)	268	33	271

Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	16 / 696 (2.30%)	6 / 108 (5.56%)	23 / 706 (3.26%)
occurrences (all)	18	6	25
Dermatitis Diaper			
subjects affected / exposed	6 / 696 (0.86%)	3 / 108 (2.78%)	3 / 706 (0.42%)
occurrences (all)	6	3	4
Dermatitis			
subjects affected / exposed	1 / 696 (0.14%)	6 / 108 (5.56%)	3 / 706 (0.42%)
occurrences (all)	1	7	3
Psychiatric disorders			
Irritability			
subjects affected / exposed	600 / 696 (86.21%)	86 / 108 (79.63%)	608 / 706 (86.12%)
occurrences (all)	1413	217	1426
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	16 / 696 (2.30%)	7 / 108 (6.48%)	21 / 706 (2.97%)
occurrences (all)	16	9	21
Bronchiolitis			
subjects affected / exposed	1 / 696 (0.14%)	12 / 108 (11.11%)	1 / 706 (0.14%)
occurrences (all)	1	13	1
Upper Respiratory Tract Infection			
subjects affected / exposed	54 / 696 (7.76%)	5 / 108 (4.63%)	61 / 706 (8.64%)
occurrences (all)	64	6	71
Rhinitis			
subjects affected / exposed	47 / 696 (6.75%)	1 / 108 (0.93%)	47 / 706 (6.66%)
occurrences (all)	56	1	50
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 696 (0.00%)	22 / 108 (20.37%)	1 / 706 (0.14%)
occurrences (all)	0	31	1
Nasopharyngitis			
subjects affected / exposed	65 / 696 (9.34%)	8 / 108 (7.41%)	64 / 706 (9.07%)
occurrences (all)	80	8	76
Gastroenteritis			
subjects affected / exposed	10 / 696 (1.44%)	9 / 108 (8.33%)	18 / 706 (2.55%)
occurrences (all)	10	11	18
Respiratory Tract Infection			

subjects affected / exposed	7 / 696 (1.01%)	2 / 108 (1.85%)	12 / 706 (1.70%)
occurrences (all)	8	2	13
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	389 / 696 (55.89%)	58 / 108 (53.70%)	372 / 706 (52.69%)
occurrences (all)	594	103	566

Non-serious adverse events	Group 3: MenACYW		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	107 / 112 (95.54%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	67 / 112 (59.82%)		
occurrences (all)	112		
General disorders and administration site conditions			
Injection Site Mass			
subjects affected / exposed	3 / 112 (2.68%)		
occurrences (all)	3		
Injection Site Pain			
subjects affected / exposed	88 / 112 (78.57%)		
occurrences (all)	430		
Injection Site Swelling			
subjects affected / exposed	41 / 112 (36.61%)		
occurrences (all)	118		
Pyrexia			
subjects affected / exposed	46 / 112 (41.07%)		
occurrences (all)	57		
Injection Site Induration			
subjects affected / exposed	6 / 112 (5.36%)		
occurrences (all)	8		
Injection Site Haematoma			
subjects affected / exposed	7 / 112 (6.25%)		
occurrences (all)	10		
Injection Site Erythema			
subjects affected / exposed	61 / 112 (54.46%)		
occurrences (all)	173		
Injection Site Bruising			

subjects affected / exposed	3 / 112 (2.68%)		
occurrences (all)	5		
Crying			
subjects affected / exposed	74 / 112 (66.07%)		
occurrences (all)	138		
Gastrointestinal disorders			
Toothache			
subjects affected / exposed	6 / 112 (5.36%)		
occurrences (all)	7		
Teething			
subjects affected / exposed	7 / 112 (6.25%)		
occurrences (all)	10		
Diarrhoea			
subjects affected / exposed	4 / 112 (3.57%)		
occurrences (all)	4		
Vomiting			
subjects affected / exposed	25 / 112 (22.32%)		
occurrences (all)	32		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 112 (0.89%)		
occurrences (all)	1		
Dermatitis Diaper			
subjects affected / exposed	6 / 112 (5.36%)		
occurrences (all)	6		
Dermatitis			
subjects affected / exposed	2 / 112 (1.79%)		
occurrences (all)	4		
Psychiatric disorders			
Irritability			
subjects affected / exposed	91 / 112 (81.25%)		
occurrences (all)	190		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	4 / 112 (3.57%)		
occurrences (all)	4		
Bronchiolitis			

subjects affected / exposed	11 / 112 (9.82%)		
occurrences (all)	12		
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 112 (2.68%)		
occurrences (all)	3		
Rhinitis			
subjects affected / exposed	1 / 112 (0.89%)		
occurrences (all)	1		
Respiratory Tract Infection Viral			
subjects affected / exposed	18 / 112 (16.07%)		
occurrences (all)	21		
Nasopharyngitis			
subjects affected / exposed	2 / 112 (1.79%)		
occurrences (all)	2		
Gastroenteritis			
subjects affected / exposed	6 / 112 (5.36%)		
occurrences (all)	6		
Respiratory Tract Infection			
subjects affected / exposed	7 / 112 (6.25%)		
occurrences (all)	7		
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	60 / 112 (53.57%)		
occurrences (all)	90		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 June 2019	Study calendar was readjusted considering the study starts (FVFS) and the same inclusion period. Study design, schedule of study procedures, and methodology were modified. Inclusion and exclusion criteria were updated. Table of study procedures for Groups 1, 2, 3, 4 and list of abbreviations was updated. Clarification was given on the need to ensure that parents/legally acceptable representative agrees for further contact to follow those specific AEs as per protocol. Definitive contraindications, labeling and packaging concomitant medications and other therapies were modified. Rewording was done in management of samples section. Future use of stored serum samples for research was updated. Immunogenicity assessment methods was modified to clarify that the testing laboratories which would perform the assays described below would be reported in the final clinical study report. Safety definitions, confidentiality of data, data protection and access to subject records and reference list were updated.
22 January 2020	Cover page was modified for team member update. History of protocol versions, planned study period, study design, schedule of study procedures, and methodology and study plan were modified. Update was made in secondary objectives, secondary endpoints, immunogenicity and observational endpoints. Inclusion and exclusion criteria were modifed. Table of study procedures for Groups 1, 2, 3, 4 and investigators and study organization details were updated. Clarified justification of the study design, vaccination and blood sampling schedule in Groups 1, 2, 3 and 4, study plan and study procedures. Planned study calendar, temporary contraindications, dose selection and timing were updated. Labeling and packaging, concomitant medications and other therapies, immunogenicity assessment methods and blood sampling schedule and testing plan in Groups 1, 2, 3 and 4 were modified. Team member updates were made in initial reporting by the investigator and reporting SAEs to health authorities and institutional ethics committee/ institutional review boards. Updated were made in the reference list.
03 February 2022	Cover page was modified for team member update. Updates were made in the table on “history of protocol versions”, planned study period, study design, schedule of study procedures, and methodology. Secondary endpoints were corrected for few inconsistencies. Observational objective and observational endpoints were modified. Updated were made in planned sample size, study plan, investigators and trial organization and planned study calendar. Clarifications were made in temporary contraindications, contraindications for subsequent blood draw, concomitant medications and other therapies, statistical methods for observational objectives and monitoring. Blood sampling schedule and testing plan in Groups 1, 2, 3 and 4 were corrected. Immunogenicity assessment method was updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported